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Using FullFlow to manage the overwhelming flood of patients' self-collected health data

A system that addresses acceptance barriers regarding the introduction of diabetes patients' self-collected health data into electronic health records and medical consultations.

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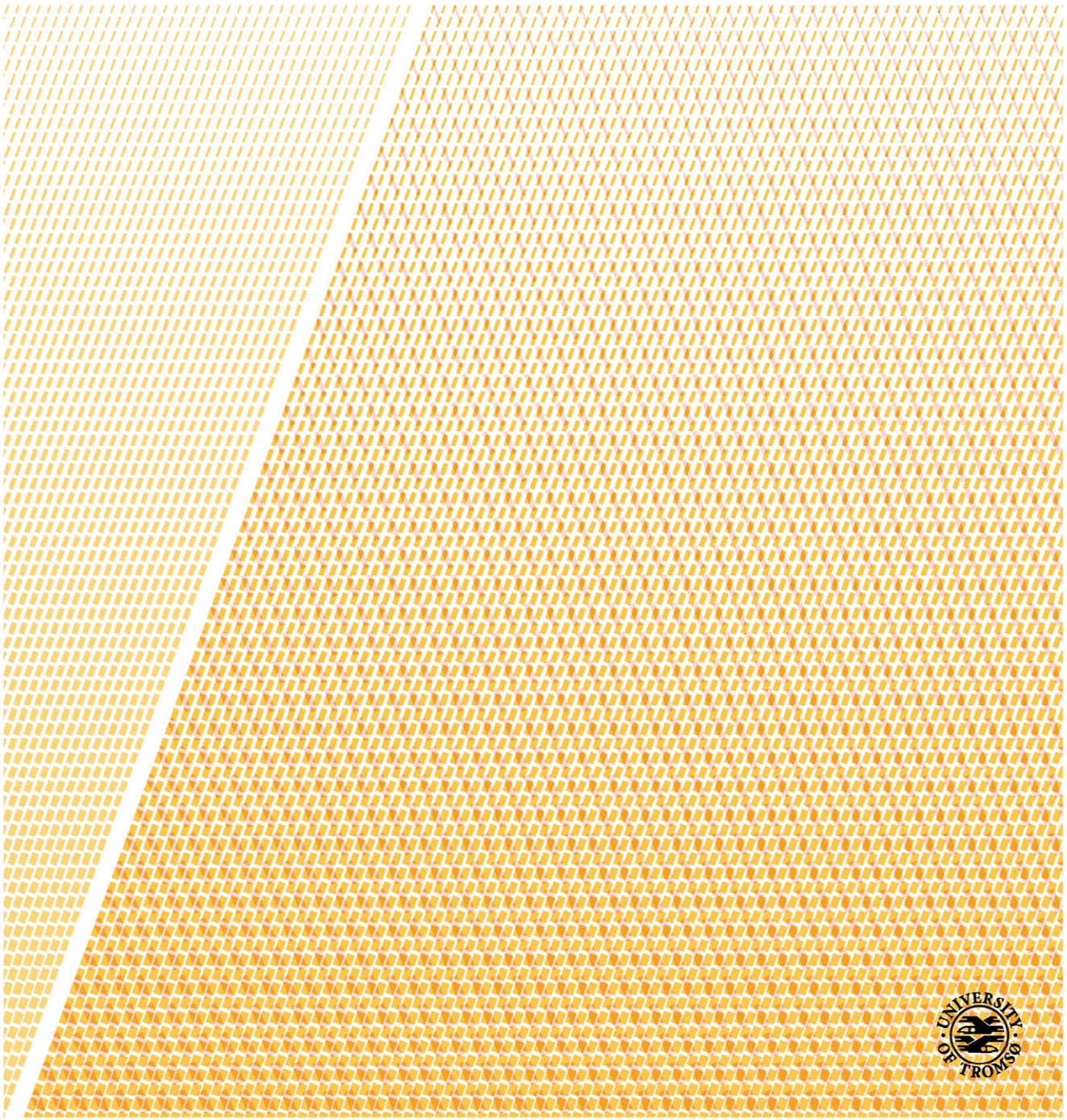

Abstract

Patients increasingly collect lifestyle and health-related data thanks to the explosion of sensors and healthcare applications. Multiple studies have shown that this data can be useful during consultations, resulting in more customised medical services. Moreover, this data permits clinicians to gain an overview of the patients' conditions and enables patients to gain knowledge about the consequences of their lifestyle choices for their health.

The goal of this thesis is to introduce self-collected health data by patients with diabetes into electronic health record systems (EHRs) and medical consultations. To achieve this goal, this thesis proposes, firstly, to study the state-of-the-art usage of self-collected health data during consultations. The thesis then identifies the acceptance barriers perceived by clinicians, patients, healthcare institutions, and EHR vendors that limit or obstruct the usage of self-collected health data during consultations. Thereafter, the thesis describes the FullFlow clinical decision support system (CDSS) addressing the identified acceptance barriers and finishes by its assessment by clinicians.

The identification of acceptance barriers and the design of the FullFlow CDSS followed a participatory design approach supported by semi-structured interviews and open discussions used during workshops and focus groups involving clinicians, EHR vendors, healthcare institutions and patients with diabetes. The implementation of the FullFlow CDSS followed a combination of Agile and waterfall methodologies supported by a test-driven development approach. The assessment of the FullFlow CDSS relied on a case-study.

Summarising, despite multiple parties being interested in using self-collected health data in a medical context, its usage is still rare and locked into controlled environments, even if some cloud-based solutions permit the integration of this type of data into EHRs. The limited usage of this type of data in medical context can be explained by the numerous acceptance barriers perceived by clinicians, patients, EHR vendors and healthcare institutions. Lack of data reliability, investment costs, lack of practice and training and time consumption are examples of acceptance barriers. The FullFlow CDSS comprises three solutions to address these acceptance barriers: 1) a computer science model for extracting relevant health data and managing data reliability, using a hypothesis-and-test strategy; 2) a dashboard permitting clinicians to consult relevant information regarding patients' conditions; and 3) an architecture facilitating the integration of patients' self-collected health data with their health applications in EHRs. The assessment of this system by clinicians showed that this system can integrate self-collected health data during medical consultations and that it would be useful during clinicians' daily consultations. The next step is to test and verify the developed system in real settings.

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Abbreviations

AHD = Application Hosting Devices
AMQP = Advanced Message Queuing Protocol
API = Application Programming Interface
BG = Blood Glucose
BP = Blood Pressure
CDA = Clinical Document Architecture
CCD = Continuity of Care Document
CDSS = Clinical decision support systems
CGM = Continuous Glucose Monitor
CONGA = Continuous Overall Net Glycaemic Action
DD = Diabetes Diary
DICOM = Digital Imaging and Communications in Medicine
DSL = Diabetes Share Live
ECG = Electrocardiography
EHR = Electronic Health Record
FHIR = Fast Healthcare Interoperability Resources
GDPR = General Data Protection Regulation
GP = General Practitioner
HIMMS = Healthcare Information and Management Systems Society's
HL7 = Health Level Seven
HRM = Heart Rate Monitor
I:C = Insulin to carbohydrate ratio
ICD = International Classification of Diseases
IHE = Integrating Healthcare Enterprise
IRC = Internet Relay Chat
JEE = Java Enterprise Edition
JNDI = Java Naming and Directory Interface
JSF = Java Server Faces
JSON = JavaScript Object Notation
KBM = Context-aware knowledge-based module
LOINC = Logical Observation Identifiers Names and Codes
MAGE = Mean Amplitude of Glucose Excursion
MMOL/L = Millimol per litre
ms = Milliseconds
NA (KBM) = Not applicable
NHN = Norwegian Health Network
NDE = Norwegian Directorate of eHealth
NGSP = National Glycohemoglobin Standardization Program
ns = Nanoseconds
OIDC = OpenID Connect
PAN (Continua) = Personal Area Network
PHA = Personal health Archive
PHD = Personal Health Devices
POJO = Plain Old Java Object
PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses
REST = Representational State
SAML = Security Assertion Markup Language
SMBG = Self-monitoring Blood Glucose
SNOMED-CT = Systematized Nomenclature of Medicine - Clinical Terms
SOAP (Computer Science) = Simple Object Access Protocol
T1D = Type 1 diabetes
T2D = Type 2 diabetes
UML = Simplified Unified Modelling Language
UNN = University Hospital of North Norway HF
vMR (HL7) = Virtual Medical Record
VoIP = Voice over Internet Protocol
WAN (Continua) = Wide Area Network
WSDL = Web Services Description Language

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1 Introduction

1.1 Background for the research

The expansion of mobile health applications [1], wearables, and sensors [2-4] has allowed patients to collect a massive amount of important lifestyle and health-related data. Patients use the monitoring and analytical capabilities of these solutions to self-manage their conditions, overcoming geographical, temporal, and organisational barriers to healthcare [5-7], without supervision by healthcare institutions. Several studies have shown that using these technologies, and the data collected, in clinical settings can be beneficial for both patients [8-10] and clinicians [11, 12]. Patients gain knowledge and guidance to improve their conditions, while clinicians gain insights into their patients' lifestyles and can provide more tailored medical services. Moreover, considering that the secondary illnesses associated with poor disease management consume the majority of healthcare spending, combining patient empowerment and the expertise of clinicians could theoretically lessen the consumption of healthcare resources and thereby reduce costs [13].

The idea of using self-collected health data to provide clinical services is not new. Clinicians can obtain this data by asking the patients directly, via interviews, or by using questionnaires, self-reports, and paper or electronic diaries completed by the patients [14]. Some patient portals integrated into electronic health record (EHR) systems provide patients with access to healthcare data and allow them to send their self-collected health data to their clinicians using either online questionnaires or simple messages [15]. Cloud platforms or standalone patient portals (not integrated into EHRs) collect and centralise patients' self-collected health data on an external platform and allow access for both patients and clinicians to consult the data [16-18]. However, these solutions do not often meet clinicians' expectations and are rarely used outside controlled settings, because they are not integrated into EHRs [19] and do not support all patients' tools and sensors, therefore limiting their potential usage. Moreover, these platforms are proprietary, meaning that the provided solutions are locked into specific hardware and specific data formats, so that semantic interoperability cannot be achieved. Semantic interoperability is the ability of a system to import, perform, and execute queries and business rules on information from another system, without prior negotiation [20], by both structuring and codifying the information using standards and publicly available vocabulary [21]. Semantic interoperability allows the value of medical systems to be maximised by delivering the right information to the right person at the right time [22] and by deriving the greatest economic benefit from these systems [23]. The lack of semantic interoperability and integration of self-collected health data further limits the possible future utilisation of this data for research or comparison purposes.

However, even if self-collected data could be seamlessly integrated into EHRs, acceptance barriers regarding the usage of self-collected health data would still exist. Acceptance barriers are elements or obstacles that cause users to resist technology, thus preventing the introduction and usage of a system in a particular environment. Physicians already struggle when using their EHRs [24], so introducing large amounts of new data that clinicians are not accustomed to consulting in their EHRs requires careful handling, considering that even minor erroneous implementation details can have a huge negative impact [25-27]. Moreover, not presenting the data in an efficient way will not permit clinicians to efficiently use it, severely diminishing its usefulness [25-28].

In this thesis, I study state-of-the-art systems for integrating self-collected health data into EHRs and the acceptance barriers perceived by clinicians, patients, EHR vendors, and healthcare institutions

regarding the usage of self-collected health data during medical consultations. I then propose and develop computer models for addressing the acceptance barriers, and finish with a pre-trial assessment, involving clinicians, to ensure that the designed solution is satisfactory for use in medical contexts. The developed clinical decision support system is called the FullFlow system in this thesis.

1.2 Research context

This thesis is part of the 'Full Flow of Health Data Between Patients and Health Care Systems' research project, supported by the Research Council of Norway (number 247974/O70), which focuses on integrating self-collected health data into EHRs in Norway, using diabetes mellitus as a case study.

Diabetes mellitus is a chronic disease that causes the increase of blood glucose (BG) levels due to the absence or insufficiency of insulin production by the body, or a lack of insulin sensitivity. The International Diabetes Federation estimated in 2017 that 425 million people had diabetes worldwide (Type 1 and Type 2) and 629 million people will have diabetes by 2045 [29]. In Norway, the number of people with diabetes is estimated to be 250,000, with 90% having Type 2 and 10% having Type 1 diabetes [30]. Norway spends approximately ten billion Norwegian kroner per year to provide health services for diabetes patients [31]. People with diabetes must adhere to complex treatment regimens, such as balancing food intake with physical activity, supported by possible insulin therapy, while managing underlying diseases.

The FullFlow project involves systems architects and system owners from the Norwegian Directorate of eHealth (NDE). The NDE is the central administrative body responsible for the eHealth infrastructure in Norway under the direction of the Ministry of Health and Care Services. This project is influenced by the NDE's vision and plans regarding the current and future state of the Norwegian health infrastructure. The NDE defines national standards and their usage, manages the integration of existing national services, and studies their potential impact on the security, privacy, and health outcomes of new health services. Therefore, the NDE defines the requirements for introducing self-collected health data in Norway. In addition, the FullFlow project involves systems architects and product owners of the three largest Norwegian EHRs, namely DIPS (secondary healthcare), Infodoc Plenario, and System X (primary healthcare). EHR vendors provide an industry sector perspective and impose further requirements.

The scope of this PhD thesis therefore addresses the intersection between computer science, medicine, academia, and industry.

1.3 Research problems and questions

The primary research problem underpinning this project is R: *how should a system that supports the integration of self-collected health data into EHRs be designed*? The secondary research problems associated with the primary research problem are as follows:

R1. What is the status regarding the usage of self-collected health data by EHRs?

R2. How can patients' self-collected health data be integrated seamlessly into consultations, overcoming the acceptance barriers to such a data sharing system?

R3. How should a system that permits the usage of self-collected health data during consultations for diabetes patients in Norway be designed and implemented?

1.4 Claimed contribution and included papers

1.4.1 Contribution of the thesis

The main contribution of the thesis is addressing the acceptance barriers regarding the usage of self-collected health data in medical consultation (contribution C1) through the design of a clinical decision support system (CDSS). This system, called FullFlow system, is a collection of three solutions: 1) a context-aware knowledge-based module permitting to extract relevant information from multiple data sources, grade the data reliability and identify information gaps (contribution C2), 2) a dashboard presenting relevant information needed by clinicians (contribution C3) and 3) a Norwegian infrastructure facilitating the introduction of self-collected health data into EHRs (contribution C4). The system has been tested by clinicians using a use case approach. This system addresses the main research question of the thesis. The four contributions (C1 to C4) and the research questions they address are listed in Table 1. The research question R1 is addressed by the background of this thesis.

Table 1: Contributions of the thesis and the research questions they are addressing

Number		Contribution	Research question
C1		**Acceptance barriers**: identification of acceptance barriers regarding the usage of self-collected health data in medical consultations. Provision of possible solutions for addressing these acceptance barriers.	R2
CDSS	C2	**Context-aware knowledge-based module**: creation and implementation of a computer science model for extracting relevant health data and managing data reliability, using a hypothesis-and-test strategy.	R2, R3
	C3	**Dashboard**: creation of a dashboard for displaying diabetes patients' relevant self-collected health data to clinicians.	R2, R3
	C4	**Architecture**: provision of a solution for integrating self-collected health data into the existing health infrastructure in Norway.	R3, R3

1.4.2 Included papers

The thesis includes six papers: three in the main track and three in the side track, as shown in Table 2. The main track contains the original research contributions of the thesis, while the side track consists of reviews, and thus not original work. However, the reviews impacted the design and the development of the presented solution by either giving background information on the state-of-the-art or investigating alternative possibilities. The Table 3 describes my contribution and the relevance of each article for the thesis.

Table 2: Included papers

Paper #	Track	Title, Authors and publication channel	Contribution
P1	Main	**Giordanengo A**, Øzturk P, Hansen AH, Årsand E, Grøttland A, Hartvigsen G. Design and development of a context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes self-collected health data. *JMIR Diabetes*. 2018;3(3):e10431. doi: 10.2196/10431. [32]	C2, C3

P2	Main	**Giordanengo A**, Årsand E, Grøttland A, Bradway M, Hartvigsen G. Acceptance barriers of using patients' self-collected health data during medical consultation. *SHI 2019. Proceedings of the 17th Scandinavian Conference on Health Informatics, November 12-13, 2019, Oslo, Norway. Linköping University Electronic Press, Linköpings universitet*. [33]	C1
P3	Main	**Giordanengo A**, Årsand E, Woldaregay AZ, Bradway M, Grottland A, Hartvigsen G, Granja C, Torsvik T, Hansen AH. Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study. *JMIR Diabetes* 2019;4(3):e14002. DOI: 10.2196/14002. [34]	C2, C3, C4
P4	Side	**Giordanengo A**, Bradway M, Muzny M, Woldaregay A, Hartvigsen G, Arsand E. Systems integrating self-collected health data by patients into EHRs: a State-of-the-art review. *Proceedings from the 15th Scandinavian Conference on Health Informatics 2017 Kristiansand, Norway, August 29–30, 2017: Linköping University Electronic Press, Linköpings universitet*; 2017. p. 43-9. [35]	Background
P5	Side	**Giordanengo A**. Possible usage of smart contracts (blockchain) in healthcare and why no one is using them. *MEDINFO 2019: Health and Wellbeing e-Networks for All,* Lyon, France, August 25–30, 2019. DOI:10.3233/SHTI190292 [36]	C4
P6	Side	Muzny M, Henriksen A, **Giordanengo A**, Muzik J, Grøttland A, Blixgård H, Hartvigsen G, Årsand E. Wearable Sensors with Possibilities for Data Exchange: Analyzing Status and Needs of Different Actors in Mobile Health Monitoring Systems. *International Journal of Medical Informatics 2020*. [3]	Background

Table 3: Relevance and contribution of the included papers

P1	**Relevance to the thesis**: this paper presents an approach and a model for addressing multiple acceptance barriers for systems that introduce self-collected health data into EHRs. It extracts relevant information and grades the reliability of the data using a context-aware knowledge-based approach, relying on a hypothesis-and-test strategy. The model used by the back-end of the FullFlow system is described in this paper. **My contribution**: I participated in all workshops and in the co-design session to gather the data regarding the barriers to acceptance and feedback on the designed system. I designed the model and implemented and tested the system. The second co-author helped me to define the methodology for use during the design phase. The third author assessed all medical-related business rules used by the model and the system. I wrote the article with useful feedback and input from the co-authors.

P2	**Relevance to the thesis**: this paper deals with the identification of the acceptance barriers relating to the use of patients' self-collected health data during medical consultations, as perceived by clinicians, patients, and healthcare institutions. This paper permitted insight into why the usage of self-collected health data is rare during medical consultations. **My contribution:** I participated in the data collection by being involved in all the workshops and focus groups involving EHRs, patients, clinicians, and the Norwegian Directorate of eHealth (NDE), in addition to the two previous studies this paper is based on. I defined the taxonomy, performed the qualitative analysis, and wrote the article with feedback from the co-authors.
P3	**Relevance to the thesis**: this paper details the design and implementation of a dashboard for displaying self-collected health data to clinicians. The article describes how the user interface attempts to meet clinicians' information needs by presenting the needed information in an efficient way, in the right place. It also contains the pre-trial assessment of the FullFlow system by clinicians. **My contribution:** I participated in all workshops, identified and analysed the requirements, and designed the graphical interface. I conducted the qualitative analysis regarding the assessment of the graphical interface and wrote the article with feedback from the co-authors.
P4	**Relevance to the thesis**: this paper provides a review of state-of-the-art systems that directly integrate patients' self-collected health data into EHRs. The paper permits an overview of the situation regarding the introduction of self-collected health data into EHRs, identifying the security- and privacy-related challenges of such an approach, and points out some barriers to the acceptance of such a solution. I used the results of this paper to create a basic design of the system described in this thesis. **My contribution**: the second author and I defined the search terms, established the criteria, and performed the first screening process using metadata fields (abstract, title, keywords). I performed full-text reviews of the selected literature and wrote the article, while the co-authors gave feedback on the writing of the article. I presented the paper at the 15th Scandinavian Conference on Health Informatics in Kristiansand in 2017.
P5	**Relevance to the thesis**: this paper presents a review of the usage of blockchain and smart contracts in healthcare situations. At the start of this project, blockchain-based technology was receiving extensive publicity because it promised improvements in healthcare data sharing and privacy [37]. I therefore studied the possibility of using blockchain and smart contracts for sharing self-collected health data between patients and EHRs. **My contribution:** as the sole author of this article, I conducted the review, read the literature, and wrote the article. I presented the article during the MedInfo conference in Lyon in August 2019.

P6	**Relevance to the thesis**: this paper presents a review of wearables and sensors with exchange capabilities that are available in the market. The main goal was to assess how data could be extracted from patients' devices and shared with EHRs. **My contribution:** As the third author, I participated in the acquisition of data by identifying relevant sensors and wearables using the Vendrico database, participated in the data analysis, and its interpretation, in addition to the article revision.

1.5 Thesis structure

The thesis is organised as follow:

Chapter	Content
2 - Background	This chapter introduces the area of my research and presents technological concepts and the current state-of-the-art. This chapter addresses the research question R1.
3 - Methodologies	This chapter presents the methodologies and materials I used for achieving the contributions described in this thesis.
4 - Results	This chapter contains the results of the research organised per contribution and per the research phases: knowledge acquisition, prototyping and assessment. This chapter addresses the research question R2 and R3.
5 - Discussion	This chapter discusses the methods, the results, possible future work, and my own experience as a PhD student.
6 - Conclusion	This chapter concludes the thesis by briefly discussing the presented results and their links to the research questions.

The original articles are described after the conclusion section.

This thesis includes (i.e. reuse) content from the main track articles (papers P1, P2 and P3), as allowed by JMIR, Linköping University Electronic Press and IOS Press publishers – the publishers of the papers -, following the Creative Commons Attribution license. Considering that the UiT – The Arctic Univeristy of Norway does not have a clear policy regarding the reuse of content from published articles, I am following the guidelines provided by the Technical University of Denmark, in a document entitled 'Guidelines for avoiding plagiarism and self-plagiarism in PhD thesis writing', available at https://www.dtu.dk/english/-/media/DTUdk/Uddannelse/PhD-Udannelse/Dokumenter/DTU-Guidelines-for-avoiding-plagiarism-and-self-plagiarism-in-PhD-thesis-writing.ashx?la=da&hash=212B0E58E5342A0FB09842CB8468F8620AC2663D [38]. Based on these guidelines, long content usage (e.g. entire sections) from the published papers is indicated at the beginning of each chapter or section concerned (e.g. 'this section is based on the section […] of the paper P*x*, entitled […] and published by […]'). The content of this thesis supersedes the content of the original articles. Short content usage (e.g. one or two paragraphs) outside the indicated sections are treated as quotations (e.g. 'content reuse' [reference to paper]).

2 Background

2.1 Usage of self-collected health data in clinical settings

The usage of self-collected health data by patients in clinical settings has the potential to improve health outcomes, partnership between patients and clinicians, social support, self-perception for patients and give better insight of patients' health than conventional methods [39-44].

However, a state-of-the-art review I performed (April 2017, paper P4 [35]) showed that there is no standard and stable end-to-end system permitting the sharing of patient-collected health data with EHRs, therefore limiting the usage of self-collected health data in clinical settings. This review revealed that functional solutions existed but are limited to controlled environments, meaning that patients cannot actively share their data with their clinicians and must be enrolled in a study beforehand. An example of such a solution is the pilot study described by Kumar et al. [45] in which glucose measurements collected from Dexcom G4 glucometers were integrated into EPIC EHR through the MyChart patient portal, HealthKit and a proprietary IOS application, Share2; however, this solution was time-consuming (a 45- to 60-minute one-time setup is required in addition to the medical consultation) and had performances issues (not being able to process more than 24 hours of data). In addition, this paper showed that due to a lack of a legal framework regarding the usage of self-collected health data in clinical settings, the complexity of integrating this type of data into EHRs and the large amount of data available could explain why the usage of self-collected health data in clinical settings is limited. More recent studies showed that this is still the case [46, 47].

More research groups have begun to use self-collected health data in their studies, and multiple international parties provide cloud-based patient portal solutions that have the potential to integrate self-collected health data into EHRs, supported by multiple standards. The lack of legislation continues, despite the adoption of the GDPR last year, which does not directly address the usage of self-collected health data during consultation.

Research studies

Regarding the research studies, Martinez et al. [48] proposed integrating diabetes patients' self-collected blood pressure (BP) measurements into EPIC EHR via HealthVault and an OMRON blood pressure monitor, using HL7 CDA. This new data would then be used by chronic care nurses to adjust medication between office visits. This study showed that the introduction of this new type of self-collected health data had both positive and negatives outcomes for patients and clinicians. For some patients, the most important positive outcomes were the feeling of gaining control of their blood pressure by understanding how lifestyle and medication changes were affecting them, enabling them to adapt to these changes. However, other patients regressed to uncontrolled blood pressure status and had negative feelings about their care and the increased workload. Clinicians found that providing medical and lifestyle recommendations was easier if patients knew their blood pressure and they saw patients progressing in their disease management. However, the introduction of this data negatively affected their workflow and it was difficult to connect with patients if they did not have regular visits. Moreover, this study was limited due to the number of participants (twenty-one) and by the fact that only one type of self-collected health data was introduced (BP).

Other studies by Peleg et al. [16, 49], financed by the European Union, proposed using a decision support system for connecting patients with gestational diabetes and patients with atrial fibrillation with clinicians, permitting them to cooperate daily and to tailor medical recommendations. Patients sent their self-collected health data through a specially designed mobile application to the EHRs, via a PHR, using HL7 Virtual Medical Record (vMR) and SNOMED-CT. There were two types of self-collected health data: 1) sensor-acquired data, comprising ketonuria, BG, BP, and ECG, and 2) self-reported events, such as symptoms, feelings, or reasons for not following clinicians' recommendations. A clinical decision system extracted at-risk situations from this data and advised both patients and clinicians to follow up. The clinical trial demonstrated that 1) patients were highly willing to self-collect the data, 2) patients felt safe using the system, and 3) clinicians agreed that the solution made it easier to manage patients. However, the improvement in patients' quality of life was inconclusive and could be either positive or negative, depending on the patients, and the data was not exportable to other EHRs. To my knowledge, this is the most advanced use of self-collected health data in a medical context to the present day.

International parties

Regarding international parties, HealthVault, one of the most advanced standalone patient portals, that proposed the integration of sensors and connectivity to EHRs relying on HL7 CDA, was shot down in November 2019 for undisclosed reasons, as shown in Figure 1.

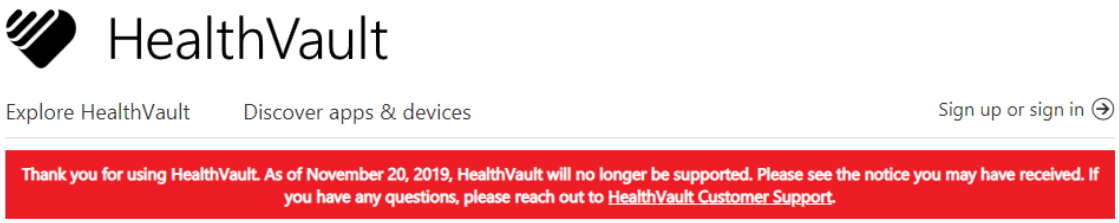


Figure 1: End of support date of HealthVault.

However, two other parties continue to provide similar services to HealthVault: GetRealHealth [50] and FollowMyHealth [51]. These companies propose access to all collected data from health devices and wearables and allow messaging between patients and clinicians. They have specific graphical interfaces depending of the conditions of the patients (diabetes, mental health, obesity, etc.). GetRealHealth relies on Smart-on-FHIR for integrating data into external systems, such as EHRs. I do not have access to any documentation regarding FollowMyHealth, but I am assuming they provide similar services.

Other companies provide specific services for using self-collected health data during medical consultations; for instance, TytoCare [17] proposes performing remote consultations using specific sensors (camera, stethoscope, thermometer) and their own mobile application combined with their own cloud-based EHR. The data collected by the sensors is available to the clinicians through their remote video-based consultation service. However, it does not seem possible to share this data with external parties and EHRs.

Glooko [18] is another example of a company providing access to self-collected health data directly within EHRs. Glooko focuses on diabetes management and proposes a mobile application that can be integrated with multiple diabetes-related sensors (e.g. insulin pumps, CGMs) and a cloud portal for storing and sharing the collected data. External EHRs can also integrate this data using proprietary

application programming interfaces (APIs), but the documentation for these APIs is not openly available.

International EHR vendors, such as EPIC, propose applications and bridges for downloading patients' data generated by EHRs to patients' health applications, using FHIR or proprietary protocols [52]. Moreover, EPIC integrates data from primary and secondary care and proposes patients to view their health information, manage their appointments and communication with their physicians through MyChart. MyChart even proposes clinicians to receive self-collected health data by patients using sensors such as weight scale [53]. However, these services are limited to simple data types and require healthcare institutions to use EPIC services.

Another organisation, the Personal Connected Health Alliance, proposes an end-to-end framework for introducing data collected from sensors and applications to a healthcare system: Continua [54]. This framework provides standards for personal health devices (PHD, sensors), application hosting devices (AHDs), and healthcare systems for storing, retrieving, and exchanging the data. Several teams relied on this framework to perform their studies [55-57]. HealthVault supports Continua.

Moreover, another non-profit organisation, Tidepool, proposes centralising self-collected health data from sensors and applications in a cloud-based solution [58]. Patients can share the data they collect with clinicians, but the solution does not offer EHR integration. A pilot study showed that this solution promoted discussions between clinicians and patients about the data and did not affect the medical workflow [59].

Patients' system providing data sharing possibilities

The study performed by my colleagues and I (paper P6 [3]) showed that only 6% of sensors available in the market (e.g. smartwatches, trackers, gloves, glasses, insulin pumps) have the '*Conformité Européenne'* (CE marked) or are approved by the Food and Drug Administration. Only 70% of these sensors allowed integration with third-party systems and permitted users to share or download the data. 95% of these systems relied on proprietary data protocols for exchanging the data. Extracting and sharing data collected from these devices is therefore challenging.

The situation is similar regarding patients' mobile health applications focusing on diabetes management. A systematic review showed that, of the eighty best health applications, only thirty-four (42%) permitted the exportation of the data stored in the applications [60]. However, none of them relied on standards, and the export was either in comma-separated values, Excel format, or portable document format (PDF).

However, an innovation addresses these issues by proposing the introduction of self-collected health data into EHRs based on standards: the Open mHealth initiative [61, 62]. Open mHealth proposes an open standard for representing mobile health data, as well as open source tools for storing, accessing, analysing, visualising, and sharing such data. The solution proposes the integration of data from multiple sources, such as Runkeeper, FitBit, and/or Apple Health. In addition, the initiative proposes a module, called Pulse, to map data from Open mHealth standards to HL7 FHIR, permitting the integration of self-collected health data into EHRs and vice-versa. However, Open mHealth lacks key data types, such as insulin, but opens up possibilities for developers to write their own data types.

In addition, patients themselves want to circumvent the limitations of the existing patient tools and cloud-based services. Patients now openly hack their devices and share their collected data using do-it-yourself solutions, such as Nightscout and OpenAPS [63]. Moreover, they organise themselves using social media such as Facebook. Figure 2 illustrates this situation.

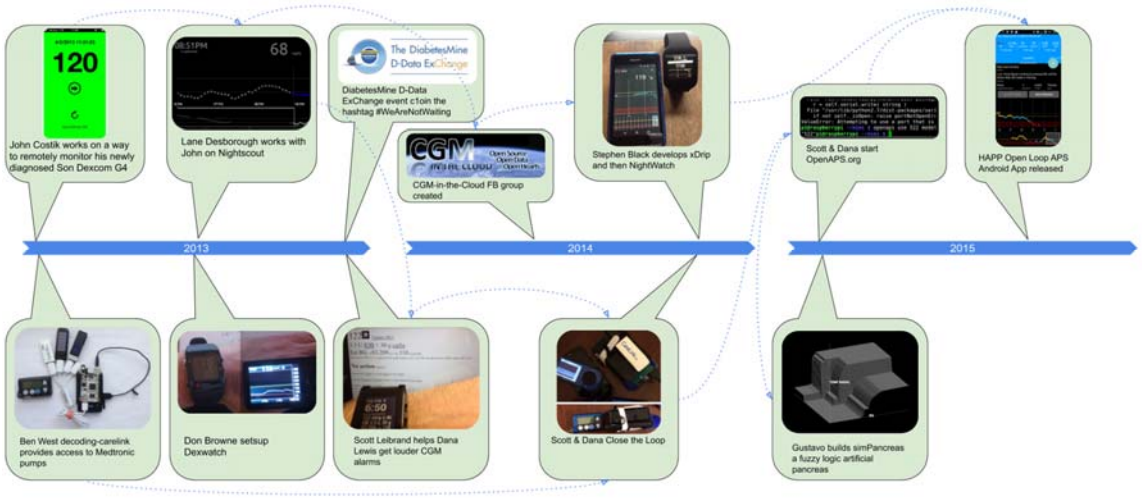


Figure 2: Example of communities of patients hacking their devices. Image created by Tim Omer on the 17 November 2015. Originally available at: https://docs.google.com/drawings/d/1n3YVRaCUeB2l80tzZ1o2FbnH-jKlk9TMwKsoAMgdD6s/edit.

In summary, multiple parties are interested in using self-collected health data in a clinical context, and the quantity and variety of data can be important. However, its usage is still rare and locked into controlled environments, despite some cloud parties permitting the integration of this type of data into EHRs. Moreover, the patients' ecosystem seems to be limited by proprietary data protocols. However, despite the availability of systems and the positive feedback of the previous studies regarding the usage of self-collected health data during consultations, one can ask the question: *why is the usage of self-collected health data not widespread today?* The chapter 4.1 of this thesis (page 38) addresses this issue by identifying acceptance barriers regarding the usage of self-collected health data by patients in clinical context.

2.2 Clinical decision support systems using self-collected health data

Introducing a large volume of diverse information into a medical context, such as patients' self-collected health data, can be confusing and overwhelming for clinicians [64], causing negative patient outcomes [65]. This is one reason leading to the development of clinical decision support systems (CDSS) [65]. CDSS are software that are designed to be a direct aid to clinical decision making by presenting case-specific advice and relevant information to clinicians rather than simply presenting raw data using artificial intelligence methods [66-68]. The first CDSS was described in 1959 by Ledley and Lusted [69], who proposed the use of computers and probabilities to improve medical diagnostics by providing clinicians with the most likely disease diagnostic based on the patients' symptoms and clinical knowledge. The systematic review performed by Belard et al. [70] in 2017 showed that CDSS are used in a multitude of clinical specialties (e.g. intensive care unit, oncology, surgery) and can improve patient safety, promote prevention, reduce medical error and improve medical outcomes in general. Similar benefits were also reported in an earlier study [71]; however, challenges regarding the usage of CDSS

remain abundant, such as the users' resistance, regulation compliance and the usage of large and heterogeneous data sets.

A multitude of taxonomies exist for classifying CDSS. For example, CDSS can be classified depending on the knowledge and data source (source, quality and customisation of the CDSS' knowledge and data [72]) or timing (before, during or after a clinical decision is made [73]). Another possibility is to classify CDSS depending on their deduction methods: knowledge-based (KB) or data-driven. KB CDSS rely on a knowledge base (i.e. rules) and a reasoning engine that analyse fact patterns and match applicable rules and a solution for displaying the results to the users [74, 75]. Data-driven CDSS rely on statistics and machine-learning methods (e.g. neural network, generic algorithm) to discover hidden patterns or relationships in the data [68, 76]. Each approach has its advantages: data-driven CDSS do not need expert inputs for defining the rules and can extract information from multi-variable datasets, while KB CDSS do not require a large dataset available and are faster during execution [77]; however, these two types of CDSS are not mutually exclusive. For instance, a hybrid system could use a knowledge base, and its reasoning engine could rely on a neural network for performing one of its tasks, combining the advantages of both approaches and providing an optimal solution for a CDSS [78].

CDSS that rely on self-collected health data by patients for providing their services exist. To my knowledge, Mobiguide—described in the previous section—is the only advanced CDSS using diverse self-collected health data to facilitate cooperation between patients and clinicians by informing users about risks situations [16, 49] using a knowledge-based approach. Other CDSS rely only on alerts when threshold values are reached. For example, the application proposed by Jiang et al. [79] generates automatic feedback messages when systolic blood pressure measurements are above 160 or when the pulse is below 60 beats per minute. A systematic review conducted in 2019 confirmed that CDSS using self-collected health data 1) are still sparse, with only 21 studies identified (including the studies referenced in this paragraph) and 2) include limited services, such as simple alerts [80]; however, I expect the number of CDSS using self-collected health data to increase in the forthcoming years, considering that multiple studies propose models to extract relevant information from this type of data without being integrated into a CDSS yet. For example, the review performed by Woldaregay et al. [81] describes machine-learning approaches for detecting blood glucose anomalies using self-collected data (e.g. blood glucose, insulin, diet), and Bini et al. [82] proposed machine-learning algorithms to predict patient-reported outcome scores using wearable sensor data.

In this thesis, I describe the design and implementation of a knowledge-based CDSS to extract relevant information from multiple data sources (including self-collected health data), grade the data reliability and identify information gaps (see section 4.2 FullFlow clinical decision support system, page 48).

2.3 Participatory design for building clinical decision support systems

Advanced health information systems, such as CDSS, are complex, involve multiple users and have a wide usage variety. Kushniruk and Patel [83] emphasised that this type of system should 'allow users to carry out their tasks safely, effectively, efficiently and enjoyably', that they should improve healthcare workflow and practices and that they should be thoroughly tested. A participatory design approach can address these challenges by identifying important factors [84-87], reducing failures [88] and reducing users' resistance [84, 89, 90], therefore increasing the chances of successful implementations of health information systems [91].

Participatory design can be described as a research approach focusing on a close cooperation between the end-users and the designers of a system in which end-users have the power to influence the designed solutions [92, 93]. Participatory design follows an iterative circle in which designers and users collaboratively identify the needs of the project, create a prototype and assess it [94]; however, participatory design is not a predefined method but a cluster of tools and techniques [95]. Such tools and techniques include but are not limited to document analyses, observation studies, questionnaires, interviews, workshops, drawings, role playing and mock-ups.

Despite being widely used in healthcare in general [96], participatory design (or tools and techniques belonging to participatory design) has only be applied by four of the 21 studies (4/21, 20%) using self-collected health data in combination with CDSS [80]. The usage of commercial, off-the-shelf technologies (e.g. sensors, applications) in combination with simple threshold alerts could explain why this number is so low.

For this thesis, participatory design has been used to identify acceptance barriers related to the usage of self-collected health data in a clinical context and to create a knowledge-based CDSS that extracts relevant information, grades the data reliability and identifies information gaps (see next chapter).

2.4 Summary

This chapter showed that the usage of self-collected health data by patients in clinical context is sparse and limited to controlled environments. The few existing systems allowing clinicians to consult this type of data are limited to simple services, such as graphical interface or simple alerts when threshold values are reached. In addition, concerned actors (e.g. patients, clinicians) are rarely involved for creating these systems.

3 Methodologies and materials

3.1 Overall research approach: participatory design

A three-phases iterative participatory cycle was used for conducting research, as shown in Figure 3. The participatory design approach was chosen to increase the chances of successful implementations of the created, identify important factors and reducing users' resistance to change, as explained in the section Participatory design for building clinical decision support systems page 20. The three phases were:

1. *Knowledge acquisition*. This phase consisted of studying, collecting, extracting, and analysing information about the usage of self-collected health data by patients in healthcare settings, including its users and context. The information collected permitted the design of the solution presented in this thesis by underpinning specifications, goals, requirements and needs of the users [97].
2. *Prototyping*. The second phase consisted of implementing prototypes to demonstrate the feasibility of the technical solution proposed in this thesis, based on the requirements identified in the knowledge-acquisition phase.
3. *Assessment*. The third phase focused on evaluating the prototypes to ensure that they met the requirements designed in the first phase [98]. The assessment included evaluation in simulated environments and real-use situations.

While other studies consider building mock-ups and testing systems as prototyping (e.g. work of Hamzah and Wahid [96]), I limit the definition of prototyping to the technical/software implementation in this thesis. Mock-up building is considered as knowledge acquisition (users expressing their needs) and user testing as assessment (users evaluating a prototype).

These three distinct phases are associated together to compose sequential life cycles. Each cycle has a life span, starts with the definition of the specifications and ends with the assessments of the software implemented to address these specifications. The assessments are then reinjected in the next cycle as new knowledge. These cycles define a continuous development process [99]. Multiple methods were used during each of these phases and are described later in the next section.

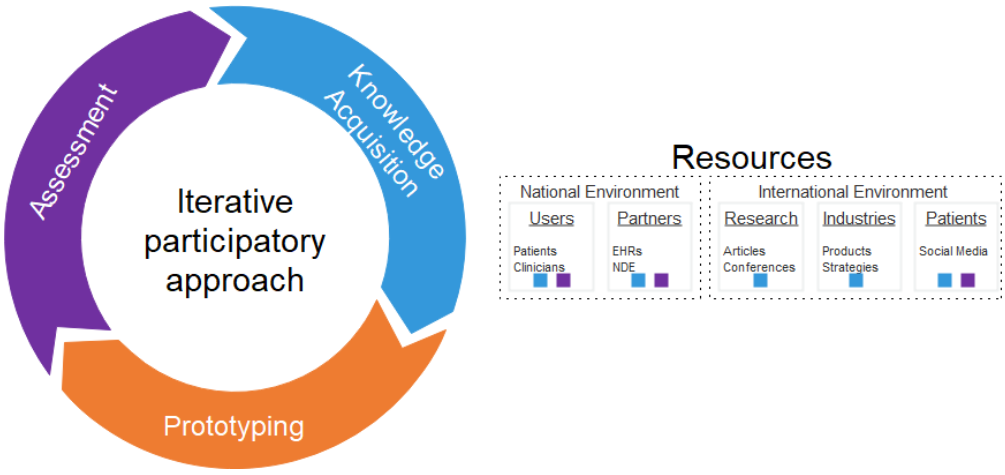


Figure 3: Overall participatory approach using an iterative cycle consisting of three phases, and the parties and sources involved in these phases.

Following the participatory design approach, users and other parties concerned with the usage of patients' self-collected health data in healthcare settings were involved as often as possible during the knowledge acquisition and assessment phases in order to maximise the accuracy of the requirements, improve the acceptance of the solution, and provide features that they perceived as useful [100]. External studies were also taken into account during the knowledge acquisition phase in order to expand the users' and other parties' knowledge.

These resources can be assigned to two contexts: national and international. The national context represents the locality of the research and involves project partners and users. The international context includes any entity outside the research locality and involves research artefacts, industry products, and patients.

Two national partners participated in this project: systems architects and product owners of the three largest Norwegian EHRs, and systems architects and system owners from the Norwegian Directorate of eHealth (NDE). Two types of national users were also involved: patients with diabetes (Types 1 and 2) and clinicians (general practitioners (GPs), diabetes nurses, endocrinologists, and dieticians).

Regarding the international context, most of the resources originated from the research sphere, represented by the scientific literature and conferences, and from the industry world, involving market products and open-source solutions in combination with white papers. International patients with diabetes (Type 1) also participated during the knowledge acquisition and assessment phases for specific tasks.

Figure 4 presents the different methodologies used chronologically per phase of the iterative participatory approach and per contribution. The beginning of the pre-trial assessment marked the end of the iterative research approach described in the beginning of this section, and no new features or functionality was added to the solution thereafter; however, a development cycle was kept open to manage possible bugs. The ongoing medical pilot is discussed after the results chapter in this thesis.

The fundamental methodologies used during the iterative participatory approach were workshops, focus groups, and a co-design supported by the results of the FI-STAR study [101] and of the state-of-the-art review presented in paper P4 [35]. I didn't participate in the FI-STAR study – the study ended before I started the Ph.D. – but I got access to results such as interviews, guides and systems though my colleagues. This study focused on displaying self-collected health data by diabetes patients to clinicians without any system integration. The information generated from these methodologies (knowledge acquisition and assessment phases) were used as continuous inputs for the prototyping phase.

While following the participatory design approach and being user-centred (i.e. focus on users' needs) and supported by semi-structured interview guides (i.e. possibility to deviate from the questions prepared), there are differences between 'classical' workshops, focus groups and co-design. Focus groups only involved one type of actor at a time (e.g. only NDE), while workshops involved multiple parties at once (e.g. clinicians and patients). The co-design allowed for a greater initiative for participants, allowing them to directly innovate. My colleagues and I chose focus groups due to their easy management and the possibility to delve deeper in discussion to identify the 'meaning behind the facts' [102].

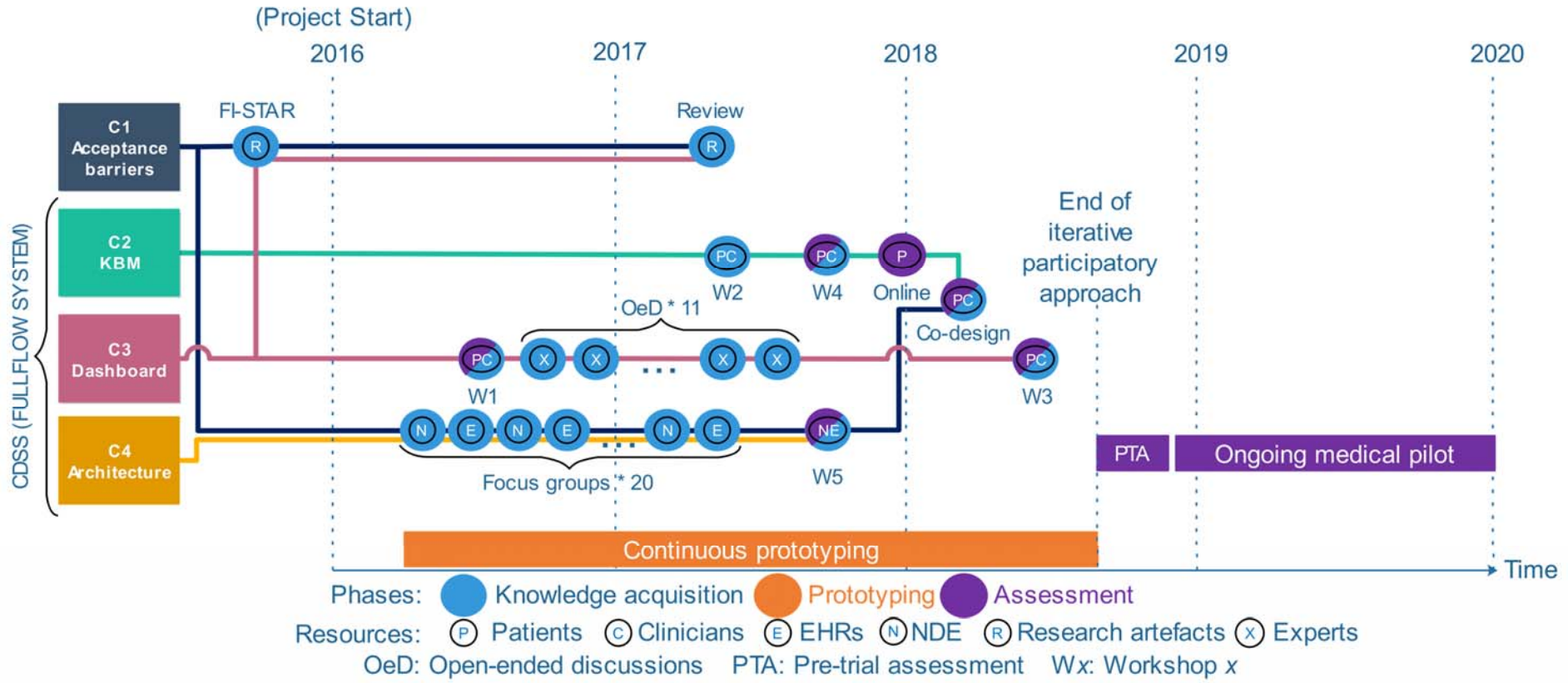


Figure 4: Timeline presenting the overview of the methodologies used per phase of the iterative participatory approach (knowledge acquisition, prototyping, assessment) and per contribution (C1 to C4) presented in Table 1.The coloured lines link the methodologies to the contributions. The start of the pre-trial assessment (PTA) marks the end of the iterative participatory design approach.

We chose to use workshops when collaboration between multiple actors was necessary to identify complex processes and where different points of view were necessary to assess a technological solution [103]. We also decided to attempt to use a co-design to support user-driven innovation, allowing for more innovation than when simply involving users [104]. These meetings were supported by semi-structured interviews, allowing us to explore participants' thoughts and sensitive issues that arose during the interviews [105]. I present my experiences regarding these approaches in the discussion section.

Regarding the contributions, contributions *C1, acceptance barriers*, relied on a workshop (W5), twenty focus groups, and the co-design; involved national diabetes patients, clinicians, EHRs, and the NDE; and the results from the FI-STAR study in addition to the state-of-the-art review I performed. Contribution *C2, context-aware knowledge-based module (KBM),* relied on two workshops (W2 and W4), the same co-design as the previous contributions, and open-ended online discussions. This contribution also relied on agile and waterfall development approaches supported by test-driven development and use cases. It involved international and national patients, clinicians, and the results of contributions *C1*. Contribution *C3, dashboard,* relied on two workshops (W1 and W3) and open-ended discussions supported by an agile approach using scenarios. It involved national patients, clinicians, researchers/experts as well as the results from contributions *C1*. Contribution *C4, architecture,* relied on one workshop (W5), twenty focus groups, an agile approach, and scalability testing. It involved EHR vendors, the NDE, and the results from the contribution C1.

Multiple methodologies were used for different contributions and for different purposes simultaneously. For instance, the co-design was used to identify acceptance barriers as well as to identify users' needs regarding the KBM (knowledge acquisition phase) and testing the KBM (assessment phase). This was possible by defining a semi-structured interview guide, as shown in Figure 5. The interview guide shows that the participants were first asked about the challenges regarding the usage of self-collected health data, formulating acceptance barriers (10:30, Post-its #5: Where do you see patient collected data as a challenge?). Then, they were tasked to build their ideal system to identify their needs (13:20, Activity #2. Built it yourself). Finally, I presented the existing system (i.e. the system existing when the co-design took place), inviting the participants to assess it (14:20: Discussion). The implementation of their feedback occurred after the co-design during the next iteration. Similar but simpler interview guides were used for workshops and focus groups (e.g. bullet points in the mail for focus groups).

Break 10:20-10:30	**10**	**Comments**
- **Post-it #3: What kind of patient-collected data (includert mobile health data via apps etc.) and information would you find interesting and useful? [one post-it per data type]** One by one present. Discuss post-its. Ask, do your responses fit in our situasjonsbilde eller klinikerbilde - **Discussion:** Explain [why and how] - **Post-its #4: Where do you see patient collected data as a positive input for clinical advice?** One by one present. Discuss post-its. Ask, do your responses fit in our situasjonsbilde eller klinikerbilde - **Post-its #5: Where do you see patient collected data as a challenge?** One by one present. Discuss post-its. Ask, do your responses fit in our situasjonsbilde eller klinikerbilde	25	Clinicians use green post-its and number each one according to the question being asked Post-it#2. Alain to place under "Pasient-innsamlet informasjon" on the poster
13:10-13:20 Break	10	

- **Activity #2. Built it yourself** Now we will build the system/interface, describing how it should look and function. How would you design a system for sharing and displaying patient-collected data during consultations? o Instructions: Feel free to use the cut-outs if you like [use the wire-frames as either a reference that we use to introduce the activity or pieces to use in your design/formation of their system. Use 5-6 minutes to draw and put it together and then we will all go around the table and present our final products. Put it up on the Tavle? - **Vote!** Put a sticker next to the functionalities or things that you like about each system o We will then discuss the ones that people find most interesting and the ones you find least interesting. - **Discussion:** Explain your votes. What do you notice or like or dislike about each other's presented systems? o Instructions: Feel free to, while we are discussing, write additional notes or change your system around	40	**Everyone, including the 2 PhDs in the research team will participate** in "building their own ideal systems" and the research team will present one or two main functionalities that they would want to have for themselves, last! After everyone presents their system ideas, researchers then explain the grouping of their systems into different types (active, passive, etc.)
Up-and-coming technologies (14:20-14:50)		
- **Discussion:** - Present Alain's slides about the different system types and technologies that are up and coming? - **Discussion:** Keeping in mind that we have been focusing on creating an environment of collaboration during the consultation, what are your thoughts on these systems?	30	Present Alain's slides about the different system types and technologies that are up and coming (e.g. closed look, if no one else bring its up)

Figure 5: Excerpt of the interview guide of the co-design (verbatim content).

Different methodologies were used during the workshops, focus groups, co-design and the pre-trial assessment for collecting and analysing the data, prototyping and assessing the implemented prototypes. These methodologies are presented in the following sections, organised per contribution (acceptance barriers, FullFlow CDSS) and finished by the pre-trial assessment. The ongoing medical pilot is presented in the discussion chapter.

3.2 Acceptance Barriers (contribution C1)

This section is based on the 'methods' section of the paper P2, entitled 'Acceptance barriers of using patients' self-collected health data during medical consultation', proceedings of the 17th Scandinavian Conference on Health Informatics and published by Linköping University Electronic Press [33].

This contribution is focused on knowledge acquisition.

3.2.1 Data collection

The data collection rested on three complementary approaches, research studies (FI-STAR and the literature review), focus groups and a workshop (W5) involving EHR vendors and the NDE, and the co-design. Figure 6 illustrates this situation.

The first research study, the literature review, focused on identifying systems integrating self-collected health data and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) approach [106] to cover both the scientific and grey literature (i.e. information not published in peer-reviewed databases, such as for commercial products) and to ensure the quality of the review process and its easy reproduction [107, 108]. This review is available in the paper P4 [35]. The second research study, FI-STAR, was a medical pilot involving sharing patients' self-collected health data with clinicians during consultations. I did not participate in this study (which ended before my Ph.D. started).

However, I got access to interviews, guides and reports thanks to my colleagues. This study is presented in an external article [101].

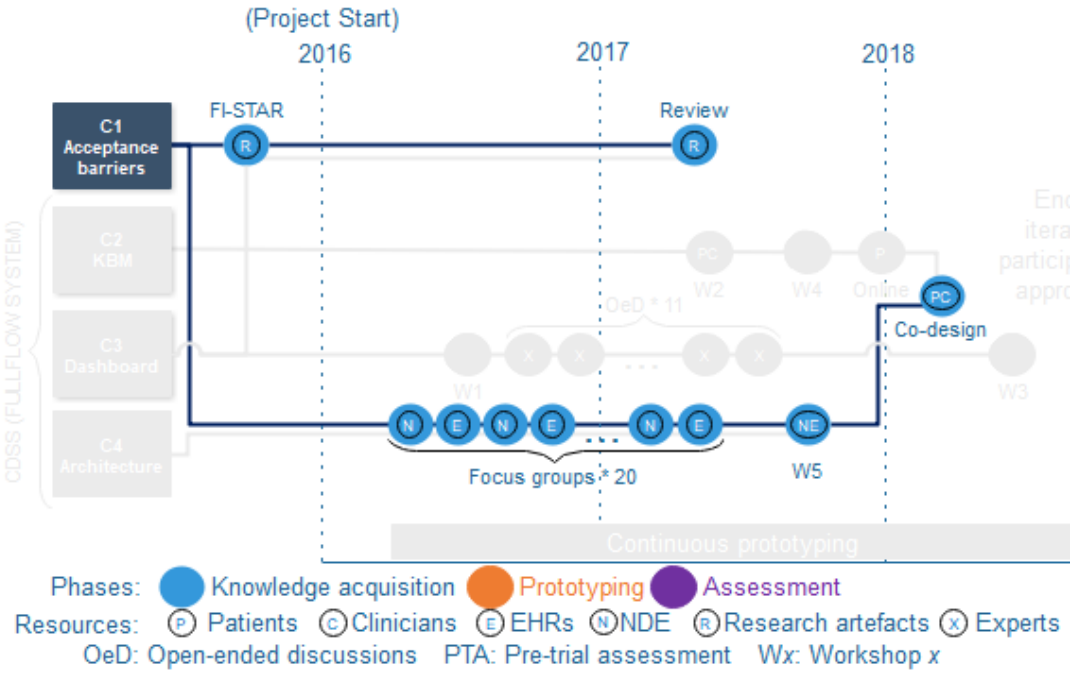


Figure 6: Methodologies used for the contribution C1, acceptance barriers. Extracted from Figure 4.

The second approach relied on twenty focus groups and a workshop (W5) that involved 1) systems architects and system owners from the NDE and 2) systems architects and product owners of the three largest Norwegian EHRs. Each focus group lasted between one and three hours. The goal was to study the challenges regarding the integration of patients' self-collected health data into the national health infrastructure and into Norwegian EHRs (e.g. standardisation, security). The data collection relied on note taking by either myself or a participant for each focus group. We decided to use note taking as the main data collection method considering its simplicity and efficiency to store information [109]. The notes were shared between the participants at the end of the meetings by email. The workshop was held in October 2017 in the NDE's headquarters in Oslo, involving all participants of the focus groups, and used the same note-taking approach. The discussions were supported by semi-structured interviews guides (similar to Figure 5). In addition, brainstorming and go-round methodologies were used during these meetings to balance creativity and problem-solving tasks.

The third approach consisted of the organisation of a co-design workshop involving five patients with Type 1 diabetes, two endocrinologists, and two nurses who specialised in diabetes. The co-design was more oriented toward participatory design—since participants were experts in their disciplines—than the workshop, which employed a simple user-centred design process [110]. The participants were not known to me or my colleagues, and were recruited by several methods: a) via our partner institution, the University Hospital of Northern Norway (UNN), b) from our internal mobile application, the Diabetes Diary [111], and our Facebook group page (https://www.facebook.com/Diabetesdagboka/). An exemption was received from the local ethics committee (REK Ref. 2018/719), and approval given by the Data Protection Officer at UNN (Ref. 2018/4027-4) to perform this study. The co-design was organised around three sessions: 1) patients only, 2) clinicians only, and 3) all participants together.

Sessions 1 and 2 were held simultaneously at different locations and before Session 3. This approach permitted the building of patients' confidence and ensured that their concerns were addressed during the common session. Multiple tools were provided, and multiple methodologies followed, for facilitating innovation, expression, and engagement: expense account (i.e. each participant used a token before speaking and could not speak once their token pile was finished), writing round robin (i.e. all participants answered a question simultaneously on paper before presenting their answers in turn) or '5 whys' (i.e. asking why 5 times in a row to reach the root cause of a problem). Audio recording was the main data collection method, which we decided to use considering that my colleagues and I could not take note efficiently because we were occupied conducting the multiple sessions. The audio recordings were then transcribed verbatim. The secondary data collection method was picture taking of facilitation tools, used by the participants. An example of a facilitation tool is a 'landscape' display, in which participants display their answers from the writing round robin on the walls, as shown in Figure 7. These pictures helped us understanding the transcription of the audio recordings and vice-versa.

Figure 7: 'Landscape' display presenting ideas generated during a co-design session.

3.2.2 Data analysis

Extracting acceptance barriers relied on a two-step process: 1) extraction of negative tones from the data collected from the focus groups, the workshop and the co-design in addition to the research studies and 2) performing a thematic analysis on the extracted tones.

A negative tone is the expression of a challenge, an issue or a negative thought related to the usage of self-collected health data in a clinical context stated by either participants or extracted from papers.

The thematic analysis was conducted to extract meanings and concepts from the negative tones. A thematic analysis was chosen due to its simplicity, flexibility and conservation of in-depth details [112]. The thematic analysis was inspired by the work of Boonstra and Broekhuis [113], who worked on acceptance barriers regarding the usage of EHRs by clinicians; however, my colleagues and I did not limit ourselves to these pre-existing conceptualisations and created conceptual components directly from the negative tones using an inductive approach to better fit our case.

3.3 FullFlow clinical decision support system

This section presents the methodologies used for designing the FullFlow system and is organised per contribution (KBM, dashboard and architecture).

3.3.1 Context-aware knowledge-based module – KBM (contribution C2)

This section is based on the 'methods' section of the paper P1, entitled 'Design and development of a context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes self-collected health data', published by JMIR Diabetes [32].

This contribution uses the three phases of the participatory design approach: knowledge acquisition, prototyping and assessment, as shown in Figure 8.

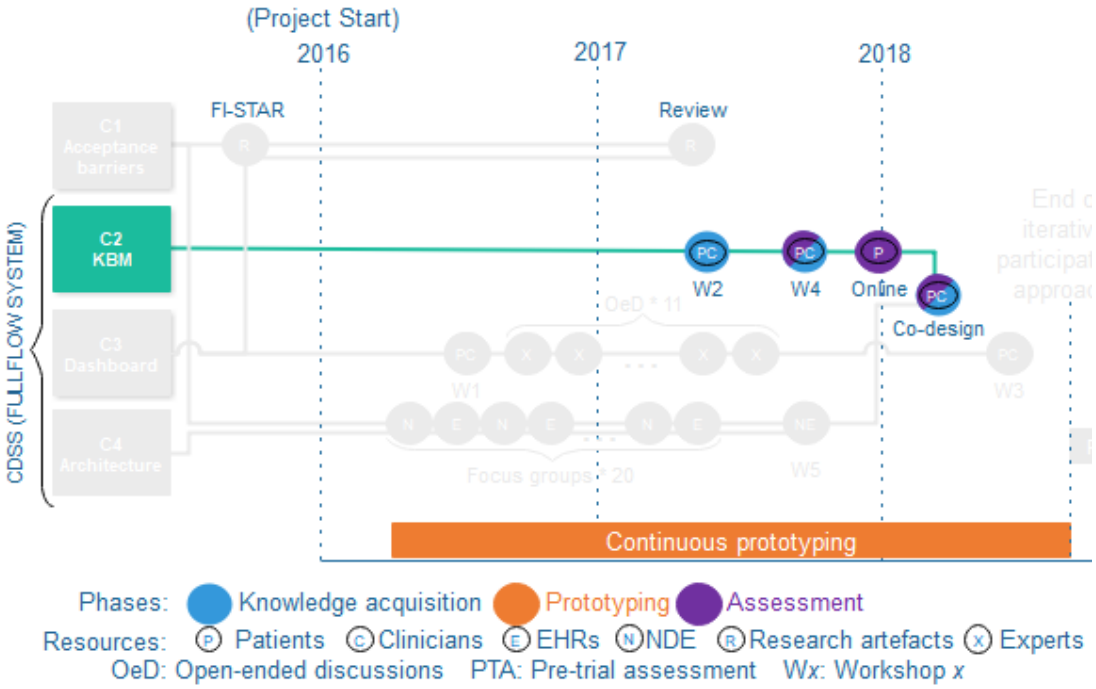


Figure 8: Methodologies used for the contribution C2, acceptance barriers. Extracted from Figure 4.

3.3.1.1 Knowledge acquisition

First, a brainstorming approach to define the scope of the module for identifying functionality and potential problems that might appear at a later stage was used by myself and one of my colleagues. The data flow, technology stack (i.e. a combination of programming languages, tools, and functionality), and data model (i.e. the standardisation of data and relationships between types of data) were also discussed. This brainstorming took place before the workshop W2 (Figure 8).

I then organised two workshops (W2 and W4) involving one patient with Type 1 diabetes (in-house researcher, referred to as the research patient henceforward) and one clinician. These workshops were used to:

1. Identify contextual information. Context was firstly identified following the approach proposed by Dey and Abowd [114].
2. Create a model of context, representing the interactions between all entities involved with the KBM (e.g. patients, medical workers, EHRs) and the contextual interaction between them. This was inspired by the model of context in computer science proposed by Bradley and Dunlop [115] and was intended to provide a complete overview of the context.

3. Define a knowledge base and a reasoning model. These were used as requirements for the development of the module and to describe the functionality of the KBM and its operation.

Contrary to the workshop used to identify the acceptance barriers (W5), these workshops used two collaborative participatory visual methods supported by brainstorming. This approach allowed for collecting and analysing the data simultaneously without requiring notes, transcripts or audio recording. The methods included mind-mapping and participatory drawing.

Mind-mapping involves visually organising a large amount of information using a diagram. Mind-mapping helps to produce more robust research by facilitating communication between participants, the identification of themes in the data and the analysis of the findings [116, 117]. Mind-mapping was used to identify contextual information and to define the knowledge base. The identification of contextual information was supported by a deductive and inductive data analysis using the pre-existing conceptualisations defined by Dey and Abowd [114] (location, identity, time and activity) before creating our own taxonomy directly from the data. The knowledge base definition relied only on an inductive qualitative analysis.

Participatory drawing involves drawing images or diagrams. This approach renders data more accessible to participants and helps them express more complex notions than they can verbalise on their own [118, 119]. Participatory drawing was used to create the model of context and the reasoning engine using a simple whiteboard as support and drawings limited to flowcharts. I then generated the flowcharts digitally.

In addition to the benefits of these methods, they allowed for the re-use of the content between the two workshops. For instance, while being primarily designed during the first workshop (W2), the contextual information was enriched during the second workshop (W4) using the same file. Similarly, I recreated the drawings during the first workshop (W2) five minutes before the start of the second workshop (W4), allowing us to continue where we previously ended.

In addition to the workshops, we used the co-design to contribute to the three points described because the two workshop sessions had a limited number of participants. This is the same co-design described in section 3.2 Acceptance Barriers (contribution C1). I updated the mind-maps and the digital flowcharts after the co-design, based on the suggestions of the participants.

3.3.1.2 Prototyping

I used an agile development process (i.e. iterative development [120]) for developing a prototype, for which evolution, changes, and adaptability were the key points (e.g. user interactions, reasoning model). Continuous input from the co-design and the workshops was included in this process. I used a more classic waterfall approach (i.e. sequential development [121]) when stability and performance were the focus, such as regarding the implementation of the core of the module (the 'engine', which does not require users' direct interaction). I used test-driven development to support the waterfall approach, firstly by defining test cases based on the acquired knowledge, and then by developing the code that satisfied the test cases. I followed a white box (i.e. testing of the internal structures of code) approach for testing the core without involving the context and the reasoning model, and followed a black box (i.e. testing of functionality) approach for testing whether the system behaved according to the definitions obtained from the previous creation process [122]. I used unit tests to support both approaches [123]. In addition, I performed load tests [124] to monitor the performances of the module.

3.3.1.3 Assessment of the module

The assessment of the module relied on two approaches supported by use cases. For the first approach, online open discussions, I recruited two other patients via the Freenode Internet Relay Chat (IRC) [125] —a group communication tool—of the diabetes subreddit [126], a social network website. I explained in the IRC the context of the KBM and its functionality. I then asked the people who were online at that time whether they were interested in testing this module using their own dataset, followed by open-ended discussion to obtain their opinions and comments. The data exchange and the discussion were conducted through Telegram [127], a messaging application. This recruitment method permitted me to reach patients I would not have been able to recruit locally, and in a very short time, without spending a great deal of effort on recruitment. The IRC was replaced by Discord, a VoIP platform [128], during 2018, with more than 1,000 users registered and an average of 100 users continually connected in March 2019 (see Figure 9). This approach was used for internal development.

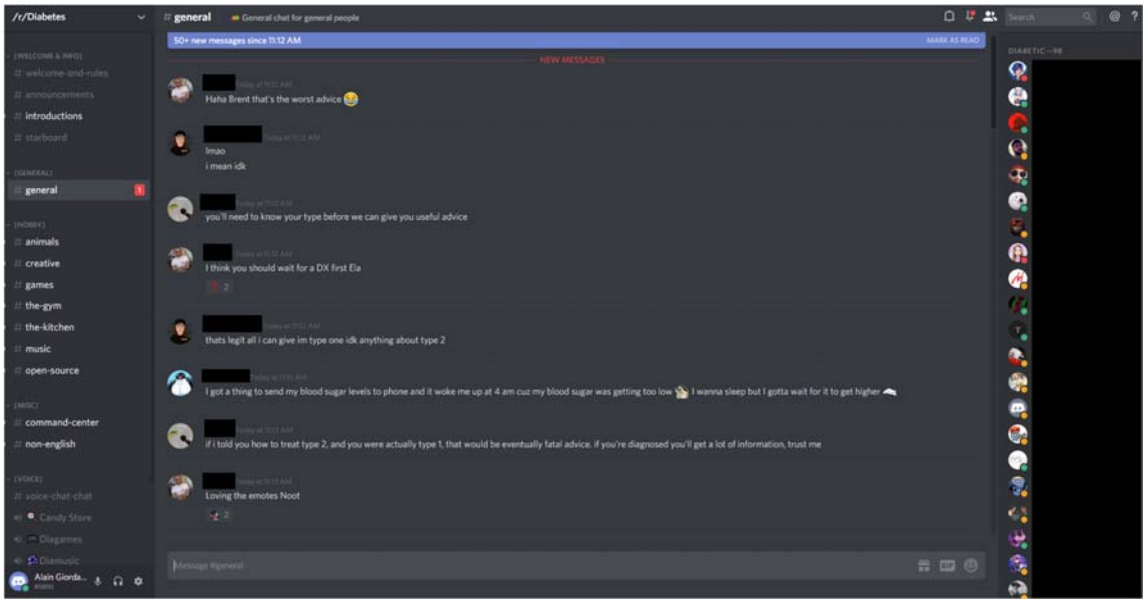


Figure 9: r/diabetes community on Discord.

For the second approach, an instance of the KBM was created using the self-collected health data from the research patient and presented to the workshop W4 and the co-design participants. The participants were asked to offer their opinions, advice, and possible adjustments to this instance.

3.3.2 Dashboard (contribution C3)

This section is based on the 'methods' section of the paper P3, entitled 'Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study', published by JMIR Diabetes [34].

This contribution uses the three phases of the participatory design approach: knowledge acquisition, prototyping and assessment, as shown in Figure 10.

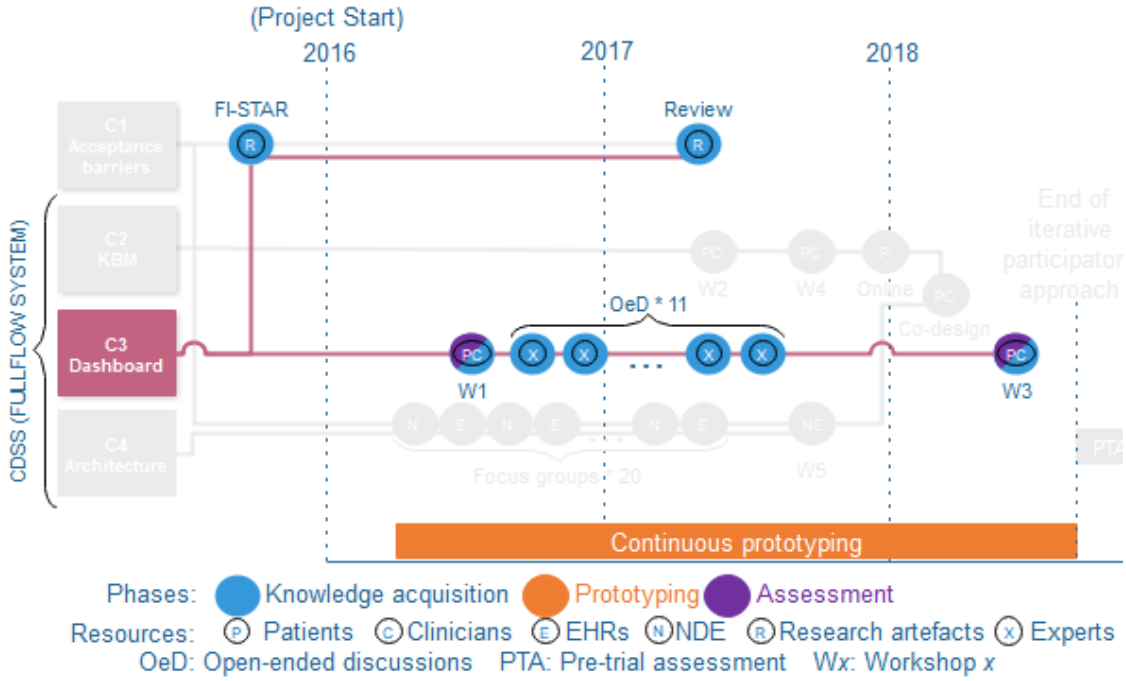


Figure 10: Methodologies used for the contribution C3, acceptance barriers. Extracted from Figure 4.

3.3.2.1 Knowledge Acquisition

I used the knowledge gained from the state-of-the-art review and the FI-STAR study to create a first dashboard prototype. This first prototype was used as a basis for starting the iterative design process.

My colleagues and I then organised and participated in two workshops (W1 and W3) involving four clinicians (two nurses and two doctors who had worked with diabetes) and two diabetes patients. The clinicians and patients were recruited by our partner, the University Hospital of North Norway. Different methodologies were used during these workshops—namely, brainstorming, IdeaStorm, and go-rounds—to balance creativity and problem-solving tasks and to reduce the pressure on the patients by allowing everyone to speak in turn. The workshops lasted three hours each, and participants were invited to contribute their own experiences to the workshops' primary objectives. A majority group decision-making technique was employed during these sessions.

In between the workshops, I organised a total of eleven sessions with open-ended discussion:

1. Three focusing on mathematical models to use for medical and statistical calculations, involving two computer scientists.
2. Four targeting the GUI usability—namely, the information to be displayed—attended by one computer scientist and one GUI expert.
3. Two providing a first assessment regarding the medical relevance of the information displayed, joined by a computer scientist and a general practitioner.
4. Two focusing on evaluation of the dashboard prototype against the requirements, involving myself and three of my colleagues.

A simulation-type scenario approach was used for the workshops and open-ended discussion sessions to model real-use situations and narratives [129]. The modelling process relied on a taxonomy containing four elements, which were completed for each scenario. These elements were:

1. Settings: the context and the situation of the scenario.

2. Agents: who participate in the scenario.
3. Goals: the functional targets of the scenario.
4. Events: the actions taken by the agents during the scenario.

Detailed information concerning the three main scenarios was collected, with the help of the participants, during the first facilitated workshop. The scenario approach 1) facilitated the cooperation of the participants during the facilitated workshops, by enabling them to see themselves in the situations and evoke their own experiences, and 2) simplified the design process of the dashboard, by providing concrete and flexible situations, especially when end-users were involved [130].

3.3.2.2 Prototyping

I exclusively followed an agile development process for implementing the graphical interface, as evolution, changes, and adaptability were necessary in view of the continuous input provided by the workshops and open-ended discussions.

3.3.2.3 Assessment

The developed prototypes were assessed during the workshops and improved during each iteration of the design process using use cases based on the scenarios created.

3.3.3 Architecture (contribution C4)

This contribution uses the three phases of the participatory design approach: knowledge acquisition, prototyping and assessment, as shown in Figure 11.

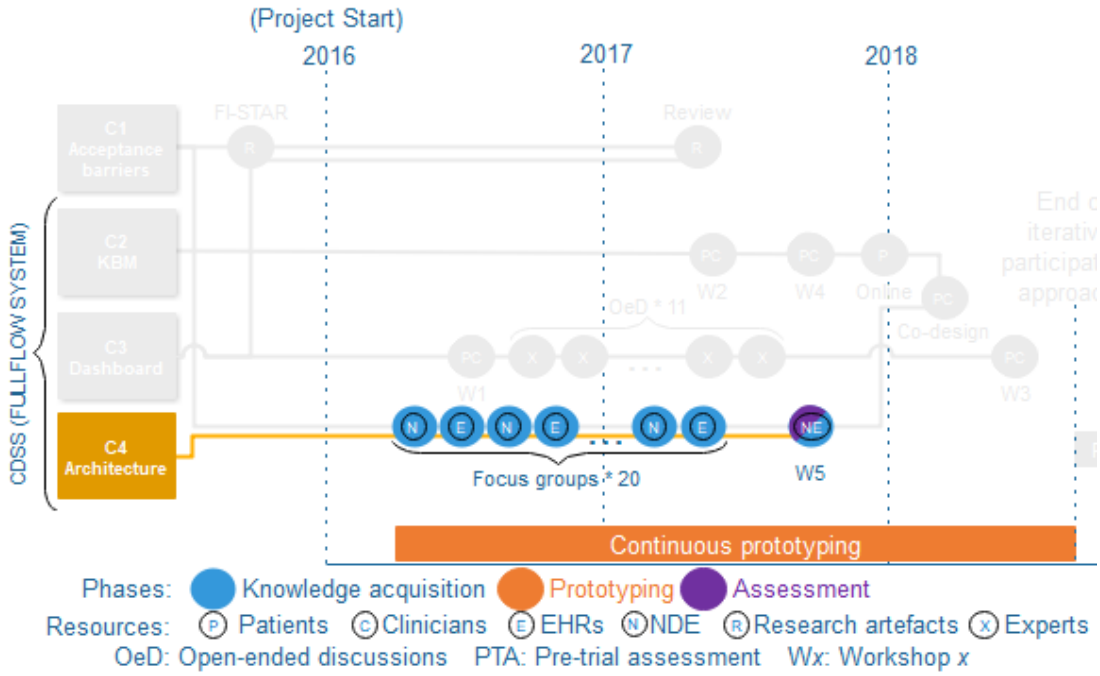


Figure 11: Methodologies used for the contribution C4, acceptance barriers. Extracted from Figure 4.

3.3.3.1 Knowledge acquisition

The knowledge acquisition relied on the same focus groups and the workshop involved the NDE and the EHR vendors, as explained in section 3.2 Acceptance Barriers (contribution C1). However, the targeted knowledge was different.

The first goal was to align the NDE's vision and plans regarding the current and future state of the national health infrastructure with the need to integrate patients' self-collected health data into it. Therefore, the knowledge acquisition focused on studying national standards; the interconnection of existing national services; and the potential impact on the security, privacy, and health outcomes of the introduction of self-collected health data. The second goal was to study how EHRs could receive the data and meet the requirements of the national standards for receiving and displaying self-collected health data. Government documents supported the note taking process.

3.3.3.2 Prototyping

A complete architecture was designed and partially developed by integrating the patients' self-collected health data into Infodoc Plenario, one of the Norwegian EHRs. The prototype focused on integrating the dynamic web-report generated by the FullFlow system, instead of implementing an FHIR-compliant module, since it represented a lower cost for the EHR and permitted a faster demonstration. The prototype was designed by a master's degree student I supervised and followed an agile approach. I contributed to the student's work by helping in resolving technical problems, suggesting alternatives, and providing knowledge and expertise regarding the NDE's vision and plans.

3.3.3.3 Assessment

While the assessment of the national infrastructure will not be possible before 2020 (see discussion section), a partial assessment was performed to ensure the feasibility of the proposed architecture and to address technical challenges regarding the introduction of self-collected health data into Norwegian EHRs.

I assessed the scalability of the backend of the FullFlow system. The tests relied on several data payloads based on real patients' self-collected health data obtained from the research patient. The payloads were used for load testing the monitored FullFlow system. Four payloads containing 750, 1,500, 9,000 and 18,000 FHIR observations were created by a scrambling process (i.e. by changing or adding self-collected health data). The total number of observations corresponded to approximately 50 observations per day for, respectively, two weeks, one month, six months, and one year. The observations were distributed between blood glucose, physical activity, insulin, and carbohydrate intake. The FullFlow system was monitored during the tests, using VisualVM [131] to monitor the heap usage, and SoapUI [132] to monitor answer time and simulate stress and loads. Several configurations of the FullFlow system were used to ensure the scalability of the system: 1) a single Glassfish server [133], 2) a Glassfish cluster containing two Glassfish servers, and 3) a Glassfish cluster containing three Glassfish servers. All the servers ran the same version of the FullFlow system and were exposed to the same payloads. For configurations 2 and 3, Membrane [134] was used as a load balancer. Membrane used a round-robin strategy. Figure 12 illustrates this configuration. All the services (SoapUI, Glassfish servers and Membrane) ran on development environment. All the services (SoapUI, Glassfish servers, and Membrane) ran in a development environment. All the Glassfish servers used the default configuration, except a memory heap defined at 2 GB and the configuration relating to clustering (when appropriate). The memory heap increase was based on previous tests during the development process using the agile methodology. For simplicity, all security protocols were disabled (e.g. no-data encryption and no user authentication). In addition, I performed negative stress testing on Configuration A to study how the system recovered from errors.

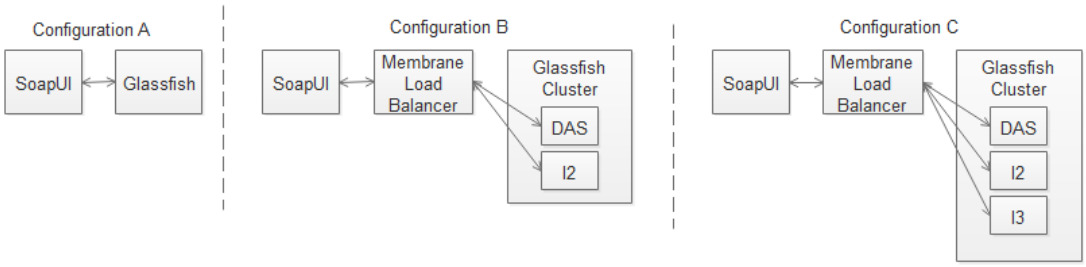


Figure 12: The three configurations used during the tests. DAS: Domain Administration Server. I2/3: Instance number 2/3.

In addition, the master's degree student and I tested the prototype that permitted the integration of the reports generated by FullFlow into Infodoc, using a use case based on the data collected by the research patient.

3.4 Pre-trial assessment

This section is based on the 'prestudy assessment of the dashboard by clinicians' section of the paper P3, entitled 'Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study', published by JMIR Diabetes [34].

Following validation by internal assessments of the KBM and the dashboard, a pre-trial assessment was conducted to validate that the proposed solution was satisfactory for use in a clinical trial, especially regarding usability and functionality. The start of the pre-trial assessment marked the end of the iterative research approach, and no new features or functionality were added to the solution thereafter. The pre-trial assessment followed a three-step sequence, as illustrated in Figure 13.

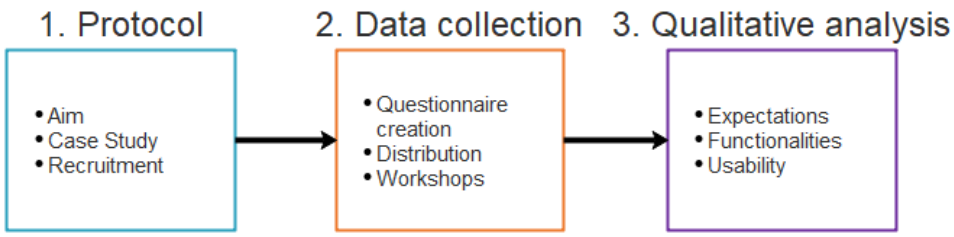


Figure 13: Methodologies used during the three sequential phases of the pre-trial assessment: protocol, data collection and qualitative analysis.

3.4.1 Protocol

The design of the pre-trial assessment was guided by the Standards for Reporting Qualitative Research (SRQR) checklist to enhance the organisation and reporting of this study [135]. A case study was presented in a total of five workshops in healthcare offices (hospital or general practitioner (GP)) and each workshop involved between two and four clinicians, up to a total of fourteen, and one or two researchers. The fourteen clinicians were recruited through UNN or by direct contact. The number of participants was limited due to external factors (e.g. time constraints, unavailability of further participants). The clinicians did not participate in any other contribution listed in this thesis.

The FullFlow system was presented during the workshops, including the final prototype of the dashboard and the KBM, using the self-collected health data from the research patient. The data was extracted from the research patient's Diabetes Diary to fill the FullFlow system, using the Diabetes

Share Live solution to transmit the data [101]. The research patient participated in all workshops, so that he could explain the different values displayed on the dashboard and answer questions regarding his lifestyle or the values themselves.

3.4.2 Data collection

A paper-based questionnaire was distributed by one of my colleagues to the participants during the workshops, after presenting the system, and was collected at the end of the session. One of my colleagues and I designed the questionnaire, based on the System Usability Scale [136] and the Computer System Usability Questionnaire [137]. A custom questionnaire was used, because the assessment did not permit inclusion of important usability factors, due to a lack of clinical context, such as patient–clinician relationships. Given that the questionnaire was administered to the participants in the pre-trial phase, obtaining important feedback using open-ended questions was essential. The questionnaire contained four questions about the system and the role of the user (e.g. nurse). The four questions were as follows:

- Q1a: Do you think the system will be useful during consultation? Q1b: Potential comments.
- Q2a: Would you like to have more information delivered by the FullFlow system? Q2b: Potential comments.
- Q3a: Would you like to remove or hide information currently delivered by the FullFlow system? Q3b: Potential comments.
- Q4: Do you have any feedback you would like to offer?

3.4.3 Qualitative analysis

I performed the qualitative analysis based on three concepts: *expectation*, *usability*, and *functionality*. I defined expectation as a general belief that positive or negative outcomes could occur in clinical settings using the proposed system. The use of this term was inspired by the work of Bialosky et al. [138]. I used the seven notions provided by Vázquez-García et al. [139] to define usability: knowability (user can understand, learn, and remember how to use the system), operability (capacity of the system to accommodate users with different needs), efficiency (capacity of the system to produce appropriate results), robustness (capacity of the system to resist errors), safety (capacity of the system to avoid risk), and satisfaction (capacity of the system to generate interest in users). I used the definition proposed by Salleh et al. [140] to describe functionality as a set of functions and their specified properties. I then used the feedback to improve the system before starting the medical trial.

3.5 Materials

The methodologies were supported by hardware and software solutions presented below.

3.5.1 Hardware

- FullFlow server: a server running the FullFlow system (i.e. the solution I developed containing a dashboard and a knowledge-based module). A virtual server running Debian 9 with two allocated cores with one thread each of an Intel Xeon Gold 5118 and a 2.30GHz processor with 4 Gb of ram.
- Development environment: a custom desktop computer with an i7-7800X processor at 3.5 GHz, 32GB DDR4 at 1200MHz, PM961 NVMe M.2 SSD on a TUF X299 Mark 2 motherboard, running Windows 10 Professional and Debian 9 in dual boot.

3.5.2 Software

- Rayyan [141]: Rayyan is a web service tool that helps in performing systematic reviews and improving the collaboration and quality assurance of the process. Rayyan was chosen based on its flexibility and low cost, even though it does not have all functionality provided by similar software, such as Covidence [142].
- JUnit 5 [143]: JUnit is a unit testing framework for Java-supported test-driven development. I used JUnit for writing unit tests.
- VisualVM 1.4.1 [131]: a Java-oriented profiling tool. I used VisualVM for tracking the memory usage of the Java virtual machine during runtime, with attention to the heap.
- SoapUI [132]: an open-source web service testing application for service-oriented architecture that permits functional testing using load and stress testing.
- Glassfish 5 [133]: Glassfish is the reference implementation of Java Enterprise Edition, which defines the enterprise features of Java, such as distributed computing and web services. The FullFlow system runs on Glassfish.
- r/diabetes [126]: a page of the social news site Reddit focusing on exchanges relating to diabetes information (lifestyle, research, etc.). I used Reddit to obtain additional knowledge and reach diabetes patients I would not have been able to contact otherwise.
- Discord [128]: Voice over Internet Protocol (VoIP) communication software providing message (text, images, etc.) exchanges between users on chat channels.
- KiwiIRC on Freenode IRC [125]: a Web Internet relay chat client used to connect to the r/diabetes IRC channel hosted by Freenode, an Internet relay chat network. I used the r/diabetes IRC channel to conduct exchanges with diabetes patients. Discord replaced this channel in 2018.
- Telegram [127]: a cloud-based instant messaging service supporting files exchanges and VoIP. I had an open-ended discussion with some diabetes patients from r/diabetes using this service.
- Membrane [134]: Membrane is an Open-Source Service proxy, supporting Representational State Transfer (REST) and Simple Object Access Protocol (SOAP). I used Membrane as a load balancer for SOAP services when performing scalability tests.
- FreeMind [144]: FreeMind is an Open-Source min-mapping application. FreeMind has been used for creating min maps during multiple workshops.

This chapter illustrated all the methodologies used during this project.

4 Results

4.1 Acceptance barriers (contribution C1)

The acceptance barriers perceived by clinicians, patients, healthcare institutions, and EHR vendors regarding the usage of self-collected health data during consultations represent obstacles to the usage of this type of data in medical context. Therefore, identifying and addressing them is essential for designing a system facilitating the introduction of self-collected health data in consultations.

This section summarises the 'results' section of the paper P2, entitled 'Acceptance barriers of using patients' self-collected health data during medical consultation', proceedings of the 17th Scandinavian Conference on Health Informatics and published by Linköping University Electronic Press [33].

4.1.1 Negative tones extraction and identification of acceptance barriers

Table 4 presents an excerpt of negative tones extracted from the focus groups, workshop (W5), research studies (FI-STAR and the state-of-the-art review) and the co-design. The taxonomy resulting from the thematic analysis contains six categories:

- *Financial*: the cost issues related to the development, maintenance and usage of an information technology system supporting the collection, transmission and consultation of self-collected health data.
- *Workload and workflow*: the impacts or potential impacts on clinicians' workload and clinical workflow.
- *Technical*: the challenges related to the usage of hardware and software tools for collection, transmission and display of self-collected health data during consultations. This category includes the barriers related to technical capabilities of the physicians, patients and suppliers operating the tools.
- *Time*: the factors leading to increased time to perform a task.
- *Trust*: the factors influencing the ability to perceive the usage of self-collected health data during consultation as trustful, on both the personal and social interaction levels.

Table 5 lists the identified acceptance barriers categorised by the taxonomy defined above and precise the parties who are concerned by them. A significant number of acceptance barriers (22 in total) were perceived by clinicians, patients, EHR vendors, and healthcare institutions that prevent widespread usage of self-collected health data during medical consultations. The *technical* category contained the greatest number of acceptance barriers, with seven (31%) listed, followed by the *trust* category, with four (18%) acceptance barriers. The *financial*, *time*, and *workflow* categories followed with three (14%) barriers each. The *legal* category contained two (9%) barriers. Clinicians were the most concerned, with sixteen (44%) barriers, followed by the healthcare institutions (nine barriers, 25%), patients (six barriers, 17%), and the EHR vendors (five barriers, 14%).

According to the healthcare institutions and EHR vendors, the most critical acceptance barriers are related to costs and to the changes in medical workflows required by the introduction of self-collected health data into consultations. Clinicians perceived time consumption and the lack of reliability of the data as the main acceptance barriers, while patients considered the burden of collecting health data to be a nuisance.

The paper P2 presents the acceptance barriers in details [33].

Table 4: Extract from the results of the thematic analysis presenting the categories identified, illustrating five negative tones from each data source (co-design, focus groups/workshop and research studies [FI-STAR/review]) selected arbitrary. Verbatim content. B -> A means A is a consequence of B.

Origin	Main category	Acceptance barriers category	Negative tones	Source	Comments
Co-design	(A)Time (B)Technical	(A) More time per patient (B)Too much data (meaningfulness)	'there is a lot of data and I see a problem about time to handle the data [per patient] (A), and also the importance – some data are very important and some data is not important (B)'	Endocrinologist A	B -> A
Co-design	Legal	Missing legal context of usage	'[we - clinicians] stopped to use to take out CGM data because it was in [international company] and that is illegal in Norway'	Endocrinologist A	Check why it is illegal
Co-design	Workflow	Heavier workload/reorganisation	'But then those patients who use the CGM, they get much more consultations with the nurses because they need to be taught the CGM, they need a follow-up after so and so many weeks and then after 1 or 2 months they need another follow-up'	Endocrinologist B	Related to 'technical support employee'
Co-design	Technical	Lack of data reliability (A) Lack of software and hardware reliability (B)	'CGM is not fantastic. Cause it measures blood glucose in the wrong site. It measuring in the cutaneous tissue and not in the blood stream.' 'No! It's delayed by 10-15minutes. So its and in some patients the delay is like 28-20minutes. So it means that the CGM shows that the blood glucose is 5 its fine and the patient has hypoglycaemia'	Endocrinologist A	B -> A
Co-design	Technical	Obsolescence of the system	it is difficult to follow technology evolution (A), you have like 20 solutions to monitor your physical activity, but you never know how long you can use them, and if you have to change in the future, and relearn how to use them (B).	Patients B	Brainstorm during lunchtime A -> B
Research study	Trust	Lack of belief	'Most of the patients don't input [data], so you have to get them to remember. If I want to use this, as a clinician, to help the patient. In my opinion, average doesn't help me at all. I need to see, one day, blood sugar, insulin dose, exercise. That's very hard for me'	Nurse C	Patients do not register enough data
Research study	Trust Workflow	Lack of belief (A) Lack of incentives/participation (B)	'they are really sort of cowboy wild guy in type one, between 15-25 and drink every weekend and give damn about and eat and overweight and blood glucose is up and down and he doesn't care. Because he is one at the highest risk, and I sort of all of you have the big experience type 1 or these they are wildcats some of them. So it is a huge problem to be able to do this [collect and sharing data] and we as GPs just send them to the hospital and hope for the best. Because they are so difficult	GP	Self-collected health data usage not adapted to everyone A -> B

			to control and some doesn't meet up at the hospital. Because they don't want to be diabetics. we have a bit the same problem with people with depression, those people that really need to do something otherwise you don't do it, and it is the same thing, being depressed and can't be bothered with anything, just leave me alone'		
Research study	Financial	Investment costs	Because the complexity and cost of big data analytics are significantly higher compared to traditional analytics approaches, it is important to justify their use	[145]	Extract from article
Research study	Time	More time per patient	Nurse workflows were negatively affected when they had to wait on the approval of a physician.	[48]	Extract from article
Research study	(A)Workflow (B)Technical	(A)Lack of incentives/participation (B)Complexity of usage	several experimental BCS [breast cancer survivors] found the Polar M400 use difficult—possibly decreasing intervention adherence.	[146]	Extract from article B -> A
Focus group	(A)Financial (B)Technical	(A)Investment costs (B)Lack of s/h reliability	the infrastructure [for sharing self-collected health data] not ready. Helsenorge and PHA [personal health archive] needs to be developed further. not the priority right now. requires a lot of tests and quality insurance. have to handle the additional [amount of] data, and maintain accessibility and availability for the whole country.	NDE architect A	B -> A (Lack of s/h -> require quality insurance and tests) From notes
Focus group	Financial Technical	Investment costs Lack of standardisation	[EHR] system not ready to handle FHIR data. lack resources to do this	EHR system architect A	From notes
Focus group	Financial Technical	Maintenance costs Obsolescence of the system	innovative in other areas [than integrating self-collected health data]. difficult to "dispatch" a dev to focus on this and keep up to date with all what is happening out there.	EHR system owner	From notes
Workshop (W5)	Workflow	Heavier workload/reorganisation	we have to measure how implementing a new service will impact the healthcare services. it is difficult to know the effects of integrating data generated by the patients, but healthcare services will have to deal with this new data and adapt their processes	NDE system owner	From notes
Focus group	Technical	Lack of standardisation	systems are not interoperable. When healthcare institutions share data they print and scan documents. it is freetext most of the time	NDE system owner	From notes

Table 5. List of identified acceptance barriers regarding the usage of self-collected health data by patients during consultations and the parties concerned. Actors: H = healthcare institutions, C = clinicians, P = patients.

Tax	Acceptance Barriers	Parties
Financial	Investment costs	H/EHRs
	Maintenance costs	H/EHRs
	Training users (clinicians)	H
Workflow	Lack of practice/training	C
	Lack of incentives/participation	C/P
	Heavier workload/reorganisation	C/H
Technical	Lack of skills	C
	Lack of data reliability	C
	Complexity of usage	C/P
	Obsolescence of the system	H/C/P/ EHRs
	Lack of software and hardware reliability	H/C/ EHRs
	Lack of standardisation	H/EHRs
	Too much data (meaningfulness)	C
Time	Time to learn	C
	More time per patient	C
	Tracking data is a burden	P
Trust	Need to control	C
	Lack of belief	C
	Interference with doctor–patient relationship	C
	Liability	C/P
Legal	Privacy/security of the data	P/H
	Missing legal context of usage	C/H

4.1.2 Relationship between acceptance barriers

It appears that all acceptance barriers are interconnected, as illustrated in Figure 14. This figure represents the unweighted connections between the acceptance barriers, identified as nodes. Unweighted signifies that the importance of the acceptance barriers (e.g. time-related barriers are important for clinicians) or the strength of the association (e.g. lack of skills is heavily associated with lack of practice) are not taken into consideration.

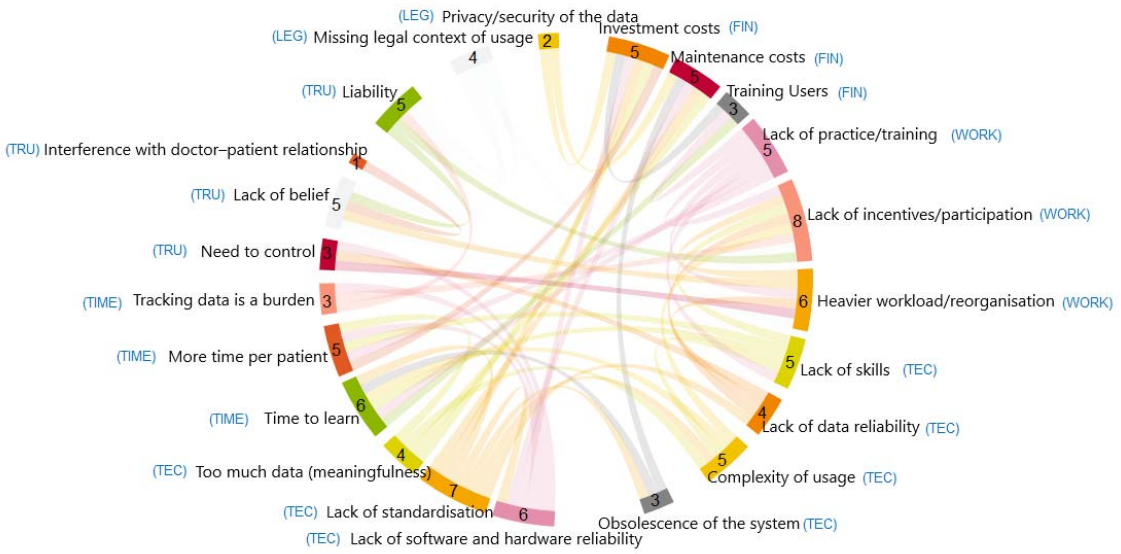


Figure 14: Chord diagram representing the unweighted connections between acceptance barriers, organised clockwise based on the taxonomy previously defined (Fin = financial, Work = workflow, Tec = technical, Time = time, Tru = trust, Leg = legal). Each acceptance barrier has a node, and each node displays the number of other nodes it is connected to.

In total, ninety-eight connections between nodes were identified, using the information from the previous subsection. The node having the highest number of connections is *lack of incentives/participation* with eight connections, and the node having the least is *interference with doctor-patient relationship* with one connection. A node has, on average, 4.5 connections and a median of five connections.

Regarding the total number of connections per taxonomy, including inner (i.e. connections between nodes of the same taxonomy) and outer (i.e. connections to nodes of other taxonomies) connections, *technical* has the highest number of connections with 34, followed by *workflow* with 19 connections, *time* and *financial* with 13 connections each, and finally, *legal* with five connections.

The information regarding the number and type of relationship for each acceptance barrier extracted from Figure 14 is shown in Table 6. The type of relationship defines whether a given acceptance barrier is a cause or a consequence of another acceptance barrier.

Table 6: Relationships between acceptance barriers, organised by number of connections, and their categorisation as causes or consequences. C = Number of connections).

Acceptance Barriers	#C	Causes	Consequences
Lack of incentives/participation	8	• Lack of practice/training • Heavier workload/reorganisation • Lack of skills • Lack of data reliability • Complexity of usage • Tracking data is a burden • Lack of belief • Liability	

Lack of standardisation	7		• Maintenance costs • Investment costs • Time to learn • Lack of software and hardware reliability • Obsolescence of the systems • Complexity of usage • Lack of data reliability
Heavier workload/reorganisation	6	• Lack of practice/training • Lack of data reliability • Need to control • Missing legal context of usage	• Lack of incentives/participation • Lack of belief
Lack of software and hardware reliability	6	• Lack of standardisation	• Maintenance costs • Investment costs • More time per patient • Tracking data is a burden • Need to control
Time to learn	6	• Lack of standardisation • Obsolescence of the system • Complexity of usage • Lack of skills • Lack of practice/training • Training users	
Lack of practice/training	5		• Training users • Lack of incentives/participation • Heavier workload/reorganisation • Lack of skills • Time to learn • More time per patient
Lack of skills	5	• Lack of practice/training	• Complexity of usage • Time to learn • More time per patient • Lack of incentives/participation
Complexity of usage	5	• Too much data (meaningfulness) • Lack of standardization • Lack of skills	• Time to learn • Lack of incentives/participation
More time per patient	5	• Too much data (meaningfulness) • Lack of software and hardware reliability • Lack of skills • Lack of practice/training	• Investment costs
Lack of belief	5	• Missing legal context of usage • Liability • Interference with doctor–patient relationship • Heavier workload/reorganisation	• Lack of incentives/participation
Investment costs	5	• Privacy/security of the data • Training users • Lack of software and hardware reliability • Lack of standardisation • Too much data (meaningfulness) • More time per patient	

Maintenance costs	5	• Privacy/security of the data • Obsolescence of the system • Lack of software and hardware reliability • Lack of standardisation • Too much data (meaningfulness)	
Liability	4	• Missing legal context of usage • Tracking data is a burden	• Lack of belief • Lack of incentives/participation
Too much data (meaningfulness)	4		• Investment costs • Maintenance costs • Complexity of usage • More time per patient
Lack of data reliability	4	• Lack of standardisation	• Lack of incentives/participation • Heavier workload/reorganisation • Need to control
Missing legal context of usage	3		• Liability • Lack of belief • Heavier workload/reorganisation
Training users (clinicians)	3	• Lack of practice/training	• Investment costs • Time to learn
Obsolescence of the system	3	• Lack of standardisation	• Time to learn • Maintenance costs
Tracking data is a burden	3	• Lack of software and hardware reliability	• Lack of incentives/participation • Liability
Need to control	3	• Lack of software and hardware reliability • Lack of data reliability	• Heavier workload/reorganisation
Privacy/security of the data	2		• Investment costs • Maintenance costs
Interference with doctor–patient relationship	1		• Lack of belief

This analysis showed that acceptance barriers are entangled and addressing all the acceptance barriers is necessary in order to maximise the acceptance of the usage of self-collected health data during medical encounters.

4.1.3 Addressing acceptance barriers

I propose a clinical decision support system, the FullFlow system, for addressing all barriers of acceptance, except two: *missing legal context of usage* and *liability* (c.f. the end of this subsection). The FullFlow system comprises three solutions:

1. A context-aware knowledge-based module (KBM), used to identify information gaps, extract relevant information, and grade the data reliability. The KBM is described in section 4.2.1 Context-aware knowledge-based module – KBM (contribution C2) page 48.
2. A dashboard, presenting relevant information needed by clinicians for consultation and providing medical services. The dashboard is presented in section 4.2.2 Dashboard.
3. A Norwegian national architecture approach for introducing self-collected health data into EHRs. The architecture is presented in section 4.2.3 Architecture.

Table 7 lists the solutions that address each acceptance barrier.

Table 7: Usage of the proposed solutions for addressing each acceptance barrier. X = solution addressing an acceptance barrier.

Tax	Acceptance Barriers	KBM	Dashboard	Architecture
Financial	Investment costs	X		X
	Maintenance costs	X		X
	Training users (clinicians)	X	X	X
Workflow	Lack of practice/training	X	X	X
	Lack of incentives/participation	X	X	X
	Heavier workload/reorganisation	X	X	X
Technical	Lack of skills	X	X	X
	Lack of data reliability	X	X	
	Complexity of usage	X	X	X
	Obsolescence of the system			X
	Lack of software and hardware reliability	X		X
	Lack of standardisation			X
	Too much data (meaningfulness)	X		
Time	Time to learn	X	X	X
	More time taken per patient	X	X	X
	Tracking data is burdensome			X
Trust	Need to control	X	X	
	Lack of belief	X	X	
	Interference with doctor–patient relationship		X	
	Liability	Not addressed		
Legal	Privacy/security of the data			X
	Missing legal context of usage	Not addressed		

4.1.3.1 Financial acceptance barriers

Investment and *maintenance cost* barriers are addressed by the proposed *architecture* and *KBM*. The *architecture* relies on existing services for authenticating users, and storing and consulting the data, supported by international standards for managing data already in use in Norway, thereby mutualising the costs. The *KBM* extracts relevant data relating to the patient context and the clinician consulting it, thereby reducing the amount of data shared and stored, limiting the costs of maintenance of the existing services.

The training users (clinicians) acceptance barrier is addressed by limiting the need to train clinicians, so that clinicians will use the EHRs they are already using (*architecture)* and an efficient *dashboard* for consulting specific information (*KBM*), without needing to investigate the whole set of patients' self-collected health data themselves.

4.1.3.2 Workflow acceptance barriers

In a similar way, using existing EHRs and providing relevant medical information relating to the situation of the patient, presented in an efficient way, could address the *lack of practice/training*

acceptance barrier, considering that clinicians would not need to spend time learning new tools. Moreover, using medical standards and grades for representing the data could ease clinicians understanding of this type of data and permit its correct use. These services could also address clinicians' *lack of incentives/participation* for the same reasons.

For facilitating the participation of the patients, the proposed *architecture* provides a way of sharing their data using their existing self-management tools and by using national tools which they are already accustomed to, thereby not requiring them to change their habits. However, the proposed solution is valid for patients willing to share their self-collected health data.

Similarly, by using the existing EHRs and avoiding changing clinicians' habits, the three solutions can address the *heavier workload/reorganisation* acceptance barrier. Moreover, clinicians will still control the tools: they can decide whether to use the data or not and when to use it during consultations. In addition, the proposed *architecture* uses loose-coupling between patients' systems and EHRs, meaning that the clinicians do not need to investigate what tools patients are using and can focus on the data instead.

4.1.3.3 Technical acceptance barriers

The points described above could address *lack of skills* and the *complexity of usage* acceptance barriers.

The *lack of data reliability* is addressed by the proposed *KBM*, which grades the data reliability by identifying information gaps (i.e. missing data) and issues relating to the data itself (e.g. regularity, erroneous data, missing values). Moreover, the proposed *dashboard* compares patients' self-collected health data values to laboratory results, increasing the validity of the reliability of the patients' data.

The *obsolescence* of the system acceptance barrier is addressed by the proposed *architecture*, which uses well-known standards for authenticating the users, and collecting, storing, and consulting the self-collected health data. The loose coupling between elements of this architecture allows the easy introduction of new tools.

The *lack of software and hardware reliability* is addressed by the proposed *architecture*, which relies on existing and widely-use, well-tested, and reliable Norwegian national services for authenticating the users, and collecting, storing, and consulting the self-collected health data. Moreover, the FullFlow system has been designed and tested to allow scalability, recovery from interruptions, and the provision of satisfactory performance (see section Assessment page 66).

The *lack of standardisation* is addressed by the proposed *architecture* using standards for representing medical data and loose coupling between services, which allows the mapping of proprietary data types from patients' systems to standard ones if necessary.

The *too much data (meaningfulness)* acceptance barrier is addressed by the proposed *KBM*, which extracts relevant data for clinicians, instead of the clinicians performing this task themselves.

4.1.3.4 Time acceptance barriers

The services provided by the proposed *KBM*, *dashboard*, and *architecture* presented above should address the time acceptance barriers by using existing tools and providing relevant data. Moreover, the KBM informs clinicians immediately if the data collected by the patients is worth their time or not.

To simplify patients' data collection, the proposed *architecture* allows them to use the tools that suit them and the Norwegian national services, which should limit the burden of data collection.

4.1.3.5 Trust acceptance barriers

The *need for control* is addressed by both the proposed *KBM* and the *dashboard*, by analysing the reliability of the data, providing interpretations of the data based on medical standards, and allowing clinicians to correlate self-collected health data with laboratory results.

By providing relevant data in a useful way, I hope that the proposed *KBM* and *dashboard* will address the *lack of belief* of clinicians.

The *interference with the doctor–patient relationship* is addressed by the *dashboard,* leaving the choice to the clinicians as to whether or not to consult the data according to their preferences, and by proposing a tool that they control, meaning they can still steer the consultation, with or without patients' input.

Addressing the *liability* acceptance barrier is outside the scope of my thesis. This acceptance barrier is due to a lack of clear responsibility between patients and clinicians regarding the usage of self-collected health data (e.g. who is responsible if predictions of a future adverse health event are present in patients' self-collected health data, but this is discovered only after the event has happened [147], who is responsible if some self-collected health data is missing or altered, such as patients hiding a hypoglycaemic event to avoid losing their driving licence [148]?) However, I hope to provide relevant information to the authorities (the NDE) regarding the effectiveness of the proposed solutions using a medical trial, thereby pushing them to create a legal framework regarding the usage of self-collected health data in medical consultations. The medical trial is presented in section 5.4 Ongoing medical trial section.

4.1.3.6 Legal acceptance barriers

The proposed architecture addresses privacy and security issues by using well tested and widely used Norwegian national services for authenticating patients and collecting, storing, and sharing the data. Moreover, the FullFlow system does not store any medical data (i.e. no persistence) and should rely on the Norwegian Health Network, being inaccessible from Internet.

Similar to *liability*, the *missing legal context of usage*, acceptance barrier is outside the scope of my thesis, but a medical trial can push the authorities to move forward in addressing this challenge.

4.1.4 Summary

Twenty-two acceptance barriers were identified by clinicians, EHR vendors, healthcare institutions, and patients, which explains why the usage of self-collected health data in clinical settings is not more widespread, despite research studies showing its benefits.

Studying these acceptance barriers showed that they are interconnected and addressing them simultaneously is required to facilitate the success of introducing self-collected health data in consultations. I am proposing a clinical decision support system to address them. The next section presents this system.

Other possibilities for addressing these acceptance barriers are described and compared in the discussion section.

4.2 FullFlow clinical decision support system

This section describes the FullFlow clinical decision support system, containing three solutions: the KBM, the dashboard and the architecture.

4.2.1 Context-aware knowledge-based module – KBM (contribution C2)

This section summarises the 'results' section of the paper P1, entitled 'Design and development of a context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes self-collected health data', published by JMIR Diabetes [32].

The context-aware knowledge-based module (KBM) is one of the three solutions I propose in order to address the acceptance barriers outlined in the previous section. The KBM focuses on grading data reliability, identifying information gaps, and extracting relevant information from the self-collected health data.

4.2.1.1 Knowledge acquisition

4.2.1.1.1 Contextual Information identification

The identification of contextual information is the first result of the workshops W2 and W4, using a mind-mapping as the main methodology. The co-design did not permit to identify more context types. The contextual information represents '*any information that can be used to characterise the situation of an entity. An entity is a person, place, or object that is considered relevant to the interaction between a user and an application, including the user and applications themselves*', as defined by Dey and Abowd [114]. The KBM requires this information to achieve its goals. In total, my colleagues and I identified nine types of context extending the four pre-existing conceptualisations defined by Dey and Abowd [114] (location, identity, time, and activity). Figure 15 illustrates the different types of context.

In summary, *patient-collected data* (e.g. blood glucose) represents only one type of context and is insufficient for characterising a consultation. *Laboratory generated data* (e.g. blood analyses), *medical standards* (e.g. recommended range for blood ketones is <0.6 mmol/L), *frequency of data registration* (e.g. number of blood glucose per day), *measurable personal goals* (e.g. keeping blood glucose between 4 and 9 mmol/L), *goal of the consultation* (i.e. what is the purpose of the consultation), *time* (e.g. pre, post or during consultation), *identity* (i.e. who the patient and clinician are) and the context generated by the KBM itself (e.g. result of an hypothesis – explained in the next section) are context types influencing on a medical consultation. The paper P1 details these context types [32].

4.2.1.1.2 Model of context

The model of context is the second result of the workshops W2 and W4, using participatory drawing as the main methodology. The goal of this model was to define the interaction between entities (i.e. the parties, such as the clinicians) and which context is generated or shared between them. The model of context inspired by Bradley and Dunlop's approach [115], as shown in Figure 16. This context model allows to have a clearer view of how the global flow of context data is in real-life situations. The paper P1 presents this model in detail [32].

Figure 15: Categorisation of contextual information types using a mind map PAPERS….

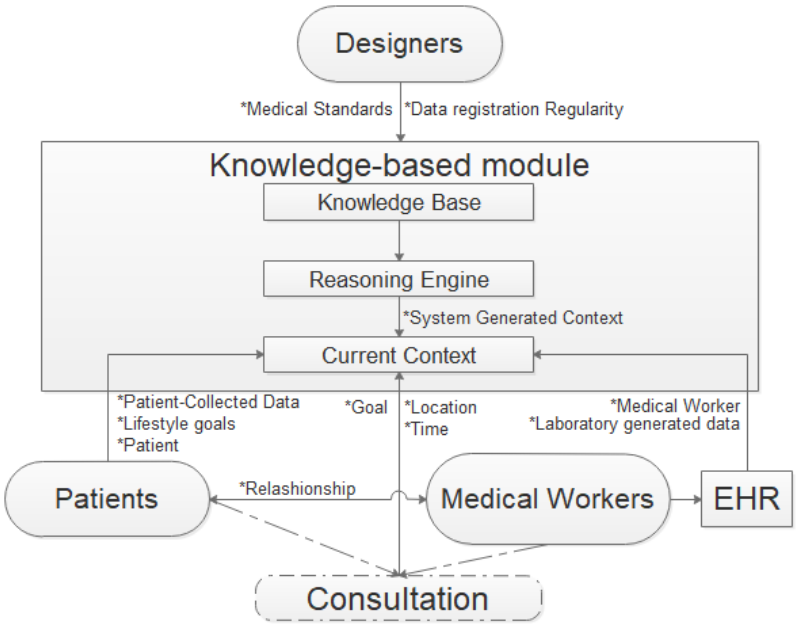


Figure 16: Model of Context. The labels next to the arrow represent the different types of context.

4.2.1.1.3 Knowledge base and reasoning engine

I established the reasoning engine and the knowledge base according to the identified types of contextual information and the model of context presented above, with feedbacks from the workshop W4 and the co-design. The feedbacks of the co-design were limited to the tailoring of the existing knowledge base (e.g. updating the rules) without generating new knowledge. The discussion chapter addresses this issue. The reasoning engine followed the participatory drawing approach while the knowledge base the mind-mapping approach.

The reasoning engine provides problem-identifying functions needed for determining the degree of reliability of the patients' self-collected health data and for identifying *noticeable events* and their potential causes. A noticeable event is a medical event discovered from the contextual information, for which feedback from the medical worker could be useful in improving the patient's situation. In order to do this, the reasoning engine relies on a knowledge base and a hypothesise-and-test reasoning strategy, as shown in Figure 17.

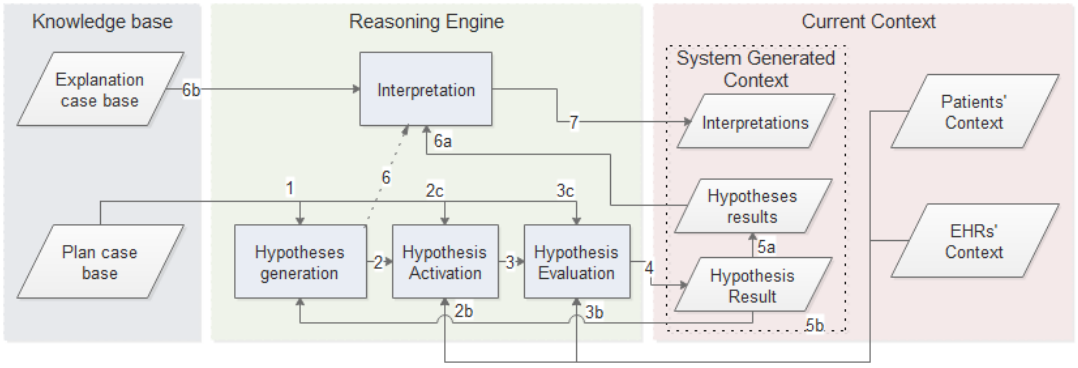


Figure 17: The created reasoning engine model.

The rectangles in the figure represent the processes of the reasoning engine, while the parallelograms show the data that the processes use or produce.

The *knowledge base* contains the domain knowledge of medical experts that the hypothesis-and-test strategy in this system needs. Currently, the knowledge base remains static: each time a patient shares their self-collected health data with a clinician, the same knowledge base creates the problem-identifying tasks, but the *current context* is dynamic. The *explanation case base* and the *plan case base* comprise the knowledge base.

The *plan case base* contains a number of plans. A *plan* consists of sequential problem-identifying tasks to be performed and can refer to, or include, other plans; for example, plan P1 (evaluates the correctness of the amount of the last insulin dose) uses the tasks P1T1 (check the blood glucose value) and P1T2 (estimate the best insulin amount for this situation) in combination with plan P2 (check the insulin sensitivity for the day), which in turn includes tasks P2T1 (define the amount of insulin intake for a day) and P2T2 (use the 1500/1800 rule for calculating the insulin sensitivity). Figure 18 illustrates this example. This hierarchical structure, however, does not indicate in what sequence the tasks and plans are executed, but this is handled by *rules*.

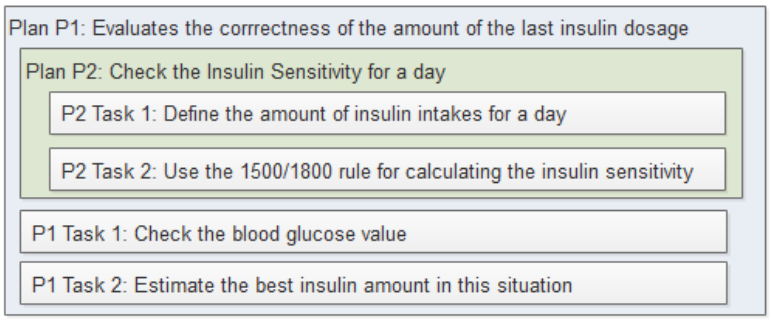


Figure 18: Example of hierarchy of plans (P) and tasks (T). P1 contains P2 and two tasks, P1T1 and P1T2.

There are three types of rule. The *plan rules* define the sequence of the plans and the tasks they consist of (e.g. perform the task 'check if insulin registrations are present' before the task 'check the amount of insulin intake for a day'). The *activation rules* define which data is necessary for performing a task (e.g. insulin and carbohydrate registrations are mandatory for the task 'check if the patient forgot to take insulin before or after a meal') and potential conditions for performing the task (e.g. 'a carbohydrate intake is considered a meal if done between 11:00 and 13:00' or 'patient should be type 1 diabetes'). The *evaluation rules* define the concrete actions to be taken in order to accomplish a task (e.g. for the task 'check if the patient forgot to take insulin before or after a meal', the rules define three actions: action 1) check the carbohydrate intake, action 2) check if the intake corresponds to a meal time, and 3) check if an insulin registration is present in a 30-minute window before or after the carbohydrate intake).

The *explanation case base* defines the complementary or hierarchical relationships between the problem-identifying tasks and the interpretation of identified problems, based on the results of the problem-identifying tasks; for example, the problem-identifying tasks 'check the amount of carbohydrate intake from the previous meal' and 'calculate the carbohydrates on board' are complementary, and compose the higher-level task 'check the amount of carbohydrates' that can characterise a hyperglycaemic event.

The first process in the reasoning engine is *hypotheses generation*. In the created model, a hypothesis represents the inferred candidate result of a task that the reasoning engine validates or invalidates; for example, the hypothesis 'there is no insulin registration before or after a meal' may be a candidate answer to the task 'check if the patient forgot to take insulin before or after a meal'. This process generates a current plan case composed of a sequence of tasks with associated hypotheses to test, based on the plan and the plan rules of the plan case base (number 1 in Figure 17) and on the system generated context (current context): the process uses the results of previously tested hypotheses to update the active case plan if necessary (5b); for example, if the hypothesis 'patient has hyperglycaemia' is true, the process updates the plan and adds 18 hypotheses according to the rules, such as 'the latest insulin intake was lower than the insulin needed as defined by the sensitivity factor for reaching 5.5 mmol/L'. The outcome of the hypotheses generation is a sequence of hypotheses to validate (or refute), each for accomplishment of a specific task constituting the plan.

The second process is *hypothesis activation*. The hypothesis generation process initiates this activation for each hypothesis listed in the current plan case (2). Hypothesis activation uses the activation rules from the plan case base (2c) and the current context from patients, EHRs, or both (2b). The *hypothesis activation* process ensures that the required context for evaluating a hypothesis is available; for example, the hypothesis 'patient has hyperglycaemia' requires blood glucose registrations drawn from the patient

entity. If the required context is not available for a hypothesis listed in the current plan case, the system flags the concerned hypothesis as NA. If the required context is available, the system activates the hypothesis. The activation of a hypothesis automatically initiates its evaluation (3).

The *hypothesis evaluation* process validates or invalidates the claim proposed by the hypothesis. To do this, the process uses the evaluation rules of the plan case base (3c) and the current context from patients, EHRs, or both (3b). The output of this process is a hypothesis result (4), which may be true, false, or NA. This output is then stored with the other hypotheses results (5a) and sent back to the hypothesis generation process (5b) for potential current plan case updates.

Once the hypotheses generation has activated all hypotheses in its current plan case, it triggers the interpretation process (6). This process uses the relationships between problem-identifying tasks and their explanations drawn from the explanation case base (6b) and the hypotheses results (6a) to create a textual interpretation of the results of the execution of the reasoning engine to allow user consultation. The textual interpretation is the final context generated by the system (7). The system then displays the context for the users.

Figure 19 describes all the hypotheses used by the KBM. The hypotheses are organised by type and order of execution (from top to bottom), according to the explanation case base and the plan case base. The interpretation of the hypotheses, rather than their internal identification codes, defines them for better clarity. For simplicity, the context requirement for their activation and generation is omitted (e.g. the generation of the hypothesis ‘there is not enough insulin’ requires that the hypothesis ‘patient has hyperglycaemia’ be true and its activation requires the registration of insulin self-collected health data). There are two types of hypothesis: data reliability and medical diagnosis. The output of the first type of hypothesis is a factor of reliability defining how much can clinicians trust the data collected by the patients. The output of the second type of hypothesis is the identification of medical problems (e.g. hypoglycaemia, lack of sleep) and their potential causes (e.g. too much insulin intake for a hypoglycaemia event). Paper P1 presents the hypotheses in detail [32].

This model permits to address multiple acceptance barriers, as explained in section 4.1.3 Addressing acceptance barriers.

4.2.1.2 Prototyping

The prototyping of the KBM relied on the reasoning engine model described in Figure 17 and was supported by a development-driven approach with black and white unit tests. However, the current prototype differs from the implementation described in the paper P1 [32]: it reorganises the knowledge base allowing a loose-coupling between hypotheses, and between the hypotheses and the interpretation process, facilitating the development-driven process and unit testing. In addition, the execution of the current prototype is twice as fast as the previous implementation. The Appendix A Current implementation of the KBM documents the implementation of the current prototype and the tests performed. Figure 22, section 1, B and section 2, C-F shows the result of an instance of the interpretation process.

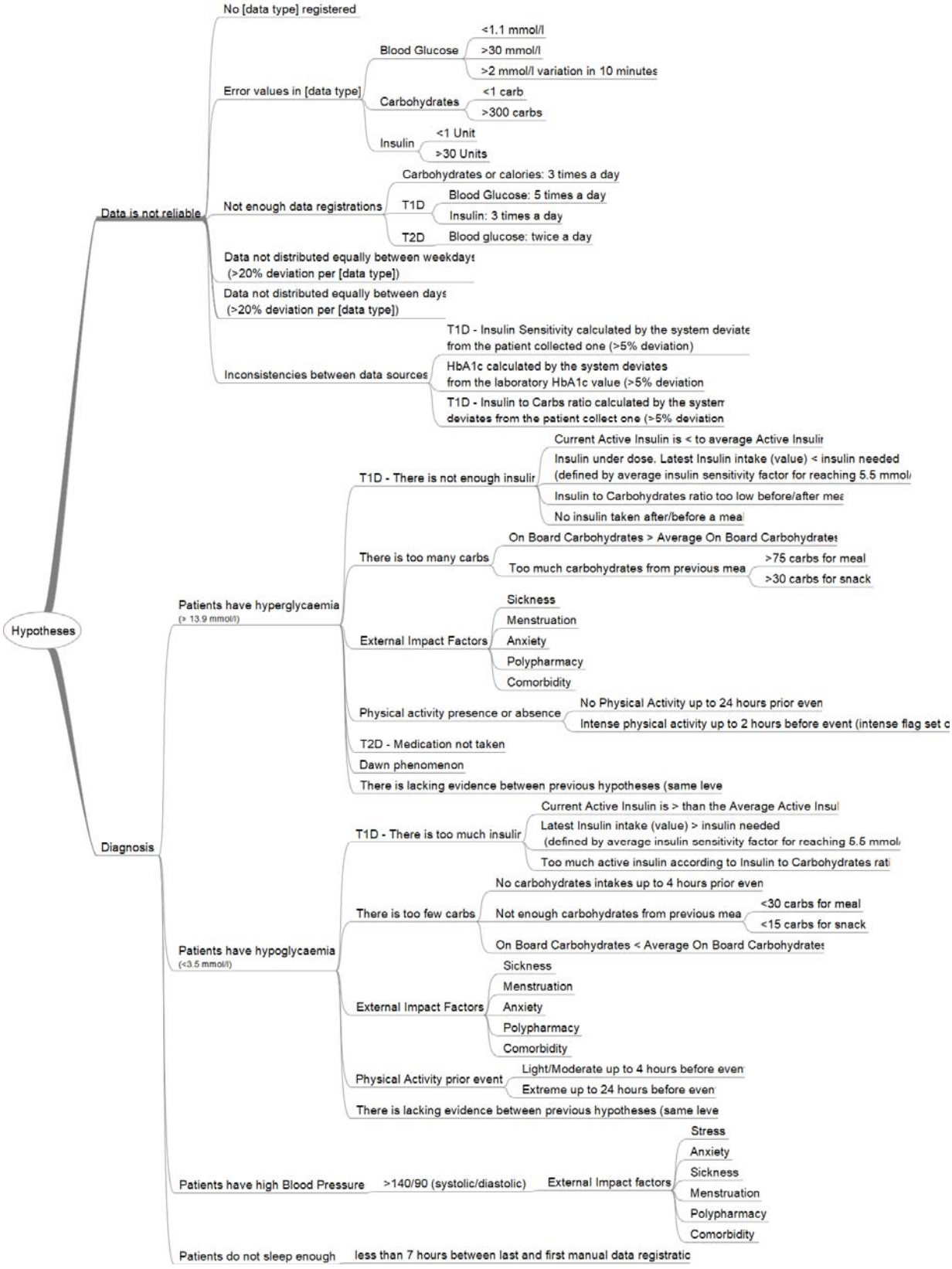


Figure 19: list of hypotheses organised per type used by the knowledge-based module (KBM). T1D = Type 1 diabetes, T2D = Type 2 diabetes.

4.2.1.3 Assessment

The goal of the assessment phase was to ensure that the designed KBM would suit the requirements of the clinicians and be relevant for both clinicians and patients during consultations.

4.2.1.3.1 Online open discussions

I presented to the two international patients the results of an instance of the first prototype of the KBM, using their self-collected health data extracted from the mySugr application [149]. I mapped the data to FHIR artefacts and prepared the system with the data, using SNOMED-CT codes as the terminology. While still based on the reasoning engine model presented in this thesis, the knowledge base was incomplete and lacked a proper plan case base and an explanation case base. That meant that the relationships between the different tasks were weaker and the system was not able to provide advanced interpretations regarding the results of the tasks. An example of a result created by the first KBM prototype is shown in Figure 20.

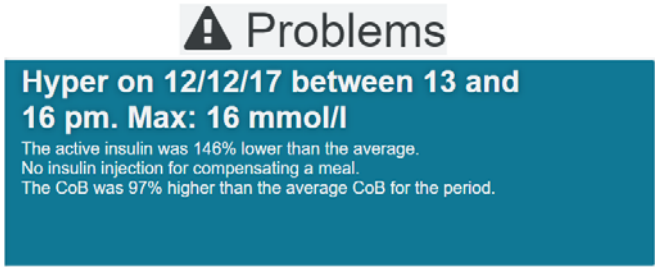


Figure 20: Example of results of the first KBM prototype regarding a hyperglycaemia event.

While the patients acknowledged that the KBM could be useful during consultations for pointing out eventual challenges to be addressed to improve their health situations, they identified multiple issues. The issues are listed in Table 8, along the solutions I used to address them.

Table 8: Issues identified by the international patients and solutions I proposed to address them.

#	Issues identified by the patients	Solutions I proposed to address the issues
1	'It is difficult to know which information is important, considering that the results are ordered chronologically. I do not want to spend time doing this'. In addition, 'the problems list different types of issues and it is extremely difficult to jump from one to another'.	Categorising the results by type (e.g. data reliability, sleep pattern, hyperglycaemia, hypoglycaemia) and ordering the results by importance (e.g. lower hypoglycaemic value first) instead of chronologically.
2	Not being able to extract patterns from the problem lists.	Providing a summary of the problems and displaying the event in graphs (per hour and per weekday).
3	'It is too difficult to remember what happened during a period (e.g. when did I eat during this period?)'. 'I think the focus should be on the value instead of the time of the problem'.	Separate the value relating to the problem (e.g. blood glucose value for a hyperglycaemic event) and facilitating its identification (colour scheme). Providing information about the most important event during a specific period, instead of the whole period (e.g. the time when highest blood

		glucose value was reached during a hyperglycaemic event).
4	'I find problems a little aggressive. Use the word 'challenges' instead?'	Replacing 'problems' with 'noticeable events'.
5	'The causes of a problem are difficult to understand. In addition, is it possible to have a more detailed justification?'	Improving the knowledge base (plan case base and explanation case base). Displaying a detailed analysis of the potential causes and classifying them.
6	'I am not interested in data reliability problems. I just want the system to provide information regarding my situation'.	Separating the data reliability issues from the others, providing a short explanation of the situation and hiding the detailed explanations (accessible by pressing a button).

I implemented the solutions described in this table before presenting the KBM to the participants of the co-design (see next section).

4.2.1.3.2 Presentation to the participants of the workshop W4 and co-design

I asked the participants in the clinician workshop W4 and the co-design session (clinicians and patients) the same question: 'do you think the module could be relevant during consultations, especially for identifying potential problems?' and all of them answered 'yes'. I showed the results of the KBM run, within a FullFlow report, to the participants. The findings were the results of a run of the KBM against self-collected health data provided by the research patient. The results contained the noticeable events, their potential causes and explanations, as well as their distribution over time, along with the reliability of the data (see Figure 22 in the next section for more details).

Two patients preferred to have this module connected to their own self-management solutions to: 1) obtain suggestions on why serious medical events occur and 2) to prepare for the consultation. The participants appreciated the concept of presenting the module as an overall view with more detailed graphs in FullFlow, because this permits faster identification of problems without having to examine the data. My colleagues and I discussed the KBM findings with the participants and asked how they felt about them. Based on these discussions:

- I removed the data reliability grade from the visual display, since it did not have concrete meaning for the participants; according to them, an alert stating the potential problems would be sufficient.
- I changed the standards of hypoglycaemia (<4 mmol/L) and hyperglycaemia (9 mmol/L) to high hyperglycaemia (>13.9 mmol/L) and low hypoglycaemia (<3.5 mmol/L) because the patients preferred to discuss the more serious events with their medical workers, rather than all events outside the recommended range.
- I updated the explanation case base by nuancing the feedback regarding medical events (e.g. 'this event *may* have been due to…') because the patients took for granted the findings of the module.

Despite these points, the participants appreciated the module because it permitted them to obtain possible explanations for why events occurred and what they could improve.

Figure 22, section 1, B and section 2, C-F shows an example of a visual KBM interpretation. Paper P1 provides detailed description of such visual interpretation [32].

4.2.1.4 Summary

The KBM, relying on a hypothesise-and-test strategy fed with context, may pinpoint the presence of information gaps in patients' self-collected health data, identify relevant health information, and define the data reliability. The hypothesise-and-test strategy is a viable approach for an inductive reasoning-based system when diverse, large, and correct datasets are not available. The context-sensitive approach permits the integration of multiple factors for decision-making and for simplifying the complexity and maintenance of the system.

The KBM could address multiple acceptance barriers. Extracting relevant information could permit the size of the data needed during a consultation to be reduced, thereby decreasing the costs of maintenance for the storage and sharing of self-collected health data. Moreover, it could increase the meaningfulness of the data and reduce the time needed for clinicians to consult the data, enabling them to concentrate on the most important noticeable events, and simultaneously reduce clinicians' lack of confidence in this type of data.

Providing information regarding the patients' self-collected health data reliability could also consolidate the previous points and directly address the lack of data reliability perceived by the clinicians.

4.2.2 Dashboard (contribution C3)

This section is based on the 'overview' and 'iterative dashboard design' sections of the paper P3, entitled 'Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study', published by JMIR Diabetes [34].

The dashboard is the second solution integrated in the clinical decision support system I propose for dealing with the acceptance barriers to the usage of self-collected health data during consultations. A dashboard is a tool that permits the graphic presentation to clinicians of relevant information relating to patients' situations, based on clinicians' needs and preferences. It includes the KBM results presented in the previous section.

4.2.2.1 Knowledge Acquisition

4.2.2.1.1 First prototype

I created the first prototype based on the results of the FI-STAR study and the literature review, as explained in the methodologies section. From previous studies, eight relevant data types for diabetes consultation were identified: blood pressure, calories, carbohydrates, heart rate, blood glucose, insulin, weight, and physical activity (Figure 21, A); and relevant medical calculations, such as the insulin to carbohydrate ratio and basal insulin to bolus insulin ratio (Figure 21, C). For the GUI, presentation of the data in different time-frames (per hour, per day, per week, and for the complete period [Figure 21, B]), and the use of a colour-scale to illustrate data ranges (Figure 21, D) were the main requirements expressed.

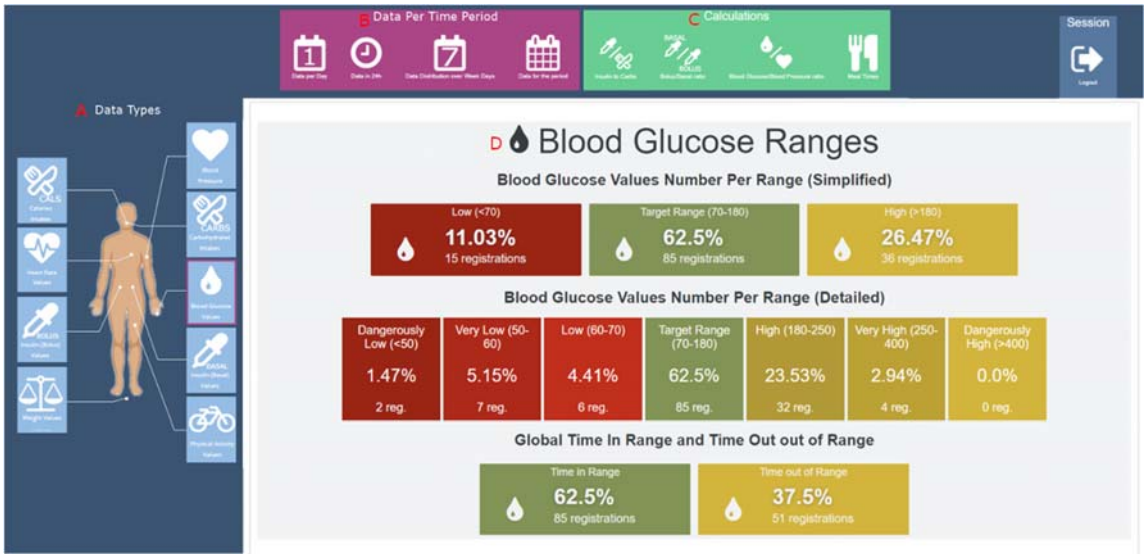


Figure 21: First prototype of the FullFlow dashboard system (without the KBM).

4.2.2.1.2 Facilitated workshops and open-ended discussions

The first prototype was presented to the participants in the first workshop (W1). Based on this prototype, and their own experiences, the participants suggested improvements to the data, functionality, and GUI. The suggested improvements were translated into requirements and incorporated in the prototype presented during the second workshop. The improvements suggested during the second workshop were used as requirements for the development of the final prototype. The requirements identified are summarised in Table 9.

Table 9: Summary of the requirements defined based on suggestions from the participants in the facilitated workshops, and their description. eA1c: Estimated HbA1c.

Requirements	**Description**
R1: display data collected by patients	At least: blood glucose, blood pressure, insulin (bolus/basal), medication, carbohydrates, calories, physical activity. Being able to accept new data types (e.g. menstruation, ketones, polypharmacy) would be a bonus. The system shall inform clinicians if the patients register life goals (e.g. what they are focusing on in their daily self-management).
R2: quantify data collected by patients	The system shall notify which data has been collected by the patients and quantify it.
R3: Display data collection period	The system shall provide clinicians the length of time during which patients collected their data.
R4: Display variabilities in the patients' data values	The system shall be able to present a variability value for all data types to indicate how much these values diverge.
R5: medical calculations	The system shall be able to provide medically relevant information (e.g. insulin to carbohydrates ratio, insulin sensitivity).
R6: grade data reliability	The system shall permit clinicians to know immediately if the data collected by the patients is reliable (= worth consulting it).
R7: hide eA1c	Removing eA1c from the GUI.

R8: reduce complexity of blood glucose ranges	The system shall use the simplified (three-levels) blood glucose range.
R9: consult all self-collected health data at once	The system shall present all self-collected health data simultaneously in graph form.
R10: pattern recognition	The system shall ease the identification of patterns in patients' lifestyles per day, per week, and for the whole period (e.g. hyperglycaemic events each day after dinner).
R11: bridge to existing data	The system shall provide information that clinicians can assess by comparing existing data with the self-collected health data.
R12: overview of the patients' situations	The system shall be able to inform clinicians of patients' struggles and successful management etc.
R13: visual helper	The system shall provide information about data that is in or out of range.

Three main scenarios were created, considering three represented a manageable number of scenarios for the workshops and open-ended discussions, while still allowing consideration of diverse situations. An example of a scenario is provided below (see paper P3 for additional information [34]):

Scenario 1:
Settings (context and situation): Patient has nightly hypoglycaemic events. The patient has an appointment with a diabetes nurse to discuss his situation and the health data collected one month prior to the appointment. The patient uses finger pricks and an insulin pen.
Agents: Patient with type 1 diabetes. Diabetes Nurse.
Goals (what are the targets of the scenario): The system should show the hypoglycaemic events and identify the nightly trends. The system should show the insulin dosage and the carbohydrate intake to help the nurse identify possible courses of action.
Events (actions taken by the agents): Patient registers, on average, per day: 10 blood glucose values, 4 carbohydrate intakes, 6 insulin injections (2 basal, 4 bolus) and 10 minutes of physical activity. Nurse discusses the patient's hypoglycaemia events with him and consults the data using the FullFlow dashboard.

4.2.2.2 Prototyping

I provide an example, in Figure 22, of the dashboard based on the self-collected health data obtained from the research patient, which was similar to the use-case presented to clinicians in the pre-assessment study. The proposed dashboard has been designed to answer the requirements listed in Table 9.

For instance, displaying information regarding the data reliability at the top of the graphical interface permits clinicians to know immediately if the data is worth consulting it, addressing the requirement R6 (Figure 22, section 1, B). Another example is the display of noticeable events (Figure 22, section 2, F) permitting to inform clinicians about difficult situations the patients encountered, which addresses the requirement R12. In addition, the dashboard proposes multiple graphs type helping clinicians identifying trends and potential challenging occurrences (Figure 22, section 3), addressing requirements R10 and R1. The paper P3 explains in detail the composition of the dashboard and how it addresses all requirements [34].

4.2.2.3 Assessment

The main goal of the assessment was to determine whether the dashboard is suitable for use during consultations. At the stage of creating the dashboard, the assessment relied on the participants of the workshops, my colleagues, and I. Together, we determined that the features of the dashboard address all the requirements and the created scenarios.

4.2.2.4 Summary

The dashboard was developed based on continuous feedback from clinicians and patients to minimise possible future user resistance.

The proposed dashboard limits the potential increase in time consumption due to the usage of this solution by 1) presenting information relating to the quality of self-collected health data (identifying whether the data is worth consulting or not), 2) displaying an overview of the patient's situation, and 3) identifying important medical events without the need to consult the complete dataset.

Moreover, using clinicians' feedback during its creation, and therefore providing relevant information in a way that clinicians are familiar with, could 1) address changing clinicians' habits, 2) reduce the necessity to train clinicians, 3) avoid the need to learn new skills, and 4) increase the data reliability by providing a bridge between self-collected health data and data provided by laboratory tests. The dashboard therefore suggests the possible presentation of the data for EHRs.

----- Section 1 ----

------ Section 2 -----

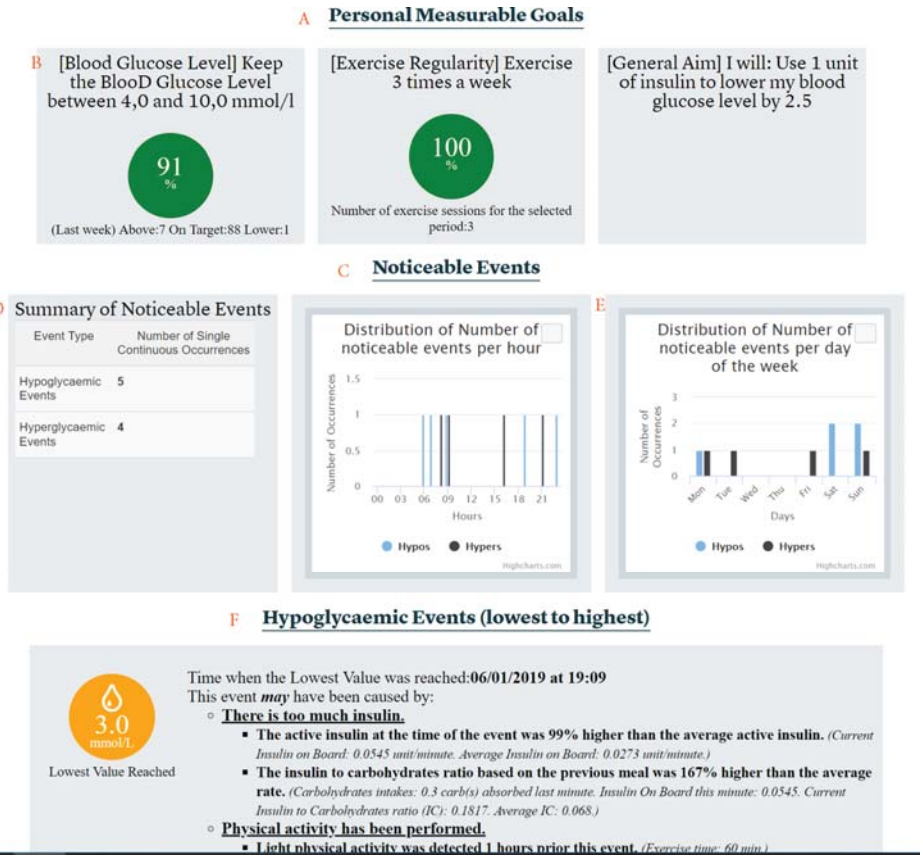


Figure 22: Example of an instance of the final prototype.

4.2.3 Architecture

The architecture is the third designed solution to address the acceptance barriers. It deals with the possibility of sharing patients' self-collected health data with EHRs using Norwegian standards and public services. The proposed architecture uses loose coupling between all systems, permitting healthcare institutions to use the EHRs that suit them best and patients to use the tools they are accustomed to.

4.2.3.1 Knowledge acquisition

4.2.3.1.1 Requirements

Multiple requirements were identified during the focus groups with the NDE and the EHR vendors. The requirements are summarised in Table 10.

Table 10: Requirements regarding the architecture. # = Number

#	Requirement
R1	Use ID-porten for authenticating patients.
R2	Use the Personal Health Archive for storing and retrieving the data on Helsenorge
R3	Use a message queue for sending messages to EHRs
R4	Use Digital Schemas for modelling the data to be shared
R5	Use FHIR for representing medical observations
R6	FullFlow must not store any medical data
R7	FullFlow must be located within the Norwegian Health Network
R8	Patients cannot send messages to EHRs directly

ID-porten is a national login solution for accessing Norwegian public services using two factors authentication and supporting Security Assertion Markup Language 2.0 (SAML 2.0) and OpenID Connect (OIDC) [150, 151]. ID-porten allows Norwegian citizens to connect to public services directly, from their mobile devices, using the mobile BankID method, which can ease the usage of the service by patients due to its simplicity and availability on all devices, without the need to close the current foreground application on their mobile devices. Figure 23 demonstrates the login process for Helsenorge.no, a nationwide health file hosting service that allows patients to consult health documents generated by, and exported from, EHRs [152], using this methodology. The login process requires 6 steps.

1. Patients select a method to log into Helsenorge.no (Screenshot A of Figure 23). Mobile BankID is the second method listed.
2. Patients enter their mobile phone number and their birth date and click 'next' (Screenshot B of Figure 23).
3. The mobile BankID cloud solution generates a temporary key (Screenshot C of Figure 23) which allows patients to verify the log in process. The temporary key contains reference words (in this example: KANTETE FLOKK) and is displayed on the screen.
4. After a few seconds, the mobile BankID cloud solution transfers the temporary key to the concerned patient's phone via their mobile carrier, using SIM application-specific instructions (Screenshot D of Figure 23). The citizens must confirm that the temporary key matched the one displayed during the previous step.

5. Once the key match is confirmed, patients are invited to enter the pin code created when the mobile Bank-ID was configured the first time (Screenshot E of Figure 23).
6. If the pin code is correct, the mobile carrier manages the authorisation token and the patients can access helsenorge.no (Screenshot F of Figure 23).

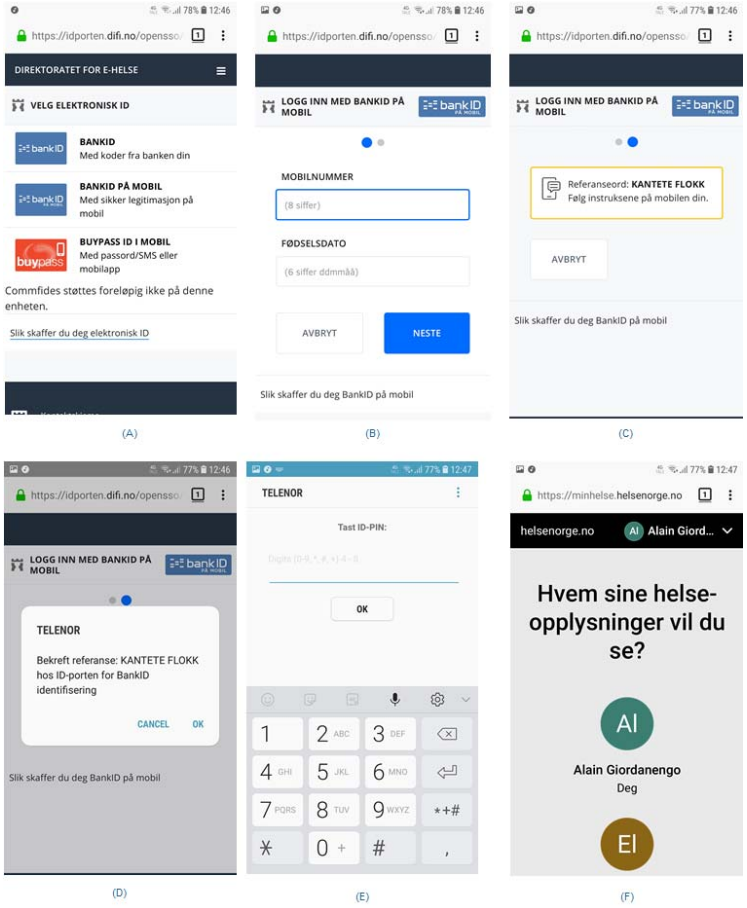


Figure 23: Log into Helsenorge.no using ID-porten mobile BankID method. (A) = login screen of Helsenorge.no, (B) = login screen of the mobile BankID method, (C) = temporary key generation, (D) = display of generated key on mobile device, (E) = mobile ID pin code, (F) = access to helsenorge.no.

The Personal Health Archive is personal cloud storage for health-related documents, currently in development and expected to be hosted by Helsenorge.no. This Personal Health Archive would permit patients to upload their own health data in the future.

The message queue is based on the Advanced Message Queuing Protocol (AMQP) that supports publish-and-subscribe routing. EHRs and health systems can retrieve and drop messages in their respective queues to exchange data with these systems, without having a direct link between them. Using an AMQP queue also permits restrictions to be applied easily.

A digital schema is a national standard for describing a collection of data. Schemas are used for exchanging data between systems, but are also used for representing web forms for manual creation or update, either by the patients or clinicians. Figure 24 illustrates the composition of a digital schema. The contents of the schemas are based on FHIR artefacts; for instance, the patient is represented by an FHIR resource patient. Schemas offer three possibilities for collecting patients' health data:

1. Patients submit their self-collected health data directly, as represented in FHIR resources or extracted, for instance, from their Open mHealth system [61], to the schemas (Figure 24, health data). Either SNOMED-CT or LOINC terminologies, and JSON or Extensible Markup Language (XML) representations, could be used.
2. Patients can answer questionnaires for sharing their data (Figure 24, schema data). While this method permits simple data, such as weight, to be collected easily, it is not suitable for the project case due to the huge quantity of daily self-collected health data.
3. Patients can attach the extracted data from their tools in a proprietary format as binary files in the schemas (Figure 24, attachments). This method requires future mapping from proprietary systems to FHIR standards.

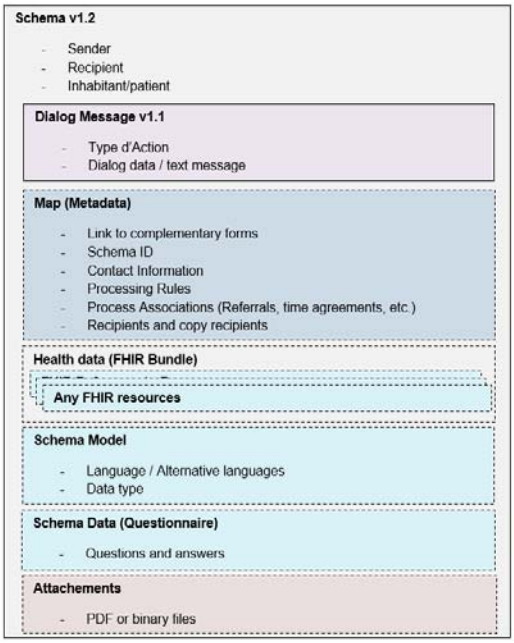


Figure 24: Digital Schema content extracted from the government document 'Digitale skjema Implementasjonsguide og dokumentasjon av standarder for skjematjenester v1.1'.

A national schema provider acts as a cloud service, hosting and providing access to schemas. Using schemas and FHIR ensures semantic interoperability between all Norwegian services.

The Norwegian Health Network acts as a subnetwork separate from the Internet, in which health systems, such as EHRs, can exchange patients' medical records generated by the health institutions [153]. Systems inside the Norwegian Health Network are not allowed to receive medical data from the Internet and they rely on Helsenorge to do this.

Based on these requirements, I propose an architecture that permits EHRs to receive self-collected health data from patients. The architecture is described below.

4.2.3.2 Prototyping

4.2.3.2.1 High-level architecture

Figure 25 illustrates the high-level architecture. Two main parties who are concerned with this project—clinicians (on the left), who are either physicians (secondary health care), general practitioners (primary health care), or involved in municipal care (e.g. home services)—consult the self-collected health data

during their working time, and patients (on the right), collect and share their self-collected health data. Other parties, including system owners and developers of the different services, have been omitted for the purposes of simplification.

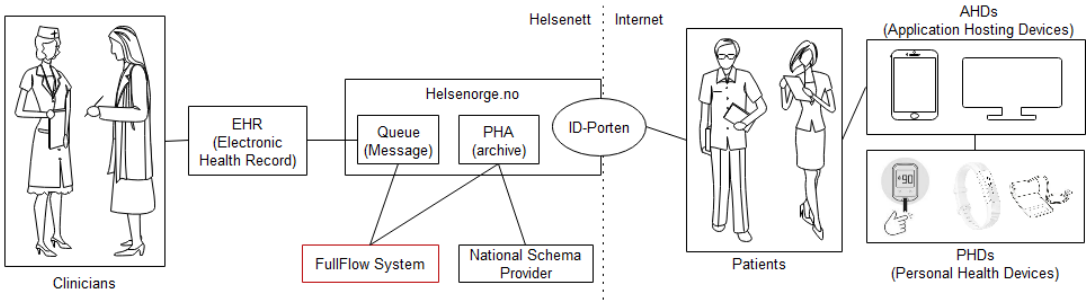


Figure 25: High-Level Architecture. (Helsenett = Norwegian Health Network).

Patients collect data using personal health devices (PHDs), such as glucometers, smart scales, fitness trackers, and blood pressure monitors, and centralise them by using application hosting devices (AHDs), which are applications available on mobile devices (e.g. mySugr [149]) or on personal computers (e.g. Shimmer [154]). Patients can share the data on the Internet (see right side of the Figure 25). Clinicians rely on their EHRs when consulting or registering data concerning their patients. Between these parties lie health systems (Helsenorge, the national schema provider, and FullFlow [requirement R7]), permitting indirect exchanges between them (requirement R8). I propose the following flow:

1. Patients self-collect health data using whatever solutions suit them best.
2. Patients connect to their Personal Health Archive through ID-porten and complete a schema with their data (requirements R1, R2 and R4).
3. FullFlow retrieves the schema from the Personal Health Archive, extracts the data either from the FHIR artefacts or from the binary files, map proprietary format to FHIR resources if necessary (requirement R5), performs analyses, updates the FHIR resources of the schema, sends it back to the Personal Health Archive and sends a copy to the message queue (requirement R3);
4. EHRs retrieve the schema from the queue during consultation when clinicians access the medical records of the patients.

During step 3, patients can consult the schema updated by FullFlow and can be deleted from the Personal Health Archive and the message queue if they wish. However, patients do not have control of the schema sent to EHRs during step 4, and they should contact the concerned institution if they wish to delete or retrieve their data from the EHRs, as stated by the General Data Protection Regulation (GDPR) [155]. The FullFlow system is not persistent regarding medical data, meaning that it does not conserve or store any medical data on its own, and it relies on the data provided by the Personal Health Archive to perform step 3, easing its compliance with the GDPR and meeting requirement R6. A detailed description of the implemented system is available in Appendix B – FullFlow system prototype and scalability tests.

4.2.3.3 Assessment

4.2.3.3.1 Scalability tests

The scalability tests demonstrated that the FullFlow system is scalable, stable (can recover from a stress situation) and can meet the Norwegian demand. Figure 7 shows an example of the scalability of the system. Appendix B – FullFlow system prototype and scalability tests describes these tests.

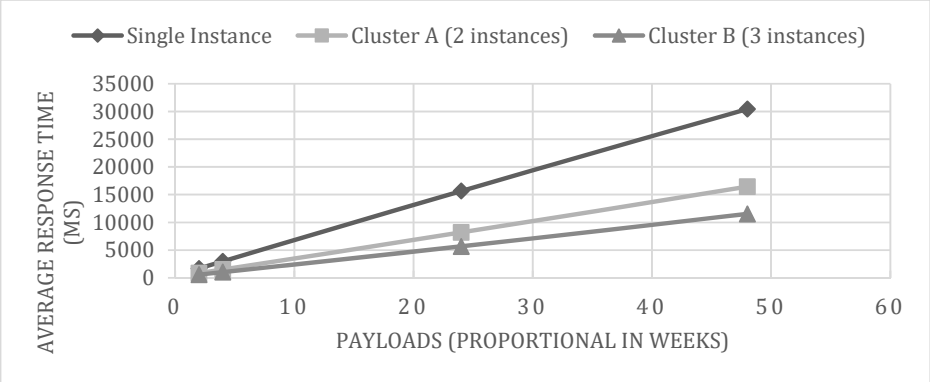


Figure 26: Average response time for the load tests for each type of payload and test.

4.2.3.3.2 Integration with Infodoc Plenario EHR

A master's degree student and I demonstrated the integration of the results of the FullFlow system into Infodoc Plenario using a use case approach. For this situation, we created a persona (a fake person with a fake identity) and pre-generated medical data, which was stored in the Infodoc application. Following the process described in the knowledge acquisition section, we were able to integrate FullFlow into Infodoc Plenario, as illustrated in Figure 27. More details are provided in the master thesis of the concerned student [156].

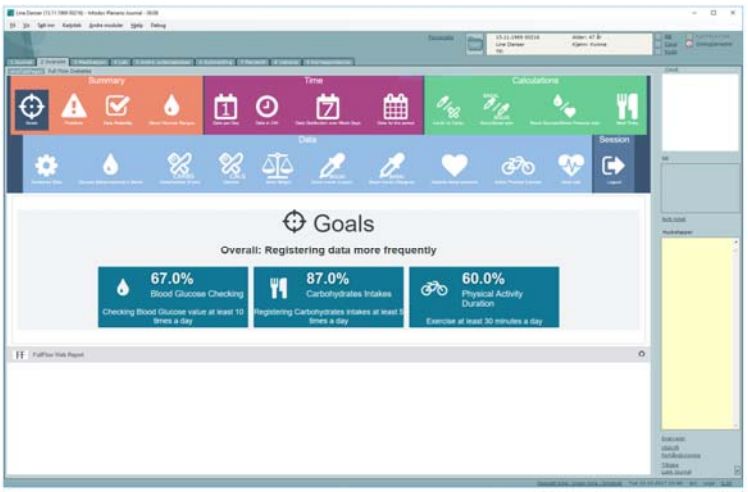


Figure 27: (Old) FullFlow prototype embedded in Infodoc Plenario EHR.

4.2.3.4 Summary

The architecture proposes a national approach for integrating patients' self-collected health data into Norwegian EHRs, while allowing both patients and healthcare institutions to choose the tools that suit them best. The scalability of the FullFlow system has been demonstrated, along with an introduction to the data transferred by the system to a Norwegian EHR.

The proposed architecture addresses financial acceptance barriers by mutualising the costs and using existing services for authenticating users, and storing and transmitting the data. The proposed architecture uses the existing EHRs to receive the data, thereby limiting changes in workflow, reducing the need for training of clinicians, and decreasing the time spent on consulting the data.

Relying on well-used and well-tested national services, and demonstrating that FullFlow can scale to meet the Norwegian demand, addresses the technical acceptance barriers regarding the lack of software and hardware reliability by not changing the habits of the users, thus limiting the necessity for clinicians to adapt to new tools. Privacy and security are ensured by both the NHN and the existing national services. Moreover, relying on FHIR standards for representing medical observations and sharing the data addresses the lack of standardisation and provides semantic interoperability between multiple systems, even if mapping patients' data could be necessary in the case of proprietary systems.

4.3 Pre-trial assessment

The pre-trial assessment presents the assessment of the FullFlow system in similar conditions than the ongoing medical trial: using the Diabetes Diary [111] as patients' tool and the Diabetes Share Live for sharing the data [101]. The medical trial is described in section 5.4 Ongoing medical trial page 81.

All the participants (nine GPs, four diabetes nurses and one dietitian) expected that the presented system—a combination of Diabetes Diary, Diabetes Share Live, and FullFlow—would be useful during their daily consultations. They forecast that the system would be good for all patients, but particularly effective for patients who entered enough data, regularly, in their diaries.

They predicted that three types of patients would be interested in this solution: 1) patients who are interested in technology and self-management; 2) patients concerned about their diabetes and quality of life; and 3) patients living in remote areas, where the usage of the system could support remote consultations, avoiding the necessity for patients to travel for several hours for a single face-to-face consultation. One participant mentioned that several patients already use self-management applications, which would ease the introduction of this system.

The majority of the participants (9/14, 64.3%) would like to keep the system in its current state, while five (5/14, 35.7%) participants suggested to adjust the provided services, either by adding supported data types (e.g. plasma glucose), adding new services (e.g. possibility to write notes or goals using directly the system) or removing existing services (e.g. removing CoB).

However, overall, the system was very well received by the participants and they were eager to start using it during consultations. However, the participants mentioned that experience of using the system would be needed to validate their expectations and confirm its usability and functionality.

A detailed qualitative analysis and the transcribed answers to the collected questionnaires are available in the paper P3 [34].

5 Discussion

5.1 Overall research approach: participatory design

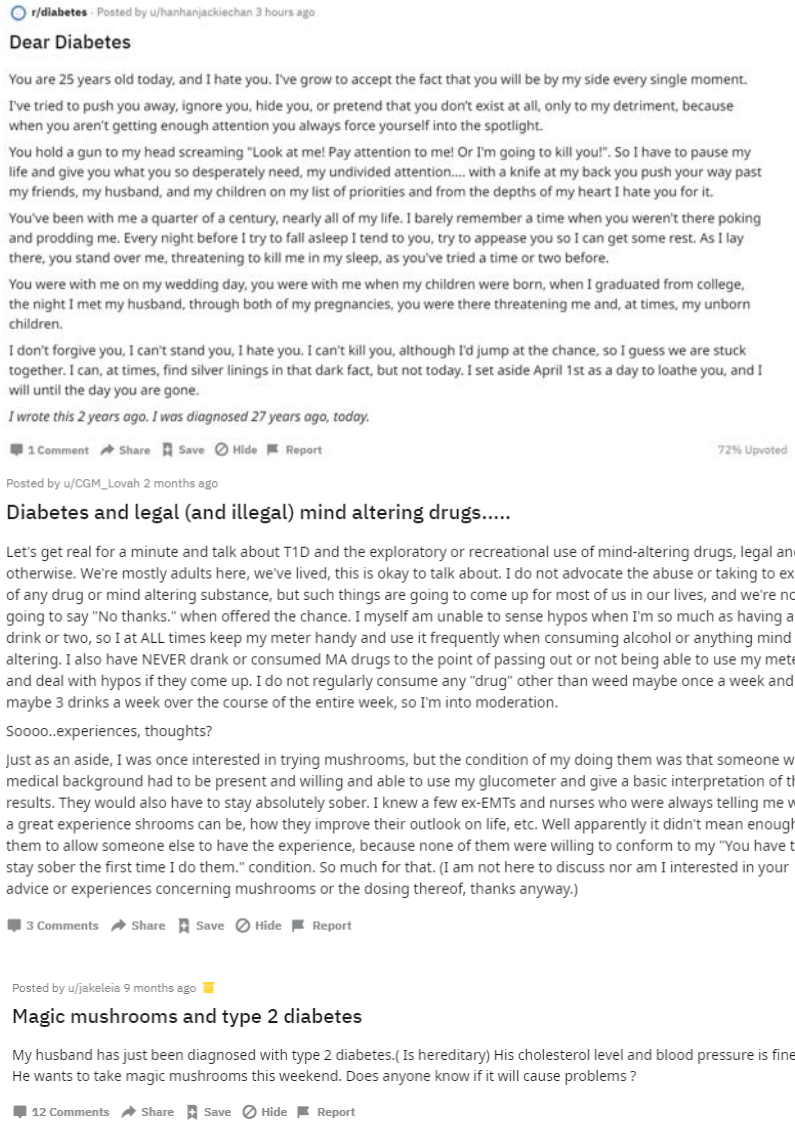
The three-phase participatory design consisting of knowledge acquisition, prototyping, and assessment permitted the rapid and continuous delivery of useful software. Involving users (clinicians and patients) and parties (the NDE and EHR vendors) throughout the knowledge acquisition and assessment phases ensured that the proposed solutions met everyone's needs precisely. Using international resources permitted the extension of knowledge in this area. However, the approach came with challenges:

1. More time and commitment. Involving users (patients and clinicians) throughout the project required a great deal of effort regarding a) writing applications to ethical committees for validating the recruitment and participation procedures, b) recruiting the users, c) planning the different workshops, and d) performing qualitative analysis of the workshop discussions. Moreover, involving multiple parties (patients, clinicians, EHR vendors, and the NDE), with different needs and requirements, necessitated extra work to ensure that everyone was satisfied with the proposed solutions. In addition, I had to ensure that the solutions I proposed, although adapted to the involved parties' needs, constituted scientific contributions from an international perspective.
2. Lack of documentation. Because the approach was time consuming, with a short lifecycle (e.g. several workshops immediately following one another), my colleagues and I lacked the time and resources to maintain proper documentation; for instance, we have not yet published articles presenting the complete qualitative analysis of the workshops and we focused on extracting the 'core' qualitative results only, to explain the construction of the proposed solutions for addressing the acceptance barriers. Similarly, a broader qualitative analysis of the input collected in the co-design has been submitted in September 2019 [157], one year and a half after the co-design was being held. This issue also applied to the code I produced, with the documentation comprising only comments, unit tests, simplified classes, and sequence diagrams.
3. Lack of tests. Due to the time constraints and constantly changing user demands, I was unable to conduct a complete range of tests; for instance, while the backend (KBM and XML endpoints) were tested with unit, load, and stress tests, I did not test the frontend (dashboard) using automated tools such as Selenium [158]. This resulted in a late discovery of a bug during the pre-trial assessment.

While these challenges may be important, I believe that the selected approach was worthwhile, considering that it permitted scientific contributions to be validated in a short space of time. Moreover, the documentation, despite not being optimal, permits peers to reproduce the results I presented.

I also tested a 'new approach' for recruiting patients and reducing the time and commitment involved, using 'alternative' social media platforms. While my colleagues focused on Facebook [159] and Twitter [160], I used Reddit and IRC (replaced by a Discord server during 2018) for reaching patients who could assist the KBM creation. While Reddit was used by some studies [161, 162], the platform is nevertheless marginal in healthcare today; for instance, Pubmed returns eighty results for the search query 'Reddit', but 3,069 results for the query 'Facebook' [July 2019]. However, Reddit, although 'pseudonymous' (i.e. it is possible to identify a user if the concerned person reveals too much information on their account), empowers participants and allows them to express views they would not reveal otherwise [163], so that

patients with diabetes feel confident enough to express their feelings or discuss mind-altering drugs (Figure 28). Combining Reddit with a more personal communication channel, such as IRC, Telegram, or Discord, permitted the easy and secure exchange of information and data. Another advantage of this approach was the ability to reach diverse international people. Figure 29 illustrates this diversity, with one person residing in the United States, one in Australia, and one in Egypt (screenshot from the Discord server of the r/diabetes community). In addition, since the self-collected health data I received from the patients was anonymised (i.e. it is not possible to link the medical data to a specific person or account), it was not necessary to involve the ethics committee. However, a limitation exists: due to the anonymisation, it is not possible to assess the validity of the patients' profiles, but this is not a deficiency in this case, because I have used self-collected health data and general discussion only to improve the KBM.



r/diabetes · Posted by u/hanhanjackiechan 3 hours ago

Dear Diabetes

You are 25 years old today, and I hate you. I've grow to accept the fact that you will be by my side every single moment.

I've tried to push you away, ignore you, hide you, or pretend that you don't exist at all, only to my detriment, because when you aren't getting enough attention you always force yourself into the spotlight.

You hold a gun to my head screaming "Look at me! Pay attention to me! Or I'm going to kill you!". So I have to pause my life and give you what you so desperately need, my undivided attention.... with a knife at my back you push your way past my friends, my husband, and my children on my list of priorities and from the depths of my heart I hate you for it.

You've been with me a quarter of a century, nearly all of my life. I barely remember a time when you weren't there poking and prodding me. Every night before I try to fall asleep I tend to you, try to appease you so I can get some rest. As I lay there, you stand over me, threatening to kill me in my sleep, as you've tried a time or two before.

You were with me on my wedding day, you were with me when my children were born, when I graduated from college, the night I met my husband, through both of my pregnancies, you were there threatening me and, at times, my unborn children.

I don't forgive you, I can't stand you, I hate you. I can't kill you, although I'd jump at the chance, so I guess we are stuck together. I can, at times, find silver linings in that dark fact, but not today. I set aside April 1st as a day to loathe you, and I will until the day you are gone.

I wrote this 2 years ago. I was diagnosed 27 years ago, today.

1 Comment Share Save Hide Report 72% Upvoted

Posted by u/CGM_Lovah 2 months ago

Diabetes and legal (and illegal) mind altering drugs.....

Let's get real for a minute and talk about T1D and the exploratory or recreational use of mind-altering drugs, legal and otherwise. We're mostly adults here, we've lived, this is okay to talk about. I do not advocate the abuse or taking to excess of any drug or mind altering substance, but such things are going to come up for most of us in our lives, and we're not all going to say "No thanks." when offered the chance. I myself am unable to sense hypos when I'm so much as having a drink or two, so I at ALL times keep my meter handy and use it frequently when consuming alcohol or anything mind altering. I also have NEVER drank or consumed MA drugs to the point of passing out or not being able to use my meter and deal with hypos if they come up. I do not regularly consume any "drug" other than weed maybe once a week and maybe 3 drinks a week over the course of the entire week, so I'm into moderation.

Soooo..experiences, thoughts?

Just as an aside, I was once interested in trying mushrooms, but the condition of my doing them was that someone with a medical background had to be present and willing and able to use my glucometer and give a basic interpretation of the results. They would also have to stay absolutely sober. I knew a few ex-EMTs and nurses who were always telling me what a great experience shrooms can be, how they improve their outlook on life, etc. Well apparently it didn't mean enough to them to allow someone else to have the experience, because none of them were willing to conform to my "You have to stay sober the first time I do them." condition. So much for that. (I am not here to discuss nor am I interested in your advice or experiences concerning mushrooms or the dosing thereof, thanks anyway.)

3 Comments Share Save Hide Report

Posted by u/jakeleia 9 months ago

Magic mushrooms and type 2 diabetes

My husband has just been diagnosed with type 2 diabetes.(Is hereditary) His cholesterol level and blood pressure is fine. He wants to take magic mushrooms this weekend. Does anyone know if it will cause problems ?

12 Comments Share Save Hide Report

Figure 28: Example of Reddit threads (discussions) drawn from the r/diabetes subreddit. The information was publicly displayed.

Figure 29: People presenting themselves on the Discord server of the r/diabetes subreddit. While the information was publicly displayed, I hid the real names and ages of the concerned patients.

Another issue was the difference between 'classical' methodologies involving the parties: focus groups, workshops, and co-design. While the methodologies followed a semi-structured (i.e. allowing deviation from the original questions) and user-centred (i.e. focusing on the parties and their needs) approach, they diverged in four respects, as follows:

1. In depth discussion, determining how deeply you can discuss a problem.
2. Facilitation, involving the difficulty of managing the interactions between the participants.
3. Broad scope, defining the diversity of methods for identifying solutions.
4. Commitment, dictating the amount of time required to prepare and conduct events.

Focus groups, by involving only one type of actor at a time (e.g. only clinicians), permitted a sharper focus on specific issues and in-depth questioning. The facilitation was easy because the participants were from the same discipline, were concerned about the same issues, and saw each other as peers. However, it was challenging to approach a problem from different angles, considering that the participants had the same perspective on problems. Using specific techniques, such as 'problem reversion' (e.g. firstly focusing on 'what could make the solution work' and then focusing on 'what could make the solution fail') partially addressed this issue. The commitment challenge was also somewhat mitigated, since 1) planning the agenda was easy because each focus group addressed one or two core challenges and 2) the running of the meetings relied on simple methods such as brainstorming.

Different challenges attended the co-design session. By involving multiple parties at once and bringing them in as experts, the discussion was limited to high-level notions only, because the parties did not share the same knowledge (e.g. the medical knowledge of patients is not as rich as that of clinicians). Facilitating the meeting was quite overwhelming, since the parties did not see each other as peers and conflicts could arise due to the different degrees of 'expertise'. My colleagues and I were aware of this

possibility and used specific methodologies, such as the writing round-robin or organising multiple sessions with one type of actor at a time, to mitigate this issue. The high-level discussion permitted a wider approach to the resolution of problems, involving the viewpoints of all participants. The required commitment was high: we had to 1) carefully plan the facilitation of the meeting and decide on appropriate methodologies for encouraging cooperation between the participants, 2) prepare the resources to support the methodologies (e.g. the writing round robin required paper and a way for everyone to see the answers of the others participants), and 3) spend time collecting and analysing the answers of the participants during and after the meeting.

The workshops lay midway between these two approaches. They were easier to organise than the co-design session since the participants, who were not experts, were guided to address specific problems, using simpler techniques such as brainstorming or mind-mapping. They also supported high-level, deep, or mixed approaches to in-depth discussion, by involving different parties at different times (e.g. patients could first explain their health problems, then clinicians could explain, in depth, the causes and consequences of these problems). By involving multiple types of parties, workshops provided a broader approach than focus groups, but narrower than the co-design session, considering that only specific parties could address specific points. The required commitment also differed between focus groups and the co-design session: workshops were more complicated to organise than focus groups but simpler than co-design. Table 11 summarises the situation.

Table 11: Differences between the focus groups, workshops, and co-design session regarding in depth-discussion, facilitation difficulty, broad scope, and required commitment.

Methodologies	**Focus Groups**	**Workshops**	**Co-design**
In-depth discussion	Deep	Mixed	High-level
Facilitation difficulty	Easy	Medium	Complicated
Broad scope	Narrow	Medium	Wide
Required commitment	Limited	Medium	High

In summary, these approaches complemented each other. However, my colleagues and I made a mistake when organising the co-design session: the timing was poor. We scheduled the co-design session in the middle of the FullFlow project's lifecycle, after having already spent two years organising focus groups and workshops. Therefore, we started the co-design session with an already deep knowledge of the project's status, and unfortunately, the results of the co-design session did not permit anything new to be learned regarding the design of the dashboard. The session was therefore limited to tailoring the knowledge base of the KBM or discussing the acceptance barriers, relying on the experience of the participants. Therefore, I recommend using the methods in this order:

1. Co-design as early as possible in a project lifespan, to get a high-level overview of the situation.
2. Workshops, to involve all concerned actors and gain deeper knowledge regarding specific situations.
3. Focus groups, when expert knowledge is required for solving a task.

5.2 Contributions

This thesis contains four contributions, which were summarised in Table 1. This table is duplicated below for ease of reference. All contributions are related to the research questions presented in section 1.3 Research problems and questions page 11.

Table 1: Contributions of the thesis and the research questions they are addressing

Number		Contribution	Research question
C1		**Acceptance barriers**: identification of acceptance barriers regarding the usage of self-collected health data in medical consultations. Provision of possible solutions for addressing these acceptance barriers.	R2
CDSS	C2	**Context-aware knowledge-based module**: creation and implementation of a computer science model for extracting relevant health data and managing data reliability, using a hypothesis-and-test strategy.	R2, R3
	C3	**Dashboard**: creation of a dashboard for displaying diabetes patients' relevant self-collected health data to clinicians.	R2, R3
	C4	**Architecture**: provision of a solution for integrating self-collected health data into the existing health infrastructure in Norway.	R3, R3

5.2.1 Acceptance Barriers (contribution C1)

This thesis has reported that twenty-two acceptance barriers were perceived by clinicians, patients, EHR vendors, and healthcare institutions that prevent broad usage of self-collected health data during medical consultations. The most important acceptance barriers perceived were related to the costs, changes in medical workflow, time consumption, lack of data reliability and the burden of collecting self-collected health data. 'It appears that most of the acceptance barriers are interconnected; for instance, the lack of standardisation of systems for sharing collected health data would force clinicians to spend time learning each system, thus contributing to increased costs and the need for training, which in turn increase the complexity of usage. Therefore, it is necessary to address these factors simultaneously' [33].

I propose a CDSS, comprising three solutions (the KBM, dashboard, and architecture), to address these barriers. The strategies were the following:

- Re-usability and support of existing systems and services.
- Design of tools adapted for use by clinicians.
- Extraction of relevant information.
- Definition of, and communication about, the data reliability.
- Provision of semantic interoperability.
- Loose coupling between components, allowing patients and healthcare institutions to choose the tools that suit them best.
- Costs mutualisation.

However, other strategies are possible. For instance, Boonstra and Broekhuis [113] proposed providing information about return on investment or similar measures, such as cost-benefit ratios, to address cost-related acceptance barriers. Nonetheless, there is no such information regarding the usage of self-collected health data in medical workflows due to the lack of large-scale studies, even though some studies have mentioned that cost reduction might be possible [13, 49]. Therefore, introducing self-collected health data into consultations does not provide a clear cost advantage compared to other approaches, such as public interventions [164], mobile health clinics [165], or telemedicine in general [166]. Therefore, it is not possible to rely on this strategy today.

Locking patients into specific hardware is a strategy for improving data reliability; for instance, Glooko forbids patients to edit or manually enter their blood glucose registrations via their mobile applications. However, this limitation could be bypassed by entering blood glucose registrations manually from a pump, as shown in Figure 30. Similarly, Martinez et al. [48] gave a specific blood pressure sensor to their patients, with a direct connection to the EPIC EHR, and forbade them to use any other tools or to share data types other than the ones defined by the study protocol. However, this strategy is not suitable for the current situation considering that 1) patients not enrolled in medical studies cannot share their data, 2) patients do not use or have access to the same tools or ecosystems, and 3) patients do not have the freedom to choose tools that suit them best, and the strategy therefore limits their willingness to participate in this type of study, which is one of the acceptance barriers I am trying to address. Similarly, these studies and solutions require the use of specific EHRs, which not all institutions are using.

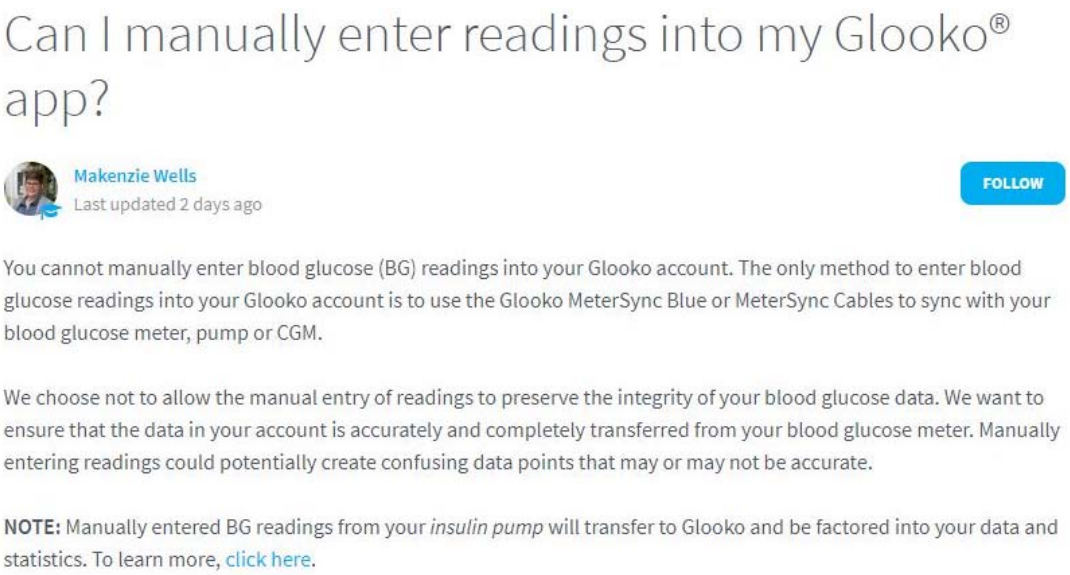


Figure 30: Glooko blocks manual registrations of blood glucose values in their application to protect the integrity of the data.

I am not aware of any other strategies used by studies or products that rely on the sharing of self-collected health data for providing medical services except the ones cited above.

5.2.2 FullFlow clinical decision support system

This section discussed the clinical decision system I proposed to address the acceptance barriers. It comprises three solutions: a context-aware knowledge-based module, a dashboard and an architecture.

5.2.2.1 Context-aware knowledge-based module – KBM (contribution C2)

5.2.2.1.1 Presented results

The KBM ‘demonstrated that using a hypothesise-and-test strategy fed with context may pinpoint the presence of information gaps in patient self-collected health data, identify relevant health information, and define the data reliability. The hypothesise-and-test strategy is a viable approach for an inductive reasoning-based system when diverse, large, and accurate datasets are not available. The context-sensitive approach permits the integration of multiple factors for decision-making and for simplifying the complexity and maintenance of the system. The KBM could address multiple acceptance barriers. Extracting relevant information could reduce the amount of data needed during consultations, thereby

reducing the cost of maintaining the storage and sharing of self-collected health data. Moreover, it could increase the meaningfulness of the data and reduce the time needed for clinicians to consult the data, enabling them to concentrate on the most important noticeable events, and simultaneously reduce clinicians' lack of confidence regarding such data. Providing information regarding the patients' self-collected health data reliability could also consolidate the previous points and directly address the lack of data reliability perceived by the clinicians' [32].

Using logic-based and multidisciplinary context modelling techniques had multiple advantages compared to other approaches: simplicity, consistency checking, rich expressiveness, and comprehensive understanding of the context [167]. Moreover, while currently limited to a diabetes context, the reasoning engine model could be applicable to any other context if the knowledge base was tailored to a given situation.

In addition, while the current implementation of the reasoning engine exclusively uses a rule-based reasoning approach, the model does not limit the type of contextual reasoning; for instance, for a given hypothesis, the activation could be rule-based while the evaluation could be probabilistic or based on Bayesian networks.

5.2.2.1.2 Comparison to other studies

I am not aware of any other studies that present a reasoning engine model for assessing the reliability of self-collected health data, identifying information gaps, and extracting relevant information from this type of data using a hypothesis-and-test strategy, context-awareness, and a knowledge-base, or different approaches. Similarly, I am not aware of any implementation that provides these types of services, based on the background presented in this thesis and on a scoped review [168].

However, the context-aware and knowledge-based approaches are not new in themselves; for instance, Forkan et al. [169] proposed a context-aware system that relied on continuous data collection from sensors such as ECGs for early detection of heart disease, using rules (knowledge-base), and De La Iglisia et al. [170] proposed using a context-aware system to preventing sudden infant death syndrome, using air quality sensors and video cameras combined with machine learning algorithms. Similarly, different approaches exist for modelling the context and for reasoning; for instance, ontology-based context modelling can provide semantic interoperability [171], which is not addressed by the proposed model, in which implementation, languages, and terminologies can vary and are left to the discretion of the developers.

Considering that there are no similar systems, it is not possible to compare the performance of the current model. However, the current model can be used as a starting point for evaluating the quality of context [172] or the accuracy and diversity of this type of system [173] for future implementations.

5.2.2.1.3 Likeliness for use

My colleagues and I 'are aware that some patients could feel uncomfortable about a system 'judging' them based on their disease management performance and their lifestyle. This could even be counterproductive for patients who are demotivated or make them less likely to adopt healthy self-management routines, but using this system is intended to be totally voluntary, relying on the patients to decide whether they want to gather and share data or not. We believe medical doctors could provide support for such patients and moderate the outcomes of modules like the proposed one during consultations' [32].

5.2.2.1.4 Chosen approach

‘The hypothesise-and-test strategy is only one approach for inductive reasoning, which is the reasoning this module uses; for example, it would have been possible to use pattern recognition or machine learning to achieve the same goal. The key point here concerns data acquisition and datasets. I do not possess high-quality patient self-collected health data at this time: insufficient patient diversity, insufficient patients, insufficient data distributed over long periods, and the quality of the data itself could be doubtful because each patient is different and focuses on different goals, using different applications. Moreover, the data could also be erroneous. The strategy for acquiring knowledge from experts could circumvent these issues, even though it is time-consuming and financially demanding’ [32].

5.2.2.1.5 Limitations

First, while the approach, the modelling, and the operation of the KBM are trusted by the clinicians who were involved in its creation, the trust in such a system during its usage especially concerning the reliability scale and the extraction of relevant information, which depends on the situation of the patients, the data collected, and the clinician consulting the data, has yet to be proved. An ongoing medical trial will address this point (see section 5.4 Ongoing medical trial page 81).

‘Moreover, self-collected data represents only one source of data for supporting decision-making, and cannot replace other sources such as laboratory tests; above all, it cannot replace the relationship between medical workers and patients. Medical feedback concerning the module will be obtained during the clinical trial mentioned above. The system may exasperate medical workers if it does not support their needs or yields imprecise or erroneous information’ [32]. However, this risk was reduced by following a participatory design involving clinicians throughout its creation process.

The last point concerns the limited number of patients participating in the assessment of this module (three in total, two international patients and the research patient). The goal of the creation test was to assess the relevance and usability of the module prior to it being tested in a medical trial.

5.2.2.1.6 Future of the KBM

Additional context information

First, the current implementation of the reasoning engine only uses a limited amount of contextual information; for instance, ketones and the emotional state of the patients were not included in the knowledge base. The participants, my colleagues and I decided to focus on the most ‘common’ possibilities for the first version of the KBM. Adding to this contextual information can enrich the KBM and widen its possibilities in the future.

Similarly, new contextual information can be added to the system, such as foot temperature for facilitating early detection of injuries due to diabetic neuropathy or glycaemic index for further tailoring the system.

Dynamic knowledge base

While the rules and hypotheses are dynamic (e.g. patients can provide their insulin to carbohydrate ratio), the current knowledge base of the KBM is static, meaning that the system cannot create and interpret rules by itself. This approach limited and simplified its creation process, but because the reasoning engine is dynamic and could support other diseases, as previously explained, it will be possible to add new dynamic knowledge during its implementation, for instance using patients’

measurable personal goals or recommendations from clinicians as well as complete plan generation based on comorbidity.

Extension to other context reasoning approaches

While the current model relies exclusively on rules for performing the inference, it could be interesting to take newer approaches to extend the scope of the KBM. One of these approaches is to use machine learning; for instance, the hypothesis 'will the T2D patient develop complications?' could use the logistic regression proposed by Dagliati et al. [174] in its evaluation process, and rely on the followed context for its activation: gender, age, time since diagnosis, body mass index, HbA1c, hypertension, smoking habits, and Type 2 diabetes. The interpretation process could rely either directly on the result of a machine learning algorithm (such as linear regression) or could rely on sub- or super-plans in the case of usage of a black box algorithm (such as a recurrent neural network).

5.2.2.2 Dashboard (contribution C3)

5.2.2.2.1 Presented results

The presented dashboard permits the display of patients' self-collected health data during consultations, using diabetes as a case example. The graphical interface uses continuous feedback from clinicians and patients to minimise possible future user resistance by providing relevant information that meets clinicians' needs. Presenting information relating to the quality of self-collected health data (identifying whether the data is worth consulting or not), displaying an overview of a patient's situation, and identifying important medical events without having to consult the complete dataset could limit the time consumption necessary for the usage of the solution.

While multiple sections of the dashboard are tailored to diabetes, such as the data summary and the noticeable events sections, some sections are adapted for displaying any type of data based on FHIR standards. The data list, the combined data, and the time period graphs can be used for displaying data not currently held in the system.

5.2.2.2.2 Comparison to other studies

Multiple research groups and companies have proposed similar dashboards: mySugr [149], Diagliati et al. [175], CareLink by Medtronic [176], Sim et al. [177], Martinez-Millana et al. [178] and Fico et al. [179] to name a few. However, the presented dashboard diverges by:

1. Displaying the result of the interpretation process of the KBM concerning 1) the reliability of the self-collected health data and 2) potential causes of noticeable events.
2. Providing loose coupling between systems, allowing the integration of multiple types of sensors (e.g. finger pricks, continuous glucose monitors, insulin pens, insulin pumps) that are not limited to specific companies.
3. Empowering patients by introducing their personal goals into medical.
4. Using graphs and tables to display any type of medical data based on FHIR.

5.2.2.2.3 Limitations

The first limitation concerns the number of participants involved in the workshops: four clinicians and two patients. While this sample is not representative of clinicians and patients within the diabetes population, it was sufficient for finalising the prototype. Moreover, my colleagues and I used support from the scientific literature and existing systems to design the dashboard.

The second limitation ‘concerns the integration of EHR data into the FullFlow system, which, while planned, is not yet available. Therefore, the FullFlow system cannot directly display EHR data, such as HbA1c, and clinicians will have to use both systems during consultations. However, while not reaching its maximum potential, FullFlow will still permit the integration of self-collected health data into consultations’ [34].

5.2.2.2.4 Future of the dashboard

‘The graphical interface could be improved in different ways: the table in the data summary section could contain information relating to in-range values for each data type and be visually graded like the rest of the overview page (green, orange, red, and white). Shortcuts to the combined graph from a noticeable event could be given, with automatic selection of data to display or hide. It may also be possible to see daily self-collected health values, with the current day being displayed in a large graph at the top of the page and all other days shown under this graph as smaller graphs, one per day; we could also add daily computational glucose variability using standard deviations at the top of the overall graph’ [34].

Moreover, a section displaying blood glucose values distributed before and after each meal (breakfast, lunch, dinner, and snack) during the whole period, using a pooled standard deviation for illustrating glucose variability, could be added in the interface.

‘The graphical interface could also be improved by adding dual signalling for visually impaired people; for instance, the data summary table in the overview section could integrate visual cues, such as equals signs or arrows pointing up or down, to indicate whether values are in range or out of range. These signs could be added below the values displayed in circles in the overview section or even used as texture.

While the system can read and display any data type as long as it is in an FHIR format, it will use only ‘registered’ data types (e.g. blood glucose, insulin, blood pressure, menstruation) for advanced services, such as grading data reliability or exploring potential causes of medical events’ [34]. As specified in the KBM section, the addition of new data types, such as foot temperature, is planned.

5.2.2.3 Architecture (contribution C4)

5.2.2.3.1 Presented results

The proposed architecture represents a complete, secure, scalable, and GDPR-compliant solution for integrating patients’ self-collected health data into Norwegian EHRs, relying on existing Norwegian public services to authenticate the patients and host sensitive health data. The FullFlow system itself addresses potential GDPR issues by not being persistent: it does not store medical data. Patient consent to use the system for conducting medical analysis is collected during the schema submission step. By relying on existing public services, patients and healthcare institutions can choose the tools that suit them best.

While focusing on FHIR, the proposed architecture allows patients using proprietary tools to share their data, by proposing a mapping between the proprietary formats and FHIR artefacts. However, this require manual development. It is used today for mapping data extracted from the Diabetes Diary to FHIR resources for example.

The scalability tests showed that the FullFlow system is scalable and can manage the needs of patients with diabetes in Norway. The performance established by these tests showed that the FullFlow system

should not significantly affect the existing infrastructure. In addition, the architecture was partially demonstrated by a prototype that displayed patients' self-collected health data in EHRs directly, by partly simulating the national services.

5.2.2.3.2 Comparison to other studies

Multiple approaches and implementation methods could have been used for introducing self-collected health data into EHRs and consultations. Examples of these possibilities (a non-exhaustive list) are:

1. Using an end-to-end system relying on the Continua guidelines for all steps.
2. Using HealthVault for centralising the data from sensors and applications and using their APIs to acquire the data.
3. Using Glooko and its APIs to extract data from patients' tools.

In these three cases, the FullFlow system would have been able to extract patients' self-collected health data and to provide the same services as the proposed architecture. However, none of these solutions are adapted to the Norwegian regulations and healthcare infrastructure; for instance, direct communication between EHRs and external systems is not allowed, and data sharing requires the use of schemas, which is a proprietary protocol developed in addition to the FHIR requirements. I also studied the possibility of using an architecture based on smart contracts (blockchain) for introducing self-collected health data into EHRs (paper P5) [36]. However, it appeared that this solution is not suitable for healthcare systems considering that the technology is extremely immature, is not adapted for sharing huge quantities of self-collected health data and does not solve any interoperability issues. In addition, using proprietary solutions for sharing self-collected health data such as EPIC MyChart [53] would not have been suitable for this project, considering the limited type of data available and the requirement of using EPIC services.

Similarly, while multiple standards could have been used for this solution, such as HL7 CDA, HL7 V3, or even archetypes, the NDE does not plan to use them to share data at this stage. Manual data mapping, or automatic data mapping with manual data cleaning, would have been necessary if the FullFlow system used any other standard than FHIR for representing medical data. This mapping and data cleaning continue to be a significant issue for assuring semantic interoperability [180]. However, even though it is a requirement, FHIR seems to be a good choice for this type of system considering that it is easy to implement solutions supporting it and that Open mHealth already provides mapping to FHIR artefacts, facilitating its introduction for sharing self-collected health data. While relying on FHIR for performing analysis, the FullFlow system maps proprietary data formats such as the one used by Diabetes Diary to FHIR artefacts. However, I believe that open standards such as Open mHealth will reduce the need for mapping in the future.

While the multiple tests showed that the FullFlow system is scalable, comparing the results to existing systems is difficult since no other system like the KBM, focusing on self-collected health data, exists today. However, it seems that most of the performance issues are linked to the usage of the HAPI library for managing FHIR resources, which has also been pointed out by other teams [181].

5.2.2.3.3 Limitations

The proposed architecture has several limitations. First, the proposed architecture, while it has been partially tested, has not been implemented yet. Although planned for 2020, the lack of complete implementation prevents the testing of the solution by patients and clinicians.

Secondly, since the proposed architecture is not implemented yet and may be subject to changes, privacy and security tests, such as penetration testing, were not performed. However, relying on existing services, limiting the triggering of the FullFlow system to Helsenorge, and not storing medical data should address these issues.

Thirdly, as stated previously, the architecture is greatly affected by Norwegian regulations. While constituting a contribution in Norway, the contribution is quite limited internationally, where other approaches might be used, such as a direct integration between EHRs and HealthVault. Even if the architecture could inspire future systems regarding which services to use and how to establish loose coupling between them, internationalisation of the solution would require customisation, which does not fit a semantic interoperability approach.

The last limitation concerns receiving data from EHRs. The FullFlow system could receive data from EHRs only if a clinician requested a schema and attached data extracted from his or her EHR. No data from EHRs can be collected by the FullFlow system if the schema is requested by the patients.

5.2.2.3.4 Future of the architecture

First, the architecture is currently being implemented, and should be ready for testing during 2020. Once the architecture is ready, multiple tests should be performed, based on either scenarios or security threat modelling, to ensure that the designed solution fits the Norwegian regulations. Patients and clinicians should then be invited to test it.

The performance of the FullFlow system could be improved. First, the load-balancer was based on a round robin strategy, meaning that the servers were selected in turn without taking in consideration their workload. A dynamic load-balancing strategy, based on monitoring resource utilisation, could improve the performance of the clusters. Secondly, replacing the DataManager singleton with a stateless bean could permit vertical scalability as well, considering that the servers will instantiate this bean according to the workload, even if the memory heap usage will be greater due to the instantiation of multiple FHIR components and validators.

5.3 Pre-trial assessment

5.3.1 Presented results

‘The pre-trial assessment showed that a combination of the FullFlow system, Diabetes Share Live, and Diabetes Diary could be effective during consultations, especially if patients live in remote areas or are interested in mobile technology and/or improving their life conditions. The majority of clinicians were satisfied with the current state of the graphical interface and all were eager to start using it’ [34].

5.3.2 Limitations

This section is based on the ‘limitations’ section of the paper P3, entitled ‘Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study’, published by JMIR Diabetes [34].

The first limitation concerns the size of the sample for the pre-trial assessment, in which a total of fourteen clinicians participated. While the sample did not permit consideration of all types of clinical roles, to identify their needs and design the graphical interface according to their preferences, it was sufficient for determining that the dashboard is ready to enter a medical trial.

During the pre-trial assessment, one of the clinicians mentioned that (s)he was afraid that the system could be time consuming. While the KBM can, in theory, address this issue, my colleagues and I fear this challenge will greatly affect the medical trial, due to the technical solutions chosen.

First, Diabetes Diary is not the optimum application for all diabetes patients, missing important factors such as insulin type, blood pressure, polypharmacy, and integration with glucometers for automatic data transmission. These missing factors might result in a degradation of the reliability of the data and the user experience for both the patients and the clinicians, who would like to have access to these missing types of data. However, the most important issue is the Diabetes Share Live solution, which requires many steps to be performed during consultations in order to view the self-collected health data: 1) patients open Diabetes Diary, 2) patients wait for the application to give a unique identification code, 3) clinicians open an Internet navigator, 4) patients give clinicians the unique code, 5) clinicians enter the code on the web page, 6) clinicians choose a time period, 7) patients acknowledge the time period given by the clinicians and select the data they want to share, and 8) clinicians consult FullFlow. The excessive number of steps will render consulting the self-collected health data time consuming during consultations and will probably play an important role in user acceptance (by both patients and clinicians) of the project at this stage. However, the FullFlow system itself is not affected by these limitations and can accept data from several applications and several operating systems, as long as it receives FHIR-based data.

Nevertheless, the medical trial will permit research to be conducted on the relevance of the information displayed, its potential impact on medical services, and the relevance of the KBM during its usage.

5.4 Ongoing medical trial

A medical trial using a combination of the Diabetes Diary (patients' tool) [111], Diabetes Share Live (data sharing using Diabetes Diary) [101] and the FullFlow system as described in this thesis (minus the architecture, which is not yet ready) started in November 2018 and is still ongoing. This trial is expected to run at least until the end of 2019, and preliminary results are expected in the beginning of the following year (2020). The medical trial is approved by the regional committees for medical and health research ethics (REK Ref. 2018/719). This section summarises the medical trial protocol and focuses on evaluation of the effectiveness of the proposed solution in addressing the acceptance barriers. An article presenting the complete medical trial protocol is being prepared.

5.4.1 Objectives

The main objective of this medical trial is to measure the efficiency, relevance of, and trust in, the KBM and the dashboard presented in this thesis, as well as to study the effects of using patients' self-collected health data on both patients and clinicians.

5.4.2 Recruitment

A continuous recruitment strategy up to 1 July 2019 was chosen for recruiting clinicians, using either our partner (UNN) or contacting clinicians directly. During the workshops conducted for the pre-trial assessment, the recruited clinicians were provided with flyers presenting the goals of the study.

Clinicians are responsible for recruiting Type 1 and Type 2 diabetes patients by giving them a recruitment letter we prepared. This letter invites patients to contact the research team I am part of before the start of the study. September 2019 is the fixed date for recruiting patients. Clinicians working in

private companies are receiving compensation of 10,000 Norwegian kroner for performing this task and participating in the study, and 1,000 Norwegian kroner per patient recruited.

There is no pre-defined sample size regarding the number of patients participating, but my colleagues and I expect to three to ten patients to be recruited by each clinician, bringing the total patient population to between 42 and 140 participants, with both Type 1 and Type 2 diabetes.

5.4.3 Data collection

Three types of data will be collected from this clinical trial: 1) medical data, 2) system usage, and 3) relationships and engagement.

Medical data can be collected by the FullFlow system or by patients and clinicians. The FullFlow system collects data relating to patients' self-collected health data (e.g. blood glucose, carbohydrates), medical calculations (e.g. insulin to carbohydrate ratio, eA1c), data reliability, and potential causes of noticeable events. Patients and clinicians submit medical data (e.g. blood pressure, HbA1c) through custom online questionnaires.

System usage data is collected exclusively through custom online questionnaires, whereby clinicians indicate which functions they used during the consultations, what their experience was, perceived benefits, and constraints.

Relationship and engagement data is collected from standard questionnaires such as the Health Care Climate Questionnaire.

5.4.4 Limitations

As described in the previous section, this medical trial cannot completely measure the potential of the FullFlow system considering that: 1) Diabetes Diary and Diabetes Share Live lack key data types such as insulin type and are complex to use, and 2) the solution used during the medical trial is not integrated with EHRs, and no interoperability is proposed. However, this medical trial will permit the assessment of the graphical interface and the results of the proposed KBM in clinical settings.

6 Conclusion

The overall research problem targeted in this thesis was motivated by challenges relating to the usage of self-collected health data by patients during medical consultations. These challenges, combined with a previous study asserting that clinicians want this data to be integrated into EHRs [19], led to the definition of the main research problem (R): *how can a system that supports the integration of self-collected health data into EHRs be designed?*

Before answering this question, it is necessary to address the secondary research problems (R1, R2 and R3). These research problems were created to help resolve the main problem and answers to these questions are described below.

R1. What is the status regarding the usage of self-collected health data by EHRs?

The conclusion to this research question is that the usage of self-collected health data by EHRs and clinicians in general is *sparse and limited to controlled environments*, despite some actors innovating and permitting the integration of this type of data into EHRs and in a clinical context. In addition, the patients' ecosystem that permits the collection of this type of data seems to be limited by proprietary data protocols.

R2. How to integrate this new source of data seamlessly into consultations by overcoming acceptance barriers of such data sharing system?

The main conclusion to the second research is that a clinical decision support system is a suitable solution for introducing self-collected health data seamlessly into consultations. A CDSS with a dashboard adapted to the needs of clinicians coupled by an artificial intelligence module extracting relevant data and supported by an open and standard architecture, which allows for interoperability between multiples systems, enables the ability to address the multiple acceptance barriers identified during this project, such as the lack of data reliability, investment costs, lack of practice and training and time consumption.

However, a clear legal context of usage (e.g. Who is responsible in case of an adverse reaction using self-collected health data for a medical decision? What are the clinical guidelines related to the usage of self-collected health data?) must be defined for a broad introduction of self-collected health data in a clinical context.

R3. How to design and implement a system permitting the usage of self-collected health data during consultations for diabetes patients in Norway?

The answer to this third research question is to *tailor* the proposed clinical decision support system by integrating the needs of the parties for managing diabetes and by taking into consideration the Norwegian healthcare ecosystem. Participatory design allows for identifying the needs of all concerned actors (type 1 and 2 diabetes patients, EHR vendors and the NDE) and assessing the created system by continuously involving them, therefore increasing the chances of success of the introduction of self-collected health data in consultations in Norway.

Overall conclusion

The main conclusion of this thesis is that *it is possible to integrate patients' self-collected health data into consultations and EHRs* by *identifying the acceptance barriers perceived by all parties* and by *providing a clinical decision support system that addresses these barriers.* The answer to the research problem (R) (how can a system that supports the integration of self-collected health data into EHRs be designed?) is that a *participatory design* provides a solid approach for creating such systems by continuously involving all actors in designing and testing the system.

The CDSS I proposed comprises three solutions:

1) A context-aware knowledge-based module (KBM), focusing on a) extracting relevant information from the self-collected health data according to patients' situations, b) identifying information gaps, and c) ensuring the reliability of the self-collected health data.
2) A dashboard, integrating the results of the KBM, to provide the right information in the right place for clinicians to be able to efficiently use the patients' self-collected health data.
3) System architecture tailored to the Norwegian context, permitting self-collected health data to be introduced into existing EHRs, relying on FHIR and schemas to allow semantic interoperability, and allowing both patients and healthcare institutions to use the tools that suit them best.

The system has been tested by clinicians and all clinicians agreed that the system could be useful during consultations. The integration of the system into EHRs has been demonstrated, so the next step consists of testing the proposed solution in a medical context.

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Appendix A: Current implementation of the KBM

The implementation of the KBM relies on the same technology used by the FullFlow server: Java Enterprise Edition 8 and Glassfish 5.

1. Current Implementation

The current implementation differs from the implementation presented in paper P1 entitled 'Design and development of a context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes self-collected health data' [1]. The reasons for these differences are explained at the end of this section. Figure 1 illustrates the composition of the KBM.

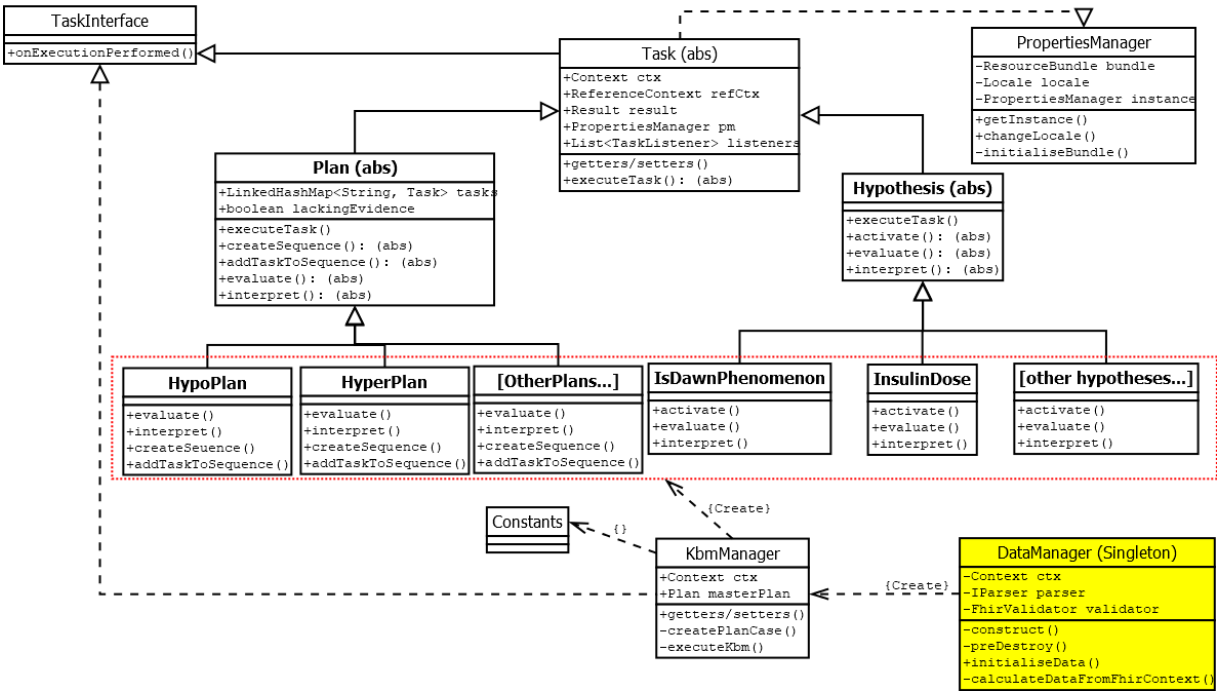

Figure 1: Simplified Unified Modelling Language (UML) classes diagram of the KBM. Yellow = bridge between KBM and JEE implementation.

The KBM is composed by Plain Old Java Objects (POJOs) for facilitating the future port of the KBM to client environments, such as Android. The implementation is based on the reasoning engine model presented in the thesis.

The bottom right class, DataManager, is a JEE Singleton containing the *external current patients' and EHRs' contexts*. This singleton oversees the live cycle of the KBM for each request received by the FullFlow system (i.e. each time a patient shares his/her data). The DataManager transmits the *external current context* to the KBM by instantiating the KbmManager class (bottom middle).

The KBMManager class represents the reasoning engine, initialising the plan case base and the relationship between problem-identifying tasks, which are part of the explanation case base, relying on the constants class. Moreover, the KBMManager manages the external current context and creates the system generated context. It also represents the hypothesis generation process and retains references

to all hypotheses and results. It also references the 'master plan', which contains all problem-identifying tasks to be performed for a specific instance.

The interpretation of task results, which are another part of the explanation case base, are contained in the PropertiesManager class (top right). Splitting the explanation case base in this manner permits the provision a multi-language interpretation (English and Norwegian). The PropertiesManager loads the correct language and the correct files depending on the location of the data.

The TaskAbstract class (top centre) represents a problem-solving task. A task instance contains the reference context (i.e. specific context to address) supported by the current context and the result of the execution of the task (true, false, or NA). It also references a list of recipients for notifying other entities of the end of the problem-solving task, through the TaskInterface (top left) interface. At this stage, there is only one recipient, the KBMManager, which can update plans depending on the task results. The Task class has two abstract subclasses: plan and hypothesis.

A hypothesis instance represents an inferred candidate result of a task. It contains three abstract methods: activate, evaluate, and interpret. These methods must be implemented via the concrete hypotheses, such as IsDawnPhenomenon, as one concrete class per type of hypothesis (e.g. the concrete hypothesis class InsulinDose can be used to verify whether the insulin dose was under- or overdosed, depending on the context). The activation method contains the activation rules: the evaluation method, the evaluation rules, the interpretation, and the internal explanation case base. The internal explanation case base represents part of the explanation case base, but is limited to the scope of the hypotheses, ignoring the complementary or hierarchical relationships between hypotheses; for instance, the internal explanation case base result for the InsulinDose concrete class could be '*Carbohydrate intake: 0.1 carb(s) absorbed last minute. Insulin on board this minute: 0.0288. Current insulin to carbohydrate ratio (IC): 0.2878. Average IC: 0.0782*'. Basically, the interpretation method only describes the internal evaluation process. The explanation of these results is left to the KBMManager, which addresses the relationship between problem-identifying tasks, as described earlier.

A plan instance represents sequential problem-identifying tasks, which could contain either hypotheses or other plans. A plan has four abstract methods: CreateSequence for creating the initial sequence of the tasks: AddTaskToSequence for updating the plans according to the results of other tasks, and Evaluate for launching the evaluation process of the tasks in the sequence and interpreting and explaining the internal evaluation process. The methods CreateSequence and AddTaskToSequence represent the plan rules of the plan case base. Each concrete plan must implement these methods.

The main differences between the current implementation and the implementation described in the paper P1 [1] relate to the management of the explanation case base and the plan, activation, and evaluation rules. Moving the explanation case base from the JEE environment to the internal KBM module will facilitate the export of the KBM to other systems. Splitting the plan, activation, and evaluation rules between all hypotheses and plans allows the implementation of loose-coupling and facilitates maintenance of the code and the development-driven process. Each hypothesis or plan can be unit-tested separately, without the need to instantiate the whole KBM, and each plan or hypothesis can be maintained separately, without the need to keep track of the relationship between all the tasks.

Figure 2 shows an example of a hypothesis verifying whether the last insulin shot (pen) was under-dosed based on the insulin sensitivity factor with pseudo-code. This hypothesis is a candidate answer to a hyperglycaemic event.

```
/**
* Example of a hypothesis verifying if the last insulin shot (pen) was
* underdosed based on the insulin sensitivity factor. This hypothesis
* is a candidate answer to a hyperglycaemia event. Pseudo code.
**/
InsulinDose extends Hypothesis {
    Context ctx;

    InsulinDose(Context ctx){
        this.ctx = ctx;
    }

    activate(){
        //Context is extracted from terminologies such as SNOMED-CT
        REQUIRED_CONTEXT = {insulin, bloodGlucose, diabetesType};

        //This hypothesis is only for T1D patients. Insulin injection
        //was performed up to 2 hours before the peak of the hyperglycaemia event.
        //Blood glucose should be above 5.5 mmol/l at injection time
        REQUIRED_REFERENCE_CONTEXT = {patient.diabetesType == T1D,
            hyperglycaemia.peakTime - 2hours <= insulin.injectionTime < hyperglycaemia.peakTime, bloodGlucoseValueAt(insulin.injectionTime) > 5.5};

        if (ctx.has(REQUIRED_CONTEXT) && ctx.has(REQUIRED_REFERENCE_CONTEXT)
            activated;
        else
            notActivated;
    }

    evaluate(){
        //extract the blood glucose value at the time of the insulin injection
        bloodGlucoseValue = extractBloodGlucoseValueAtTime(insulin.injectionTime);

        //use insulin sensitivity submitted by the patient if available, if not use 1500 rule
        insulinSensitivity = ctx.isInsulinSensitivitySubmitted() ? ctx.getSubmittedInsulinSensitivity()
            : ctx.getCalculatedInsulinSensitivity();

        //Calculate the ideal amount of insulin for reaching 5.5 mmol/l
        recommendedInsulinAmount = calculateRecommendedInsulinAmount(bloodGlucoseValue, insulinSensitivity);
        result = insulin.amountInjected < recommendedInsulinAmount ? TRUE : FALSE;
    }

    interpret(){
        if notActivated
            print "Hypothesis not activated because of missing context.";
        else
            print "Time: insulin.injectionTime. Blood Glucose at insulin.injectionTime: bloodGlucoseValue. Insulin dose: insulin.amount. Recommended insulin dose: recommendedInsulinAmount.";
    }
}
```

Figure 2: Example of a hypothesis verifying if the last insulin shot (pen) was under-dosed based on the insulin sensitivity factor. This hypothesis is a candidate answer to a hyperglycaemia event. Pseudo code.

2. Tests

Following the test-driven methodology, I used unit tests to support white and black box approaches, as described in the methodology section. Figure 3 shows an example of unit tests for the InsulinDose hypothesis presented above.

```
1.  public class InsulinDoseTests {
2.
3.      private static Context ctx;
4.
5.      @BeforeAll
6.      public static void setup(){
7.          enableFHIR();
8.          ctx = readDemoDataset(1);
9.      }
10.
11.     @Test
12.     public void testNoContext(){
13.         InsulinDose h = new InsulinDose(null);
14.         //Should not activate with no context
15.         assertEquals(false,h.activate());
16.     }
17.     (...)
18.     @Test
19.     public void testHyperglycaemia(){
20.         //Context is set
21.         InsulinDose h = new InsulinDose(ctx);
22.
23.         //But reference context is missing
24.         //hyperglycaemia.peakTime - 2hours <= insulin.injectionTime < hyperglycae-
    mia.peakTime is false
25.         h.setReferenceContext(ctx.getContextAtPosition(25));
26.         //Should not activate with missing required reference context
27.         assertEquals(false,h.activate());
28.
29.         //Reference context complete, should activate
30.         h.setReferenceContext(ctx.getContextAtPosition(43));
31.         assertEquals(true,h.activate());
32.
33.         //For the reference context, the amount of insu-
    lin is greater than the one calculated from the system, therefore the result of the hy-
    pothesis should be false
34.         assertEquals(Constants.result.FALSE,h.evaluate());
35.
36.         //Reference context complete, should activate
37.         h.setReferenceContext(ctx.getContextAtPosition(65));
38.         assertEquals(true,h.activate());
39.         //For the reference context, the amount of insulin is lower than recom-
    mended, therefore the result should be true
40.         assertEquals(Constants.result.TRUE,h.evaluate());
41.         (...)
42.     }
43.    (...)
44. }
```

Figure 3: Example of unit tests for the InsulinDose hypothesis.

Context (line 3) represents all contexts available at runtime. The method setup (lines 5 to 9) instantiates an FHIR parser and an FHIR validator (line 7) based on the HAPI library, a Java library for managing FHIR resources [2], which has already been used by several research teams [3, 4]. These FHIR components parse JavaScript Object Notation (JSON) data and validate the FHIR artefacts created from the parsing. I

created the JSON data by editing the real data collected by the research patient. The created data was replicated and edited to allow changes in the context and, therefore, test the rules of the KBM; for instance, the insulin sensitivity value changes between data sets to support black unit testing of the usage of this type of data. The validated artefacts are then assigned as the current context (line 8), and in this case, correspond to dataset number one.

The first test (lines 11 to 16) is an example of a white unit test, where I tested what happens if the context is not defined (= null). In this case, the hypothesis should not be activated because of the missing required context (line 15).

The second test (lines 18 to 41) contains three white and two black unit tests concerning the same class. The white unit tests concern the assessment of the activation of the hypothesis. In the first situation, I provided the required context (line 21), but not the required reference context (line 25). The reference context number 25 (which is an extraction of context from the current context) designates a hyperglycaemic peak event, without an insulin injection performed for up to two hours before the peak time. Therefore, according to the activation rules, the hypothesis should not be activated due to the missing context (see Figure 2 for the rules). The test for the non-activation is shown on line 27. In the second situation, I provided another reference context that contained all the required information (line 30). Therefore, the hypothesis should be activated (line 31). The third white unit test used another reference context containing all the required context, and the hypothesis was expected to be activated (line 38).

The black unit tests assessed the results of the evaluation of the hypothesis class based on the evaluation rules. In the first situation (lines 30 to 34), the reference context designates a hyperglycaemic situation, where the patient had a blood glucose value of 12 mmol/L at the time of the insulin injection and used four rapid insulin units. The patient had an insulin sensitivity of two, and one unit of rapid insulin should decrease the blood glucose levels by 2 mmol/L. Therefore, the patient injected a higher dose than recommended to reach a blood glucose value of 5.5 mmol/L, which is estimated at 3.25 insulin units. Therefore, in this situation, this hypothesis is not a candidate answer for addressing the hyperglycaemic event, and the expected result of the hypothesis is false (line 34). The second black unit test illustrated a different situation, wherein the insulin injected was lower than the expected insulin amount, and therefore the result of the hypothesis should be true, defining a candidate answer for this hyperglycaemic event (line 40, with reference context change at line 37).

Figure 4 shows an example of the console output when running the test class presented above. Lines 1 to 3 relate to the FHIR instance. Lines 4 to 12 show the number of medical observations read from the JSON data (6 to 10) and calculated (11 to 12) and their types. Line 14 shows that all the tests were validated.

```
1. [main] INFO ca.uhn.fhir.util.VersionUtil - HAPI FHIR version is: 3.2.0-SNAPSHOT
2. [main] INFO ca.uhn.fhir.context.FhirContext - Creating new FHIR context for FHIR version [DSTU3]
3. [main] INFO ca.uhn.fhir.util.XmlUtil - FHIR XML procesing will use StAX implementation 'Java Runtime
Environment' version '1.8.0_111'
4. -----FHIR DATASET READY-----
5. Total Records: 34092
6. ----type: Blood Glucose ----number: 136
7. ----type: Carbohydrates ----number: 112
8. ----type: Insulin (Bolus) ----number: 102
9. ----type: Insulin (Basal) ----number: 30
10. ----type: Physical Activity ----number: 13
11. ----type: COB ----number: 12513
12. ----type: IOB ----number: 21186
13.
14. Process finished with exit code 0
```

Figure 4: Example of console output when executing a unit test.

A different message appears when a test fails, as shown in Figure 5.

```
1. junit.framework.AssertionFailedError:
2. Expected :FALSE
3. Actual   :TRUE
4.  <Click to see difference>
5.
6. Process finished with exit code -1
```

Figure 5: Example of a failed unit test.

I also used load tests to monitor the performance of the KBM. The elapsed time for the execution of each process (e.g. current context instantiation) and each task (e.g. plans and hypotheses) during a KBM run were monitored using the System.nanoTime() method, which measures the elapsed time in nanoseconds (ns). However, the nanosecond timing can be affected by the optimisation of the Java Virtual Machine (JVM) and/or the GlassFish server, as well as the system host. To address this issue, these tests were performed in a development environment with a fresh Debian 9 with no customisation (e.g. default heap space, default domain).

The Figure 6 shows the result of an excerpt run. The patients' current context is as follow:

- Patient is a 43 years old male with T1D (line 3).
- One month of self-collected health data with 9289 registrations in total (lines 2 and 3).
- The registrations are divided between blood glucose with 8,810 measurements (CGM, line 4), carbohydrates with 224 registrations (line 5), insulin lispro with 224 registrations (line 6) and physical activity with 11 registrations (line 7);

In total, the KBM needed 247 milliseconds (ms) to perform all the processes and execute all the tasks, as shown in line 39. Line 12 shows the creation of the explanation case base: the first version of the current base case with the loading of the current context. This task took 3 ms (3,298,700 ns).

Lines 16 to 24 concern the execution of the plan 'error values in [data type]' (line 24), with two sub-plans shown ('error values in Carbohydrates' [A], line 22 and 'error values in blood glucose' [B], line 19) and five hypotheses (lines 16 to 18 and lines 20 to 21). Sub-plan A has three hypotheses: blood glucose

values below 1.1 mmol/L (line 16), blood glucose values above 30 mmol/L (line 17), and blood glucose variation above 2 mmol/L in 10 minutes (line 18). Sub-plan B contains two hypotheses, with carbohydrate registrations below 1 carbohydrate (line 20) and carbohydrate registrations above 300 carbohydrates (line 21). The results of all these tasks were FALSE, meaning that no registration errors were found by the KBM. The KBM took between 0.03 and 62 ms to perform each task, depending heavily on the current context (e.g. more registrations equal an increase in time elapsed).

```
1.  ---- Data ----
2.    DATE: 2019/04/23 - 2019/05/23
3.    P: M 43 T1D R: 9289 //Only registrations provided by patients
4.    RT: 15074-8 Size:8810 //Blood glucose (LOINC)
5.    RT: 227991002 Size:224 //Carbs (SNOMED)
6.    RT: 388454007 Size:244 //Insulin (SNOMED LISPRO)
7.    RT: 86047003 Size:11 //Physical Activity (SNOMED)
8.    RCALC: COB Size:22111
9.    RCALC: IOB Size:31574
10.
11. ---- LOAD CONTEXT ----
12.   KBM_ECB_PCB ToE (ns): 3298700
13.   (...)
14. ---- EXECUTION ----
15.       (...)
16.           H_id:HYP_ID_DR_EV_BG_LESS RESULT:FALSE ToE:445300
17.           H_id:HYP_ID_DR_EV_BG_MORE RESULT:FALSE ToE:401300
18.           H_id:HYP_ID_DR_EV_BG_VAR RESULT:FALSE ToE:61443300
19.       P_id:HYP_ID_DR_EV_BG RESULT:FALSE ToE:62319000
20.           H_id:HYP_ID_DR_EV_CARBS_LESS RESULT:FALSE ToE:65500
21.           H_id:HYP_ID_DR_EV_CARBS_MORE RESULT:FALSE ToE:22500
22.       P_id:HYP_ID_DR_EV_CARBS RESULT:FALSE ToE:93800
23.       (...)
24.   P_id:HYP_ID_DR_EV ToE:62506900
25.   (...)
26.         H_id:HYP_ID_DIAG_HYPER_SE_TOO_LITTLE_INS_ACT RESULT:TRUE ToE:127600
27.         H_id:HYP_ID_DIAG_HYPER_SE_TOO_LITTLE_INS_FACTOR RESULT:NA ToE:4800
28.         H_id:HYP_ID_DIAG_HYPER_SE_TOO_LITTLE_INS_CARBS_RATIO RESULT:TRUE ToE:816700
29.         H_id:HYP_ID_DIAG_HYPER_SE_TOO_LITTLE_INS_MEAL_NO_INS RESULT:NA ToE:22300
30.       P_id:HYP_ID_DIAG_HYPER_SE_TOO_LITTLE_INS RESULT:TRUE ToE:982500
31.       (...)
32.       H_id:HYP_ID_DIAG_HYPER_SE_NO_MEDIC RESULT:NA ToE:1200
33.       H_id:HYP_ID_DIAG_HYPER_SE_DAWN RESULT:FALSE ToE:4700
34.     P_id:HYP_ID_DIAG_HYPER_SE RESULT:TRUE ToE:1134900
35.   P_id:HYP_ID_DIAG_HYPER RESULT:TRUE ToE:93909000
36.   (...)
37. ----------------------------
38. --- TOTAL EXECUTION TIME ---
39. KBM_ACT_EVA_IN ToE(ns):246985600 ToE(ms):247
```

Figure 6: Excerpt of the results of one instance of the KBM. ToE = Time of Execution.

Lines 26 to 34 present an excerpt of a diagnosis plan for a hyperglycaemic event. Similarly, this plan contains sub-hypotheses and sub-plans, with two sub-hypotheses (line 32 to 33) and one sub-plan (line 30) containing four hypotheses (line 26 to 29) as illustrated in this figure. For this run, the KBM decided

that an insufficient insulin dosage was a potential cause of the hyperglycaemic event (line 30, with the result of the plan set to TRUE), considering that there was too little active insulin (hypothesis line 26 set to TRUE) and that the insulin to carbohydrate ratio was insufficient for covering the carbohydrates on board (hypothesis line 28 set to TRUE). Line 32 shows an example of a non-activated hypothesis due to missing required context: this hypothesis is reserved for T2D patients who forget to take their medication. Line 33 shows an example of a refusal of the dawn phenomenon as a cause for the hyperglycaemic event (result set to FALSE).

The execution time of the KBM depends heavily on the current context; for example, the KBM took only 11 ms for another run with 870 registrations, as shown in Figure 7. However, the current implementation dramatically improves the performance compared to the implementation presented in the paper P1, entitled 'Design and development of a context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes self-collected health data' [1], which took 26 ms to treat a similar current context using the same hardware and configuration as the current implementation.

```
1.  ---- Data ----
2.    DATE: 2018/12/26 - 2019/01/25
3.    P: ? R: 870 //Only registrations provided by patients
4.    RT: 15074-8 Size:421 //Blood glucose (LOINC)
5.    RT: 227991002 Size:195 //Carbs (SNOMED)
6.    RT: 388454007 Size:240 //Insulin (SNOMED LISPRO)
7.    RT: 86047003 Size:14 //Physical Activity (SNOMED)
8.    RCALC: COB Size:21354
9.    RCALC: IOB Size:30106
10.
11. ---- LOAD CONTEXT ----
12.   KBM_ECB_PCB ToE (ns): 203999
13.   (...)
14. ----------------------------
15. --- TOTAL EXECUTION TIME ---
16. KBM_ACT_EVA_IN ToE(ns):10720701 ToE(ms):11
```

Figure 7: Excerpt of the results of one instance of the KBM. ToE = Time of Execution.

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Appendix B – FullFlow system prototype and scalability tests

This appendix illustrates the implementation of the FullFlow system, and the scalability tests performed.

Prototyping

Sequence of tasks

This section relates to the series of actions performed by the parties when sharing self-collected health data from patients' application hosting health devices with EHRs. Figure 1 illustrates the *five steps* necessary to share self-collected health data.

The *first step* represents the digital schema creation. In this flow, the digital schema references the patients' self-collected health data along (either in FHIR or proprietary format) and metadata, such as the schema creator or the person who requested it. The schema also contains time-to-live information defined by the patients, which describes a period during which the schema is valid. An invalid schema is destroyed. The schema also references recipients, which determines who can consult it. The description uses FHIR artefacts. Designers, either researchers or a collective of medical workers, create the schemas. The first step ends with the designers uploading the created schemas into the national schema provider's site.

The *second step* describes a digital schema request for data sharing. Two parties can perform this step: medical workers who want to use patients' self-collected health data in their diagnostic process, or patients who want to use self-collected health data to support the discussion of issues with their clinicians. Medical workers initiate the request through their EHRs, which forward the request to the national schema provider along with the ID of the schema, the ID of the clinician, the ID of the clinical department, and the national ID of the patient. On the other end, patients must log into their Personal Health Archive on Helsenorge through ID-porten to request the schema. In this case, patients select the schema they want to use and define the recipients of the schema, either their general practitioner or a department that has already begun communication with the patient. During the next step, the Personal Health Archive sends the request to the national schema provider, providing the patient's ID, the schema's ID, and the recipient's ID. The national schema provider validates the request from a patient or from a medical worker and delivers the requested schema to the Personal Health Archive of the concerned patient. The Personal Health Archive then sends an alert to the concerned patient via SMS or e-mail once the schema transfer has been acknowledged and the schema stored in the correct personal archive.

The *third step* is schema completion. To complete a schema, a patient logs into the Personal Health Archive using ID-porten, as explained during the previous step. The patient then opens a pending schema that he or she wants to complete. From the point of view of the patient, a schema is a simple web form. By using the mobile BankID portal, patients can attach exported data files from their application of choice or use their phone's data buffer (clipboard) to copy and paste the data.

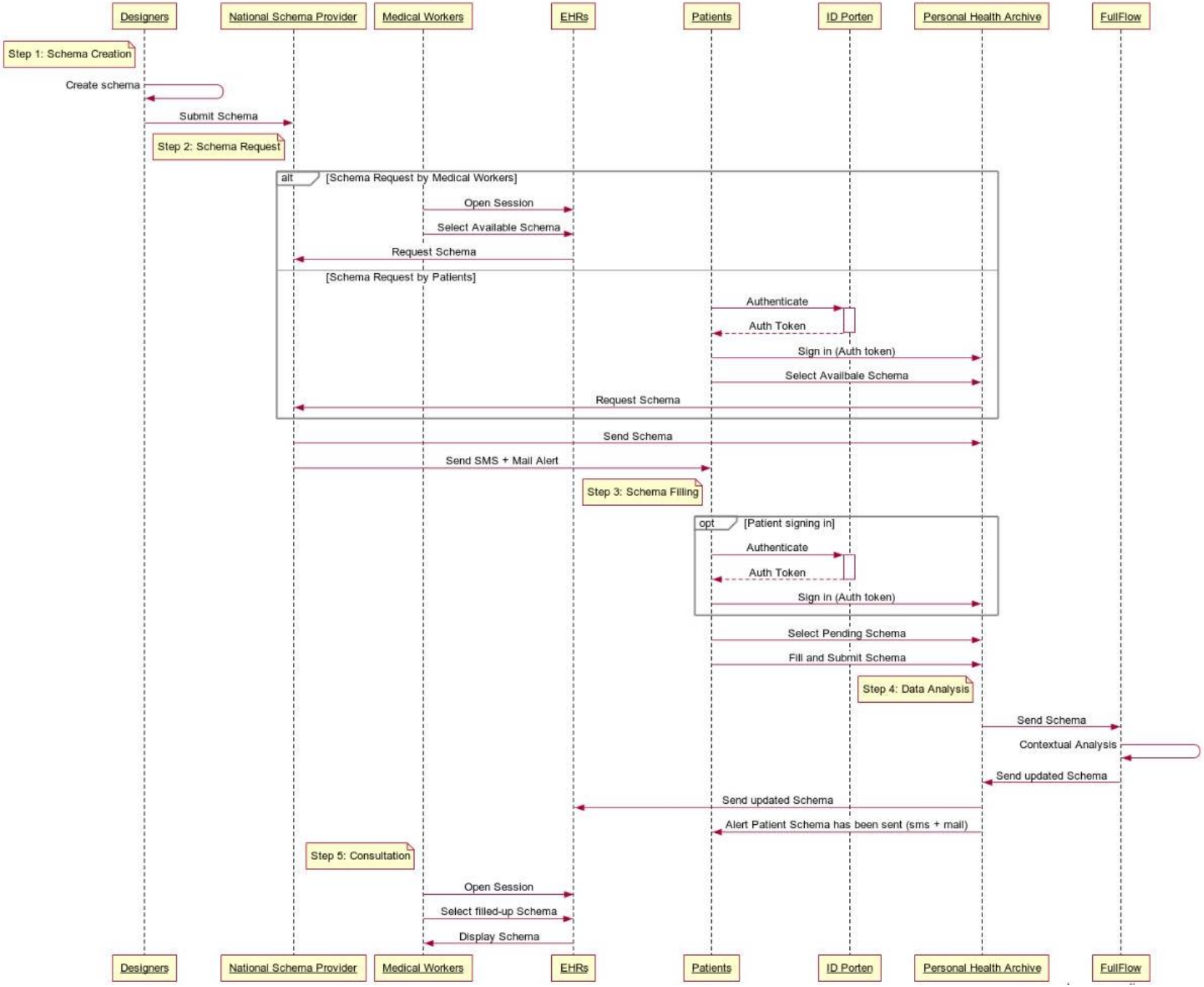

Figure 1: Simplified sequence diagram for the proposed patients' self-collected health data sharing process.

The *fourth step* concerns data analysis performed by the FullFlow and the KBM. Once the patient submits the schema, the Personal Health Archive triggers the FullFlow system, which in turn analyses the self-collected health data from the schema, eventually maps proprietary data to FHIR resources, updates the health data part of the schema, and sends it back to the Personal Health Archive. FullFlow also sends a copy to a message queue to allow EHRs to retrieve the data. The Personal Health Archive informs the patient that the schema has been updated by SMS or e-mail.

The *final step* concerns consultation. When medical workers want to consult patients' self-collected health data before, during, or after a consultation, they can use their EHRs. The EHRs list the available schemas in the message queue. To be available for consultation by a clinician, the schema request must be performed by a clinician from the same medical department or by the patient if she or he has specified who the recipient is. Then, the schema can be collected and displayed in EHRs directly.

FullFlow system

Figure 2 shows the high-level architecture of this system, corresponding to the Step 4 of the Figure 1. The FullFlow system follows the three-tier application model of the Java Enterprise Edition: client, server (business components), and back-end (persistence, called 'datacenter' in the schema). The FullFlow system contains three applications packaged in the Web application archive (WAR), which are deployed on Glassfish servers.

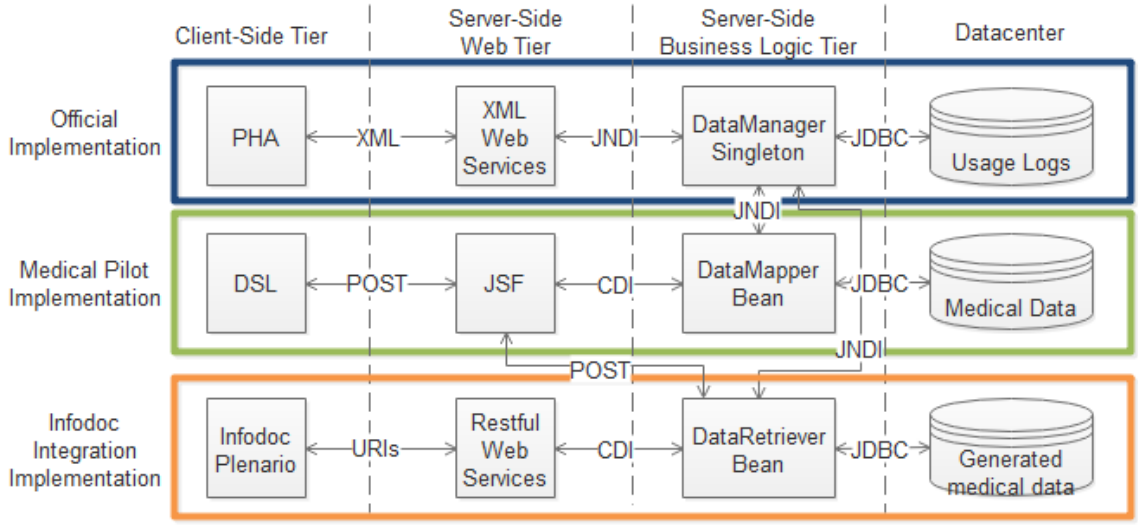

Figure 2: High-level architecture of the FullFlow System.

The *first application*, 'official implementation', represents the complete FullFlow system as it should be in the global infrastructure described in the previous section. This application exchanges schemas (payloads) with the Personal Health Archive, the client, through XML Web services, which represent the web tier of the business components. The Web services look up the DataManager singleton using the portable Java Naming and Directory Interface (JNDI) syntax. The DataManager represents the business logic of the system, and manages the performance of medical calculations and the management of the KBM, as described previously. I decided to opt for a singleton instead of a stateless bean, considering the limited resources available on the server (4GB of ram in total) and based on the performance impact of the HAPI-FHIR library (see below), which manages the provision of FHIR services, such as context or validation. In addition, it can be accessed by different threads. I chose the portable JNDI syntax, based

on the option to choose different providers to access resources provided by the singleton across different applications. The singleton also saves the usage logs of the system, which primarily contain metadata about the schemas (e.g. schema ID, creation time). However, they do not store personal information or medical data. They use the Java Database Connectivity (JDBC) application programming interface (API) to perform this task.

The *second application*, the 'medical pilot', is used for clinical trial. Considering that the PHA will not be available before 2020, my colleagues and I decided to use our proprietary sharing solution, Diabetes Share Live (DSL), connected to our mobile application Diabetesdagboka, which was used in a previous study [1], to replace the Personal Health Archive and ID-porten. The DSL is therefore the client in this application and exchanges payload via JavaServer Faces (JSF), the web tier of the business components, which produces HTML5 web pages. The DataMapper bean backs up the JSF page, allowing custom presentation of the results of the DataManager singleton, and maps proprietary data from the DSL to FHIR standards. Context and Dependency Injection (CDI) is used to bind the JSF and backing bean resources. The medical pilot implementation looks up the official application via JNDI in the DataManager singleton, which provides the same services as the official implementation. However, since this application is used for a medical trial, medical data and personal information received from the DSL and generated by the official implementation are saved in a database through JDBC, for research and analytical purposes. The clinical trial is described in the thesis summary.

The *last application*, Infodoc Plenario, was used to demonstrate the integration of the results of the FullFlow system with the Infodoc Plenario EHR, the client. The test used generated patients' self-collected health data stored in a database to simulate the message queue. Infodoc Plenario submits an ID-key containing a Norwegian national ID to the application through restful Web services (Web-tier), which is then transmitted to a stateless bean via CDI. The bean looks up the data generated from the database and sends it to the official implementation via JNDI in order to obtain the FHIR artefacts or through the medical pilot implementation to obtain the visual reports (depending on the restful methods used) and send the results back to the client.

Infodoc system

The Infodoc system integrates the data generated by the FullFlow system with Infodoc Plenario, one of the Norwegian EHRs. This corresponds to steps 4 and 5 of the Figure 1.

Figure 3 shows the simplified architecture of the implemented prototype. Infodoc Plenario is built using a three-tier architecture wherein a database containing medical data, server components, and client software is installed on the premises of the GPs' offices.

The clinician opens a session from client software, which connects to the Infodoc Plenario server for authentication purposes (called IDServer 4) and retrieval of data through several APIs. For this prototype, two new services were implemented: 1) a separate database for storing patients' self-collected health data and 2) a receiver, which connects to an AMQP queue in order to simulate the Helsenorge message queue. The queue is filled manually by pulling self-collected health data from FullFlow via the rest APIs described earlier.

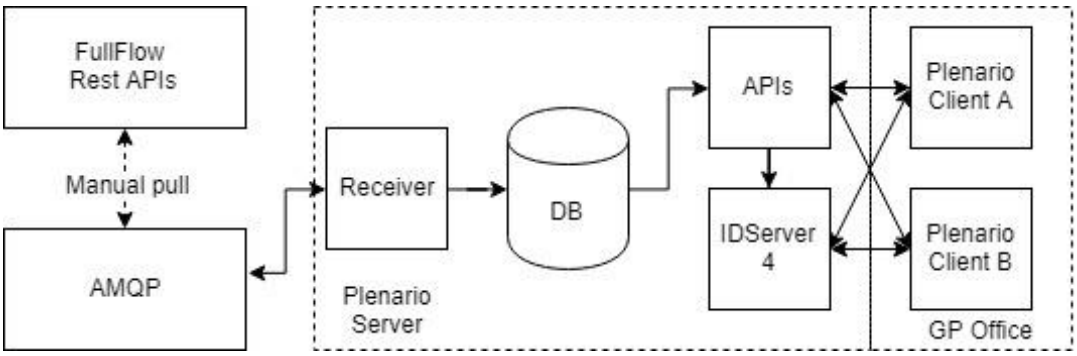

Figure 3: Simplified architecture of the prototype

The data flow is started by manually filling the message queue via the FullFlow rest APIs. A queue entry contains metadata about the patient (e.g. national identification number) as well as the dynamic report provided by FullFlow. The receiver then retrieves the data from the queue and stores it in a separate database. The flow continues after one clinician logs into the Infodoc Plenario server, using the Infodoc Plenario client. IDServer 4, based on OpenID, validates the connection and provides a token to access the APIs. When a clinician opens a health record, an API-call is triggered that retrieves the self-collected health data from the database.

The API verifies whether the authenticated clinician can access the patients' self-collected health data, based on the patients' wishes. If access is granted, the data is automatically displayed in Infodoc Plenario client. A more detailed implementation is described in another document [2].

Scalability tests

Table 1 shows the results of the load and scalability tests, using the official implementation. This table shows seven components:

1. Test type represents the type of test performed. There are four types of tests. The first is the 'single request' test, in which the payloads are sent individually to the single server without creating a stress situation. It is used as a reference for performance. The three other tests are based on running load tests against a single server, a cluster containing two servers, and a cluster containing three servers, as explained in the methodologies section.
2. Payload describes the payload types used for a test (representing two weeks', one month's, six months', and one year's data, as specified in the methodologies section). Each payload was tested separately for the load tests because of restrictions on the free version of SoapUI.
3. Average response time represents the average response time in milliseconds for all the requests. A response is validated when SoapUI receives the FHIR artefacts produced by the FullFlow system, based on the internal calculations of the system.
4. The total number of requests performed in 180 seconds, which represents the total number of requests performed with eight threads (see below for more explanation).
5. The number of requests per second, which is the total number of requests divided by 180 seconds.
6. Megabytes per second, which represents megabytes per second treated by the FullFlow system, based on the average execution time of the requests.
7. The number of errors in the transactions (e.g. timeouts or connections closed).

Table 1: Results of load and scalability testing.

Test Type	Payload	Average Response Time (ms)	Total Number of Requests in 180s	Request per Second	Megabytes per Second	Error Count
Single Request	2 weeks	240	-	-	-	-
	1 month	556	-	-	-	-
	6 months	2575	-	-	-	-
	1 year	4998	-	-	-	-
Load Test Single Server	2 weeks	1680.56	850	4.72	2.754795	0
	1 month	2976.42	479	2.66	3.033076	0
	6 months	15669	89	0.49	3.160953	0
	1 year	30439.68	44	0.24	3.106344	0
Load Test Cluster (2)	2 weeks	847.31	1678	9.32	5.436424	0
	1 month	1510.07	944	5.24	5.973199	0
	6 months	8170.22	173	0.96	6.186336	0
	1 year	16442.42	84	0.47	5.979901	0
Load Test Cluster (3)	2 weeks	576.93	2455	13.64	7.9636	0
	1 month	1036.81	1374	7.63	8.699728	0
	6 months	5661.11	251	1.39	8.973022	0
	1 year	11527.97	122	0.68	8.635866	0

Single Requests

The measurement of the average response time for the single request tests was based on five manual requests involving different payloads. Figure 4 shows an example of a single request performed using the SoapUI software. In this case, the concerned payload has one year of data. The address on the top bar (http://localhost:8079/FullFlow/services/fullflow) represents the Web Services Description Language (WSDL) endpoint of the single server. The left window shows the payload sent to the server, while the right window shows the answer of the FullFlow system. In this case, the response time was 4,997 ms (bottom left of the figure).

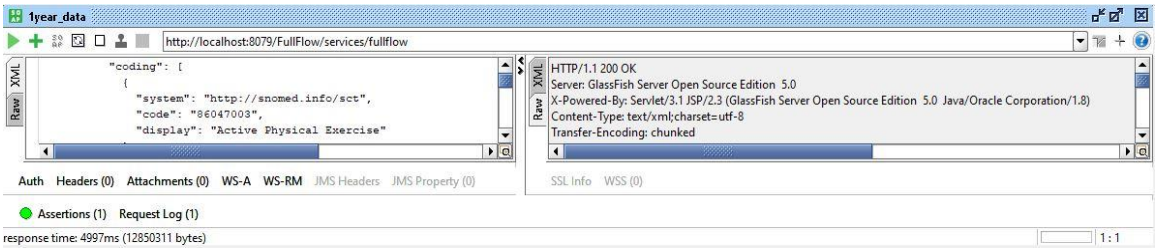

Figure 4: Example of a test step involving a single test of a one year of data payload, using SoapUI.

Using this approach five times for each payload, I found an average response time of 240 ms for two weeks of data payload, 556 ms for one month of data payload, 2,575 ms for six months of data payload, and 4,998 ms for one year of data payload, which represented an average execution time per day of 13 ms for all cases. Plotting the average response time per payload, represented in weeks, shows a linear progression of the average response time (see Figure 5).

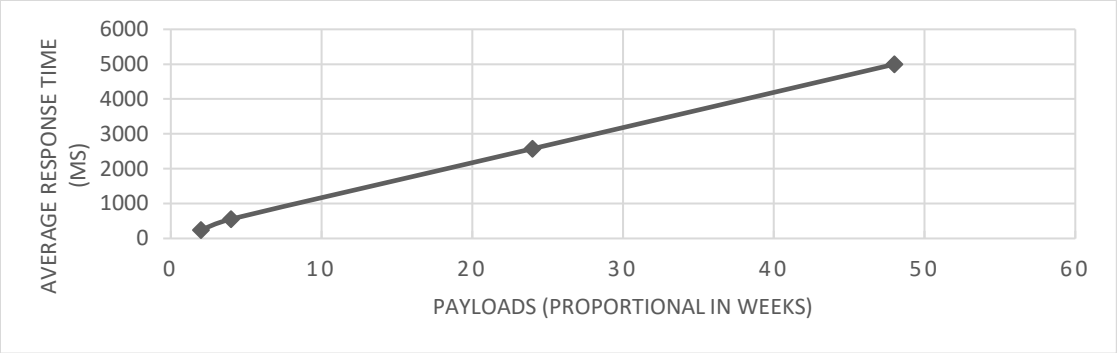

Figure 5: Average response time in milliseconds for the single request test.

Memory heap usage

I used single requests to monitor the memory heap dynamically, track the memory usage, and identify potential memory leaks. I configured SoapUI to run the single requests individually in a loop for ten minutes. The results are shown in Figure 6. I compared the usage logs of the FullFlow server to the time provided by VisualJM to identify which payload was treated at which time.

Based on this test, I discovered that no memory leak occurred and that the heap used after the test came back to the pre-test level of 632 MB. I identified the average heap usage increase for all payloads: 399 MB for the one-year payload (b in Figure 6), 204 MB for the six-month payload (d), 32 MB for the one-month payload (f), and 17 MB for the two-week payload (e). (c) is an example of garbage collection for almost 1.5 GB of data and (a) is a slight increase in the heap, due to the DataManager singleton moving from the 'non-existent state' to the 'ready for invocation' state. While the heap used followed a quasi-linear progression regarding the type of payload, I wanted to analyse further how the memory was used.

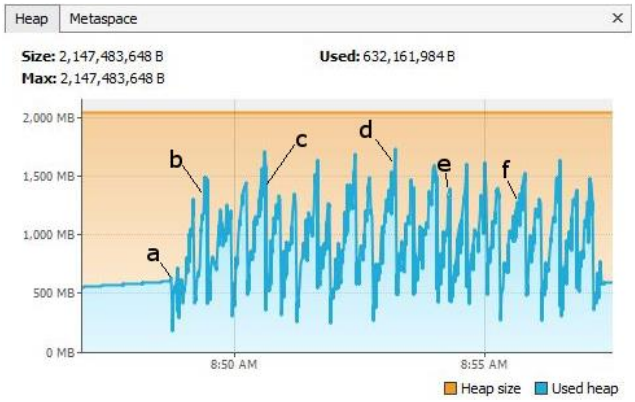

Figure 6: Memory heap usage for 10 minutes of continuous single requests. a = DataManager singleton ready for invocation, b = one-year payload, c = garbage collection, d = six-month payload, e = two-week payload, f = one-month payload.

To do so, I profiled the memory and created a snapshot while the system was running for a single request. Figure 7 shows an example of memory usage for the one-month payload and displays the five classes that used the most memory heap. It shows that almost 70% of the memory heap (representing approximately 22.4 MB of data) is used by the HAPI-FHIR library for indexing, querying, navigating, and creating the FHIR data.

Name	Live Bytes
com.google.gson.internal.**LinkedTreeMap$Node**	9,719,424 B (30.2%)
java.lang.**String**	8,527,704 B (26.5%)
com.google.gson.internal.**LinkedTreeMap**	2,332,560 B (7.3%)
java.util.**TreeMap$Entry**	2,046,560 B (6.4%)
com.google.gson.**JsonPrimitive**	1,814,272 B (5.6%)

Figure 7: Top five classes using the most heap space based on memory profiling for the one-month payload.

The HAPI library uses the Google Gson library (representing 43.1% of the memory heap or 13.9 MB) to serialise and de-serialise FHIR artefacts to and from JSON. While FullFlow accepts both XML and JSON for representing FHIR artefacts, I chose the JSON parameters over those of XML Web-services to test, considering the reduced size of the data. The Gson library also uses almost exclusively (>99%) the Java.Lang.String class (26.5% of the memory heap or 8.5 MB) with the methods NextQuotedValue() and NextString() when reading the JSON. Combined with the previous classes, Gson occupied 69.6% of the memory heap.

The util.TreeMap$Entry (6.4% of the memory heap or 2 MB) contains the objects the FullFlow system uses internally to perform medical calculations and reference the FHIR artefacts being examined. The rest of the memory heap is used either by the KBM or the Glassfish server itself. I found similar percentages for the memory usage of other payloads.

This situation renders difficult any improvement in memory usage, and it limits vertical scalability, especially considering the limited resources of the FullFlow server. HAPI-FHIR consumes most of the heap. The library is used three times during a single run: the first time to read the data, the second time to add FHIR artefacts based on the results of the medical calculations and the KBM, and the third time for exporting the data. I decided to focus the efforts on horizontal scalability.

Load tests and horizontal scalability

I created several load tests to stress test the FullFlow system and demonstrate its horizontal scalability. For each payload and each server configuration, I ran a load test for 180 seconds, sending payloads with eight threads every 10 ms. Figure 8 shows a load test of the two-week payload against the cluster containing two servers.

LoadTest 1

Limit: 180 Seconds 100%

Threads: 8 Strategy Simple Test Delay 10 Random 0.5

Test Step	min	max	avg	last	cnt	tps	bytes	bps	err	rat
1year_data (disabled)	0	0	0	0	0	0	0	0	0	0
6months_data (disabled)	0	0	0	0	0	0	0	0	0	0
1month_data (disabled)	0	0	0	0	0	0	0	0	0	0
2weeks_data	225	1515	847.31	234	1678	9.29	981769274	5436424	0	0
TestCase:	225	1515	847.31	234	1678	9.29	981769274	5436424	0	0

Figure 8: Example of a load test with SoapUI. The two-week payload was run against a cluster comprising two servers.

I reported the information provided by SoapUI on the Table 1 presented earlier.

The first noticeable result was that there was no error when handling the load tests, for all configurations, meaning that the system is stable enough to handle bursts of requests.

Regarding the average response times, I obtained for the single server 1,681 ms for the two-week payload, 2,976 ms for the one-month payload, 15,669 ms for the six- month payload, and 30,440 ms for

the one-year payload. Under stress, the treatment of a two-week payload lasts seven times longer than that for single requests, 5.3 times longer for the one-month payload, and six times longer for the six-month and one-year payloads. For the cluster containing two FullFlow instances, I obtained 847 ms for the two-week payload (3.5 times longer than for single requests), 1,510 ms for the one-month payload (2.7 times longer), 8,170 ms for the six-month payload (3.2 times longer), and 16,442 ms for the one-year payload (3.3 times longer). Regarding the cluster with three FullFlow instances, I obtained for the same payloads, 577 ms (2.4 times longer), 1,037 ms (1.9 times longer), 5,661 ms (2.2 times longer), and 11,528 ms (2.3 times longer). These results show that FullFlow is horizontally scalable: the average response time is proportionally decreased by the number of servers present in a cluster. For example, the average response time decreases nearly twofold for all payloads when using two instances (between 1.85 and 1.98) and threefold when using three instances (between 2.64 and 2.91) compared to the single instance, as illustrated by Figure 9 and Figure 10. The addition of the Membrane service and the Glassfish cluster configuration contribute to the small differences in proportion compared with the single instance. However, it is interesting to note that the increase in average response time is higher for the two-week payload than the other payloads (see Figure 9). This occurrence can be explained mostly by the HAPI-FHIR library, which uses more time in percentage for loading its internal component than the internal calculations of the FullFlow for smaller payloads. This trend is inverted for larger payloads.

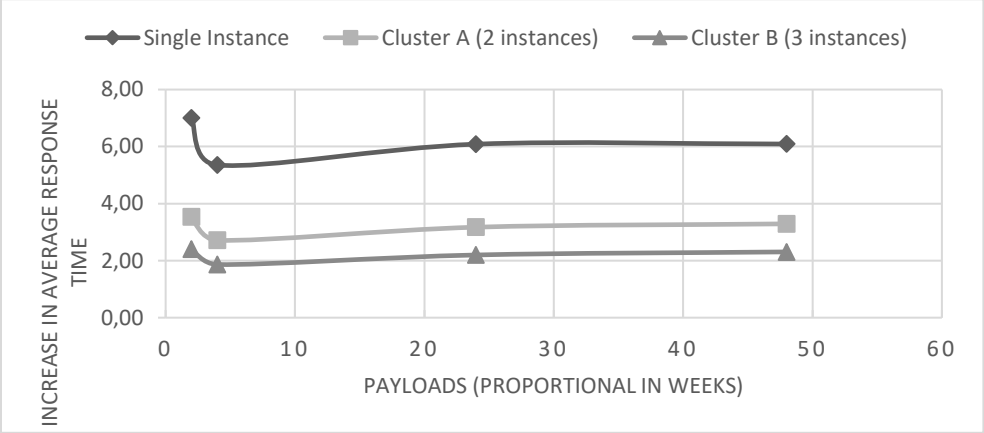

Figure 9: Increase in average response time for the load tests compared with the average response times for the single requests (i.e. x times longer than average time for the single requests).

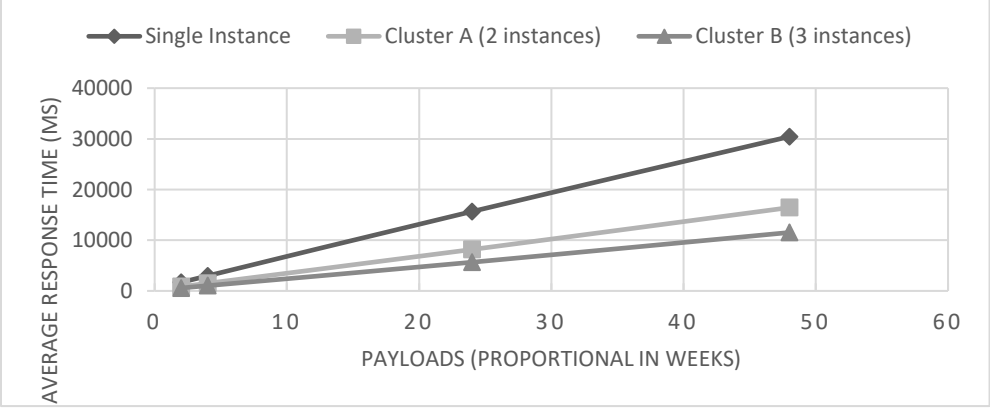

Figure 10: Average response time for the load tests for each type of payload and test.

I noticed an important decrease in the total number of requests answered during the 180 seconds of load tests for the larger payloads. A single server manages to answer 850 requests in 180 seconds (= 4.7 requests per second [r/s]) for a two-week payload, 479 requests (2.66 r/s) for a one-month payload, 89 requests (0.5 r/s) for a six-month payload, and 44 requests (0.2 r/s) for a one-year payload), which corresponds to the average response time described previously and the test type. Compared with the period length, the single server manages 1.77 times fewer requests for a payload twice as large as the base payload (two weeks), 9.55 times fewer requests for a payload 12 times larger than the base one, and 19.31 times fewer requests for a payload 24 times larger than the base payload. Adding more instances to a cluster causes a proportional increase in the number of requests managed: 1,678 (9.3 r/s), 944 (5.2 r/s), 173 (1 r/s), and 84 (0.5 r/s) for the cluster with two instances, and 2,455 (13.6 r/s), 1,374 (7.6 r/s), and 122 (0.7 r/s) for the three instances cluster, with a similar proportion for the decreased number of requests for payloads. Figure 11 and Figure 12 illustrate this phenomenon.

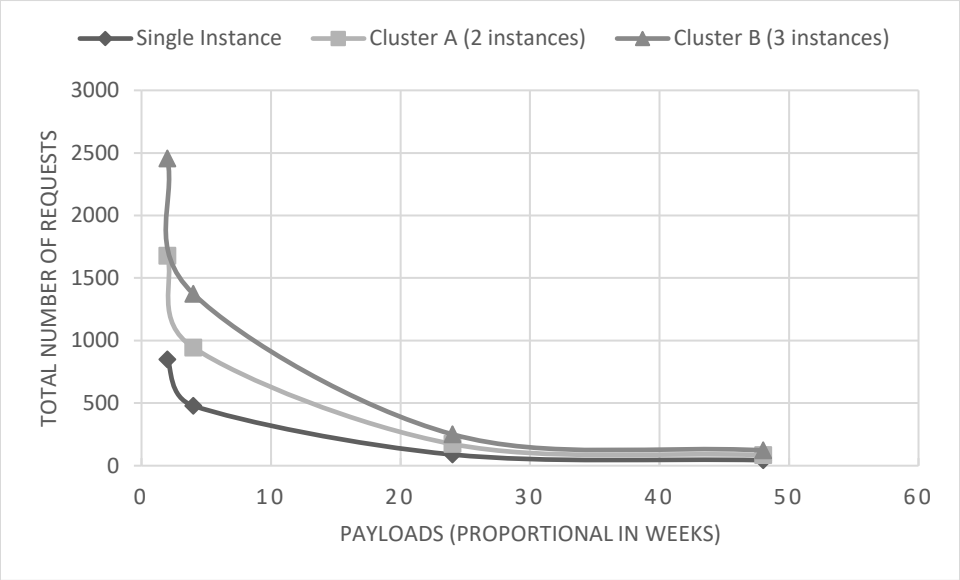

Figure 11: Total number of requests during 180s for each type of payload and test.

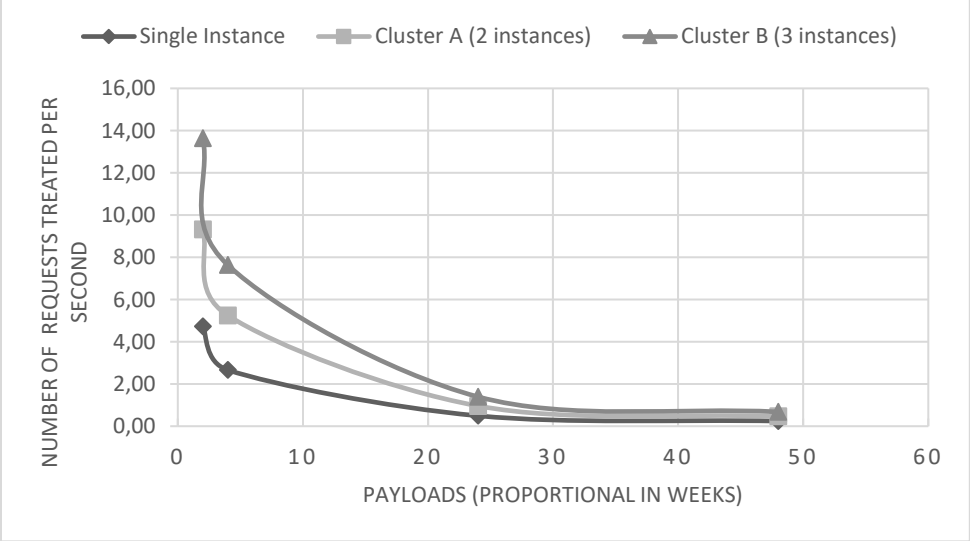

Figure 12: Number of requests treated for each payload and each test.

Regarding the megabytes treated per second, the values are almost constant for all types of payloads and tests: approximately 3Mb/s for a single instance, approximately 6Mb/s for two instances, and approximately 9Mb/s for three instances, as illustrated by Figure 13. The slightly lower rate of the two-week payloads compared with the others can be explained by the payload size, where the system uses a greater amount of time in percentage to serialise and de-serialise the payloads than it does to perform calculations.

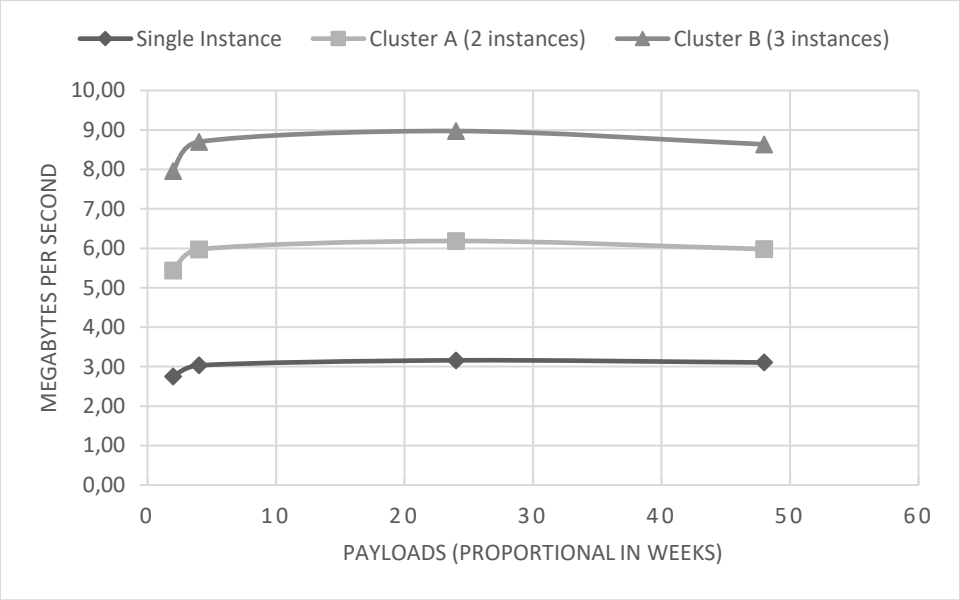

Figure 13: Megabytes per second for each payload and each test

While internal optimisation is possible, the different tests demonstrated that FullFlow can horizontally scale and can manage bursts of requests.

National Scalability

I can use the results from the previous section and the statistics provided by the Statistics Norway, the central agency providing statistics of the population in Norway [3], to estimate the needs of the system in a production environment. I focus first on patients with diabetes and secondly on the total Norwegian population.

In 2017, the total number of consultations for patients with diabetes (all types) for the whole of Norway was 531,295 consultations (140,844 consultations at general hospitals, 387,856 consultations with general practitioners, and 2,595 consultations in emergency primary healthcare). Assuming that Norway has approximately 250 working days per year [4], the number of average consultations per working day for patients with diabetes is 2,125 for the whole of Norway. Assuming that 1) all consultations require self-collected data, 2) all patients share two weeks of self-collected data at the same time during a day, and 3) I ignore possible external bottlenecks or points of failure (e.g. the queue managed by Helsenorge.no), the cluster containing three servers is able to answer all of the requests in Norway in fewer than 180 seconds, meaning that the implementation already exceeds the requirement for a real-use situation.

The total number of consultations in Norway in 2017 (including all diagnoses and all healthcare institutions) is 14.4 million, representing roughly 57,600 daily consultations on average using the same

approach described in the previous paragraph. With the same assumptions, the cluster with three servers can treat all requests in 70 minutes. The system is therefore capable of processing the Norwegian load, even if better architecture should be implemented to avoid possible single points of failure, congestion, and latency.

Negative stress testing

Considering that the previous tests showed that FullFlow system is scalable to the Norwegian needs, I wanted to test how the system reacts to failures. The scenario for the negative stress testing is as follows: using the same load test approach as before (10 threads, 180 seconds), with the six month payload against configuration A with a reduced heap size of 256 MB. The goal was to provoke internal out-of-memory errors and study what happened to the requests. Figure 14 illustrates the results of this test and Figure 15 shows the evolution of the heap size usage during this test.

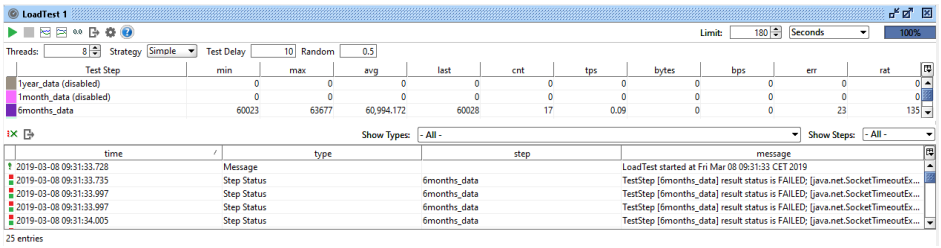

Figure 14: Negative stress testing results using the six months payload against the configuration A.

Compared to the load tests, the negative stress testing provoked out of memory errors in the server of the configuration A. On the forty requests send to the server, only seventeen succeeded (42.5%) while twenty-free failed (57,5%), meaning that the ratio errors to successes was 1.35 (or 135%). In this condition, the server managed to correctly answer less than 20% of the requests of a normal situation (17 successes versus 89 successes) and took four times longer to answer a single request on average (60,994 ms vs 15,669 ms).

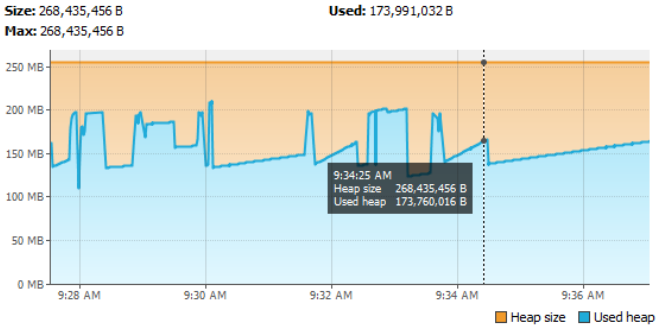

Figure 15: Heap size evolution during negative stress testing.

During this test, the memory usage was chaotic, as shown in Figure 15. The server followed two strategies to reduce its load. The first one ignored incoming new requests while being overloaded and the second one dropped requests and forced a memory garbage collection to reduce the usage of the memory heap. For the client side, errors produced could be either socket timeouts or connection resets by peers, depending on the strategy chosen by the server. In a completely stateless configuration, the FullFlow system is not able to re-process the dropped requests, and the client (in this case SoapUI)

should re-send the requests for them to be performed again. In a real-use situation, the Personal Health Archive takes care of this situation.

However, once the load requests ceased, the server was able to return to its normal situation and provide normal services and, therefore, the negative test succeeded.

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INCLUDED PAPERS

Original Paper

Design and Development of a Context-Aware Knowledge-Based Module for Identifying Relevant Information and Information Gaps in Patients With Type 1 Diabetes Self-Collected Health Data

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Abstract

Background: Patients with diabetes use an increasing number of self-management tools in their daily life. However, health institutions rarely use the data generated by these services mainly due to (1) the lack of data reliability, and (2) medical workers spending too much time extracting relevant information from the vast amount of data produced. This work is part of the FullFlow project, which focuses on self-collected health data sharing directly between patients' tools and EHRs.

Objective: The main objective is to design and implement a prototype for extracting relevant information and documenting information gaps from self-collected health data by patients with type 1 diabetes using a context-aware approach. The module should permit (1) clinicians to assess the reliability of the data and to identify issues to discuss with their patients, and (2) patients to understand the implication their lifestyle has on their disease.

Methods: The identification of context and the design of the system relied on (1) 2 workshops in which the main author participated, 1 patient with type 1 diabetes, and 1 clinician, and (2) a co-design session involving 5 patients with type 1 diabetes and 4 clinicians including 2 endocrinologists and 2 diabetes nurses. The software implementation followed a hybrid agile and waterfall approach. The testing relied on load, and black and white box methods.

Results: We created a context-aware knowledge-based module able to (1) detect potential errors, and information gaps from the self-collected health data, (2) pinpoint relevant data and potential causes of noticeable medical events, and (3) recommend actions to follow to improve the reliability of the data issues and medical issues to be discussed with clinicians. The module uses a reasoning engine following a hypothesize-and-test strategy built on a knowledge base and using contextual information. The knowledge base contains hypotheses, rules, and plans we defined with the input of medical experts. We identified a large set of contextual information: emotional state (eg, preferences, mood) of patients and medical workers, their relationship, their metadata (eg, age, medical specialty), the time and location of usage of the system, patient-collected data (eg, blood glucose, basal-bolus insulin), patients' goals and medical standards (eg, insulin sensitivity factor, in range values). Demonstrating the usage of the system revealed that (1) participants perceived the system as useful and relevant for consultation, and (2) the system uses less than 30 milliseconds to treat new cases.

Conclusions: Using a knowledge-based system to identify anomalies concerning the reliability of patients' self-collected health data to provide information on potential information gaps and to propose relevant medical subjects to discuss or actions to follow

could ease the introduction of self-collected health data into consultation. Combining this reasoning engine and the system of the FullFlow project could improve the diagnostic process in health care.

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KEYWORDS

context aware; knowledge-based system; diabetes; self-collected health data; information gaps

Introduction

Background

Providing the right explanations regarding the situation of a patient at the right time is a key for improving the diagnostic process in health care [1]. Data collected by the patients, using various applications, can be a precious source of information for characterizing and explaining the situation of a patient suffering from chronic illnesses, especially diabetes [2], for both patients as well as their clinicians. Studies have shown that patients are increasingly using applications for automatically collecting, storing, and analyzing their data [3]. However, clinicians cannot effectively use self-collected health data until it is integrated into their daily workflow and clinical systems, and often ignore the data if they do not know that it is "accurate, reliable and aligned with their agenda" [4].

The "Full Flow of Health Data Between Patients and Health Care Systems," referenced as FullFlow in this article proposes to address these issues. This can be achieved by providing a platform for integrating the patient's self-collected health data from diabetes self-management applications (eg, Diabetesdagboka [5], mySugr [6]) and wearables (eg, FreeStyle Libre [7]) into Norwegian Electronic Health Records (EHRs) and Norwegian Personal Health Records (PHRs) through Norwegian public services. FullFlow aims to (1) facilitate diagnostic processes conducted by specialists, general practitioners (GPs), and nurses, by presenting patients' self-collected health data directly in their EHRs and PHRs, and (2) empower patients and help them understand their disease. We limited the focus of FullFlow to diabetes, even if it can provide a more general service.

FullFlow consists of 3 components. First, there is a data collection component, which aggregates self-collected health data from the patients' tools, by either using application programming interfaces (ie, automatic collection from patients' tools) or Web-based schemas (ie, manual collection done by the patients). Second, there is a data analysis module, which processes the data and provides statistical analyses and medical calculations (eg, deviations, insulin sensitivity factor). Third, there is a Bundles Builder, which organizes the data into Fast Health Care Interoperability Resources (FHIR). FullFlow uses FHIR for facilitating its integration with Norwegian public services starting to implement this standard, especially Helsenorge.no [8], which contains a collection of health records generated by health care institutions (PDF only in May 2018) and accessible by both patients and clinicians in Norway. In addition to the FHIR-based data, the Bundles Builder provides reports to help medical workers consulting the data and to facilitate the integration of self-collected health data for the EHRs, which are not yet ready to handle FHIR resources but started to implement it [9]. These reports are dashboards, similar to the dashboard proposed by Dagliati et al [10] or to Carelink by Medtronic [11] but differs regarding several points: (1) FullFlow proposes the usage of self-collected health data as source of the dashboard, (2) FullFlow is aiming to integrate self-collected data into clinical systems directly without the use of external services, and (3) FullFlow is not limiting the data source to specific companies, sensors or applications. These reports are in PDF or Hypertext Markup Language and are directly sent to Norwegian EHRs and PHRs.

Figure 1 illustrates this composition and the data flow, from the patients to the medical workers.

The reports (see Figure 2) contain distinct areas, each focusing on a specific need:

1. Overview Area-provides a summary of the data period.
2. Period-displays patient-collected data as linear graphs.
3. Daily Evolution and Daily Distribution-contain graphs with all types of data available summarized per day and hour.
4. Data List-provides a list of all data collected for the period in text format.
5. Combined Data-displays all data in a unique graph.

These areas permit clinicians to obtain an overview of a patient's self-reported health condition, as well as identify problematic events or trends, and to recommend actions for managing them. However, testing the dashboard of the FullFlow revealed unaddressed challenges.

First, the presence of information gaps in the self-collected health data. Information gaps are missing problematic events (eg, unreported hypoglycemic event) and lack of information for pointing out their causes (eg, undocumented extreme physical activity before a hypoglycemic event). Multiple factors lead to these information gaps (1) sensors and wearables used by the patients are not well calibrated, imprecise or even defective [12,13], (2) sensors and wearables are incorrectly operated by the patients [14], (3) patients make errors when registering data manually, and forget to register data or do not register at all [15], and (4) patients deliberately lie and edit the data to hide their poor performance to avoid unfavorable judgment by medical workers [16] and to avoid potential penalties. For example, in Norway, patients with more than 2 severe hypoglycemic events risk losing their driving license [17]. The information gaps limit the possibility for clinicians to interpret the data correctly and constitute the main barrier to the acceptance of the FullFlow, as the clinicians are considering the self-collected health data as less reliable compared to laboratory results for example.

Second, our workshops with clinicians showed that even when information gaps are not present, clinicians are unable to extract

and analyze the data in an acceptable amount of time, especially during a consultation, even with the help of graphs. According to them, self-collected health data is too time consuming because of the amount of self-collected health data (ie, the number of registrations performed by the patients), of the noise in self-collected health data (ie, irrelevant data regarding the self-reported health condition of a patient), and clinicians need to link and compare different types of health data to extract information. This constitutes the second main barrier to the acceptance of the FullFlow.

Figure 1. Simplified data flow of the FullFlow project. API: application programming interface; EHR: electronic health record; FHIR: Fast Health care Interoperability Resources; PHR: personal health record.

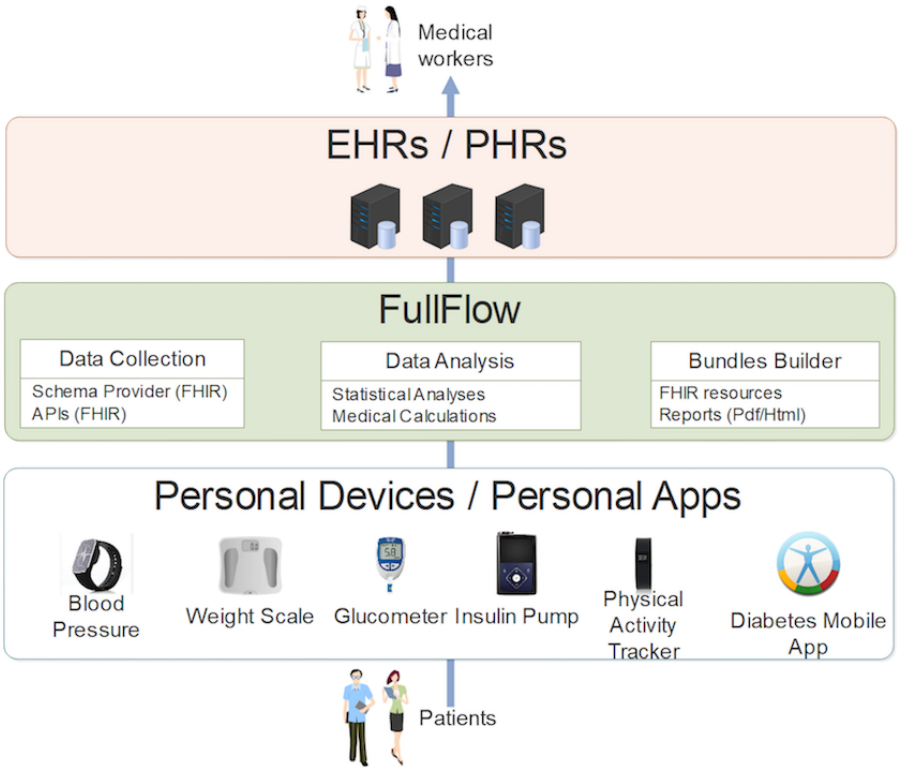
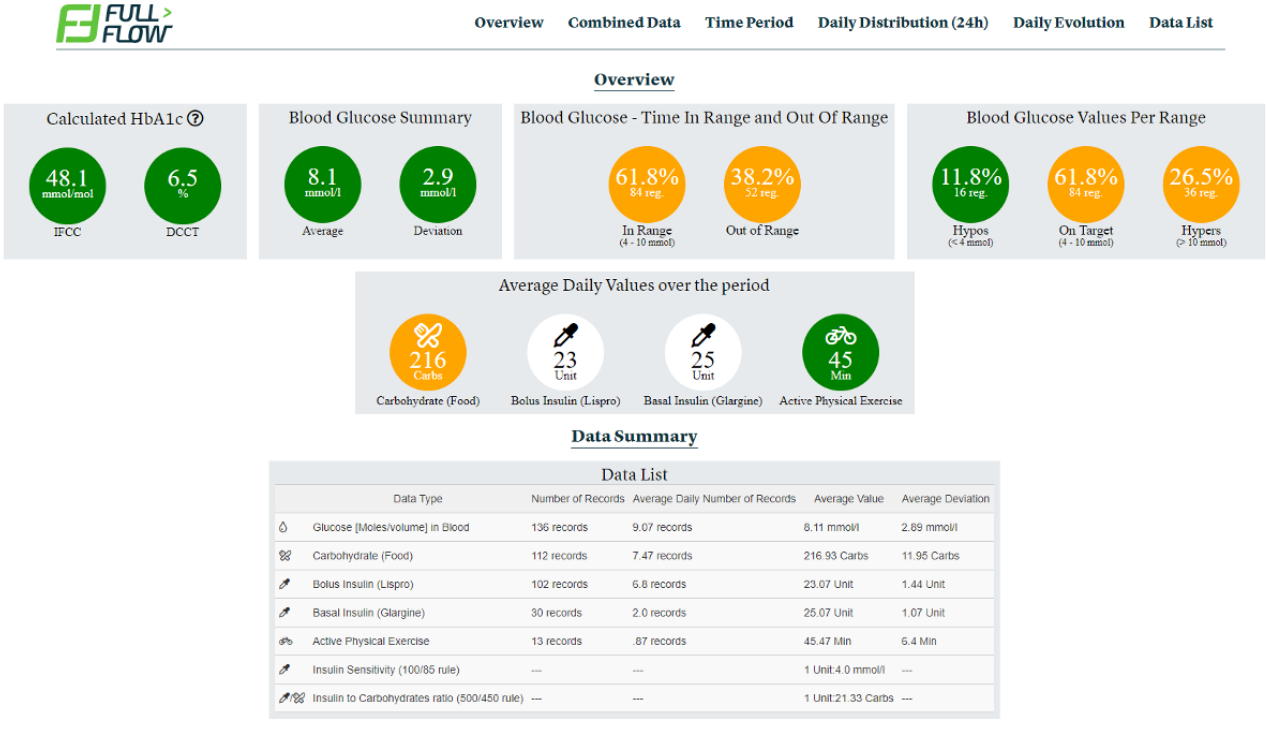
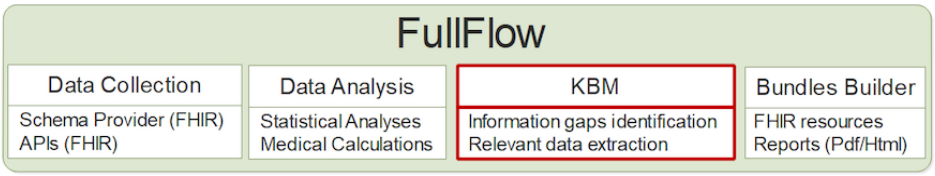


Figure 2. Example of a FullFlow Report.



Data Type	Number of Records	Average Daily Number of Records	Average Value	Average Deviation
Glucose [Moles/volume] in Blood	136 records	9.07 records	8.11 mmol/l	2.89 mmol/l
Carbohydrate (Food)	112 records	7.47 records	216.93 Carbs	11.95 Carbs
Bolus Insulin (Lispro)	102 records	6.8 records	23.07 Unit	1.44 Unit
Basal Insulin (Glargine)	30 records	2.0 records	25.07 Unit	1.07 Unit
Active Physical Exercise	13 records	.87 records	45.47 Min	6.4 Min
Insulin Sensitivity (100/85 rule)	---	---	1 Unit:4.0 mmol/l	---
Insulin to Carbohydrates ratio (500/450 rule)	---	---	1 Unit:21.33 Carbs	---

Figure 3. FullFlow components with the knowledge-based module (KBM; red). API: application programming interface; FHIR: Fast Health care Interoperability Resources.



In this paper, we address these challenges: information gaps, time-consuming processing of data and extraction of the relevance of the data by presenting the design, and implementation of a context-aware knowledge-based module (KBM). The KBM improves the FullFlow system by (1) providing information on the reliability of self-collected health data and the potential presence of information gaps, and (2) presenting relevant information about the self-reported health of a patient and the origins of problematic events.

The KBM is a complimentary module to dashboard systems such as FullFlow and could permit clinicians to focus on specific and relevant information during consultation instead of spending time consulting the self-collected health data and trying to extract information on their own. Figure 3 presents the FullFlow components with the KBM. The result section shows the impacts of the KBM on the Bundles Builder.

The knowledge base contains rules formulated by medical experts and relies on a reasoning engine (ie, component deducing information), based on contextual information, to identify and interpret relevant data. Dey and Abowd [18] define context as "any information that can be used to characterize the situation of an entity". An entity is a person, place, or object that is considered relevant to the interaction between a user and an application, including the user and applications themselves. In our setting, medical evidence, such as patients' self-collected health data, laboratory results and metadata, such as the identities of the patients and medical workers, and the rules of the knowledge base themselves compose the context. The reasoning engine combines these data using a hypothesize and test strategy for identifying data reliability problems as well as information gaps and highlighting relevant data related to problematic events.

This paper also presents the methodologies we followed from the creation to the assessment of this module, including its integration in the main system, and its future use.

Methods

This section presents an overview of the different phases and methodologies used for the design, the implementation and the testing of the KBM, as shown in Figure 4.

Design of the Module

First, a brainstorming approach to define the scope of the module for identifying functionalities and potential problems appearing at a later stage was used by the main (AG) and the second author (PO). The data flow, technology stack (ie, a combination of programming languages, tools, and functionalities) and data model (ie, the standardization of data and relations between types of data) were also discussed.

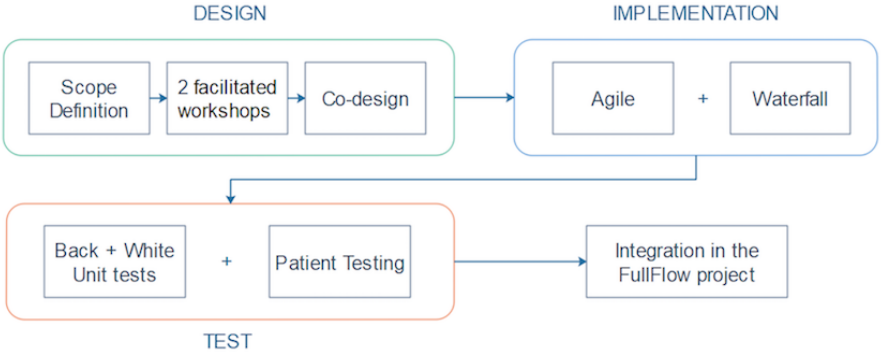
Then, 2 facilitated workshops were organized for designing the KBM, involving the main author (AG), one patient with type 1 diabetes (in house researcher), and one clinician (AH). The workshops were used for different purposes (see Textbox 1). However, a wider range of people were invited to participate in a co-design workshop to contribute to the 3 points described above, as the 2 facilitated workshops sessions had limited participants. There were 5 patients with type 1 diabetes, 2 endocrinologists, and 2 nurses specializing in diabetes were involved in this co-design. The participants were not known to the authors and were recruited through the authors' partner institution, the University Hospital of Northern Norway and on social media. Acknowledgment from Regional Ethical Committee was applied and an exemption was received September 2017. The co-design was organized around 3 sessions: (1) patients only, (2) clinicians only, and (3) all participants together. Sessions 1 and 2 were held simultaneously at a different location and before the session 3. This approach permitted to build the patients' confidence and to ensure their thinking points were addressed during the common session. The patients' pressure and bias were lowered by the facilitators (ie, the authors) giving everyone a chance to speak and by using different methodologies, such as (1) the expense account where each participant has to use a token before speaking and cannot speak once their token pile is empty, (2) the Writing Round Robin where all participants answer a question on paper simultaneously and then present the answers in turns, and (3) the 5 whys where a participant is asked "why" 5 times to find the root of a problem. The methodologies were defined beforehand by the authors through brainstorming sessions. Time was also reserved for participants to ask their questions throughout the sessions.

The co-design was audio recorded, and the audio registrations were transcribed by the authors for further classification and analysis. All medical related decisions from these events were assessed by the third author, who is a medical doctor.

Implementation of the Module

An agile development process (ie, iterative development) was used for the software implementation when evolution, changes, and adaptability were the key points (eg, user interactions, reasoning model). Continuous input and involvement of patients and health workers were included in this process. A more classic waterfall approach (ie, sequential development) was used when stability and performance were the focus, such as the implementation of the core of the module (ie, the "engine" which does not interact directly with the users).

Figure 4. Methodologies used in three different phases: Designing, Implementing and Testing of the KBM.



Textbox 1. The different purposes of the workshops.

1. For identifying contextual information. The context was first identified following the approach proposed by Dey and Abowd [18] with the support of brainstorming: organizing context around location, identity, time and activity and using a tiered system for further categorization per type of context, and point of view of the KBM.
2. For creating a model of context, representing the interactions between all entities involved with the KBM (eg, patients, medical workers, EHRs) and the context interacted between them. This was inspired by the model of context in computer science proposed by Bradley and Dunlop [19] and was created to provide a complete overview of the usage of the context.
3. For defining a knowledge base and a reasoning model. They were used as requirements for the implementation of the module and to describe the functionalities of the KBM and its operation.

Testing of the Module

Testing was performed in different ways: a white box (ie, testing of internal structures of code) approach was used for testing the core without involving the context and the reasoning model, while a black box (ie, testing of functionality) approach was followed for testing whether the system behaved according to what was defined by the previous creation process. Both approaches were made using unit tests. Load tests were used for determining if the performance of the modules could affect FullFlow in the event of its integration.

Results

System Architecture

This section presents a complete overview of the architecture of the KBM.

Contextual Information

The first step in the architectural design process (ie, the sequence of steps to create the KBM) was to identify the contextual information necessary for the KBM to achieve the goals for which it was designed. We adopted the context definition suggested in Dey and Abowd [18]. Their 4 main categories of context were location, identity, time, and activity. However, since the types of contextual information in health care domain is much richer than the context presented by Dey and Abowd, we introduced several types of context particularly instead of "activity" category of context.

In total, we identified 9 types of context, as shown in Figure 5. The first type is *health data*, containing *patient-collected data* and *laboratory generated data*. *Patient-collected data* represents data a patient can bring to the consultation using their sensors, mobile applications or diaries**.** The data usually collected by patients with diabetes are mostly blood glucose, basal-bolus insulin, carbohydrates, physical activity, and to a less degree also calories, blood pressure, heart rate, medication, ketones, stress, menstruation, sickness, insulin sensitivity, polypharmacy, comorbidity, insulin-to-carbohydrate ratio (I:C), and carbohydrate absorption rate. Units of measurements can further characterize each type of the collected data. For example, physical activity could be expressed as the number of steps, a period or intensity (eg, light, moderate, extreme), while insulin intakes could be expressed in international units (UI) or mg.

Laboratory generated data represents data originated from laboratory tests (eg, blood analysis). Today, FullFlow only has automatic access to the glycated hemoglobin (HbA_{1c}) data from several EHRs and cannot obtain other types of data such as leukocytes, which are associated with diabetes complications [20], or creatinine which is useful for tracking the progression of diabetic kidney disease [21]. Therefore, they are not included in Figure 5.

Medical standards are the third type of context, which covers reference values for a specific data type. For example, the recommended range for blood ketones is less than 0.6 mmol/L or the formulae used for calculating medical values (eg, 1500/1800 rule for approximating the insulin sensitivity factor [22,23]).

Data registration regularity refers to the registration frequency for each type of data for different periods. The rationale behind this context type is to provide information on the regularity of measurements or samplings made by patients for each type of data they collect. The data registration contains the total number of registrations per self-collected data type for the whole period, as well as the distribution of the number of registrations per day, per weekday, and per hour, as well as a minimum number of registrations per data type and per period.

Figure 5. Categorization of Contextual Information Types.

Measurable personal goals are the next type of context. Patients define them according to their preferred lifestyle or based on the feedback from their clinicians. There are several types of goals: (1) keeping the values of a specific data type within a specific target range (eg, keeping blood glucose between 4-9 mmol/L), (2) reaching a specific number of measurements for a fixed period (eg, checking blood glucose values 6 times a day with a glucose meter), and (3) reaching a threshold value for a specific data type (eg, weighing 65 kilograms or under).

Goal of the consultation refers to the reason for an appointment between a patient and the clinician. Clinicians can define the goal when planning a follow-up with patients, but patients can also define it if they need help regarding their health situation. The goal of the consultation may or may not be part of the patients' diabetes situation.

System generated context refers to the context produced by the KBM itself during its execution. It includes hypotheses generated by the system that needs to be validated or refuted. The context *hypothesis result* further characterizes a hypothesis, with 3 possible states: (1) TRUE if the hypothesis is validated, (2) FALSE if the hypothesis is rejected, and (3) NOT APPLICABLE (NA) if the required context is missing (eg, the invalidation of a hypothesis stating that "the patient has eaten too much carbohydrates a day" cannot be done if the patient did not register any carbohydrate intake).

We identified 3 main entries under the *identity* type of context, which defines who uses the KBM in an actual situation. It encompasses patients, medical workers, and their relationship. Further context characterizes patients: age, sex, diabetes type. and emotional state (eg, personality, life goals, intentions, and preferences). Further context also characterizes clinicians: their specialty (eg, GP, nurse, endocrinologist) and their emotional state.

The *time* type of context *defines* when a patient and a medical worker use the KBM. In our situation, the usage of the module corresponds to the usage of the FullFlow system: mainly during consultations. However, medical workers and patients could also use it before and after consultation. In the first case, to prepare for the consultation, and in the second case, to look up data they did not have time to view during the consultation.

Concerning the *location* type of context, the KBM can be used everywhere: at a clinician's workplace (eg, GP's office,

municipal care office, hospital department), at home or on the go for both patients and doctors, if they are willing to do so.

Instantiation of all these types of contextual information with the current situation where the KBM operates creates the "current context". The current context is dynamic and changes across patients and different situation of the same patient (eg,, a particular consultation at a certain date and time and with a particular clinician for a particular purpose). In the section "Knowledge base and reasoning engine," we describe the role of current context in the reasoning process of the reasoning engine.

Model of Context

The context taxonomy (ie, a classification scheme) in Figure 5 is the outcome of the first step of the design process. This has strong implications of the knowledge to be represented in the knowledge base as well. Context identification and modeling were performed by the designer group that consists of computer scientists and medical experts. There were 2 types of context predefined and do not change across situations: "Medical Standards" and "Data Registration Regularity".

Once we identified the categories and the taxonomy of contextual information, we needed to define the interaction between entities (ie, the actors) and the specific part of the context shared during the interactions. To address this issue, we created a model of context inspired by the approach described by Bradley and Dunlop [19], as shown in Figure 6.

The *knowledge-based module* contains 3 components: the *knowledge base*, the *reasoning engine*, and the *current context*. There are 3 sources that create different parts of the current context—in addition to the designer defined ones. The first is patients. Patients interact with the module directly or through their PHRs (not displayed in the figure for simplicity) by sending their metadata (eg, age, sex, diabetes type) and self-collected health data. Second is medical workers and EHRs. Medical workers are not interacting directly with the KBM for sharing context, but through the EHRs they are using. EHRs provide the KBM with an authentication token for the medical workers in combination with the laboratory-generated data. Medical workers and patients interact with each other during a consultation, which could be face-to-face, remote, in real-time, or not. Third, is the reasoning engine. Outcomes of the reasoning engine of the KBM can dynamically change the current context. Here we refer to "system generated context" in Figure 5. For example, the original goal of the consultation could have been to discuss and manage nocturnal hypoglycemic events. However, the goal could shift toward discussing the insulin correction factor if the KBM finds that these events are due to wrong insulin dosage after meals, for example.

This context model allows us to have a clearer view of how the global flow of context data is in real-life situations.

Knowledge Base and Reasoning Engine

We established the reasoning engine and the knowledge base by the identified types of contextual information and the model of context presented above. The reasoning engine provides problem-identifying functions needed for determining the degree of reliability of the patients' self-collected health data and for identifying "noticeable events" and their potential causes. A noticeable event is a medical event discovered from the contextual information, where feedback from the medical worker could be useful for improving the patient's situation. To do so, the reasoning engine relies on a knowledge base and a hypothesize-and-test reasoning strategy, as shown in Figure 7.

The rectangles in the figure represent the processes of the reasoning engine, while the parallelograms show the data the processes use or produce.

Figure 6. Model of Context. The labels next to the arrow represent the different types of context. EHR: electronic health record.

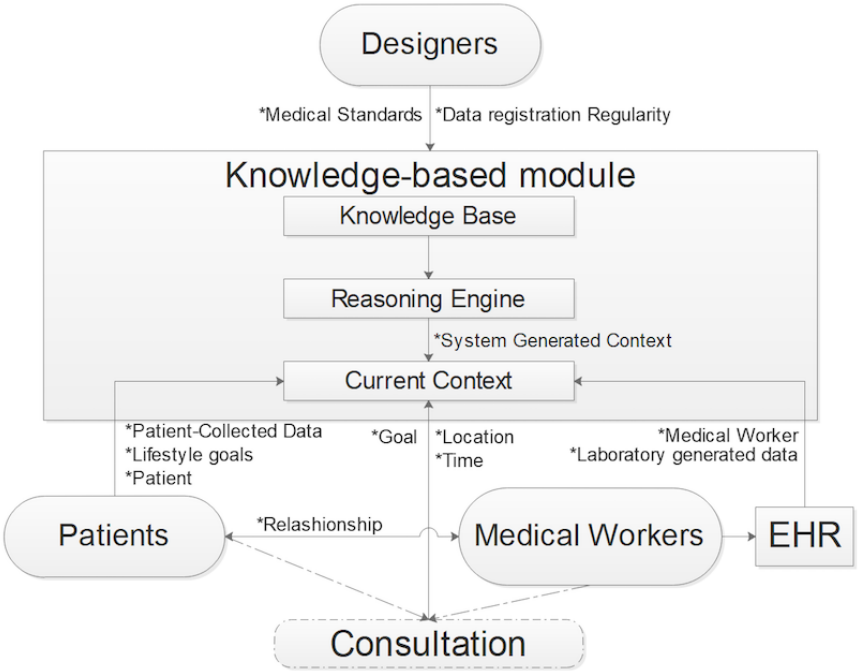
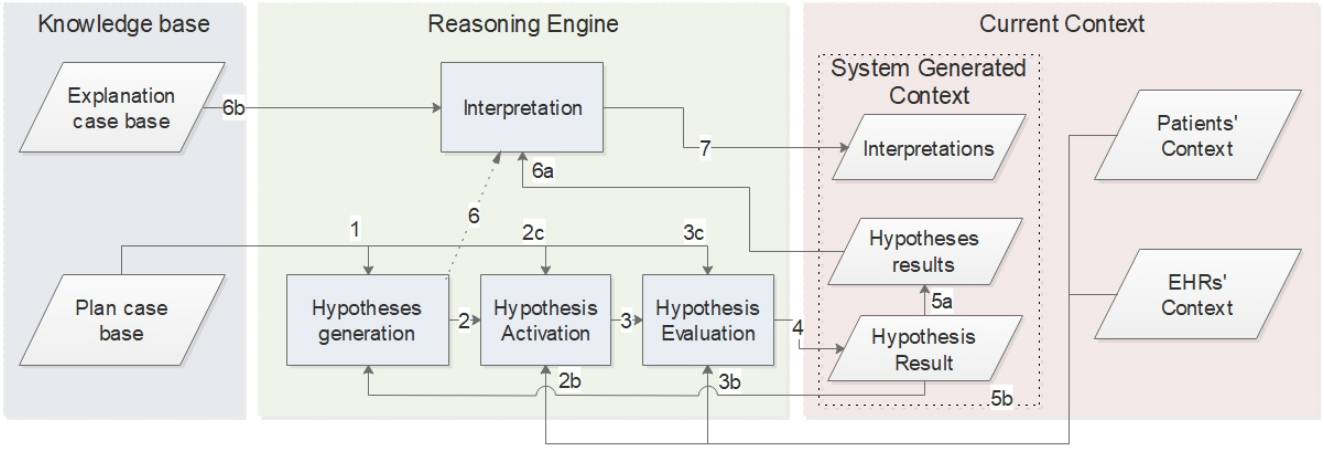


Figure 7. Our reasoning engine model.



The *knowledge base* contains the domain knowledge of medical experts that the hypothesis-and-test strategy needs in this system. Currently, knowledge base remains static. Each time a patient shares their self-collected health data with a clinician, the same knowledge base creates the problem-identifying tasks, while the Current Context is dynamic. The *Explanation Case Base* and the *Plan Case Base* compose the KB.

We now describe the structure of the *Plan Case Base,* which comprises many plans. A plan consists of sequential problem-identifying tasks to perform and can refer to or include other plans. For example, plan P1 (ie, evaluates the correctness of the amount of the last insulin dosage) uses the tasks P1T1 (ie, check the blood glucose value), and P1T2 (ie, estimate the best insulin amount in this situation) in combination with the plan P2 (ie, check the insulin sensitivity for the day), which in turn includes the tasks P2T1 (ie, define the amount of insulin intakes for a day), and P2T2 (ie, use the 1500/1800 rule for calculating the insulin sensitivity). Figure 8 illustrates this example. This hierarchical structure, however, does not indicate in what sequence the tasks and plans are executed, but this is handled by *rules*.

There are 3 types of rules. The *Plan Rules* define the sequence of the plans and the tasks composing them (eg, perform the task "check if insulin registrations are present' before the task 'check the amount of insulin intake for a day"). The *Activation Rules* define which data are necessary for performing a task (eg, insulin and carbohydrates registrations are mandatory for the task "check if the patient forgot to take insulin before or after

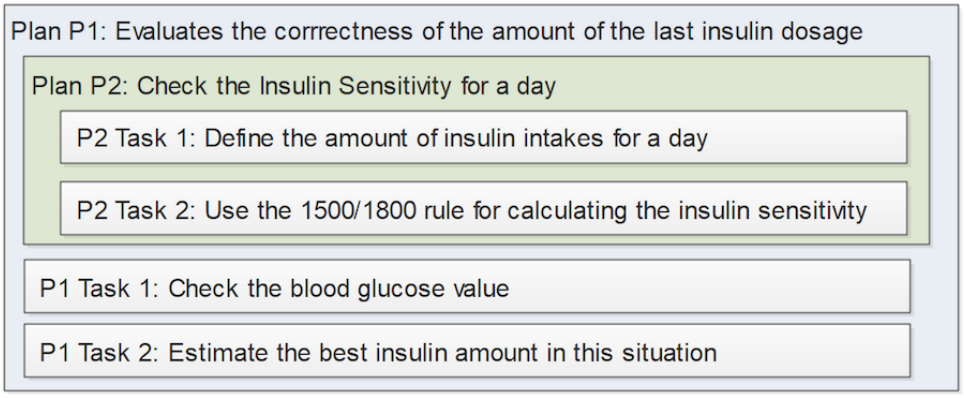
a meal") and potential conditions for performing the task (eg, "a carbohydrate intake is considered a meal if done between 11:00 and 13:00"). The *Evaluation Rules* define the concrete actions to be taken in order to accomplish a task (eg, for the task "check if the patient forgot to take insulin before or after a meal," the rules define 3 actions: (1) check the carbohydrates intakes, (2) check if the intakes correspond to a meal time, and (3) check if an insulin registration is present in a 30 minutes window before or after the carbohydrates intakes).

The *Explanation Case Base* defines the complementary or hierarchical relations between the problem-identifying tasks and the interpretation of identified problems based on the results of the problem-identifying tasks. For example, the problem-identifying tasks "check the amount of carbohydrate intake from the previous meal" and "calculate the carbohydrates on board" are complementary and compose the higher-level task "check the amount of carbohydrates", which can characterize a hyperglycemic event.

The first process in the reasoning engine is *Hypotheses Generation*. In our model, a hypothesis represents the inferred candidate result of a task that the reasoning engine validates or invalidates. For example, the hypothesis "there is no insulin registration before or after a meal" may be a candidate answer to the task "check if the patient forgot to take insulin before or after a meal". This process generates a current plan case composed of a sequence of tasks with associated hypotheses to test based on the plan and the Plan Rules of the Plan Case Base (Figure 7, no. 1) and on the System Generated Context (current context). The process uses the results of previously tested hypotheses to update the active case plan if necessary (Figure 7, no. 5b). For example, if the hypothesis "patient has hyperglycemia" is true, the process updates the plan and adds 18 hypotheses according to the rules, such as "the latest insulin intake was lower than the insulin needed defining by the sensitivity factor for reaching 5.5 mmol/L". The outcome of the Hypotheses Generation is a sequence of hypotheses to validate (or refute), each for the accomplishment of a specific task constituting the plan.

The second process is *Hypothesis Activation*. The hypotheses generation process initiates this process for each hypothesis listed in the current plan case (Figure 7, no. 2). Hypothesis Activation requires the Activation Rules from the Plan Case Base (Figure 7, no. 2c) and the current context from Patients, EHRs or both (Figure 7, no. 2b). The *Hypothesis Activation* process ensures that the required context for evaluating a hypothesis is available. For example, the hypothesis "patient has hyperglycemia" requires Blood Glucose registrations from the Patient entity. If required context is not available for a hypothesis listed in the current plan case, the system flags the concerned hypothesis as NA. If the required context is available, the system activates the hypothesis. The activation of a hypothesis automatically initiates its evaluation (Figure 7, no. 3).

Figure 8. Example of hierarchy of plans (P) and tasks (T). P1 contains P2 and two tasks, P1T1 and P1T2.



The *Hypothesis Evaluation* process validates or invalidates the claim proposed by the hypothesis. To do so, this process uses the Evaluation Rules of the Plan Case Base (Figure7, no. 3c) and the current context from Patients, EHRs or both (Figure7, no. 3b). The output of this process is a hypothesis result (Figure7, no. 4), which could be true, false, or NA. This output is then stored with the other hypotheses results (Figure7, no. 5a) and sent back to the Hypothesis Generation process (Figure7, no. 5b) for potential current plan case updates.

Once the Hypotheses Generation activated all hypotheses in its current plan case, it triggers the Interpretation process (Figure7, no. 6). This process uses the Relations between problem-identifying Tasks and their Explanations from the Explanation Case Base (Figure7, no. 6b) as well as the hypotheses results (Figure7, no. 6a) to create a textual interpretation of the results of the execution of the reasoning engine to allow users to consult it. The textual interpretation is the final context generated by the system (Figure7, no. 7). The system then displays the context to the users.

Hypotheses List

Figure 9 describes all the hypotheses used by the KBM at this stage. We organized the hypotheses per type and per order of execution (ie, from top to bottom), according to the Explanation Case Base and of the Plan Case Base. The interpretation of the hypotheses defines them, instead of their internal identification code, for better clarity. For simplicity, we omitted the context requirements for their activation and generation in this paper. For example, the generation of the hypothesis "there is not enough insulin" requires that the hypothesis "patients have hyperglycemia" be true and its activation requires the registration of insulin self-collected health data.

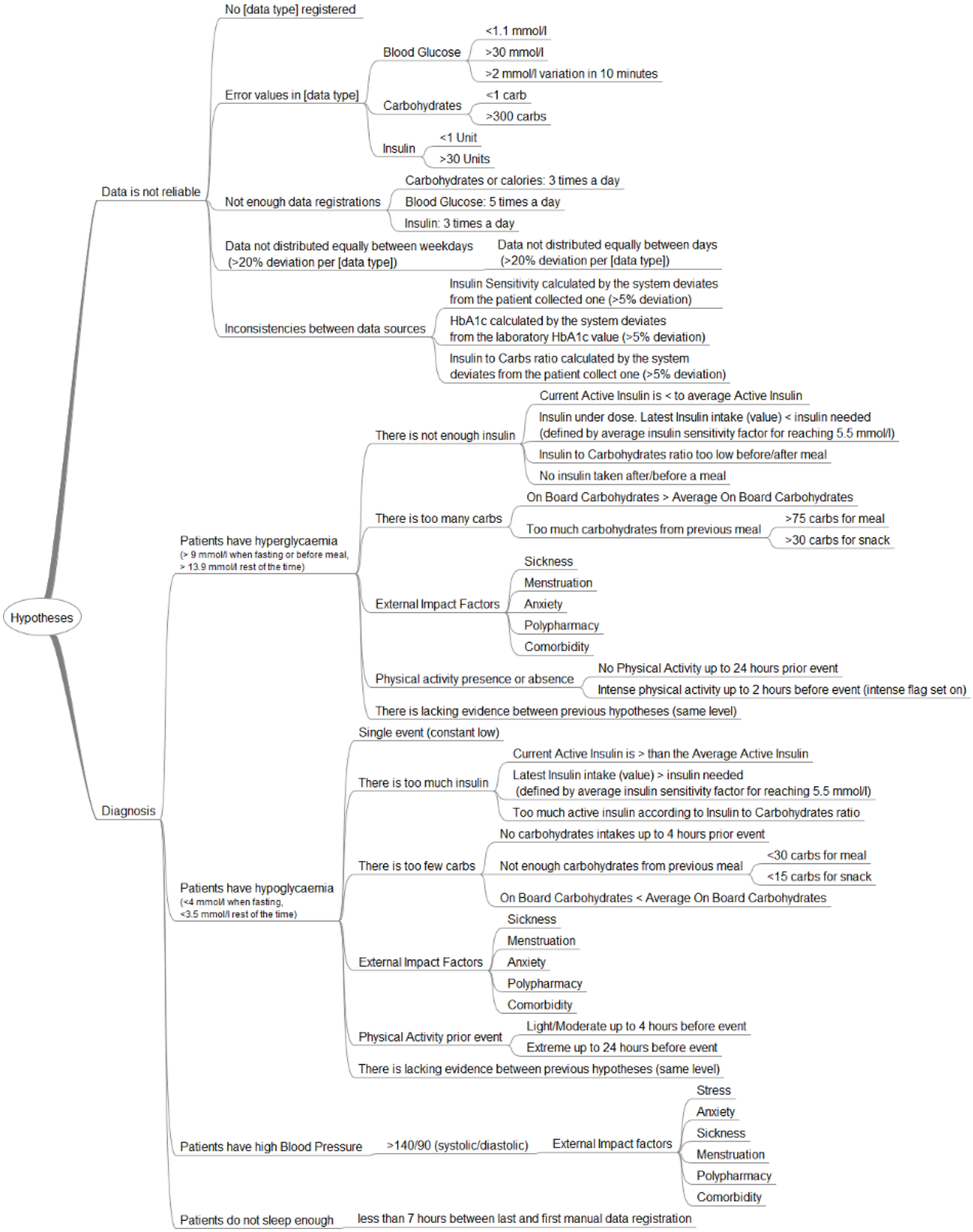
Data Reliability

The first type of hypothesis relates to the *data reliability* of patients' self-collected health data. The first hypothesis "data is not reliable" is automatically activated. The output of the evaluation process of this hypothesis is an impact factor of reliability, which defines how much the results of other hypotheses and the self-collected data can be trusted based on a scale of 0-50, from distrust to trust. The trust level is calculated by subtracting the sum of the value (or grade) of each sub-hypothesis evaluated to true by the system listed in the plan case of data reliability. For example, if the HbA_{1c} value calculated by the module (ie, based on blood glucose self-measurements) deviates by more than 5% (ie, based on the approximation of the translation of A1C to estimated average blood glucose by Nathan et al [24] and the inaccuracy of the blood-glucose monitoring systems for self-testing [25]) of the HbA_{1c} value determined by laboratory tests, the trust level decreases by 10 points. There are several types of sub-hypothesis. For example, "No [data type] registered" indicates that the most relevant data type is missing from the patient's data: blood glucose, carbohydrates, insulin, and physical activity. Several sub-hypotheses compose this hypothesis: one per data type. For each hypothesis validated by the evaluation process (eg, "no blood glucose registered" is true), the interpretation process displays a message to users proposing that they register a new type of data with the support of examples. For example, if the patient is using insulin and the hypothesis "no carbohydrates registered" is true, the system displays "registering carbohydrate intakes will permit a better estimation of your insulin correction dosage as well as …and could help you reduce variation, ie, highs and lows of your blood glucose values".

"Error values in [data type]" means that the registered values for a specific data type are probably incorrect. For example, a blood glucose value of 1.1 mmol/L is probably due to error either in the registration or measurement process. Importantly, blood glucose levels less than 1.1 mmol/l provoke neurological damages [26]. However, the KBM conveys a specific message to users regarding these events, in addition to grading the trust level of the data, for them to validate the origin of these values. Currently, the module focuses only on blood glucose, carbohydrates, and insulin values for this sub-hypothesis.

"Not enough data registrations" focuses on the minimal number of registrations per type of data and per day to calculate trends. For example, patients should check their blood glucose at least 5 times a day for this sub-hypothesis to be false. The National Institute for Health and Care Excellence (NICE) recommends self-testing blood glucose level at least four times a day [27], but we increased this number for better accuracy. The interpretation process also displays a motivational message to encourage patients to register data more often if some hypotheses are true.

Figure 9. List of hypotheses organized per type used by the knowledge-based module (KBM).



"Data not distributed equally between days" concentrates on the regularity of the total number of registrations per day and per type of data for the whole data self-collection period. The participants suggested allowing 20% deviation in the number of registrations and days. The "Data not distributed equally between weekdays" follows the same principle but organizes the day per weekdays instead (eg, Monday, Tuesday.). These 2 hypotheses ensure that patients register data regularly and that the registrations are not impacted by their lifestyles (eg, working during the week and performing outdoor activities on the weekend).

"Inconsistencies between data source" is another hypothesis where the system checks the difference in the value of the same data type from different sources and allows 5% deviation between them. The module implements 3 sub-hypotheses. The first is checking the HbA_{1c} value calculated by the module itself against the same value determined by a laboratory test as explained previously. The second is checking the insulin sensitivity calculated by the module against the same value reported by the patient, and the last is checking the Insulin to Carbohydrates ratio (I:C) calculated by the module against the same value reported by the patient. The system alerts the user to this deviation with warning messages.

The evaluation of the previous hypotheses gives (1) an indication about the accuracy and the reliability of the self-collected health data for the clinicians, and (2) recommendations for improving the reliability of the data for the patients.

Medical Problem Identification

The second type of hypotheses relates to *medical problem identification*. The activation of these hypotheses depends on the value of the patients' self-collected data and concerns hyperglycemia, hypoglycemia, high blood pressure events, and short sleeping patterns. The time of the highest blood glucose value in a continuous hyperglycemic event (6 hours maximum—suggested by the participants) and the time of the lowest blood glucose value in a continuous hypoglycemic event define a reference time where the possible causes could be easier to detect by the module.

Hyperglycaemia

In the case of hyperglycemia, Hypotheses Generation activates the hypothesis and set its result to true if it detects one or more blood glucose values greater than 9 mmol/L when fasting or before a meal (ie, if the information is available) or 13.9 mmol/L at other times of the day during a single continuous event. A single event is a continuous hyperglycemic event without blood glucose levels returning to the normal range. We chose a higher hyperglycemic level than the standard ones (eg, greater than 7mmol/L when fasting [27]) based the input of the co-design (see section "Relevance of the " for more details).

Once a hyperglycemia event is detected, the system updates the plan case automatically and adds 5 sub-hypotheses. The first is "there is not enough insulin," whose result is true by default and which the module tries to invalidate. To do so, the Hypotheses Generation activates 4 sub-hypotheses and all of them should be false or NA to invalidate the parent hypothesis. This includes the current active insulin is less than the average active insulin. Active insulin, or insulin on board (IOB), is the amount of insulin remaining active at a time in the body. The IOB calculation follows the Open Artificial Pancreas System (OpenAPS) approach [28]. A current IOB lower than the average IOB means that less insulin is present at this time, which could be a factor of the hyperglycemic event. Next, the dose of the last insulin shot was insufficient: the amount of the last insulin intake was insufficient for bringing the blood glucose value to 5.5 mmol/L. This is the mean value of the recommended range of blood glucose values defined by several guidelines [27,29]. The hypothesis evaluation process calculates how many units of insulin are necessary to bring the blood glucose value to this level based on the insulin sensitivity factor. If the insulin sensitivity factor is not provided by the patient, it is calculated by using the 1500/1800 rule [22,23]. Then, the I:C is too low if a meal was taken up to 4 hours (ie, one hour more than the time needed for the serum glucose level to return to near-fasting values in healthy patients [30]) prior to the hyperglycemic event. The hypothesis evaluation process checks if the amount of carbohydrates consumed are "covered" by a shot of insulin using the I:C provided by the patient. If unavailable, the hypothesis evaluation process uses the daily I:C calculated from the total carbohydrates and total rapid-acting insulin of the same day. If the patient did not register carbohydrate intakes, the system uses the 500/450 rule [23,31]. Finally, no insulin taken after or before a meal. The hypothesis evaluation process checks if there was an insulin injection before or after the meal (ie, 30 minutes window—decided by the participants) to compensate for the carbohydrate intake.

The second sub-hypothesis is "there are too much carbohydrates". As with the last hypothesis, this hypothesis is true unless all sub-hypotheses are false or NA. First, there are greater carbohydrates on board (COB) than the average COB. COB is the amount of carbohydrates remaining unabsorbed at a time. The COB uses the carbohydrate absorption rate reported by the patient. Too much unabsorbed carbohydrates can lead to a hyperglycemic event. Second, for patients not following a low-carb diet, the last carbohydrate intake was greater than the recommendation: more than 75 carbs for a meal and more than 30 carbs for a snack [32]. The module uses standards mealtime by default (eg, lunchtime from 11:00 to 13:00) but patients can report them as well. As with the previous one, a too-high carbohydrate intake could lead to a hyperglycemic event if not planned.

The third sub-hypothesis is the presence of external factors, such as menstruation or polypharmacy. External factors can greatly affect the patient's metabolism and render calculations difficult [33]. The system currently flags their presence in case other hypotheses fail to find potential causes of the hyperglycemic event.

The fourth sub-hypothesis is addressing the lack of physical activity to explain the hyperglycemic event and is set to true if patients did not engage in any physical activity up to 24 hours before the noticeable event happened (ie, blood glucose levels can be impacted by physical activity 24 hours after it ended [34]).

The last sub-hypothesis is "lack of evidence". The hypothesis evaluation process checks if the module has identified possible causes of the hyperglycemic event based on the results of other hypotheses. If the system detects a possible cause, the hypothesis is false. However, it is true if all other hypotheses have false or NA results. Having a true result for this hypothesis means that a potential *information gap* is present at the time of this event, and the system informs the user and invites them to investigate the data around the time of this event.

Hypoglycemia

Regarding hypoglycemic events, the system follows the same approach. It activates the hypothesis and sets its result to true if it detects one or more blood glucose values lower than 4 mmol/L when fasting (ie, if the information is available) or 3.5 mmol/L at others time of the day during a single continuous event. We chose a lower hypoglycemic level than the standard ones (ie,less than 4 mmol/L when not fasting [27]) based the input of the co-design session. See section "Relevance of the " for more details. Once a hypoglycemia event is detected, the system further activates 5 sub-hypotheses automatically. The first is "there is too much insulin," whose result is true by default and which the module attempts to invalidate. To do so, it activates 3 more sub-hypotheses and all of them should be false or NA to invalidate the parent hypothesis. First, the current active insulin is greater than the average active insulin. Having a high amount of insulin could be the cause of a hypoglycemic event. Second, the last insulin injection was too high: the amount of the last insulin intake was greater than the requirements (based on the insulin sensitivity factor) for bringing the blood glucose value to 5.5 mmol/L (mean value of the recommended range of blood glucose values defined by several guidelines [27,29]). Third, the current active insulin is greater than required according to the I:C.

The second hypothesis is "there are too few carbohydrates". This hypothesis is also true by default until invalidated by processing 2 sub-hypotheses. First, there was no carbohydrate intake up to 4 hours prior to the hypoglycemic event. This is one hour more than the time needed for the blood glucose level to return to near-fasting values in healthy patients [30]. Second, for patients not following a low-carb diet, the last carbohydrate intake was lower than the recommendation of less than 30 carbs for a meal or less than 15 carbs for a snack [32].

The third hypothesis concerns the presence of external factors and functions the same way as the hyperglycemic event.

The fourth hypothesis is about physical activity prior to the hypoglycemic event. The module automatically activates and process 2 sub-hypotheses. First, the patient engaged in light to moderate physical activity up to 4 hours prior to the hypoglycemic event. Light to moderate physical activity intensity can be expressed with an intensity tag (ie, text), in time (ie, less than 60 minutes—defined by the participants), in steps (ie, less than 3000 steps [35]) or in Metabolic Equivalent of Task unit (ie, less than 6 METs [36]). Second, the patient engaged in extreme physical activity up to 24 hours prior to the hypoglycemic event [34].

The last hypothesis activated addresses the lack of evidence for finding possible causes of a hypoglycemic event and functions in the same manner as its counterpart for a hyperglycemic event.

Regarding high blood pressure events, a hypothesis is activated and set to true automatically when high blood pressure is detected (ie, greater than 140/90 (systolic/diastolic) [37]). The sub-hypotheses then checks the presence or absence of external factors and function in the same manner as that for the hyperglycemia and hypoglycemic events.

The last hypothesis concerns the patient's sleeping pattern. One hypothesis per night is activated and focuses on identifying the time elapsed between 2 registrations performed manually by the patient (ie, not done automatically by sensors). The hypothesis is set to true if there is less than the recommended 7-hour sleep period [38].

After a discussion, the designers decided to discard patient-defined target values as input for the hypotheses. For example, the detection of hyperglycemia and hypoglycemic events could rely on patient-defined goals focusing on maintaining a blood glucose range between 3.5-12 mmol/L instead of the value the module currently uses. However, these values override medical standards already defining these events and could potentially induce errors in medical workers. The designers discarded other contextual information such as ketones and heart rate for the first version of the module, as patients rarely measure ketones themselves compared to the other data, and heart rate not being available on the Diabetesdagboka or Mysgr applications.

The presence or absence of information gaps also evaluates the relevance of the data for the clinicians (ie, no information gap means reliable data). The identification of the potential causes of a problem could provide conversational topics for clinicians and a retrospective review of medical events for patients and clinicians.

Testing

The goal of the testing phase was to ensure that the designed KBM module works, does not affect the performance of FullFlow and that participants of the workshops find the module useful during a consultation. All conditions were met, and the module was integrated into the FullFlow project.

Testing the relevance of the medical outcome of the module was out of scope at this stage and will be performed during the clinical study of the FullFlow project. The discussion section presents more details on the situation.

Technical Implementation and Performance Assessment

The implementation of the KBM relied on the reasoning engine model described in Figure 7 and follows the same processes and sequences. Black and white unit tests were performed against the KBM (see Methods section) to ensure that the KBM provides the services defined in the Knowledge base and reasoning engine section. The assessment of the performance of the KBM showed that the execution time is lower than 30 milliseconds with a typical load of data and, therefore, does not affect the performance of FullFlow. Details about the technical implementation, the tests performed and an excerpt of the results of one instance of the KBM are provided in Multimedia Appendix 1.

Relevance of the Module

We asked the participants of the clinician workshops and the co-design (ie, clinicians and patients) the same question: "do you think the module could be relevant during a consultation, especially for identifying potential problems?" and all of them answered yes. Then we showed the findings of the KBM within a FullFlow report to the participants. The findings are the results

of a run of the KBM against self-collected health data provided by the in-house researcher. The results contained the noticeable events, their potential causes, and explanation, as well as their distributions through time, along with the reliability of the data (Figures 10, 11, 12, and 13 in the next section for more details).

There were 2 patients that preferred to have this module connected to their self-management solutions to (1) obtain suggestions on why serious medical events occur, and (2) to prepare for the consultation. The participants appreciated the concept of presenting the module between the overall view and the more detailed graphs in FullFlow because it permits faster identification of problems without having to examine the data. We discussed the KBM findings with the participants and how they felt about them. Based on these discussions the following actions were taken. First, we removed the data reliability grade from the visual display because it did not mean anything concrete to the participants. According to them, an alert stating the potential problems would be sufficient. Second, we changed the standards of hypoglycemia (ie, less than 5 mmol/L when fasting and less than 4 mmol/L at other times of the day) and hyperglycemia ie, greater than 7 mmol/L when fasting or before meals and greater than 9 mmol/L at other times) defined by the NICE [27] and the Norwegian Directorate of Health [29] to high hyperglycemia (ie, greater than 9 mmol/L when fasting or before meals and greater than 13.9 mmol/L) and low hypoglycemia (ie, less than 4 mmol/L when fasting and less than 3.5 mmol/L at other times) because the patients preferred to discuss the more serious events with their medical workers rather than all events outside the recommended range. Third, we updated the text displaying the feedback regarding medical events to be more nuanced (eg, "this event *may* have been due to…") because the patients took for granted the findings of the module. However, in real life, we believe that medical workers also play a role here by limiting the impact on the patients.

Other than these points, the participants appreciated the module because it permitted them to obtain possible explanations for why events occurred and what they could improve.

Figure 10 shows an example of an Interpretation of the KBM regarding a hypoglycemic event. It this case, 4 potential causes were identified for explaining this event: (1) higher active insulin than average, (2) higher insulin to carbohydrates ratio, (3) presence of moderate or extreme physical activity before the event, and (4) a low-carbohydrates meal. The system provides justifications for all potential causes (ie, italic and smaller font text in the figure). Figure 11 shows an example of a representation of an information gap concerning a hypoglycemic event. Figure 12 shows a summary of noticeable events found by the KBM. It summarizes the number of hypoglycemic and hyperglycemic events (ie, 10 and 4 respectively) and the number of their potential main causes (eg, 9 hypoglycemic events may have been caused by having too much insulin). A single noticeable event can have multiple potential causes (eg, 14 potential causes are linked to 10 hypoglycemic events in the figure). The summary also contains a distribution per hour and per weekdays of the noticeable events. It can help clinicians identifying trend regarding daily or weekly routines followed by the patients.

Figure 13 shows a reliability grading of the self-collected health data. For example, the figure shows that there is a significant difference regarding the Blood Glucose registrations during the week, with a deviation of almost 6 registrations, while the rules allow a deviation of almost 3 registrations.

Figure 10. Example of potential causes expressed by the knowledge-based module of a single hypoglycaemic event.

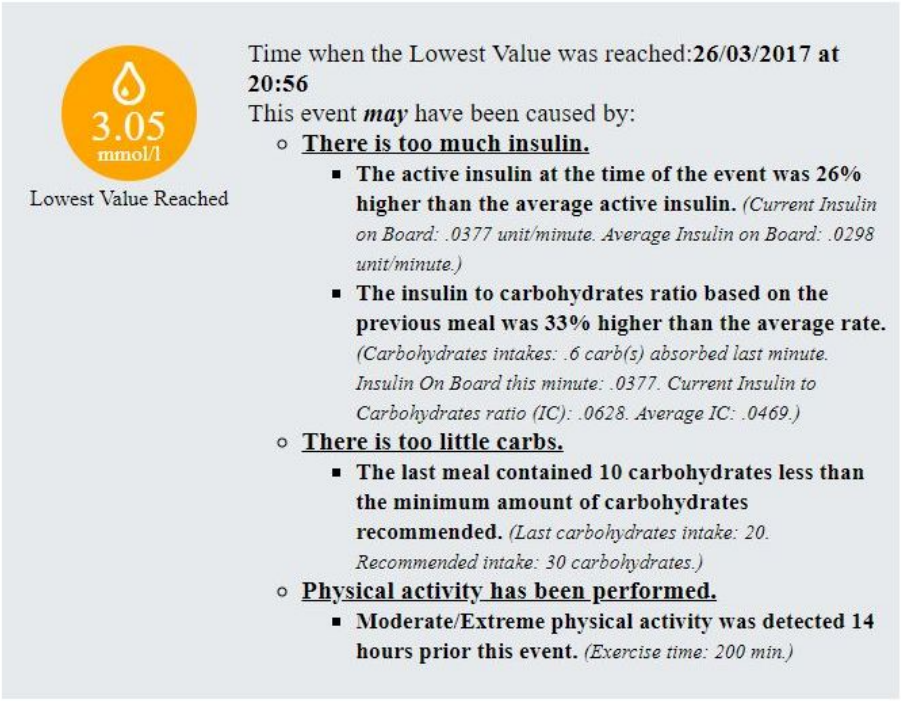


Figure 11. Example of information gap expressed by the KBM of a single hypoglycaemic event.

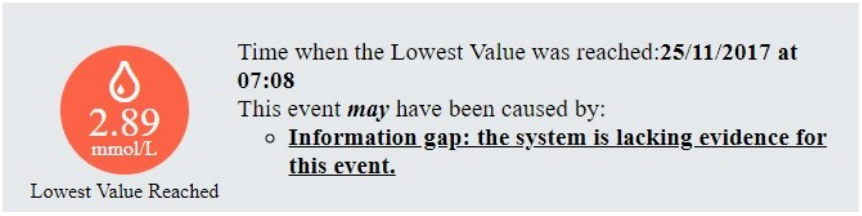


Figure 12. Summary of noticeable events detected by the knowledge-based module, their main potential main causes (top) and their distribution per hour and per weekdays (bottom).

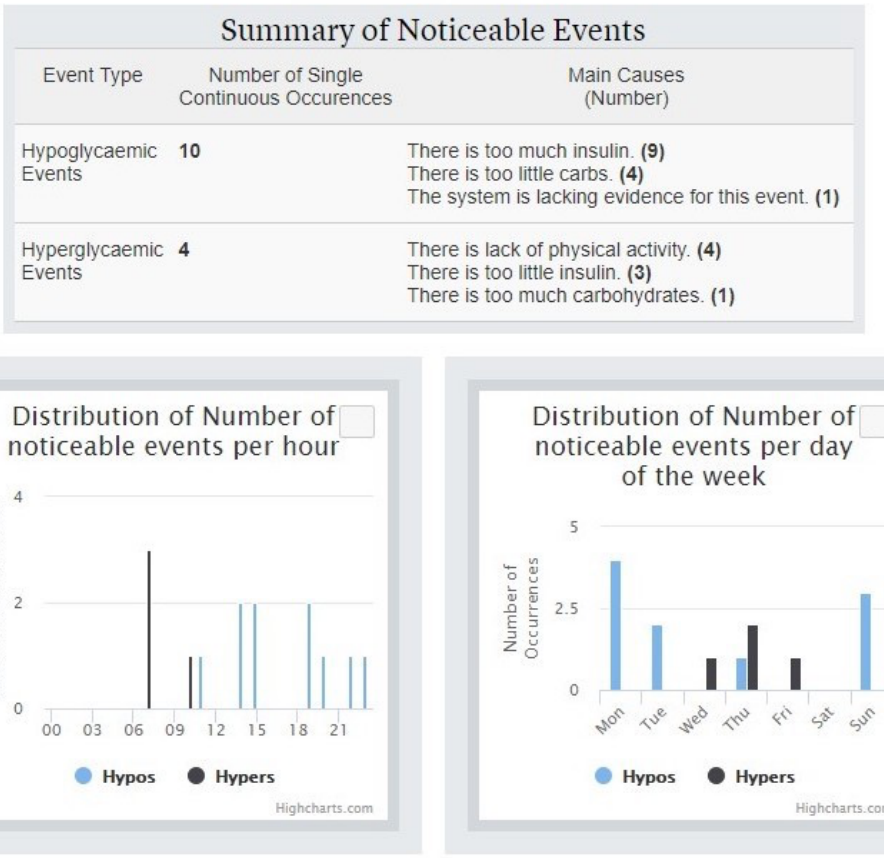
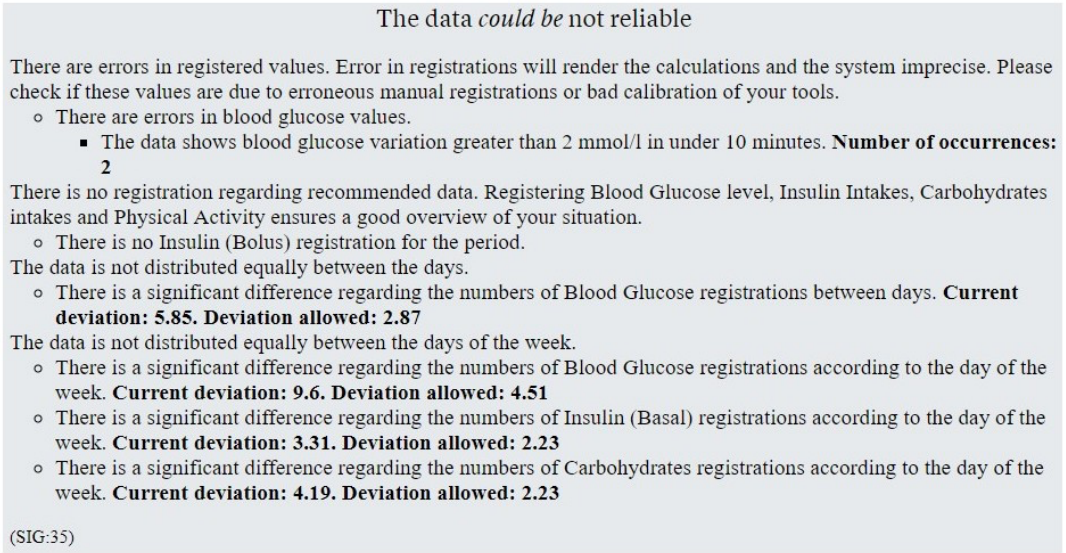


Figure 13. Summary of the data reliability issues found by the knowledge-based module.



In 1 out of 14 (8%) noticeable events, the module lacked evidence to explain why a specific event occurred, which define an information gap. When discussing this with the patient concerned, he suggested that this could have been due to factors such as that he did not register, or estimated incorrectly carbohydrate intakes, for example.

The discussion showed that the module has a potential to improve the consultation between patients and clinicians and has, therefore, be integrated into the FullFlow.

Discussion

Demonstrated Potential

This paper demonstrated how a KBM using a hypothesize-and-test strategy fed with context may pinpoint the presence of information gaps in patient self-collected health data and identify relevant health information. It could address the barriers of acceptance regarding the introduction of patient self-collected health data into consultation: defining the reliability of the data and identify information gaps and reducing the necessary time for extracting the relevant information from the data. The recommendation of actions to follow to improve the self-collected data provided by the system could also motivate and empower patients by allowing them to be more aware of the possibilities offered by the technology. The suggestion of medical subjects related to the causes of medical events could also help steer the consultation and improve its efficiency.

Likeliness for Use

We are aware that some patients could feel uncomfortable by a system judging them based on their disease management performance and their lifestyle. This could even be counterproductive for patients who are demotivated or make them less likely to adopt healthy self-managing routines, but using this system is intended to be voluntary and based on the patients deciding whether they want to gather and share data or not. We believe medical doctors could provide support to such patients and moderate the outcomes of modules like the one proposed during consultations. However, such patients are difficult to recruit for participation in studies for analyzing their needs, but we believe that by demonstrating the potential of such a system with examples like proposed in this paper, we will be able to recruit participants for the coming FullFlow project pilot. We also plan to organize workshops involving clinicians and psychologists focusing on motivation to address this issue.

Chosen Approach

The hypothesize-and-test strategy is only 1 approach for inductive reasoning, which is the reasoning the module uses. For example, it was possible to use pattern recognition or machine learning to achieve the same goal. The key here concerns data acquisition and data sets. We do not possess high-quality patient self-collected health data at this time: insufficient patient diversity, insufficient patients, insufficient data distributed over long periods and the quality of the data itself could be doubtful because each patient is different and is focusing on different goals and using different applications. On top of that, the data could be erroneous as well. The strategy to acquire knowledge from experts can circumvent these issues, even if it is time-consuming and financially demanding.

Limitations

First, the authors did not perform field-tests involving clinicians and patients in a real situation since the scope of this paper was to present and discuss the integration of the KBM into FullFlow.

Moreover, self-collected data represent only one source of data that could affect decision support and cannot replace other sources such as laboratory tests; above all, it cannot replace the relationship medical workers and patients have. Medical feedback concerning the module will be obtained during the clinical pilot of the FullFlow project, where patients and clinicians will be involved in a real consultation setting.

Third, we limited the focus of the KBM to patients with type 1 diabetes at this stage. However, the authors designed the reasoning engine model for supporting a multitude of medical conditions, especially patients with type 2 diabetes. An update of the knowledge base can adapt the KBM for patients with type 2 diabetes. The existing hypothesis “There is not enough insulin” can be activated only for patients with diabetes type 1 and for patients with diabetes type 2 on insulin therapy, while a new hypothesis “medication is not taken” can be created and activated for a patient with type 2 diabetes for example.

The system can exasperate medical workers if it does not support their needs or yields imprecise or erroneous information. However, as we defined the system with input from medical experts, we have reduced this risk.

The last point concerns that one patient only provided the self-collected health data. The target was to assess the relevance and usability of the module prior to possible integration into the FullFlow system, and subsequent trials will involve a larger number of patients and clinicians. The feedback provided by this patient and the participants in the workshops was used for justifying the KBM and prepare the FullFlow system for the main study.

Dynamic Knowledge Base

At this stage, we decided to limit the scope of the KBM by keeping the knowledge base static for all situations, meaning that the system cannot create and interpret rules on its own. However, the reasoning engine model is dynamic and could support other diseases with an update of the knowledge base, as illustrated in the previous section. In addition, the inputs of the rules are dynamic, meaning that patients can provide their insulin to carbohydrates ratio or their mealtime to tailor the execution of the rules relying on these data. More dynamic inputs can be considered in the future such as measurable personal goals or recommendations from clinicians for example.

For the next iteration, we plan to use patients’ and clinicians’ context for generating the Plan Base Case and the Explanation Case Base to provide a more tailored experience for users, by using for example comorbidity as an input for generating the rules.

Conclusion

To conclude, the hypothesize-and-test strategy is a viable approach for an inductive reasoning-based system when diverse and large and correct datasets are not available. The context-sensitive approach permits the integration of multiple factors for decision making and for simplifying the complexity and maintenance of this system.

By integrating this module to the FullFlow project, we hope to bring closer health institutions and self-managing patients, who do more on their own with seemingly less guidance from health institutions, by using the foundation for providing tailored health services during consultation: self-collected health data.

Our future clinical study will document user experience and medical outcomes through usage logs, interviews and medical and general surveys, and will help us adjust and improve this module further.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Implementation of the KBM.

[PDF File (Adobe PDF File), 227KB - diabetes_v3i3e10431_app1.pdf]

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Abbreviations

API: application programming interface
COB: carbohydrates on board
EHR: electronic health record

FHIR: Fast Health care Interoperability Resources
GP: general practitioner
HbA $_{1c}$: glycated haemoglobin
IOB: insulin on board
IU: international unit
KBM: knowledge-based module
MET: Metabolic Equivalent of Task
NA: not applicable
NICE: National Institute for Health and Care Excellence
PHR: personal health record

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Appendix 1: Implementation of the KBM

This appendix presents the implementation and the performance testing of the KBM.

Implementation

The implementation relies on the same technologies used by the FullFlow server for easy integration: Java Enterprise edition (JEE) 8, Glassfish 5, Java Server Faces (JSF) 2.2 and the Java API for Extensible Markup Language (XML) Web Services (JAX-WS). However, we also wanted to allow execution of the KBM on Android OS, and integration with the Diabetesdagboka[1] application for future tests. We decided to use Plain Old Java Objects (POJOs) to represent most of the reasoning engine. This code is executable on both systems without requiring any supplementary work. However, the FullFlow server injects the current context and interpretation of the results to the KBM through contexts and dependency injection (CDI). For Android, it is necessary to use the DiabetesDagboka proprietary API for gathering the current context, and a string resource for collecting the interpretation. This section focuses on FullFlow implementation only, as shown in Figure 1.

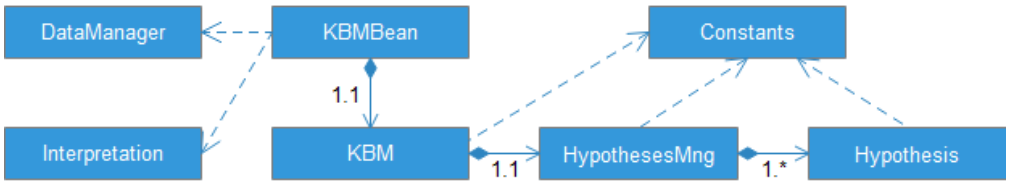

Figure 1: Simplified Unified Modeling Language (UML) diagram

The implementation is based on the reasoning engine model described in Figure 7 of the article “Context-aware knowledge-based module for identifying relevant information and information gaps in patients with type 1 diabetes’ self-collected health data” and follows the same processes and sequences, even if minor changes are observed. The Constants class (top right) contains the Plan Case Base of the system and the relation between the problem-identifying tasks, which is part of the Explanation Case Base. The Interpretation class (bottom left), which is a session bean, contains the interpretation of identified problems, which is another part of the Explanation Case Base. Splitting the Explanation Case Base permits multi-language management easily (in our case, English and Norwegian).

The DataManager class contains the current context collected by FullFlow. The HypothesesMng (Manager) represents the Hypotheses Generation process and keeps references to all hypotheses and their results. The Hypothesis class contains the Hypothesis Activation and Evaluation processes as well as the Hypothesis Result.

The KBM class represents the entire reasoning engine, initializing the Knowledge Base and the Current Context, and keeps references to all processes and data related to them. In addition, it contains the Interpretation process. We decided to include this process into this class for

simpler code maintenance and calls between classes, even if the model of reasoning engine separates them into two entities. The KBMBean exists as a bridge between the POJOs and the JEE environment.

The POJOs class share their execution status through interfaces. For example, a hypothesis calls a method, OnHypothesisResult(), which is implemented by the HypothesesMng to update the plan case. The HypothesesMng also calls a method, OnEvaluationPerformed(), for informing the KBM to initiate the interpretation process.

The reception of a request from a XML Web Services Interface or a patient visit on a JSF webpage initiates the flow of this system. The KBMBean is created and is injected with the DataManager and Interpretation beans, and creates a single KBM object by giving it all of the context available as parameters, which then perform the tasks described in the results section of the article.

Figure 2 shows an excerpt of the KBM execution results.

```
1   .   ###### KBM START ######
2   .   KB_LOAD ToE:1084ns
3   .   -KBE_LOAD ToE:341ns
4   .   -KBP_LOAD ToE:292ns
5   .   -EXT_C_LOAD ToE:451ns
6   .   **********************************
7   .   ******D: Patient: M [redacted] T1 831R
8   .   **********************************
9   .   **** HM HYP RUN ****
10  .   HYP_ID_DR:TRUE PT:42 ToE:292ns
11  .   -HYP_ID_DR_EV:TRUE ToE:292ns
12  .   --HYP_ID_DR_EV_BG:FALSE ToE:3507ns
13  .   ---HYP_ID_DR_EV_BG_LESS:FALSE ToE:28055ns
14  .   ---HYP_ID_DR_EV_BG_MORE:FALSE ToE:7890ns
15  .   ---HYP_ID_DR_EV_BG_VAR:FALSE ToE:467580ns
16  .   [...]
17  .   --HYP_ID_DR_EV_INS:TRUE ToE:585ns
18  .   ---HYP_ID_DR_EV_INS_LESS:TRUE ToE:26886ns
19  .   ---HYP_ID_DR_EV_INS_MORE:FALSE ToE:6137ns
20  .   [...]
21  .   -HYP_ID_DR_NOT_ENOUGH:TRUE ToE:584ns
22  .   --HYP_ID_DR_NOT_ENOUGH_BG:FALSE ToE:64292ns
23  .   --HYP_ID_DR_NOT_ENOUGH_INS:FALSE ToE:15488ns
24  .   --HYP_ID_DR_NOT_ENOUGH_CARBS:TRUE ToE:14612ns
25  .   [...]
26  .   -HYP_ID_DR_DIST_DAILY:FALSE ToE:2046ns
27  .   --HYP_ID_DR_DIST_DAILY_15074-8:FALSE ToE:7154850ns
28  .   --HYP_ID_DR_DIST_DAILY_388454007:FALSE ToE:22795ns
29  .   --HYP_ID_DR_DIST_DAILY_411529005:FALSE ToE:9060ns
30  .   --HYP_ID_DR_DIST_DAILY_86047003:FALSE ToE:8475ns
31  .   [...]
32  .   -HYP_ID_DR_DIST_WEEKDAYS:FALSE ToE:1461ns
33  .   --HYP_ID_DR_DIST_WEEKDAYS_15074-8:FALSE ToE:14320ns
34  .   --HYP_ID_DR_DIST_WEEKDAYS_388454007:FALSE ToE:6430ns
35  .   --HYP_ID_DR_DIST_WEEKDAYS_411529005:FALSE ToE:4383ns
36  .   --HYP_ID_DR_DIST_WEEKDAYS_86047003:FALSE ToE:4675ns
37  .   [...]
38  .   -HYP_ID_DR_INC:NA ToE:293ns
39  .   --HYP_ID_DR_INC_HBA1C:NA ToE:6430ns
40  .   --HYP_ID_DR_INC_INS:NA ToE:4091ns
41  .   [...]
42  .   *** DIAG ***
43  .   HYP_ID_DIAG:TRUE ToE:22210ns
44  .   -HYP_ID_DIAG_HYPO:TRUE ToE:1168ns
45  .   ************ Event From:16/12 2:28 to 16/12 2:28 BG:2.2222222222222223 ToE:584ns
46  .   --HYP_ID_DIAG_HYPO_SE:TRUE ToE:584ns
47  .   --CHANGE_OF_PLAN_INITIATED:LOAD_NEW_PLAN ToE:295ns
48  .   ---HYP_ID_DIAG_HYPO_SE_TOO_MUCH_INS:TRUE ToE:585ns
49  .   ----HYP_ID_DIAG_HYPO_SE_TOO_MUCH_INS_ACT:FALSE ToE:37114ns
50  .   ----HYP_ID_DIAG_HYPO_SE_TOO_MUCH_INS_FACTOR:TRUE ToE:22502ns
51  .   ----HYP_ID_DIAG_HYPO_SE_TOO_MUCH_INS_CARBS_RATIO:TRUE ToE:242264ns
52  .   ---HYP_ID_DIAG_HYPO_SE_TOO_LITTLE_CARBS:TRUE ToE:292ns
53  .   ----HYP_ID_DIAG_HYPO_SE_TOO_LITTLE_CARBS_NO:FALSE ToE:21626ns
54  .   ----HYP_ID_DIAG_HYPO_SE_TOO_LITTLE_CARBS_INF:TRUE ToE:21918ns
55  .   ---HYP_ID_DIAG_HYPO_SE_EXT:FALSE ToE:293ns
56  .   ----HYP_ID_DIAG_HYPO_SE_EXT_STRESS:FALSE ToE:5845ns
57  .   ----HYP_ID_DIAG_HYPO_SE_EXT_MENS:FALSE ToE:2338ns
58  .   ----HYP_ID_DIAG_HYPO_SE_EXT_SICKNESS:FALSE ToE:2338ns
59  .   ----HYP_ID_DIAG_HYPO_SE_EXT_PHARM:FALSE ToE:2046ns
60  .   ----HYP_ID_DIAG_HYPO_SE_EXT_COMORBID:FALSE ToE:1753ns
61  .   ---HYP_ID_DIAG_HYPO_SE_PA:FALSE ToE:292ns
62  .   ----HYP_ID_DIAG_HYPO_SE_PA_LIGHT:FALSE ToE:7598ns
63  .   ----HYP_ID_DIAG_HYPO_SE_PA_EXT:FALSE ToE:4384ns
64  .   ---HYP_LACK_OF_EVIDENCE:FALSE ToE:5553ns
65  .   ************
66  .   [...]
67  .   -HYP_ID_HIGH_BP:FALSE ToE:8182ns
68  .   -HYP_ID_NOT_ENOUGHT_SLEEP:TRUE NB_N:18/20 ToE:4209095ns
69  .   **** HM HYP RUN END ToE:25464019ns ****
70  .   ###### KBM END ToE:25465103ns ######
```

Figure 2: Excerpt of the results of one instance of the KBM. ToE = Time of execution

Performance testing

Before measuring the performance of the module, unit tests supporting the white and black box approaches (see Methods section of the article for more details) were performed against the KBM POJOs (Plain Old Java Objects, used in reasoning engine). The unit testing framework Junit

[2] was used for all tests. An example of a unit test for verifying that the KBM detects a variation greater than 2 mmol/L blood glucose in an interval of less than 10 minutes is shown in Figure 3.

```
@Test
public void verifyBloodGlucoseVarianceDetection(){
    Hypothesis h = new Hypothesis();
    Calendar c = Calendar.getInstance();
    long ref = c.getTimeInMillis(); //now
    c.add(Calendar.MINUTE,9);
    long low = c.getTimeInMillis(); //9 minutes in the future
    c.add(Calendar.MINUTE,2);
    long high = c.getTimeInMillis();//11 minutes in the future (9+2)
    assertEquals(Result.FALSE, h.bgVar(2.1, 4.1,ref,low), "<2mmol/l");
    assertEquals(Result.TRUE, h.bgVar(2.1, 4.2,ref,low), ">2mmol/l & <10min");
    assertEquals(Result.FALSE, h.bgVar(2.1, 5,ref,high), ">10min");
    assertEquals(Result.FALSE, h.bgVar(2.1, 4.1,ref,high), ">10min & <2mmol/l");
}
```

Figure 3: Example of a Unit Test

Then, to measure the potential impact on the performance of the FullFlow system, the time of execution for each method of the POJOs (KBM, HypothesesMng and Hypothesis classes; see Figure 1) were measured using nanoseconds. The Figure 2 shows the result of an excerpt run. However, the nanoseconds timing can be affected by the optimization of the Java Virtual Machine (JVM), the GlassFish server as well as the system host. To address this issue, these tests were performed on a fresh Debian 9 installation, with JVM 8 (Oracle) and Glassfish 5, with no customization (e.g. default heap space, default domain) and on a local computer (i7-7800X @3.50 GHz). The second problem of this test is that the current context will affect the performance. For example, more blood glucose registrations mean more time for calculating the deviation, and no insulin registrations mean no evaluation process for some hypotheses. To address this issue, we simulated a typical load for the module: 3 weeks of self-collected health data. According to the authors and participants of the workshops, 3 weeks could represent the average time between consultations when patients are actively addressing health issues. A super-user of the Diabetesdagboka (Diabetes Diary) app provided the self-collected health data. We define a super-user as a patient with diabetes who is extremely active in self-management and who register data regularly.

Figure 2 shows an excerpt of the KBM results and its time of execution. In total, less than 26 milliseconds (ms) were necessary for the KBM to perform its task as shown in line 70. In fact, the majority of the methods were executed in less than 1 ms. This is mainly due to the KBM focusing on applying rules on looked-up context already provided by FullFlow, with some exceptions. The next paragraph describes the most important parts of the excerpt.

Lines 2–5 show the creation of the KBM class, with the creation of the Explanation Case Base and the first version of the current plan case, based on the Plan Base Case, with the loading of the current context. This task took less than 1 ms (1084 nanoseconds).

Line 7 shows the case to be treated by the KBM. The patient is male, has type 1 diabetes and registered 831 records in his diary application over 3 weeks. This represents almost 40

registrations per day. For comparison, *reliable* patients included in our previous studies registered their health data between 10 and 20 times per day.

The remaining lines show the time of execution of each hypothesis according to the plan defined by the KBM class and executed by the HypothesesMng class. See Section Hypotheses List for an explanation on the calculation done by the hypotheses.

Lines 10–41 concerns all hypotheses under the category ‘data is not reliable’, and are part of the current plan defined by the KBM. The reliability grade obtained by this run is 42 out of 50, as shown in line 10, and means that the data is reliable. Two methods took more than 1 ms to be executed: HYP_ID_DR_EV_BG_VAR (line 15, 5 ms) and HYP_ID_DR_DIST_DAILY_15074-8 (line 27, 7 ms). The first corresponds to verification of blood glucose variation, which should be under 2 mmol/L in 10 minutes, and the second corresponds to the daily distribution of the number of blood glucose registrations that should be under 20% deviation (15074-8 is the Logical Observation Identifiers Names and Codes [LOINC] code of glucose [moles/volume] in blood). This section of this excerpt shows that the patient did not register enough carbohydrates regularly (line 24, <1 ms), and registered erroneous insulin values lower than 1 unit (line 18, <1 ms), resulting in a penalty of 8 points of the data reliability score.

Lines 42–68 show an example of health problem-identifying hypotheses. Lines 44–64 show a hypoglycaemic event. According to line 45, this event occurred on the 16th December 2017 at 02:28. The *from* and *to* fields of line 45 are the same because a single blood glucose registration was made during this hypoglycaemic event. This would not have been the case if the patient was using a continuous glucose monitor (CGM), for example. The blood glucose values were stored in the application in mg/dL and the system converted it to mmol/L, which explains the value displayed in the same line. Line 47 shows that HypothesesMng updated the current plan case when it detected a hypoglycaemic event. Therefore, it added hypotheses to the plan, which correspond to lines 48–64.

These hypotheses show that this event could have been caused by excess insulin (line 48, <1 ms) based on the insulin factor calculation (line 50, <1 ms) and the I:C (line 51, <1 ms). It also shows that the last carbohydrate intake was lower than the recommended value (line 54, <1 ms). If the hypothesis on line 64 is true, that means there is a potential information gap regarding this event, as the module did not find any causes that could have led to this event.

Line 67 shows that the patient had correct blood pressure measurements (<1 ms) and line 68 shows that the patient did not sleep correctly according to recommendations on 18 out of 20 nights (4 ms).

This load test proved that the potential negative impacts on the FullFlow performance were insignificant

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Acceptance barriers of using patients' self-collected health data during medical consultation

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Abstract
Patients increasingly collect health-related data using mobile health apps and sensors. Studies have shown that this data can be beneficial for both clinicians and patients if used during medical consultations. However, such data is almost never used outside controlled situations or medical trials. This paper explains why the usage of self-collected health data is not widespread by identifying acceptance barriers perceived by clinicians, patients, EHR vendors and healthcare institutions. The identification of the acceptance barriers relied on a literature review, a medical pilot, a co-design and focus groups using diabetes as a case.

Keywords
Acceptance barriers, self-collected health data, consultation.

1 INTRODUCTION

The explosion of mobile health (mHealth) applications, wearables and sensors allows patients to collect an increasing amount of health- and lifestyle-related data [1-3]. Previous studies have shown that this data can be useful during consultations, for both clinicians and patients [4-6]. However, it appears that such data is rarely used outside of controlled studies, despite the fact that 60% of patients are open to giving their doctors real-time access to their health- and lifestyle-related data [7].

This paper is part of the 'Full Flow of Health Data Between Patients and Health Care Systems' project, supported by the Research Council of Norway (number 247974/O70), which focuses on integrating self-collected health data into consultations in Norway. This paper explains why the usage of self-collected health data in medical consultations is not more widespread beyond controlled studies by identifying, categorising and analysing acceptance barriers perceived by clinicians, patients, electronic health record (EHR) vendors and healthcare institutions (HI). Healthcare institutions are organisations providing healthcare services, including but not limited to patients care and equipment or materials used for the provision of health care.

2 METHODS

2.1 Identification of acceptance barriers

Three complementary approaches and sources were used for identifying the acceptance barriers to the usage of self-collected health data during medical consultations.

The first, primary sources of information were the results of two studies we conducted: one literature review regarding systems that integrate self-collected health data into EHRs [8] and one medical pilot involving sharing patients' self-collected health data with clinicians during consultations [9]. The review allowed identification of technical issues regarding the introduction of self-collected health data into consultations, while the medical trial focused on patients' and clinicians' expectations regarding the usage of patient-gathered data during consultations.

The second source of data relied on ten focus groups that involved 1) system architects and system owners of the Norwegian Directorate of eHealth (NDE, the central administration responsible for the eHealth infrastructure in Norway under the direction of the Ministry of Health and Care Services) and 2) system architects and product owners of the three largest Norwegian EHRs, namely DIPS (secondary healthcare), Infodoc Plenario and System X (primary healthcare). Each focus group lasted between 1 and 3 hours. The goal was to study the challenges regarding the integration of patients' self-collected health data in general into the national health infrastructure and into Norwegian EHRs (e.g. standardisation, security). The EHR vendors are partners in the FullFlow project. We used brainstorming and go-round methodologies supported by open-ended discussions during these focus groups to balance creativity and problem-solving tasks.

The third approach consisted of the organisation of a co-design workshop involving five patients with type 1 diabetes, two endocrinologists and two nurses specialising in diabetes. This co-design workshop was also part of broader study focusing on facilitating collaboration in diabetes care [10]. The participants were recruited through our in-house mobile self-management application, Facebook and by our partner, the University Hospital of Northern Norway (UNN). We received an exemption from the local ethics committee to perform this study (REK Ref. 2018/719), and acknowledgement by the Data Protection Officer at UNN (Ref. 2018/4027-4). Three sessions

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comprised the co-design workshop: (a) the first with patients only, (b) the second with clinicians only and (c) the third with all participants. Each session lasted half a day, and sessions (a) and (b) were held simultaneously in different locations before session (c). We used different methodologies during these sessions, namely writing round-robin (all participants answer a question on paper simultaneously and then present the answers in turn orally to the group) and brainstorming. The methodologies permitted a balance of creativity and problem-solving tasks while lowering pressure on the participants by allowing them to speak in turn. We used this co-design workshop to gather feedback on opportunities, acceptance barriers and interface design ideas generated by both patients and clinicians using scenarios based on the experience of the participants (e.g. diabetes patients sharing the data they collect with their clinicians). A more thorough description is available in another article [10].

This paper focuses on reporting the acceptance barriers.

The acceptance barriers were identified when a challenge, an issue, or a negative though related to the usage of self-collected health data during medical consultations was either expressed by the participants or described by a study.

2.2 Data categorization

The first author defined a taxonomy inspired by the work of Boonstra and Broekhuis [11] to present a global overview of the current barriers to acceptance of the introduction of self-collected health data into medical consultations. The taxonomy contains six categories:

- *Financial*: the cost issues related to the development, maintenance and usage of an information technology system supporting the collection, transmission and consultation of self-collected health data. Cost is the most important factor related to the failure of eHealth interventions [12].
- *Workload and workflow*: the impacts or potential impacts on clinicians' workload and clinical workflow. Workflow-related issues are one of the main factors in failure of eHealth interventions [12].
- *Technical*: the challenges related to the usage of hardware and software tools for collection, transmission and display of self-collected health data during consultations. This category includes the barriers related to technical capabilities of the physicians, patients and suppliers operating the tools.
- *Time*: the factors leading to increased time to perform a task.
- *Trust*: the factors influencing the ability to perceive the usage of self-collected health data during consultation as trustful, on both the personal and social interaction levels.
- *Legal:* concerns related to formal laws, such as privacy or security.

The next section presents the identified acceptance barriers using the taxonomy defined above.

3 RESULTS

Table 1 lists the identified acceptance barriers and the actors concerned by them, following the methodologies described in the previous section.

In total, 21 acceptance barriers were identified. The *technical* category contains the most acceptance barriers, with seven (33%) listed. The *financial*, *time*, *cognitive* and *workflow* categories follow with three (14%) barriers each. The *legal* category contains two (11%) barriers.

In total, the actors mentioned these barriers 33 times. Clinicians were the most concerned, with 15 (46%) barriers, followed by the HIs (nine barriers, 27%), the EHRs (five barriers, 15%) and the patients (three barriers, 12%). The next sections present the acceptance barriers in detail.

Table 1. List of identified acceptance barriers to the usage of self-collected health data by patients during consultations and the actors who identified them. Tax = taxonomy, Fin = financial, Tec = technical, Tim = time, Tru = trust, Leg = Legal, Work = workload and workflow. Actors: H = healthcare institutions, C = clinicians, P = patients.

Tax	Acceptance Barriers	Actors
Fin	Investment costs	H/EHRs
	Maintenance costs	H/EHRs
	Training users (clinicians)	H
Work	Lack of practice/training	C
	Lack of incentives/participation	C/P
	Heavier workload/reorganisation	C/H
Tec	Lack of skills	C
	Lack of data reliability	C
	Complexity of usage	C
	Obsolescence of the system	H/C/P/ EHRs
	Lack of software and hardware reliability	H/C/ EHRs
	Lack of standardisation	H/EHRs
	Too much data	C
Tim	Time to learn	C
	More time per patient	C
	Tracking data is a burden	P
Tru	Need to control	C
	Lack of belief	C
	Interference with doctor–patient relationship	C
Leg	Privacy/security of the data	P/H
	Missing legal context of usage	C/H

3.1 Financial acceptance barriers (Fin)

HIs and EHRs were uneasy about potential cost increases related to the support of self-collected health data

because, firstly, they have to invest in new information technology (IT) services or systems for supporting this new type of data and ensuring portability and interoperability [13] and, secondly, because they must address the challenges linked to the amount of self-collected health data available: system availability, continuity and scalability [14], which require yet more investment. Furthermore, the on-going maintenance of these new functionalities would constitute a new source of cost. HIs were also concerned by the need to organise courses for clinicians to ensure that they correctly use these new functionalities. For these institutions, this represents a *double cost: clinicians have to spend time learning new tools instead of providing clinical services.*

3.2 Workload and workflow acceptance barriers (Work)

Three barriers to acceptance were identified corresponding to this category. Firstly, clinicians expressed their lack of practice and training in the usage of self-collected health data for providing medical services. They were *dubious regarding their own skills for using this type of data correctly* and were *afraid that this data will distract them during consultations,* resulting in a degradation of the quality of their medical services. In some cases, patients' situations might even regress [15].

Secondly, clinicians and patients mentioned that there could be a lack of incentives and participation. Clinicians' motivation to use self-collected health data in consultations may be weakened by their lack of confidence and the absence of clinical standards and procedures for the usage of this type of data. Patients could be demotivated because daily registering of health data is time consuming and reminds them that they are sick [16]. Moreover, some patients, being afraid to be judged on their self-management performances, could be refractory to participate.

Thirdly, clinicians and HIs were concerned that the introduction of self-collected health data into consultations would increase the workload of the clinicians, who are already overwhelmed by their work schedules, which, in turn, could degrade their quality of life [17, 18]. The effect could be even greater if patients' systems provide a real-time communication channel [4], and it could also impact the current medical workflow because HIs and clinicians must integrate this new source of data into their procedures and use them side-by-side with existing data, such as laboratory results. In addition, there are currently no clear standard approaches to using such data. Clinicians were also afraid of becoming '*technical support employees'* for helping patients use their systems and collect their data correctly.

3.3 Technical acceptance barriers (Tec)

The first technical barrier mentioned was the clinicians' lack of skills and awareness regarding the usage of patient-oriented technologies, such as wearables, sensors or applications. Therefore, they were *doubtful regarding which solution is adapted for which patient for a given situation.*

The second barrier concerned the lack of reliability of the self-collected health data, which was perceived by clinicians as less reliable than laboratory results due to multiple factors [19-22] (e.g. defective patients' sensors, operator error when manually registering). Clinicians perceived this barrier to be important.

The third barrier, which concerned the clinicians, was the complexity of systems that patients present in consultations, mainly due to a lack of a common graphical interface because of the wide variety of applications, wearables and sensors available [1, 2]. Clinicians are unable to learn how to use all such systems considering their daily clinical responsibilities and limited schedules.

The fourth barrier mentioned by all actors was the obsolescence of IT systems. Patients and clinicians were afraid of failing to keep up with the constant changes of the ecosystems (new products rolled out while others become unsupported). EHRs and HIs were concerned that their IT systems could not support the evolution of healthcare informatics standards [23].

The fifth barrier to acceptance mentioned was the lack of software and hardware reliability, which concerned HIs, clinicians and EHRs. Hardware reliability refers to ability of the hardware to perform its functions as intended. For instance, patients' systems could be defective in registering data or become disconnected from the internet and unable to share data, and data stored in HIs' systems could be unavailable due to the amount of data to manage. Software reliability issues mainly relate to the software used for consulting data, which could be unstable due to the amount and variety of data collected [24]. This situation would make work difficult for clinicians, who may not have the most suitable tools for using self-collected health data during consultations.

The sixth barrier was the lack of standardisation of the patients' systems. Most systems are proprietary, specialised (e.g. diseased-oriented) and require specific equipment for accessing the data. For instance, Glooko [25] focuses on diabetes and provides hardware and APIs for accessing the data, while Tytocare [26] proposes general tools requiring their own platform for accessing data. EHRs and HIs must therefore rely on multiple external actors for providing self-collected health data to clinicians. This lack of standardisation inhibits semantic interoperability between patients' and EHRs' systems to be achieved.

The last barrier concerned the abundance of self-collected health data gathered by the patients. Clinicians were afraid they would '*not be able to separate relevant data for providing adapted care from data noise'* using their existing tools.

3.4 Time acceptance barriers (Tim)

Clinicians perceived the time-related barriers as the most important, as they already feel they are time-starved. These barriers are further affected by multiple barriers mentioned earlier. In general, clinicians felt they would

have to spend a lot of time learning how to use self-collected health data for providing relevant medical services, redesigning their workflows to include this new type of data and investigating patients' systems and the data collected. This task would be difficult to handle considering the wide variety of systems available, their non-standardisation and the different data types available.

Moreover, clinicians perceived that they would need more time per patient. Clinicians must determine whether the systems used by the patients and the data collected is useful, considering the various patients' situations. Clinicians would have to deal with the emotional state (e.g. anxious, depression), motivation and skills of patients regarding the usage of self-management technologies. For instance, the platform proposed by Kumar et al. [24] requires 45 to 60 minutes of configuration per patient before any consultation can happen.

Patients mentioned that they might not register regularly for long periods, considering that collecting data can be '*time consuming and bothersome.'* Moreover, they would prefer to focus on managing their current situation in real-time instead of retroactively analysing their actions. However, they mentioned that '*thoroughly registering for a short period, one or two weeks, could be feasible to address or to investigate specific health issues, with the help of clinicians*.'

3.5 Trust acceptance barriers (Tru)

The first acceptance barrier mentioned by the clinicians in this category was related to the need to control the medical workflow. Clinicians do not fully trust the procedures of the data collected by patients, believing that they are less reliable than laboratory results. They therefore expressed the need to know how the data is registered (i.e. which methodology, which sensor) and at what intervals.

There was also a lack of belief in the usefulness of the data by some clinicians, who believed that self-management should not interfere with classical healthcare. Moreover, demotivated patients may not use mHealth or collect data reliably, let alone fully follow providers' self-management recommendations. Therefore, other types of interventions would be needed for them.

The last point concerns interference with the doctor–patient relationship. Empowering patients and permitting them to bring their self-collected health data to a consultation could create difficulties in the doctor–patient relationship, considering that clinicians prefer a more traditional approach, relying on their training and their working colleagues [27].

3.6 Legal acceptance barriers (Leg)

Patients and HIs mentioned that the regulations regarding privacy and security in the sharing and usage of self-collected health data could represent a barrier to acceptance, especially since the implementation of the General Data Protection Regulation (GDPR). The GDPR requires 1) explicit consent to use self-collected health data, 2) a transparency notice explaining what data is used and 3) full access to the stored data for patients [28]. However, the application of the regulations would be difficult as most of the patients' systems are proprietary..

Another point was related to a lack of legal context for the usage of self-collected health data in medical workflows. To our knowledge, there is no juridical protection for clinicians, patients or HIs regarding the usage of this type of data. For instance, clinicians are neither permitted to nor prohibited from making a medical decision based on patient-collected health data. However, clinicians mentioned that it would be safer to use self-collected health data only as an input to the investigative process, rather than making medical decisions at that stage of the medical examination.

4 DISCUSSION

Regarding the defined taxonomy, we defined two categories not listed in the original taxonomy of Boonstra and Broekhuis [11]: workload and workflow, and trust. The latter is inspired by the original psychological category which concerns acceptance barriers related to personal issues, knowledge and perceptions of clinicians regarding the adoption of EHR systems. The former is a grouping of two original categories: change process and organisational acceptance barriers. The changes rendered the classification process easier and the created categories fit better the identified acceptance barriers in this study. The other original categories (financial, technical, time and legal) were unchanged.

Concerning the representativeness of the population, only a limited number of patients with type 1 diabetes were involved in the medical pilot (n=20) and in the co-design (n=5). These patients were already using self-collected health data to manage their conditions and were aware about collaborating with their clinicians using this data. Similarly, a limited number of clinicians involved in the co-design study (n=4) is not representative of all medical specialties. The clinicians were also exposed to self-collected health data by patients during medical consultations (e.g. consulting logs or messages sent by patients). Therefore, the acceptance barriers identified in this study could be more pronounced for a population not exposed to self-collected health data and to technology in general [29]. However, the literature review and the open-ended discussion in the focus groups involving system architects and owners permitted to expand the focus to any type of patients' self-collected data in the process of identifying the acceptance barriers.

In addition, there is a lack of clear documentation about the potential return on investment (ROI) or cost–benefit ratio (CBR) when using self-collected health data in medical workflows due to the lack of large-scale studies. Therefore, the introduction of self-collected health data in consultations are still not documented as a clear advantage, in terms of ROI or CBR, compared to public interventions [30], telemedicine [31], mobile health clinics [32] or healthcare command centres [33]. Similarly, the improvements in patients' quality of life when using self-collected health data in a collaborating way with clinicians is uncertain and depend on the context of the study [34].

5 CONCLUSION

This paper reported that a significant number of acceptance barriers are perceived by clinicians, patients, EHRs and HIs that prevent broad usage of self-collected health data during medical consultations.

According to the HIs and EHRs, the most critical acceptance barriers were related to costs and to the changes in medical workflow required by the introduction of self-collected health data into consultations.

Clinicians perceived time consumption and the lack of reliability of the data as the main acceptance barriers, while patients considered the burden of collecting health data to be a nuisance.

However, it appears that most of the acceptance barriers were connected to each other. For instance, the lack of standardisation of systems sharing collected health data would force clinicians to spend time learning each system, which would contribute to increased costs, with the need for courses, which in turn links to an added complexity of usage.

Proposing a solution for sharing self-collected health data addressing all these acceptance barriers therefore presents a challenge, and more research is necessary.

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Original Paper

Design and Prestudy Assessment of a Dashboard for Presenting Self-Collected Health Data of Patients With Diabetes to Clinicians: Iterative Approach and Qualitative Case Study

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Abstract

Background: Introducing self-collected health data from patients with diabetes into consultation can be beneficial for both patients and clinicians. Such an initiative can allow patients to be more proactive in their disease management and clinicians to provide more tailored medical services. Optimally, electronic health record systems (EHRs) should be able to receive self-collected health data in a standard representation of medical data such as Fast Healthcare Interoperability Resources (FHIR), from patients systems like mobile health apps and display the data directly to their users—the clinicians. However, although Norwegian EHRs are working on implementing FHIR, no solution or graphical interface is available today to display self-collected health data.

Objective: The objective of this study was to design and assess a dashboard for displaying relevant self-collected health data from patients with diabetes to clinicians.

Methods: The design relied on an iterative participatory process involving workshops with patients, clinicians, and researchers to define which information should be available and how it should be displayed. The assessment is based on a case study, presenting an instance of the dashboard populated with data collected from one patient with diabetes type 1 (in-house researcher) face-to-face by 14 clinicians. We performed a qualitative analysis based on usability, functionality, and expectation by using responses to questionnaires that were distributed to the 14 clinicians at the end of the workshops and collected before the participants left. The qualitative assessment was guided by the Standards for Reporting Qualitative Research.

Results: We created a dashboard permitting clinicians to assess the reliability of self-collected health data, list all collected data including medical calculations, and highlight medical situations that need to be investigated to improve the situation of the patients. The dashboard uses a combination of tables, graphs, and other visual representations to display the relevant information. Clinicians think that this type of solution will be useful during consultations every day, especially for patients living in remote areas or those who are technologically interested.

Conclusions: Displaying self-collected health data during consultations is not enough for clinicians; the data reliability has to be assured and the relevant information needs to be extracted and displayed along with the data to ease the introduction during a medical encounter. The prestudy assessment showed that the system provides relevant information to meet clinicians' need and

that clinicians were eager to start using it during consultations. The system has been under testing in a medical trial since November 2018, and the first results of its assessment in a real-life situation are expected in the beginning of next year (2020).

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KEYWORDS

dashboard; self-collected health data; diabetes; mHealth; decision support system

Introduction

Personal health information, such as data generated by sensors or data collected by patients themselves through their diaries, contains important information regarding the people's daily lifestyle. Previous studies have shown that clinicians can use these patient data to provide tailored medical services, especially for patients with chronic diseases [1-3], and that 60% of the patients are open to providing real-time access to their self-collected health information [4]. The use of self-collected data is especially relevant for patients with diabetes, because they often have to adhere to complex treatment regimes. If, for example, a patient is treated with insulin, the dosage has to be adjusted in concordance with not only the calorie intake, but also other factors such as physical exercise [5] and undercurrent disease [6]. Patients with diabetes and physicians have traditionally relied on analog diaries, but as personal computers and smartphones have become commonplace, there has been an explosive increase in the use of digital diaries and wearables [7,8]. In addition, several research projects and private companies are providing solutions to allow clinicians to consult data collected by the patients themselves [2,9]. However, none of these solutions are widely used, mainly because they are proprietary and require specific hardware and software to collect and access the data. This makes it difficult to provide fluid integration between such devices and the physicians' existing tools and constitutes an important barrier of acceptance for the introduction of these types of data [10].

This paper is part of the "Full Flow of Health Data Between Patients and Health Care Systems" project, which focuses on integrating self-collected health data into consultations in Norway using diabetes and Fast Healthcare Interoperability Resources (FHIR) as a case.

Major health care actors such as Epic Systems Corporation and Cerner propose application programming interfaces relying on FHIR standards [11,12]. Open source projects such as OpenMRS and Open mHealth also provide access to FHIR resources [13,14], and studies propose to use FHIR to improve the health care sector [15]. Norwegian electronic health records (EHRs) are currently working on implementing FHIR standards in their respective solutions [16], but none of them are ready to manage FHIR resources today, as they are not able to receive and display FHIR data. We therefore provided clinicians with a standalone dashboard (ie, view providing key performance indicators) displaying the patients' self-collected health data to be used as an addition to their current EHR.

Even if self-collected data could be seamlessly integrated, user acceptance is not guaranteed. Patients with diabetes can collect large amounts of data. If the data cannot be presented in an efficient way, it cannot be efficiently comprehended, severely diminishing its usefulness [17-20]. Many physicians struggle to obtain an overview of constantly expanding EHRs. The introduction of a potentially large amount of new data that the physicians are not used to utilizing must therefore be handled with great care, as even minor ill-considered implementation details can have a huge negative impact [18-20]. Optimal presentation of health data depends on the information needed by the clinicians. There is no optimal way of presenting clinical data, because these needs vary a lot [21-25].

This paper presents the design of a dashboard for displaying the self-collected health data from patients with diabetes and describes how the user interface attempts to meet the clinicians' information needs. Furthermore, the paper presents the prestudy assessment of the dashboard by clinicians.

Methods

Phases

In the two main phases of the study, we used different methodologies: iterative dashboard design and prestudy assessment (Figure 1). The iterative design phase supported the conception and implementation of the dashboard, while the prestudy assessment was used to collect the clinicians' experiences with the developed dashboard as well as their recommendations.

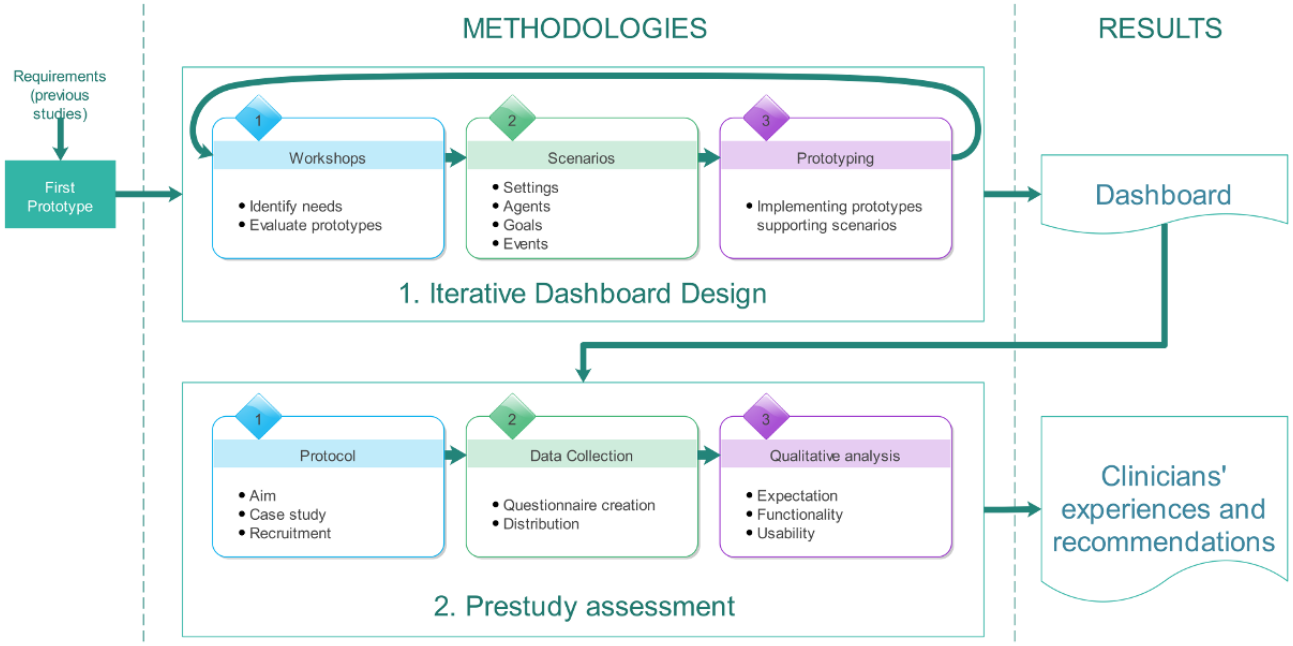
Based on previous studies by the authors [26,27], we created the first prototype of the dashboard to be used as a first input for the iterative design process. The information collected from the studies [26,27] was used to identify the data required during diabetes consultations and to define the requirements for the graphical user interface (GUI) of the dashboard.

Iterative Dashboard Design

The development of the dashboard followed a three-step iterative process to approach the following primary objectives: (1) identify the needs of both patients and clinicians regarding information with clinical relevance during a consultation, information suitable to be collected by patients, and how to present the information in the GUI in order to improve its usability during consultations; (2) evaluate early prototypes and propose adjustments; and (3) develop prototypes based on the proposed adjustments identified in step two.

To achieve these objectives, we organized facilitated workshops, supported by open-ended discussions, to approach specific tasks in rapid development cycles.

Figure 1. The two main phases of the study, with their components and results.



Facilitated Workshops and Open-Ended Discussions

Facilitated workshops are sessions bringing users, stakeholders, and partners together to define and evaluate product requirements [28].

We organized two facilitated workshops using a participatory design approach [29] involving four of the authors (AGi, AGr, EÅ, and AH), four clinicians (two nurses and two doctors who have worked with patients with diabetes), and two patients with diabetes. The clinicians and patients were recruited by our partner—the University Hospital of North Norway. Different methodologies were used during these workshops, namely, brainstorms, idea storms, and go-rounds, to balance creativity and problem-solving tasks and to reduce the pressure on the patients by allowing everyone to speak in turn. The facilitated workshops lasted 3 hours each, and participants were invited to use their own experiences to contribute to the workshops' primary objectives. The majority group decision–making technique was employed during these sessions.

In addition to the facilitated workshops, we organized a total of 11 sessions with open-ended discussion—three focused on mathematical models to use for medical and statistical calculations and involved two computer scientists; four focused on targeting the GUI usability, namely, the information to be displayed, which was attended by one computer scientist and one GUI expert; two focused on a first assessment regarding the medical relevance of the information displayed, which was joined by a computer scientist and a general practitioner; and two focused on the evaluation of the dashboard prototype against the requirements and involved four of the authors (AGi, AGr, EÅ, and AH).

Scenarios

We used a simulation-type scenario approach to model real-life situations and narratives [30]. The modelling process relied on a taxonomy containing four elements that were used for each scenario. These elements were as follows:

1. Settings: the context and the situation of the scenario
2. Agents: those who participate in the scenario
3. Goals: the functional targets of the scenario
4. Events: the actions taken by the agents during the scenario

The detailed information concerning the three main scenarios was defined together with the participants during the first facilitated workshop. We chose to use a scenario approach because it facilitates the cooperation of the participants during the facilitated workshops, who can see themselves in the situations and evoke their own experiences, and it simplifies the design process of the dashboard by providing concrete and flexible situations [31].

Prototyping

The prototyping phase consisted of implementing the dashboard to support the given scenarios by using computer-generated data that express the data requirements for the scenarios.

The dashboard was then built to achieve the objectives described in the scenarios. An agile development process [32] was exclusively used for this task, as evolution, changes, and adaptability were necessary, considering the continuous inputs provided by the workshops. The implementation relied on Java Enterprise Edition 8, Java Server Faces 2.2, and Glassfish 5. The developed prototypes were assessed during the workshops and improved during each iteration of the design process.

Once the authors and participants in the workshops decided that the dashboard was satisfactory to be used in a real situation, we stopped the iterative design process and selected the last prototype for a prestudy assessment by different clinicians.

Prestudy Assessment of the Dashboard by Clinicians

Protocol

The design of the prestudy assessment was guided by the Standards for Reporting Qualitative Research checklist to enhance the organization and reporting of this study [33]. The aim of the prestudy assessment was to evaluate the pertinence of the functionalities presented in the dashboard GUI and its usability prior to a medical trial.

We used a case study approach, organizing a total of five workshops in health care offices (hospital and general practitioner [GP] office), each involving one to four clinicians, accounting to a total of 14 clinicians, and one or two researchers. The 14 clinicians were recruited through our partner, the University Hospital of North Norway, or by direct contact initiated by us; none participated in the dashboard design and all are currently participating in the medical trial. We were limited in the number of participants to include due to external factors (eg, time constraints and unavailability of further participants).

During the workshops, we presented the FullFlow system, which included the last prototype of the dashboard, by using the self-collected health data from one in-house researcher who has type 1 diabetes (an exemption was obtained from the local ethics committee: Ref 2018/719 [34]), hereafter referred to as Research Patient. We extracted these data from the Research Patient's Diabetes Diary to fill the FullFlow system, using the Diabetes Share Live solution to transmit the data in a way similar to that used in a previous study [27]. The use case presented in the workshops was based on the Research Patient's real-life diabetes data (ie, insulin intake, carbohydrate intake, blood glucose values, physical activities, weight, medication, and personal aims) and is similar to one scenario created in the dashboard design process. The Research Patient participated in all workshops, where he could explain the different values displayed in the dashboard and answer questions regarding his lifestyle and the recorded values.

Data Collection

During the workshops, we distributed a paper-based questionnaire to the participants after presenting the system and letting the clinicians test it. We then collected the questionnaires at the end of the session. The first and second (AGi and EÅ) authors designed a specific questionnaire based on the System Usability Scale [35] and the Computer System Usability Questionnaire [36].

We decided to use a custom questionnaire, as the assessment did not permit inclusion of important usability factors due to a lack of clinical context such as patient-clinician relationships. Given that the questionnaire was administered to the participants before the study, we wanted to provide open-ended questions to obtain important feedback for this iterative process before starting the medical trial. The questionnaire contained four questions about the system and the role of the user (eg, nurse):

- Q1a: Do you think the system will be useful during consultation? Q1b: Potential comments.
- Q2a: Would you like to have more information delivered by the FullFlow system? Q2b: Potential comments.
- Q3a: Would you like to remove or hide information currently delivered by the FullFlow system? Q3b: Potential comments.
- Q4: Do you have any feedback you would like to offer?

Qualitative Analysis

The first author (AG) performed a qualitative analysis based on three keywords: *expectation*, *usability*, and *functionality*. In our context, we defined *expectation* as a general belief that positive or negative outcomes could occur in clinical settings by using our proposed system. The use of this term was inspired by the work of Bialosky et al [37]. We used the seven notions provided by Vázquez-García et al [38] to define *usability*: knowability (user can understand, learn, and remember how to use the system), operability (capacity of the system to accommodate users with different needs), efficiency (capacity of the system to produce appropriate results), robustness (capacity of the system to resist error), safety (capacity of the system to avoid risk), and satisfaction (capacity of the system to generate interest in users). We used the definition proposed by Salleh et al [39] to describe *functionality*: a set of functions and their specified properties. We then used the feedback to improve the system before starting the medical trial. We used the feedback obtained in order to improve the system before starting the medical trial.

Results

Overview

From previous studies, we identified eight relevant data types for diabetes consultation—blood pressure, calories, carbohydrates, heart rate, blood glucose, insulin, weight, and physical activity (Figure 2 A)—and relevant medical calculations such as insulin-to-carbohydrate (I:C) ratio and basal insulin to bolus insulin ratio (Figure 2 C). As a requirement for the GUI, we identified the need to present the data in different time frames (per hour, per day, per week, and for the complete period [Figure 2 B]) and the use of a color scale to illustrate data ranges (Figure 2 D).

Iterative Dashboard Design

Facilitated Workshops and Open-Ended Discussions

The first prototype was presented to the participants in the first facilitated workshop. Based on this prototype and their own experiences, the participants suggested improvements to both data, functionalities, and GUI. The suggested improvements were translated into requirements and implemented in the prototype presented during the second workshop. The improvements suggested during the second workshop were used as requirements during the development of the final prototype. The requirements identified are summarized in Table 1.

Scenarios

We created three main scenarios (Table 2); this was considered a manageable number of scenarios for the workshops and open-ended discussions while still allowing diversification of the situations.

Figure 2. First prototype of the FullFlow dashboard system.

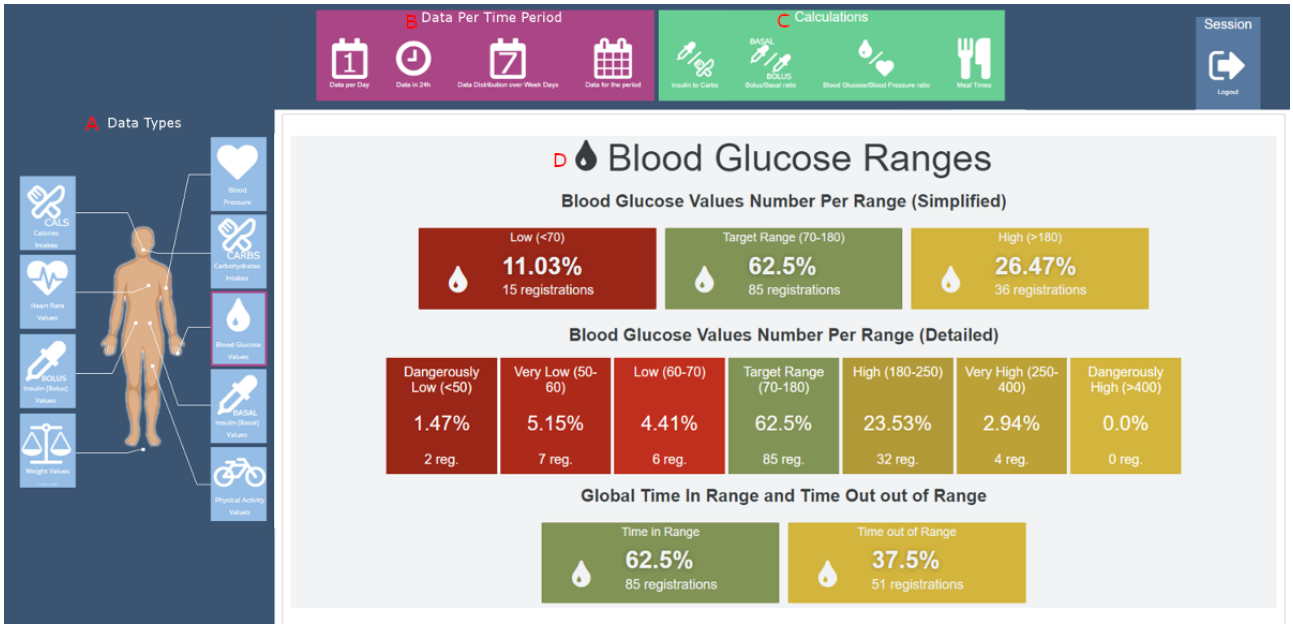


Table 1. Summary of the requirements defined based on suggestions from the participants in the facilitated workshops and their description.

Requirements	Description
R1: Displaying data collected by patients	At least blood glucose, blood pressure, insulin (bolus/basal), medication, carbohydrates, calories, and physical activity. Being able to accept new data types (eg, menstruation, ketones, and polypharmacy) would be a plus. The system shall inform clinicians if the patients register life goals (eg, what they are focusing on in their daily self-management).
R2: Quantify data collected by patients	The system will notify which data have been collected by the patients and quantify them.
R3: Displaying data collection period	The system will provide clinicians the length of time during which patients collected their data.
R4: Variabilities in the patients' data values	The system will be able to present a variability value for all data types to indicate how much these values diverge.
R5: Medical calculations	The system will be able to provide medically relevant information (eg, insulin-to-carbohydrate ratio and insulin sensitivity).
R6: Grading data reliability	The system will permit clinicians to know immediately if the data collected by the patients are reliable (ie, worth their time consulting the data).
R7: Hiding eA_{1c}[a]	Removing eA_{1c} from the graphical user interface.
R8: Reduce complexity of blood glucose ranges	The system will use the simplified (3 levels) blood glucose range.
R9: Consulting all self-collected health data at once	The system will present all self-collected health data at once in a graph.
R10: Pattern recognition	The system will ease identifying patterns in patients' lifestyle per day, per week, and for the whole period (eg, hyperglycemic events each day after dinner).
R11: Bridge to existing data	The system shall provide information clinicians can assess by comparing existing data to the self-collected health data.
R12: Overview of the patients' situations	The system will be able to inform clinicians about what the patients struggle with, what they manage, etc.
R13: Visual helper	The system will provide information about which data are in and out of range.

[a]eA_{1c}: estimated hemoglobin A_{1c}.

Table 2. Scenarios created to support the user requirements. Settings: the context and situation of the scenario. Agents: actors in the scenario. Goals: targets of the scenario. Events: the actions taken by the agents during the scenario.

Taxonomy	Scenario 1	Scenario 2	Scenario 3
Settings	Patient has nightly hypoglycemic events. The patient has an appointment with a diabetes nurse to discuss his situation and therefore collected health data for 1 month prior to the appointment. The patient uses finger pricks and an insulin pen.	Patient struggles with carbohydrate counting and always ends up in hyperglycemia after meals, despite using a hybrid closed-loop system (continuous glucose monitor and a pump). Patient also reaches hypoglycemic levels after the insulin action ("yoyo" effect). Patient has an appointment with a dietitian after having collected 1 week of data.	Patient always has high fasting blood glucose levels, despite being on medication and following cooking courses. Patient has a meeting with his general practitioner after collecting 2 weeks of data.
Agents	Patient with type 1 diabetes and diabetes nurse	Patient with type 1 diabetes and dietitian	Patient with type 2 diabetes and general practitioner
Goals	The system should show the hypoglycemic events and identify the nightly trends. The system should show the insulin dosages and the carbohydrate intakes to help the nurse identify possible points of action.	The system should show the relationship between meal intakes, insulin-on-board levels, and blood glucose levels.	The system should show the high glucose situations, the calorie intakes that are above the recommended levels, the patient's lack of physical activity, the high blood pressure, and that the patient sometimes forgets to take his medication.
Events	Patient registers, on an average, per day: • 10 blood glucose values, • 4 carbohydrate intakes, • 6 insulin injections (2 basal, 4 bolus), and • 10 minutes of physical activity. Nurse discusses the patient's hypoglycemic events with him and consults the data using the FullFlow dashboard.	Patient registers, on an average, per day: • 288 blood glucose values, • hourly insulin bolus dosage, and • 5 carbohydrate intakes. Dietitian discusses with the patient his "yoyo effect" after meals and consults the self-collected health data using the FullFlow dashboard.	Patient registers, on an average, per day: • 1 blood glucose value, • 2 medication intakes, and • 5 calorie intakes. Patient also has: • 2 weight registrations, • 1 blood pressure registration, and • 3 physical activity registrations (<10 minutes). General practitioner discusses the situation with the patient and uses the FullFlow system to get an overview of his situation.

Final Prototype

We provide an example of the dashboard based on the self-collected health data obtained from the Research Patient, which was similar to the use case presented to clinicians in the preassessment study. The proposed dashboard contains six main sections accessible from a menu displayed at the top of the page (Figure 3):

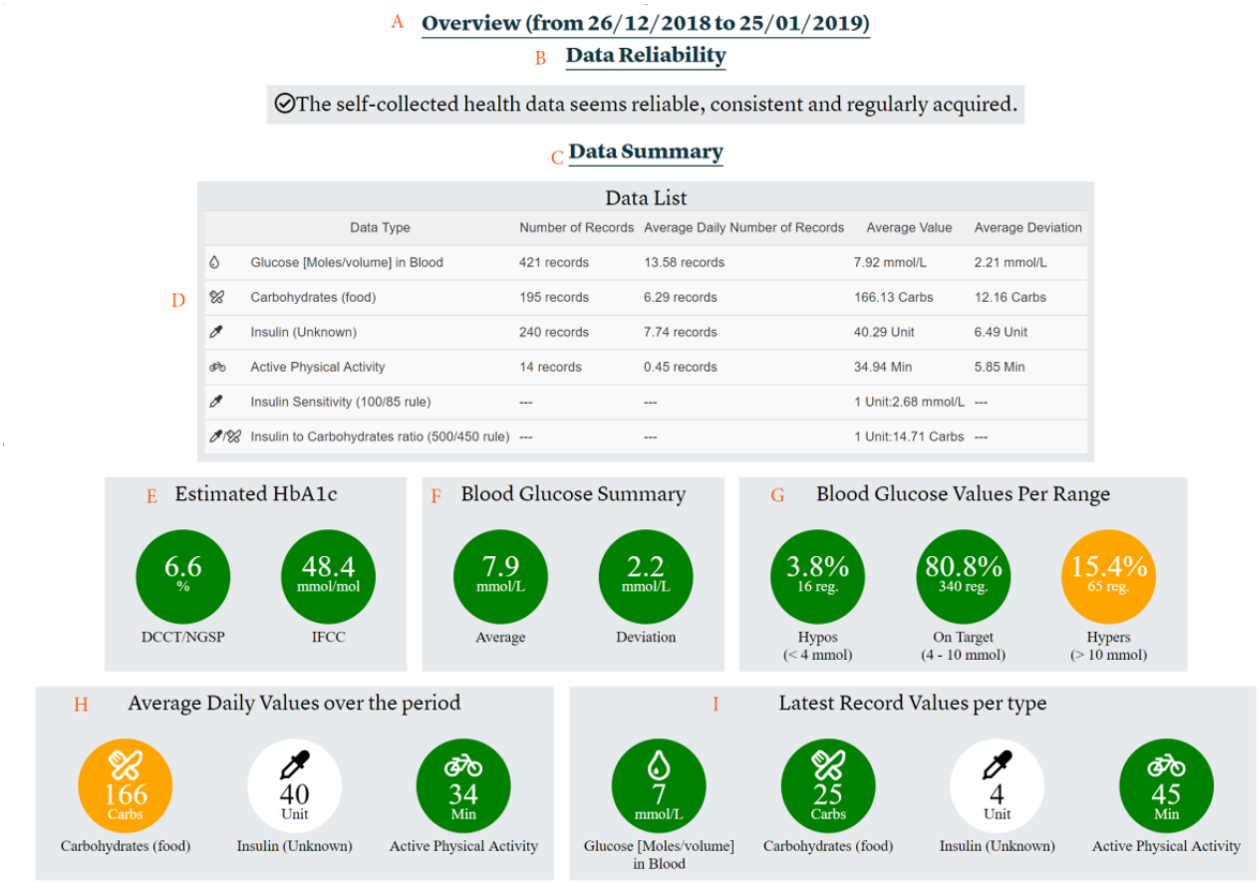
1. The *Overview* contains information regarding the data reliability, the data collected, the patients' personal goals, and a list of noticeable events and their potential causes. It is the landing page of a FullFlow report.
2. The *Combined Data* displays all the quantifiable data sent by the patients in combination with the calculated information for the whole period in a unique graph.
3. The *Daily Distribution* distributes all quantifiable data per hour in multiple graphs (one graph per data type).
4. The *Daily Evolution* summarizes the data per day in multiple graphs (one graph per data type).
5. The *Time Period* displays the data for the whole period in multiple graphs (one graph per data type).
6. The *Data List* lists all the data collected by the patients in a table.

Overview Section

The Overview section provides a summary of all data collected by the patients and the results of the FullFlow analyses (Figures 4 and 5). The objective of this section is to provide an overview of the patients' situation and the medically related events found to be important to discuss or address, without the need to consult the whole data set. The first data displayed are the time period (Figure 4 A), determined by the first and last FHIR artefacts ordered by date. This addresses the requirement R3 (Table 1).

Figure 3. Dashboard menu.

Figure 4. Overview section, part 1. (A) Title and period of time. (B) Data reliability. (C) Summary of the data. (D) List of all the data collected by the patients. (E) Estimated hemoglobin A1c. (F) Blood glucose summary. (G) Time in range and time out of range for blood glucose registrations. (H) Average daily values of data collected by the patients for the period. (I) Latest values for each type of data collected by patients.



The second dataset displayed is related to the reliability of the patients' self-collected health data (Figure 4 B). A knowledge-based module (KBM) grades the reliability of the self-collected health data based on the presence or absence of registered data, potential errors in data values, inconsistencies between data sources, the number of data registrations, and the regularity of the registrations made by the patients. This service addresses the requirement R6 (Table 1) by providing clinicians information about the quality and reliability of data at an early stage of consultation. In this example, the system graded the data as reliable. The system provides a list of issues if the data are graded as not reliable. We explained and illustrated this system in a previous article [40].

The next subsection, the Data Summary (Figure 4 C), first contains a table (Figure 4 D) listing all the patients' self-collected health data with important calculations for diabetes patients, such as insulin sensitivity and insulin to carbohydrates ratio (I:C), if the data collected permit the calculation of these components. These values are displayed side by side with the ratios submitted by the patients, if available, permitting a simple comparison. The table contains the number of registrations and the average daily number of registrations per day for all types of data collected. The table also provides the average of all the values as well as the pooled SD per data type (called "average deviation" for the clinicians, see Discussion). The pooled SD is calculated using the formula:

$$\sigma_p = \sqrt{\frac{(n_1-1)s_1^2+(n_2-1)s_2^2+\cdots+(n_k-1)s_k^2}{n_1-1+n_2-1+\cdots+n_k-1}}$$

...where n_k represents the number of registrations for a day and s_k^2 represents the variance for a day. We used the same approach for appropriate data types (eg, not used for blood pressure where the system considers only the latest registered value per day). The table also contains specific diabetes rules, such as the 100/85 rule for estimating the insulin sensitivity (also called "correction factor") [41] or the 400 rule for estimating the insulin-to-carbohydrate ratio [42]. Patients can also provide this information, and in this case, both collected and calculated values will be listed one above the other for easy comparison. This table addresses requirements R2, R4, and R5 (Table 1).

The next dataset provided is the estimated hemoglobin A_{1c} (eA_{1c}) value (Figure 4 E), calculated from the average blood glucose value of all blood glucose registrations, based on the formula proposed by Nathan et al [43]: $eAG_{mmol/L}=1.59*A_{1c}-2.59$, where eAG is the estimated average glucose level in mmol/L and A_{1c} the hemoglobin A_{1c} value. The system calculates the eA_{1c} only if there are at least 3 blood glucose registrations a day and 21 blood glucose registrations in total. This system provides two standards for the eA_{1c} value—National Glycohemoglobin Standardization Program (NGSP; %) and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (mmol/mol)—considering that Norway

replaced NGSP with IFCC in 2018 [44]. To convert NGSP to the IFCC value [44], we use the following formula:

$$eA1c_{IFCC}\left[\frac{mmol}{mol}\right] = 10.931 * (eA1c_{NGSP}[\%]) - 2.152$$

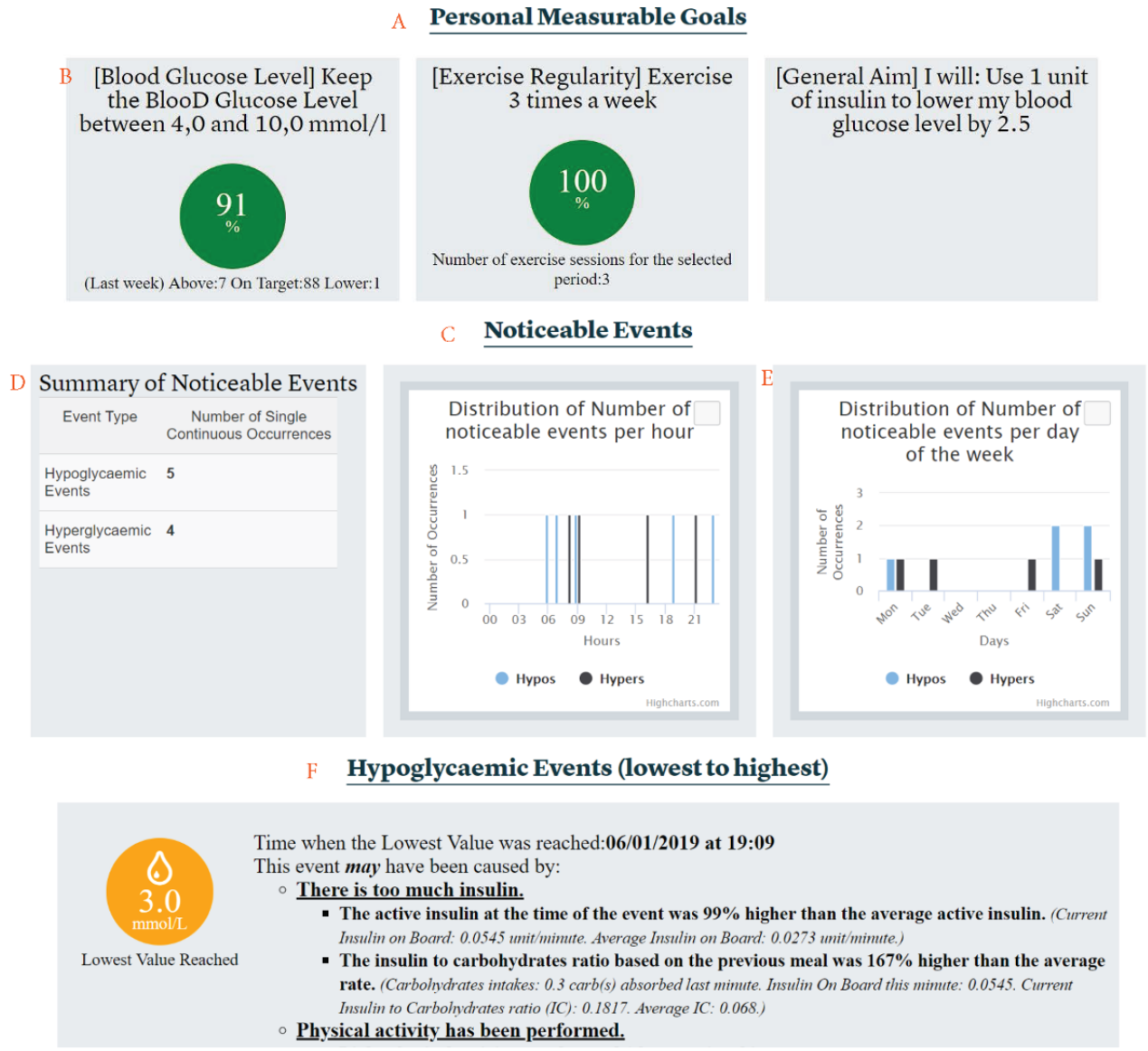
This service addresses the requirement R11 (Table 1) by providing a possible comparison between self-collected health data and laboratory results. However, it also conflicts with the requirement R7 (Table 1). Therefore, we decided to hide these values during the medical trial.

The blood glucose summary (Figure 4 F) displays the average blood glucose value and the pooled SD (same values as in Table 1). The blood glucose values per range (Figure 4 G) display the number of registrations and their percentages per range (low, on target, or high), which are defined as per the standards [45,46]. This addresses requirement R8 (Table 1).

The average daily values (Figure 4 H) display the average of all collected data when appropriate (same values as in Table 1). The final dataset displayed is the last value for each data type the patients have registered (Figure 4 I).

FullFlow grades each piece of information presented in Figure 4 E-I and provides four background color states: green, orange, red, and white. These colors have different meanings: green indicates that the value is in the recommended range, orange indicates that the value is slightly above or under the recommended range, red indicates that the value is out of range, and white indicates that a value is not graded because of a lack of standards or that the value depends heavily on context. The visual representation is inspired by the work of Sim et al [47], who are using a similar grading system, and the work of Diagliati et al [48], who used traffic lights. This grading addresses requirements R13 and R12 (Table 1).

Figure 5. Overview section, part 2. A: List of personal goals defined in the patients' diary. B: Example of a personal goal. C: List of noticeable events based on the collected data. D: List of events detected organized by type. E. Distribution of event types per day and per hour. F: Example of a noticeable event.



Next, the overview section contains personal goals (Figure 5 A) defined by the patients with or without clinician involvement. Personal goals can be measurable (eg, keeping your blood glucose level between 4 and 10 mmol/L [Figure 5 B]) or nonmeasurable (eg, more proactive). FullFlow provides progress and description for measurable goals. Displaying personal goals addresses requirement R1 (Table 1).

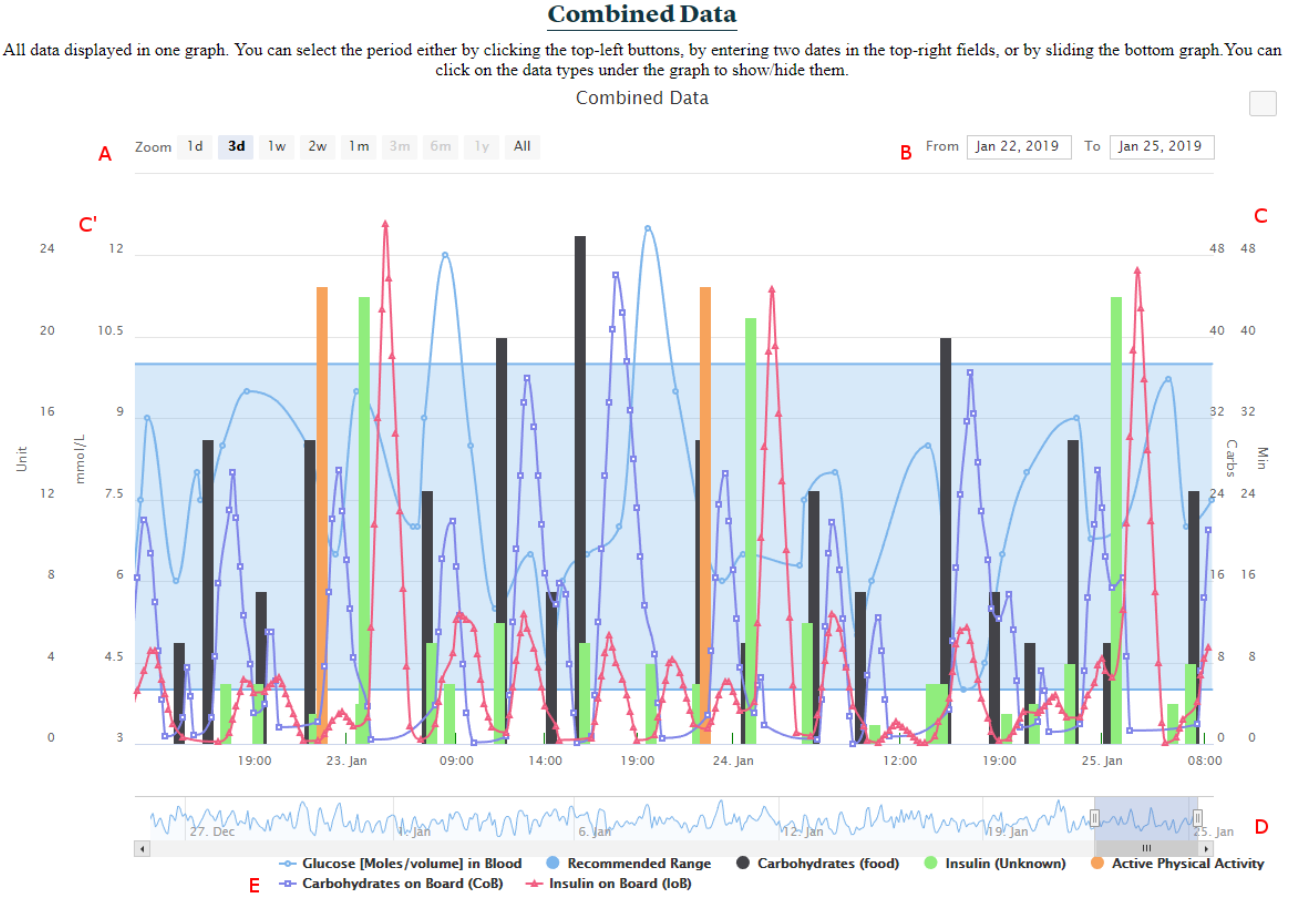
The next section provides information about noticeable events (Figure 5 C). Noticeable events are important events that clinicians and patients should address to improve the health situation of the patients. FullFlow identifies them using KBM in combination with the patients' self-collected health data and statistical calculations. FullFlow first summarizes the noticeable events by displaying the number of occurrences (Figure 5 D) and distributing the events during the day and the day of the week based on the time, to potentially identify trends (Figure 5 E). Subsequently, FullFlow displays one event at a time, ordered from the most to the least serious, and provides potential causes and explanations for them (Figure 5 F). This section includes other medical conditions related to blood pressure or sleeping pattern in addition to hypoglycemic and hyperglycemic events shown in Figure 5. We described the KBM in detail in a previous article [40]. Noticeable events address requirement R12 (Table 1).

Combined Data Section

The combined data section presents all the quantifiable data available in FullFlow (self-collected health data and calculations), as shown in Figure 6. This graph is based on the Highstock library [49] and addresses requirement R9 (Table 1).

Clinicians can change the timeframe by selecting a start and an end date (Figure 6 B) and selecting a predefined time length such as 3 days or 1 week (Figure 6 A) or by sliding, extending, or narrowing the data range selector (Figure 6 D). Clicking on a data type in the lowest part of the graph hides or shows the data type in the center of the graph, allowing clinicians to focus on what they would like to analyze (Figure 6 E). The vertical axes are built automatically (either left or right, Figure 6 C and 6C') depending on the data type available. The frequency of measurements or the data type extracted from Logical Observation Identifiers Names and Codes or the Systematized Nomenclature of Medicine Clinical Terms contained in FHIR artefacts define the data representation in the graph. Series represent data types having at least 20 registrations per day or being of a specific type, such as blood glucose, while bars represent the rest. Areas represent the reference range of the FHIR artefacts (eg, in-range for blood glucose values) linked to a data type. A mouse hovering above a point shows the exact time and value for all data types with the exact same time. We used the OpenAPS approach to calculate the insulin on board (IoB) [50] and the work of Dana Lewis [51] to calculate the carbohydrates on board (CoB).

Figure 6. Combined data. (A) Period selection by predefined time length. (B) Period selection by dates. (C, C'): Multiple y-axes. (D) Period selection by range selector. (E) List of all data types represented in the graph.



Daily Distribution Section

The daily distribution section distributes all the available data in a single day to help clinicians identify daily patterns (requirement R10 in Table 1), such as hypoglycemic events during the nights or hyperglycemic events during the afternoon. This section proposes one graph per data type (Figure 7), which displays all the blood glucose measurements available in a single day. In this example, only finger prick registrations are shown. In addition to displaying the data, FullFlow calculates a moving average of all the values. FullFlow uses either a simple moving average or a weighted moving average, depending on the data type and how patients have collected them (see Discussion for more details). This type of graph also contains reference ranges when provided.

Daily Evolution Section

The daily evolution section simply presents the sum, the average, or the latest data per day for the whole period, depending on the data type (Figure 8). For instance, blood glucose values are averaged per day, insulin amount values are summed per day, and the latest of the blood pressure values of the day are used for each day. This type of graph also contains reference ranges when provided. Each data type has its own graph.

Time Period Section

The time period section shows all data available for the whole period by using the same approach as the combined data, except that one graph contains only one data type (Figure 9).

Data List Section

The data list section presents extracted information from all health data self-collected by patients in a list, without the calculated values of the FullFlow, as shown in Figure 10. The section displays the number of registrations made by the patients and shows the date, data type, value, unit, and comment for each entry. Clinicians can order the table by clicking on the head of a column (eg, ordering data per data type) or look up specific registrations using the search field (top right in Figure 10).

The different sections in this dashboard permit the display of any type of data collected by the patients and addresses the requirement R1 (Table 1).

Figure 7. Daily distribution of blood glucose values.

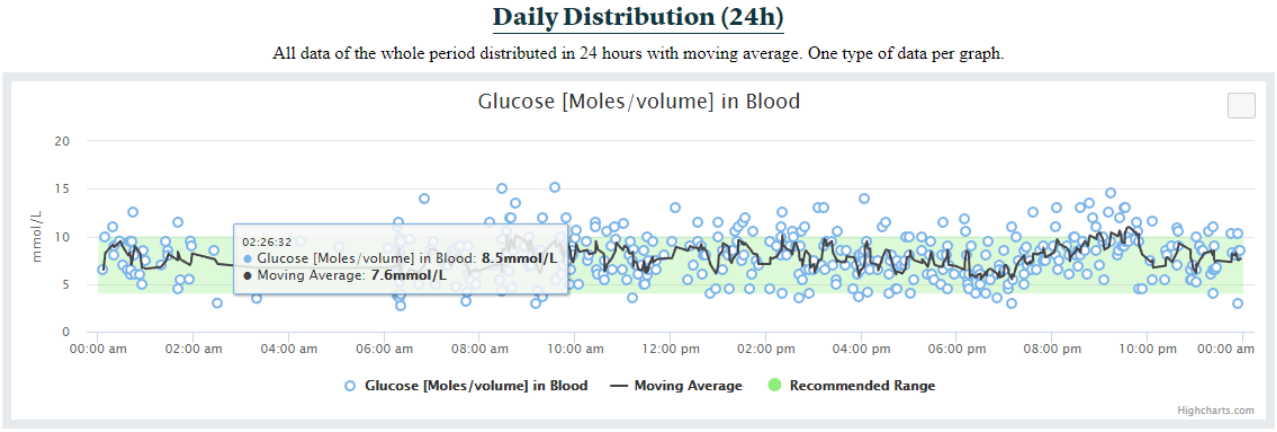


Figure 8. Daily evolution of the blood glucose for the whole period.

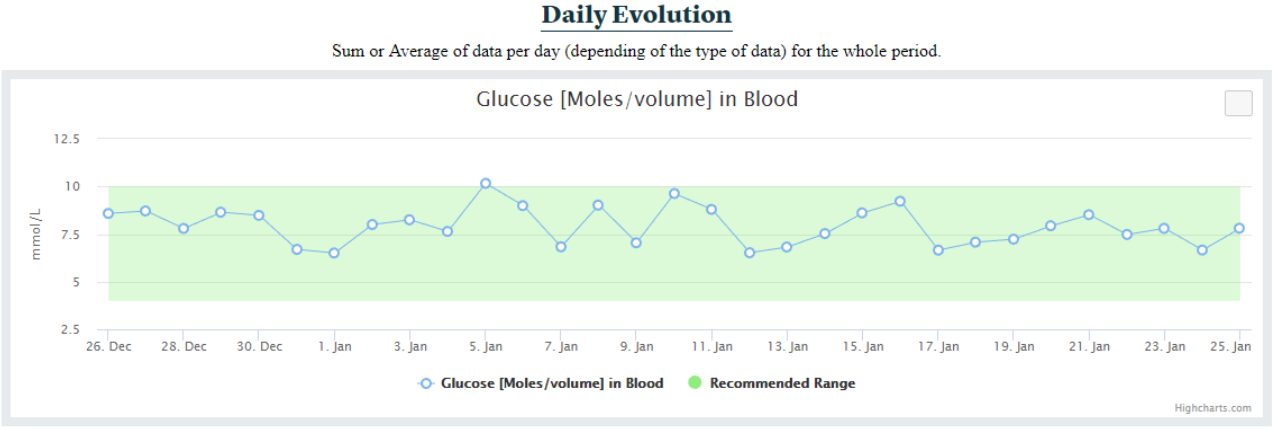


Figure 9. Time period for blood glucose values.

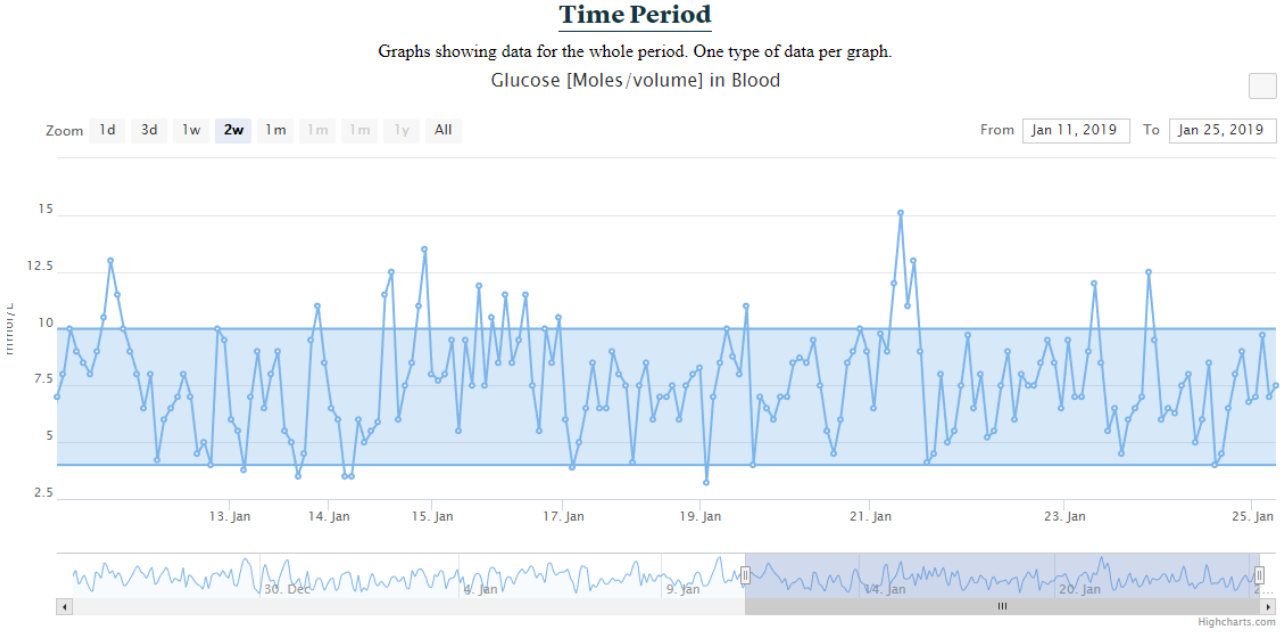
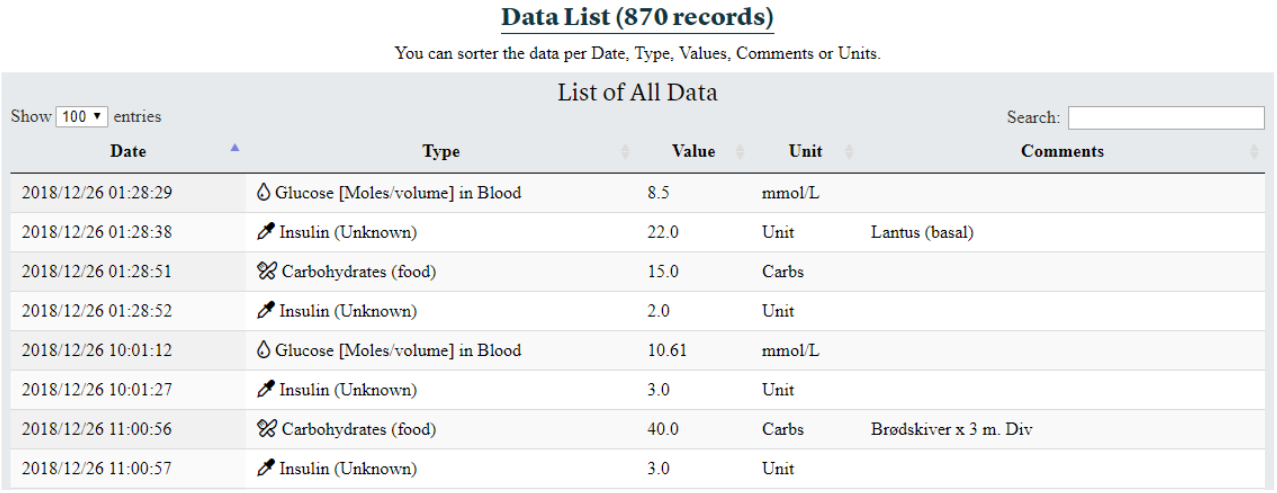


Figure 10. Data list section.



Date	Type	Value	Unit	Comments
2018/12/26 01:28:29	Glucose [Moles/volume] in Blood	8.5	mmol/L	
2018/12/26 01:28:38	Insulin (Unknown)	22.0	Unit	Lantus (basal)
2018/12/26 01:28:51	Carbohydrates (food)	15.0	Carbs	
2018/12/26 01:28:52	Insulin (Unknown)	2.0	Unit	
2018/12/26 10:01:12	Glucose [Moles/volume] in Blood	10.61	mmol/L	
2018/12/26 10:01:27	Insulin (Unknown)	3.0	Unit	
2018/12/26 11:00:56	Carbohydrates (food)	40.0	Carbs	Brødskiver x 3 m. Div
2018/12/26 11:00:57	Insulin (Unknown)	3.0	Unit	

Prestudy Assessment of the Dashboard by Clinicians

This section presents the assessment of the full system (a combination of the Diabetes Diary [52], Diabetes Share Live [27], and FullFlow) by clinicians, following the approach described in the Methods section. As mentioned in the previous section, the graphical interface was presented without the eA_{1c} value displayed in Figure 4. Multimedia Appendix 1 contains the transcribed answers to the collected questionnaires. The following subsections present the results of the analyses of the questionnaires organized using the taxonomy defined in the Methods section (Data Collection subsection) and concerning the FullFlow system only (the Diabetes Diary and Diabetes Share Live are outside the scope of this study).

Participants

Fourteen clinicians participated in the prestudy assessment: nine (64.3%) were GPs, four (28.6%) were diabetes nurses, and one (7.1%) was a dietitian.

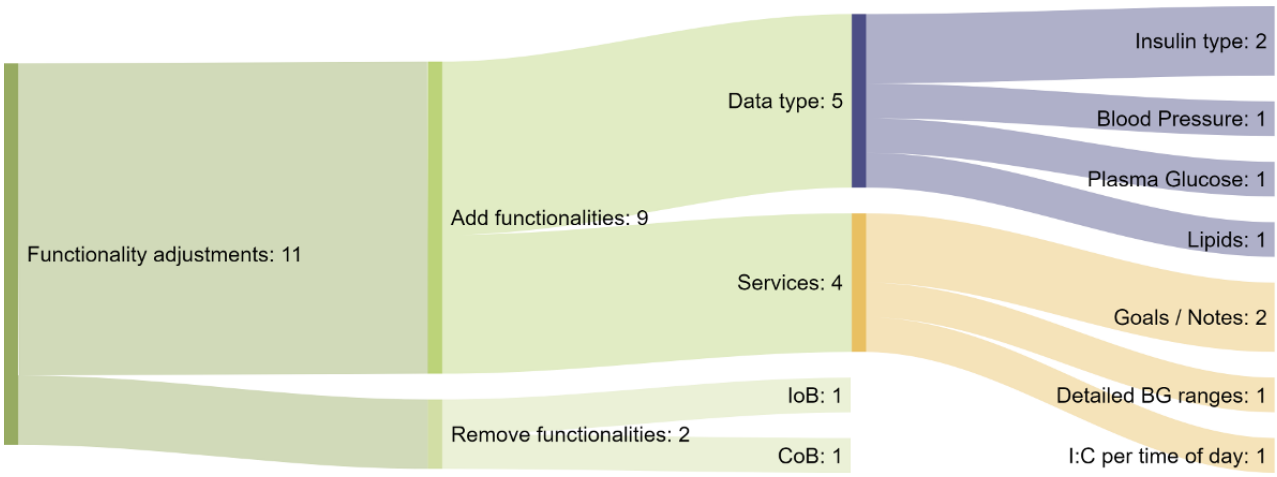
Pertinence of the Functionalities Provided by the FullFlow System

Regarding the relevance of the functionalities provided by the system, the overwhelming majority of the participants (9/14, 64.3%) considered them relevant and would like to keep the system in the current state, without adding or removing any functionalities, as shown in Table 3. Five (35.7%) participants would have liked to add or remove one or more functionalities in the system. Although the majority of the primary health care personnel (GPs) were satisfied with the information available in the system (7/9 or 77.8% would like to keep the system in its current state, while 2/9 or 22.2% would like to alter it), the situation was less clear for the secondary health care personnel (nurses and dietitian), with three (of 5, 60%) clinicians wanting to adjust functionalities and the other two (40%) not wanting to change the system. Regarding functionality alterations, five clinicians proposed 11 points to improve the system and offer more pertinent data (Figure 11).

Table 3. Clinicians' evaluations of potential required adjustments to FullFlow, categorized by the results of the evaluation (to keep or adjust functionalities) and by clinical role (general practitioner, diabetes nurse, and dietician).

Role	General practitioner, n	Diabetes nurse, n	Dietitian, n	Total, n (%)
Adjust functionalities	2	2	1	5 (36)
Keep functionalities	7	2	0	9 (64)

Figure 11. Sankey diagram of the functionality adjustments proposed by the clinicians. Each color corresponds to a specific type of adjustment. Orange: new service; lilac: new data type; light green: remove functionality; green: add functionality; dark green: proposed functionality adjustment. The numbers represent the number of times an adjustment was mentioned. BG: blood glucose; IoB: insulin on board; CoB: carbohydrates on board; I:C: insulin to carbohydrate ratio.



Of the eleven functionality adjustments proposed, nine (of 11, 81.8%) were related to adding new functionalities and the other two (18.2%) were related to removing functionalities. Proposals for adding new functionalities were divided into two subgroups: new services (n=4) and new data types (n=5). New data types would require adding data types not available in the system when they were presented to the clinicians, while adding new services would mean creation of new functionalities using the data currently available in the system. Of the suggested new data types, insulin type (eg, slow or fast acting) was mentioned twice by clinicians, with the suggestion that it be available in both the overview section and the graphs. The other data types suggested were blood pressure, plasma glucose, and lipids. Of the suggested new services, clinicians twice expressed the desire to enter goals and notes directly into the Diabetes Diary of the patients through the FullFlow system. Another clinician requested more detailed blood glucose ranges such as high hypoglycemia in the overview section, and a second suggested displaying I:C values by time of the day (eg, fasting, morning, afternoon, and night). Depending on the situations of the patients, these new data types and services could "help provide more tailored advice" and "facilitate cooperation with the patients," according to the clinicians. Of the functionalities suggested for removal, one clinician proposed removing IoB and CoB from the graphical interface, suggesting that "they will not have time to investigate this data."

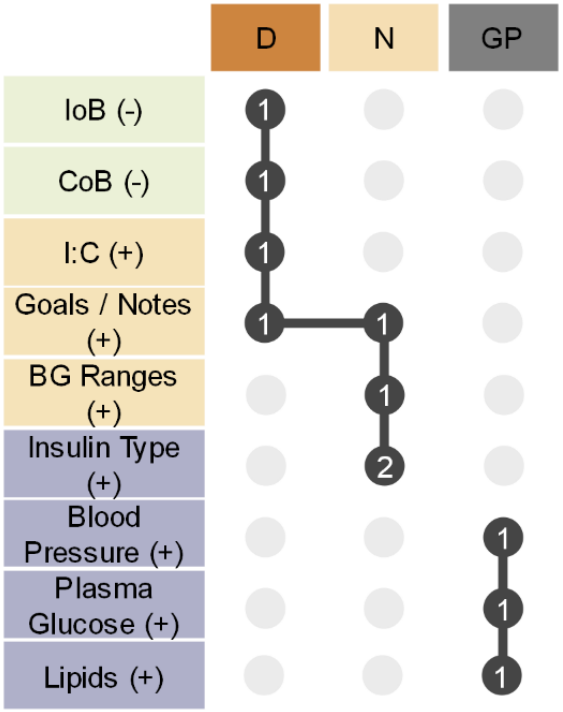
Figure 12 shows the correlation between the suggested adjustments and clinical roles. The data show that adjustment needs were disjointed between the primary and secondary health care personnel: The former group expressed the need to add blood pressure, plasma glucose, and lipids to the functionalities of the FullFlow system (mentioned once each), while the latter group did not need them. The secondary health care personnel group proposed adjusting the services available in FullFlow, while the GPs focused only on new data types.

The needs of the dietitian and diabetes nurses intersected, with the proposal of writing goals and notes directly in the Diabetes Diary of the patients via the FullFlow system (mentioned once per group). The nurses proposed recording the insulin type (mentioned twice) and a more detailed blood glucose range (mentioned once) in the FullFlow system. The dietitian was the only clinician to suggest removing features from the FullFlow system (IoB and CoB) and displaying the I:C values by time of the day.

Usability of the FullFlow System

One clinician pointed out the possibility of the system being time consuming during consultation, which could reduce its efficiency. Querying the robustness of the FullFlow system, one participant noted that insulin and carbohydrate intake times should be matched in the Combined Data graph. A bug resulting in movement of registrations on the time axis (x) when hiding or showing data types (Figure 6 E) was corrected, and registrations having the same time were shown close to each other.

Figure 12. Matrix presenting the correlation between the suggested adjustments and clinical roles (general practitioner, diabetes nurse, and dietitian). The columns represent the clinical roles and use the same color coding as the previous figures (D/orange: dietitian; N/beige: diabetes nurse; GP/grey: general practitioner). The rows represent the adjustments proposed by the clinicians and follow the same categorization and color coding as the previous figure (light green: remove functionality; beige: new service; lilac: new data type). (-) denotes a proposed functionality removal, while (+) denotes a proposed functionality introduction. The dark grey circles represent a suggested adjustment by a specific clinical role and the number of times it was mentioned by that role. The vertical lines represent logical sets, while the horizontal lines denote the intersections of the logical sets, like a Euler diagram. BG: blood glucose; IoB: insulin on board; CoB: carbohydrates on board; I:C: insulin-to-carbohydrate ratio.



Expectations and Summary

All the participants (14/14, 100%) expected that the presented system—a combination of the Diabetes Diary, Diabetes Share Live and FullFlow—would be useful during their daily consultations. They forecast that the system would be good for all patients, but particularly effective if patients enter enough data regularly in their diaries.

They predicted that three types of patients would be interested in this solution: (1) patients who are interested in technology and self-management; (2) patients concerned about their diabetes and quality of life; and (3) patients living in remote areas, where the usage of the system could support remote consultations and avoid patients travelling several hours for a single face-to-face consultation. One participant mentioned that several patients already use self-management apps, which would ease the introduction of this system.

Overall, the system was very well received by the participants and they were eager to start using it during consultations. However, the participants mentioned that experience using the system will be needed to validate their expectations and clarify the system's usability and functionality.

Discussion

Principal Results

This paper presented a dashboard for displaying patients' self-collected health data during consultations, using diabetes as a case example. The graphical interface was implemented using continuous feedback from clinicians and patients to minimize possible future user resistance by providing relevant information to meet clinicians' needs. We limited the potential increase in time consumption due to the usage of this solution by proposing information related to the quality of self-collected health data (identifying whether the data are worth consulting), displaying an overview of the situation of a patient, and identifying important medical events without the need to consult the complete data set.

The prestudy assessment showed that the solution could be effective during consultations, especially if patients live in remote areas or are interested in either mobile technologies or improving their life conditions. The majority of clinicians were satisfied with the current state of the graphical interface, and all clinicians were eager to start using it.

The prestudy assessment also showed that the needs of primary and secondary health care personnel are disjointed: GPs do not need the same data and services as diabetes nurses or dietitians. However, due to the limitations of the Diabetes Diary (see below), their wishes cannot be fulfilled.

Dashboard Functionalities and Graphical User Interface

The information provided by the KBM module, namely, the grading of the self-collected health data (Figure 4 B), the identification of trends (Figure 5 C-E), and the identification of potential causes of medical events (Figure 5 F) address two

of the main barriers of acceptance of introducing self-collected health data into consultation, namely, the distrust of this source of data [53-56] and a time increase in consultation.

The calculations presented in the overview table (Figure 4 D) can facilitate diabetes management [57-60] for both patients and clinicians. We chose to use a table for representing this information, considering that clinicians are accustomed to using tables for visually representing data, which can surpass graphs in certain conditions [61]. We used a standard pooled deviation for illustrating the variability of data type, considering that diabetes, as a chronic disease, is a day-to-day management disease and that a routine (ie, less variability of medical values) can improve the condition of patients drastically [62,63]. For instance, a low glucose variability is more important for diabetes patients than having an in-range hemoglobin A_{1c} for preventing complications [64]. Therefore, providing an indication about how much patients are able to stabilize their blood glucose values during each day is important for them. Although previous studies proposed several methods for measuring glucose variability using SD, coefficient of variability, mean amplitude of glycemic excursion, or continuous overall net glycemic action with CGM, there is a lack of consensus on which method should be used [64,65]. Moreover, these methods have drawbacks when using self-monitoring blood glucose values due to a lack of sufficient and regular number of measurements. Since our system uses available data either from CGM, self-monitoring of blood glucose, or a combination of the two, we are looking for a generic model that can work for all types of available data from the patient. It is quite optimistic to assume that patients self-register data regularly every day, because it reminds them that they are sick [66]; we used pooled SDs to weight the average of each day's SD. This weighting gives larger groups (days with more registrations) a proportionally greater effect on the overall estimate of the variability [67] and allows us to increase the robustness of statistical calculations. Clinicians agreed to use this approach. Another point to discuss is our decision to use the more accessible term "average deviation" instead of "pooled SD." We believe that this term will prevent patients and clinicians from being exposed to mathematical concepts in order to understand the value. However, the complete definition, with the formula and explanations of the term, is presented to users if they hover the mouse over the "average deviation" term. Moreover, we expect feedback on this taxonomy from the medical trial.

We decided to use the eA_{1c} functionality, although its use is contested by some authors [68,69] for allowing clinicians to compare the eA_{1c} with the hemoglobin A_{1c} results of the laboratory tests, since previous studies showed that there is a correlation between the hemoglobin A_{1c} and eA_{1c} values [70]. An important deviation between these two values could indicate a poor quality and reliability of the self-collected health data due to, for example, an insufficient number of registrations per day and can therefore be used as one of the indicators of the quality and reliability of the self-collected health data. Today, due to technical restrictions, the FullFlow system cannot integrate EHRs' data and display the hemoglobin A_{1c} value side by side with the eA_{1c}. Clinicians can consult the hemoglobin A_{1c} values in their EHRs and use FullFlow for consulting the eA_{1c}. In addition, this approach is used by the American Diabetes Association [71] and MySugr [72] and is cited in the NGSP's website [73]. However, we decided to hide the eA_{1c} value, considering that clinical workers were concerned that this value can confuse patients in Norway. Nonetheless, the system will still collect the value, allowing us to compare the calculated values against the laboratory test results or the hemoglobin A_{1c} values reported through questionnaires, to determine how this approach fits real situations. The dashboard containing the eA_{1c} may be of interest to clinicians, patients, researchers, and computer scientists.

Regarding the grading of each piece of information (Figure 4 E-I), the system uses different approaches depending on the type of data. For instance, the FullFlow relies on medical standards given by the Norwegian Directorate for Health [74] and international public entities [75] (eg, hemoglobin A_{1c} values) or values we defined during our workshops (eg, grades for the blood glucose in-range values). Some values are not graded, such as the daily amount of insulin used, because each patient follows tailored insulin therapy, depending on physiological conditions such as weight as well as lifestyle factors such as meal times and physical activity [76].

Displaying the patients' personal goals in the overview section (Figure 5 A) before the noticeable events will help the patients steer the medical consultation toward what they would like to discuss with their clinicians, as some of them are too shy to interrupt the clinicians directly, according to the feedbacks collected in the workshops.

The moving average and weighted moving average used by the daily distribution section (Figure 7) further facilitate the visual detection of patterns by clinicians, which can be useful for improving patients' lifestyle [77,78]. We are aware of other types of moving averages such as the exponential weight moving average [79] or the Hull moving average for reducing lag [80]. However, we decided to use a simple weighted moving average in the first version of the FullFlow. The decision regarding the usage of a weighted or simple moving average relies on the analysis of the FHIR artefacts. For instance, a blood glucose value obtained from a finger prick has twice the weight of a blood glucose value measured with a CGM, considering that finger pricks are more accurate than the CGMs, which require calibration [81]. The window size for calculating the moving average is set to five registrations to suppress the sheer power the CGM readings have over the self-monitoring blood glucose measurements (ie, five registrations maximum are used for calculating one value of the weighted moving average). This fact remains true even though the CGMs are becoming more accurate [82] and some do not require calibration at all [83].

Comparison with Previous Studies

The dashboard we proposed differs from others such as MySugr [84], the dashboard of Diagliati et al [48], Carelink by Medtronic [85], the clinical decision system by Sim et al [47], the system proposed by Martinez-Millana et al [86], and the platform proposed by Fico et al [87]. The main differences are listed below:

1. FullFlow does not limit the integration of data to specific companies or types of sensors: finger pricks, CGMs, insulin pens or insulin pumps can all be used by the patients.
2. FullFlow analyzes the data and proposes recommendations regarding potential causes of medical situations.
3. FullFlow provides indicators regarding the reliability of the self-collected health data.
4. FullFlow empowers patients by introducing their personal goals in the medical consultation.

Limitations

The first limitation is the size of the sample for the design and prestudy assessment phases, in which 18 clinicians and 2 patients participated. Although the sample did not permit involvement of all types of clinical roles to identify their needs and evaluate the graphical interface according to their preferences, it was sufficient for determining that the dashboard is ready to enter a medical trial.

During the prestudy assessment, one of the clinicians mentioned that (s)he was afraid that the system could be time consuming. Although the KBM can, in theory, address this issue, as we explained in a previous article [40], we fear this challenge will greatly impact the medical trial due to the technical solutions chosen.

We know that the chosen patient platform, the Diabetes Diary, is not the optimum app for all diabetes patients, as it lacks important features such as the insulin type, blood pressure, polypharmacy, and integration into glucometers and physical activity trackers for automatic data transmission. These missing features might result in a degradation of the reliability of the data and experience for the patients as well as for the clinicians, who would like to have access to these missing data, as specified in the Prestudy Assessment section. Moreover, the Diabetes Share Live solution platform, which requires many steps to be performed during consultation for viewing the self-collected health data, could degrade the experience of the users. This platform requires eight steps to share the data: (1) patients open the Diabetes Diary, (2) patients wait for the application to give a unique identification code, (3) clinicians open an Internet Navigator, (4) patients give clinicians the unique code, (5) clinicians enter the code on the Webpage, (6) clinicians choose a time period, (7) patients acknowledge the time period given by the clinicians and select the data they want to share, and (8) clinicians consult the FullFlow.

However, the FullFlow system itself is not affected by these limitations and can accept data from several applications and several operating systems. For example, while the insulin type will not be displayed during the medical trial (the system displays “Insulin Unknown”; Figure 4 D and 4 H), the FullFlow differentiates types of insulin and treats them differently when such information is available. Figure 13 shows an example of different insulin types for data collected using the MySugr app, where bolus and basal insulin types are treated as separate entities and combined to calculate the IoB by using different profiles [50]. Multimedia Appendix 2 shows an instance of the dashboard populated with other data types and demonstrated that the system is able to display any FHIR data.

Nevertheless, the medical trial will still allow us to conduct research on the relevance of the information displayed, its potential impact on medical services, and the relevance of the KBM. Although the approach and business rules of the KBM are trusted by the clinicians who were involved in its creation, the medical trial will measure trust in the system during its usage, which will depend on the situation of the patients and the data collected by them. It could also be suitable for remote consultation.

The last limitation concerns the integration of EHR data into FullFlow, which, while planned, is not yet available. Therefore, FullFlow cannot directly show EHR data, such as hemoglobin A_{1c}, and clinicians will have to use both systems during consultations. However, while not reaching its maximum potential, FullFlow will still permit the study of the integration of self-collected health data into consultations.

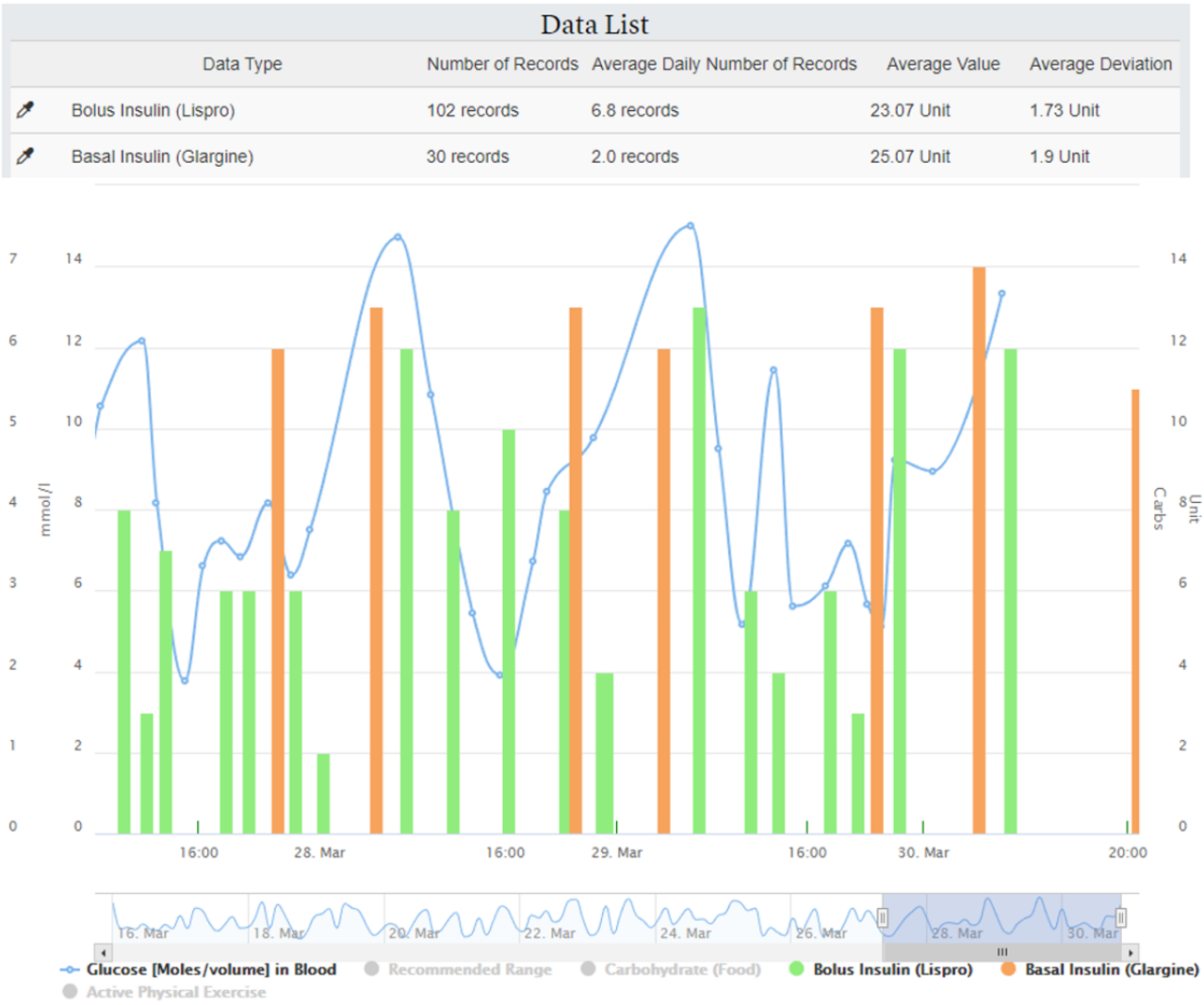
Future Research

The graphical interface can still be improved in different ways: The table in the Data Summary section could contain information related to the in-range values of each data type and be visually graded like the rest of the overview page (green, orange, red, and white). Shortcuts to the combined graph from a noticeable event could be made, with automatic selection of data to display or hide. It may also be possible to see self-collected health values day by day, with the current day values displayed in a large graph at the top of the page and all other days’ values listed under this graph as smaller graphs, one per day; we could also add daily computational glucose variability using SDs to the top of the overall graph.

We believe that the results from the medical trial, in which clinicians use FullFlow in their daily consultations, are necessary to assess what information is useful to add or remove, before changing the graphical interface. Nevertheless, we believe that the proposed dashboard is a viable temporary solution, and ensuring interoperability of the data using standards and terminologies will allow the independence of the EHRs and permit users to display the information in the ways that benefits most of their users.

The graphical interface could also be improved by adding dual signaling for visually impaired people. For instance, the data summary table in the overview section could integrate visual cues, such as equals signs or arrows pointing up or down, to indicate whether values are in range or out of range. These signs could be added below the values displayed in circles in the overview section or even used as texture.

Figure 13. Example of data list and combined data with different types of insulin.



In addition, reports do not contain information regarding the patients themselves (eg, names or identity numbers). This is due to the usage of the Diabetes Diary and Diabetes Share Live. It will not affect the medical trial, given that clinicians and patients use the system in real time together and clinicians can export the reports to their EHRs, where the patient will already be selected. Notably, clinicians would like to write goals or notes directly into the patients' apps using the FullFlow system, which is outside the scope of the study at this stage; we would suggest that patients use their mobile apps themselves to directly create the goals defined in collaboration with their clinicians during consultation.

Although the system can read and display any data types as long as they are in an FHIR format, it will use only "registered" data types for advanced services (eg, blood glucose, insulin, blood pressure, and menstruation), such as grading data reliability or exploring potential causes of medical events. The registered data types are listed in another article [40]. We plan to add new business rules for new data types in the future, such as lipids (as requested by a clinician) or foot temperature for early detection of injuries due to diabetic neuropathy. Multimedia Appendix 2 shows an example of the graphical interface containing lipids as "unregistered" data type and six registered data types.

Conclusions

The designed dashboard could ease the introduction of self-collected health data during medical consultation by providing relevant information about the situation of the patients, the reliability of the data, and important medical events without the need to consult the data in details. Moreover, the designed dashboard could be an effective solution for face-to-face and remote consultations.

A medical trial, started in November 2018, will provide medical context and document user experience and medical outcomes through usage logs, interviews, and surveys and will help us adjust and improve the dashboard in terms of its graphical interface and functionalities. The results are expected in the beginning of 2020.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Transcribed answers to the collected questionnaires.

[PDF File (Adobe PDF File), 73KB - diabetes_v4i3e14002_app1.pdf]

Multimedia Appendix 2

Example of the graphical interface with different data types.

[PDF File (Adobe PDF File), 149KB - diabetes_v4i3e14002_app2.pdf]

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Abbreviations

CGM: continuous glucose monitor
CoB: carbohydrates on board
eA $_{1c}$: estimated HbA_{1c}
EHR: electronic health record
FHIR: Fast Healthcare Interoperability Resources
GP: general practitioner
GUI: graphical user interface
I:C: insulin-to-carbohydrate ratio
IFCC: International Federation of Clinical Chemistry and Laboratory Medicine
IoB: insulin on board
KBM: knowledge-based module
NGSP: National Glycohemoglobin Standardization Program

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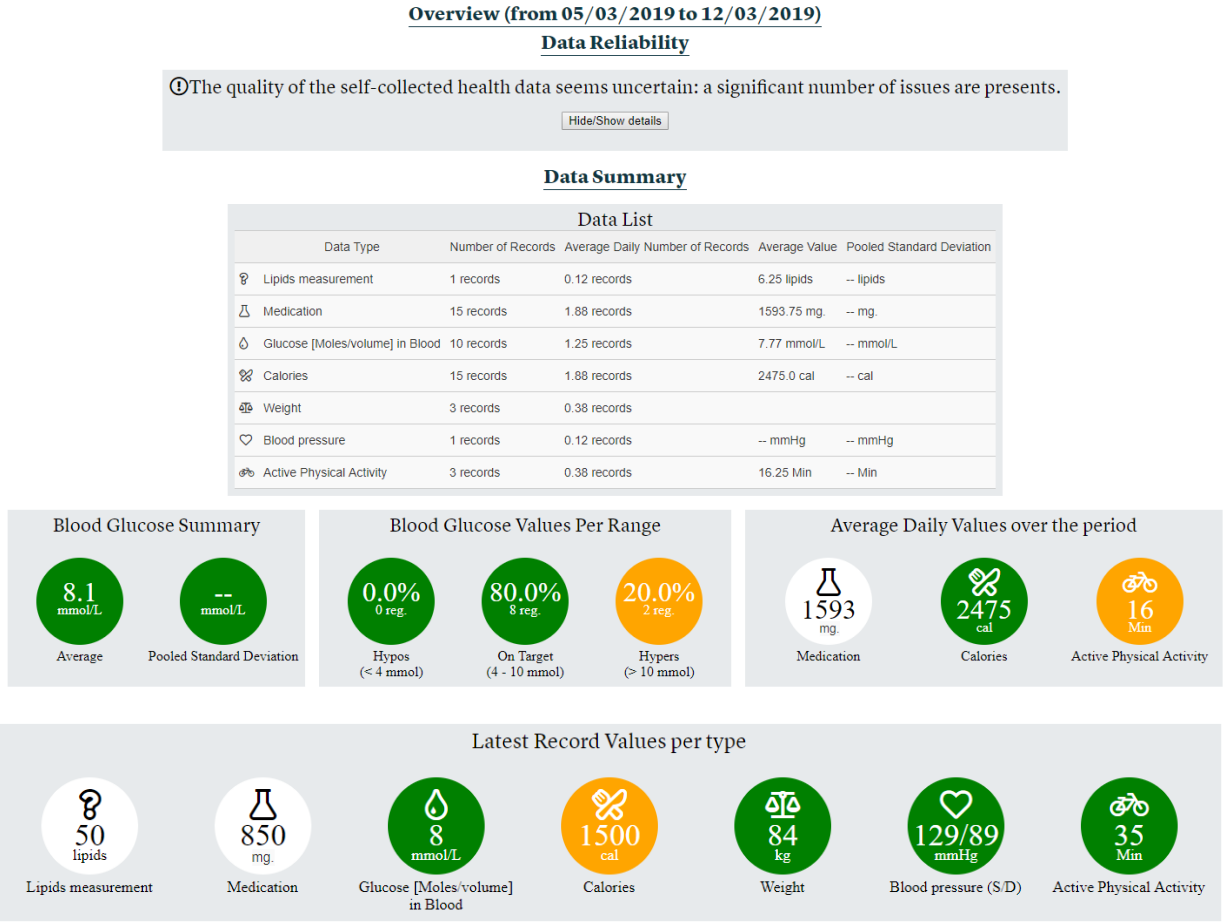
Example of the graphical interface with different data types. Differences with the screenshots provided within the article:

1) Concerns T2D patient with oral medication, blood pressure and weight;
2) Low data quality;
3) Unregistered data type (Lipids) – manually generated;
4) No Hba1c due to too low number of blood glucose registrations;



Role	Q1	Q1b	Q2	Q2b	Q3	Q3b	Q4
Dietitian	Yes	Useful for patients *who have Android phones* and are technologically interested only.	Yes	Possibility to use the system to define and write goals. More detailed insulin to carbohydrates ratio at different times of the day (breakfast, lunch, afternoon, evening)	Yes	Active Insulin Carbohydrates on Board	Match between time for insulin and time for carbohydrates intakes
Diabetes Nurse	Yes	I think the system will be useful, but I have few consultations per day. This is a good option for users who like to use mobile application for registrations.	No	*Patients would like to enter non-diabetes related drugs taken at fixed time, and this could be automatic and/or easy to enter*	No	Not now	*Have patients' opportunity to write the type of carbohydrates they eat (the amount may not be always enough)* This solution may be good for everyone, and especially for patients living at long distances and for patients who follow technology development.
Diabetes Nurse	Yes	*The Diabetes Diary can replace written diary.* Several patients use other apps today and are used to them and their functionalities	No	I think the system can be time consuming. No more information should be added now.	No	-	When hovering over the carbohydrates registration show what the patients have eaten.
Diabetes Nurse	Yes	-	Yes	Insulin type.	No	Need experience to answer this	Notes from the consultation should be possible to add to the diary
GP	Yes	Only for patients who are a bit concerned about their diabetes	No	-	No	-	Must use the system to be evaluated again.
Diabetes Nurse	Yes	It depends if the patient has entered enough data.	Yes	Would like to have the distribution of slow and fast acting insulin.	No	Don't know yet, but I think I'm going to use the Combined data Section the most	What about different colors on the bar for slow-acting and fast acting insulin? On the overview, display blood glucose above 15 mmol/L and under severe hypos (under 2.8 mmol/L) in a separate body.
GP	Yes	-	Yes	Blood Pressure	No	-	Desire to insert lipids
GP	Yes	-	No	-	No	-	-
GP	Yes	-	No	-	No	-	*Have the possibility to register data automatically directly from Strava, blood glucose devices, insulin pen etc.*
GP	Yes	-	Yes	Plasma glucose	No	-	-
GP	Yes	-	No	-	No	-	-
GP	Yes	Can motivate new patients to join in	No	-	No	-	-
GP	Yes	-	No	-	No	-	-
GP	Yes	-	No	-	No	Do not know yet	-

- Q1: Do you think the system will be useful during consultation? Q1b: Potential comments
- Q2: Would you like to have more information delivered by the FullFlow system? Q2b: Potential comments
- Q3: Would you like to remove or hide information delivered by the FullFlow system today? Q3b: Potential comments
- Q4: Do you have any feedback you would like to give to us?

Comments in green concern the Diabetes Diary only and are outside of the scope or the article.

Systems integrating self-collected health data by patients into EHRs and medical systems: a State-of-the-art review

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Abstract

This template may be used for articles in journals or conference articles. Differences may occur, of course, and this template is only a guide how it may appear. Patients are being more and more autonomous in their disease management by collecting, viewing and analyzing health data themselves with the support of sensors, wearables and smartphone apps. Self-collected health data can be used by the medical environment to provide more tailored and efficient therapies. This paper presents a state-of-the-art review (per April 2017) on systems integrating self-collected health data by patients into Electronic Health Record (EHR) systems and other medical systems assessable for the clinicians at the point of care.

Keywords

self-collected data, wearable, sensor, EHR, integration

1 INTRODUCTION

Patients are increasingly using m-health services and applications for storing, viewing and analyzing their self-collected data, as an answer to geographical, temporal and organizational barriers in healthcare (Tachakra et al., 2003). Studies have showed that self-collected data and self-management is beneficial and effective for managing chronic diseases, especially in diabetes (Norris et al., 2001). Moreover, wearable devices and sensors become more and more important for long-term self-management (Haghi et al., 2017) by allowing automatic data collection without the intervention of patients. Also, systems permitting cooperation between empowered patients, collecting their own health data, and medical workers, have been proved to have a positive effect on their satisfaction managing patients' chronic diseases (Peleg et al., 2017) by providing patients mentoring and knowledge they will not be able to gain on their own. However, these studies are limited to specific cases and relies on custom cloud systems and on specific sensors to deliver their services. Therefore, these studies do not present a standard integration between patients' and EHR systems, i.e. enabling only exchange of some kind of data in separate systems. This is curbing cooperation between patients and medical workers, leading to security, transparency and privacy issues. Also, needing to relate to vendor-specific systems implies that patients cannot choose freely among systems or sensors that suit them the most, according to their experiences or preferences.

This paper presents a comprehensive review of the state of the art of systems that directly integrate patients' self-collected data into EHRs and similar medical systems, and the implications on security and privacy of such systems.

The results will be used as a basic set for the design and the development of a system allowing self-collected health data transmission between diabetes patients and healthcare institutions systems in Norway.

2 METHODS

2.1 Scientific literature search

The scientific literature search followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology. Keywords and the search query were selected through brainstorming sessions with the authors (see Figure 1). Terms including "Fast Healthcare Interoperability Resources (FHIR)" or "OpenEHR" were omitted because they represent solutions for solving interoperability issues and usually do not include specific systems as was the target of this review. Considering the novelty of sharing patient-collected data, only peer reviewed articles published after 2012 were considered. The following online databases were searched: Pubmed, ACM Digital Library, IEEE Xplore and Scopus. The search query has been adapted for each online database considering their operational functions and restrictions and was run using the metadata fields: title, abstract and keywords.

All scientific papers resulting from the database searches were imported into Rayyan (Ouzzani et al., 2016), a web service allowing a structured review of titles and abstracts, which was used by the authors for improving collaboration and quality assurance of the process.

Paper from the SHI2017 conference, 29-30 August 2017, Kristiansand, Norway
Conference Proceedings published by Linköping University Electronic Press.

(EHR or "Electronic Health Record" or "Health System" or "Medical System" or "Health Information System" or CDS or "Clinical System" or "Clinical Decision Support" or "Clinical Decision Support System" or EMR or "Medical Records" or EJS or "Electronic Journal System")
and
(interoperability or communication or exchange or integration or collect or transfer* or shar* or stor* or gather* or record*)*
and
(wearable or mhealth or phone or apps or "Mobile health" or sensor)

Figure 1: Search query and keywords used for the scientific literature review

Two of the coauthors identified irrelevant articles using metadata fields while considering inclusion and exclusion criteria. The first author then reviewed the remaining articles for inclusion based on relevance of the full texts.

2.1.1 Inclusion and exclusion criteria

To be included in the review, the paper should describe a solution that facilitate a direct integration of patients' self-collected data into the healthcare system, pre- or at the point-of-care, or in real-time.

Studies are included only if they describe an evaluation, an implementation, a review, a working solution or prototype transferring patient self-collected data into medical systems, or are related to the security or privacy for accessing and managing the medical data self-collected by the patient by such system.

Studies that required healthcare workers to log onto a service outside their healthcare institution's EHR system in order to consult the data (e.g. a cloud-based data consultation service such as a Personal Health Record System (PHR) on Internet) were excluded. Several reasons justify this exclusion:

1. Healthcare workers are not willing to spend time to use separate Internet tools (Bradway et al., 2017).
2. The healthcare workers do not have knowledge of all relevant cloud-based or Internet-based solutions available, and how to use them(Bradway et al., 2017), and.
3. The data from such systems is usually not directly transmitted to the healthcare system (often the healthcare workers must take screenshots or copy the data into their EHR system manually).

However, studies including PHRs directly integrated within EHRs, were included, being part of the healthcare institution system.

In addition, the papers must describe data that is collected by the patient themselves using their own system, e.g. apps or sensor systems, which could be obtained from a healthcare or a research institute. Studies relying on "collector agents", typically medical workers visiting patients at home for collecting data, were also excluded.

2.1.2 Data categorization and data collection

The information mined from the papers was organized into categories, defined by the authors through brainstorming sessions, and were used to present an aggregated overview of the current situation:

1. *Patient data sources*: systems, e.g. sensors, apps or aggregators, that allow patients to collect data themselves.
2. *Data collection*: whether data sharing required automatic or manual interaction from the patients or the medical workers.
3. *Patient data type*: whether the data collected from the patient is structured (e.g. measurements values with units) or un-structured (e.g. videos or general notes).
4. *Interoperability*: which standards the system is using for data transfer, representing clinical documents, and/or terminologies (e.g. SNOMED-CT). Note, again, that for this review, we focused only on interoperability between the patient system and the medical system.
5. *Security*: which security protocols or approaches have been followed for either collecting, sharing, storing or analyzing the data; for authenticating patients; or for ensuring privacy.
6. *System services*: the types of services, applications or state of development of the project (e.g. proof of concept, prototype, or commercial).

The evaluation and analysis were based on these categories and each paper is expected to fulfill at least one of them to be included.

2.2 Grey literature search

The search query (Figure 1) was also applied to both the Google and Bing search engines. The same inclusion and exclusion criteria were applied, but was extended to different type of results, including webpages and business documents. The data categorization, data collection and literature evaluation followed the same procedure.

3 RESULTS

3.1 Combined reviews on literature

As shown in Figure 2, 811 articles were identified from the scientific literature and 4 from reviews of commercial product and business reports. Eighty-three duplicates were identified and removed in Rayyan after importing the articles. Two of the co-authors reviewed the resulting articles' titles and abstracts independently based on the inclusion and exclusion criteria. Discrepancies (i.e. when articles were included by one author but excluded by the other) were resolved through discussion. In total, 682 articles were excluded, leaving 50 articles for full-text assessment. The first author then identified n=40 articles for exclusion based upon the following reasons:

- Out-of-scope study or review (e.g. focus only on reducing latency between mobile phone and healthcare systems) (34).
- Inaccessibility of the full-text article (3).

- Inappropriate study objectives and methods: description or testing of a model for integrating self-collected patient data that does not have either a working prototype or any low-level description of such system for replication (2).
- Inappropriate technology usage, e.g. use of Short Message Service (SMS). This technology for chronic disease management restricts the patient regarding how they enter and exchange data (1).

At the end, 10 articles were included for final data collection.

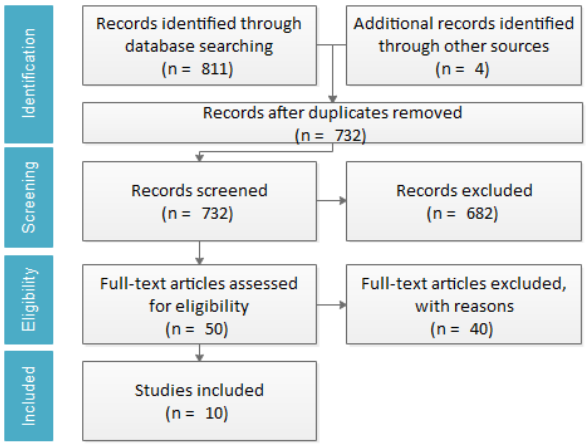

Figure 2: PRISMA flow diagram

3.2 Data Extraction from included articles

The evaluation and analysis of the included articles (Table 1) is based on the categorizations described previously in the methods section.

3.2.1 Functional solution

To the best of our knowledge, there were no standard and stable end-to-end systems permitting patients to share their own-collected data with EHR systems when this review was completed (April 2017). Eight of the papers presented a functional solution that described the design and usage of custom interfaces, Application programming interfaces (APIs), apps and/or restricted sensors in order to provide their services. Only three described an end-to-end system.

The closest solution to a fully operational system is the pilot described by Kumar et al. (2016), in which glucometer measurements were collected automatically by a specific IOS application, Share2, from the Dexcom G4 glucometer sensor worn by the patient. The data is then transmitted to HealthKit, then transmitted to the EPIC EHR system through MyChart app, a patient portal integrated with EPIC, to display data. This system requires explicit consent of the patient before allowing data transfer between the HealthKit and MyChart. Unfortunately, this system includes some limitations:

- Time consuming: the one time setup requires to spend between 45 to 60 minutes in addition to the clinic visit;
- Performance issue: with up to 288 glucose readings per day, MyChart standard flowsheet was unable to visualize the patient trends over weeks to months and the MyChart app displayed errors and froze due to the high volume of data communication. These errors were fixed by limiting the import of data only from the preceding 24 hours and developing a custom web-service in the EHR system.

The second end-to-end system was a proof of concept (POC), described by Marceglia et al. (2015), where data was collected from an IOS app and sent to OpenMRS EHR through the Clinical Document Architecture standard (CDA), and using data related to heart failure. The opposite flow (from EHR to mobile app) was implemented as well. Unfortunately, this POC was validated using a simulated environment only.

The third end-to-end system, presented by Pfiffner et al. (2016), focused on gathering self-collected patient data for research purposes. To do so, the system relies on Ctracker, an IOS created by this project, in combination with ResearchKit and Healthkit. On the medical side, the solution relies on the Informatics for Integrating Biology and The Bedside (i2b2), which is a research framework aiming to facilitate the design or tailoring of therapies and integrated in academic health centers. While i2b2 is not an EHR system, it is part of medical systems and therefore fulfills our inclusion criteria. Surveys and HealthKit data are collected. FHIR is used to manage the data exchange between all of these components.

Five articles dealt with systems that do not provide an end-to-end solution, but instead describe interfaces to missing components. For instance, the self-managed mobile personal health record system (SmPHR) described by Park et al. (2016) relies on the personal area network (PAN) and the wide area network (WAN) interfaces defined by the Continua standards to collect data from sensors and transmit them to health systems. Blood pressure, body weight, blood glucose and oxygen saturation are collected from sensors paired to the SmPHR and transmitted into a PHR. Other studies (Leijdekkers and Gay, 2015, Gay and Leijdekkers, 2015) describe the same smartphone application, MyFitnessCompanion, which aggregates fitness data from different online services (e.g. FitBit), Bluetooth Low Energy (BLE) and Universal Serial Bus (USB) devices and rely on other online services like HealthVault for *potentially* sharing data with EHR systems, using Health Level Seven (HL7) standard family for ensuring interoperability. The learning health system PORTAL (Young et al., 2014) relies directly on the EHR systems part of their network for gathering patient data which *could* be self-collected. The personal mobile health record system (PmHR) proposed by Song and Qiu (2016) relies on a PHR cloud solution for sharing data, using CDA documents in combination with Snomed and Logical Observations Identifiers, Names, Codes (Loinc). Blood glucose, blood pressure, heart rate and heart rate variability, electrocardiography (ECG), weight, height and temperature are measurements used by the app.

On the 8 studies, 7 mention using apps as a source for data gathering, 6 reference using managers or aggregators, 5

declare using sensors. An EHR and a Cloud system are also mentioned 1 time each. The data collecting process is automatic in 7 cases, and none but one describes a required manual setup to access the services. The data collected is structured in 6 cases, unstructured in 1 and both in 1.

3.2.2 Security and privacy

Concerning the privacy, Hordern (2016) proposes an analysis of the protection of health data. According to this study, Health data is defined as personal data including *medical aspect of a person such as test results, doctors' notes, medical research* but as well as data collected by self-management sensors. However, a legal framework is lacking for Health data due to its diversity of services (e.g. smartphone apps, cloud, big data, and sensors). However, in a general approach, there are three requirements:

- Explicit consent from the patient to process health data, except if this data is necessary for carrying out obligations or in case of emergencies or medical diagnosis;
- A transparency notice informing the patient which, how and why the health data has been collected, and how it will be used;
- Full access to the health data collected, for allowing patients to consult and move data between providers.

The study also highlights the need to have controllers and processors. A controller is an entity which collects data for its own purposes (e.g. hospital) and is responsible for legacy compliance. A processor is a third party entity that uses personal information on behalf of the controller. This should comply with the controller instructions regarding health data storage and process, which requires a contract. This adds complexity: if the data is collected by a hospital directly from a patient, the hospital is a controller, in which case, it is straightforward to comply with the laws. However, in a situation where a sensor, an app, a cloud solution and an EHR are required to mutually share self-collected patient data (example described in the previous section), there are several unanswered questions: is the EHR, the app or the cloud service the controller and provider? Should all of these entities have a contract with the patient or merely between each-other? Should the end service (EHR) validate the whole exchange?

Concerning the security, Rubio et al. (2016) propose an analysis of and possible improvements for the security of the European standards regarding communications between medical, health care and wellness devices, sensors or systems (CEN ISO/IEEE 11073), especially involving personal health data (X73PHD). In our case, the highest level security described in this study corresponds to our criteria: level annotated layer 2.5 and it describes solution '*intended for applications which may require integration with EHR systems […] intended for patient remote monitoring, follow-up and laboratory-test*'. The study by Rubio et al. (2016) proposes the use of improved Integrating Healthcare Enterprise (IHE) profiles in 4 security-related categories: user identification, device identification and authentication, time coordination and encryption and proposes solutions and algorithms for doing so such as Twofish, RSA2048 or ECDSA256.

Considering that patient data could be stored on servers outside of the European Union (e.g. Healthvault or FitBit servers) and the huge amount of services/apps available, implementing a service for sharing self-collected patient data with EHR systems compliant with European privacy and security rules is extremely challenging.

3.2.3 Semantic interoperability

The semantic interoperability ensures that different systems are able to exchange, understand and analyze the data correctly by using standards for communication, medical representation (documents) and terminologies (Mead, 2006).

Among the previous 8 studies, 6 of them are describing the use of the HL7 family to ensure interoperability (4: CDA/ Continuity of Care Document (CCD)), 1: FHIR, 1: Continua WAN). Snomed-CT is described in 3 of them, 2 mentioned using the International Classification of Diseases (ICD), 1 Digital Imaging and Communications in Medicine (DICOM) and 1 LOINC. Surprisingly, there is no implementation of archetypes or the OpenEHR approach in these studies, even if there are mentioned (Marceglia et al., 2015).

However, using the same standard family is not enough for insuring interoperability, but the discussion is outside of the scope of this paper. None of the solutions described in the previous studies provide interoperability with each other's, and relies upon a custom approach as described in the previous section.

4 DISCUSSION

The focus on Decision Support Systems extracting data from patient self-collected health data systems and EHRs could explain the limited number of relevant papers identified in the scientific literature review (10 of 732), on top of the reasons cited in the results section.

Also, the trend of patients managing their diseases in the palm of their hands with health applications, e.g. PHRs, sensors and hacking commercial systems, which collect data without using proprietary solution, for privacy reason (Gay and Leijdekkers, 2015), is growing (Muzny, 2017). New sensors are developed and launched on the market at a more rapid pace than ever before, and more types of data can used directly by patients. One example is Tytocare (http://www.tytocare.com), which is providing new sensors for examining the ears, throat, heart, lungs, abdomen, skin, and capturing heart rate and temperature. New open source operating systems for wearables and sensors such as Google Wear will also help standardize the ecosystem and improve the semantic interoperability between components in the future. Even if there is no standard exchange between patients' self-collected data system and EHRs today, the authors believe this situation will evolve quickly. Businesses and researchers are more frequently acknowledging the new trend where patients are the center and key decision makers of their health services. This will lead to the design of new medical protocols and procedures in which patients are more

empowered (Mantwill et al., 2015, Lamprinos et al., 2016). Additionally, businesses will increasingly shape their communication around the patients themselves (e.g. "With the Patient at the heart" catchphrase of EPIC Systems, http://www.epic.com). Even legal authorities are aware of these evolutions, but have not yet been able to provide an operational legal framework for the security and privacy for protecting patients and health institutions. It is also necessary to protect such systems against data forging(Hordern, 2016), which could lead to medical errors, and hacking of wearables, and subsequent risks to patients including death in certain circumstances (Halperin et al., 2008).

5 CONCLUSION

Our findings indicate that there are no standard and stable end-to-end system permitting the sharing of patient-collected data with EHR systems when this review was completed (April 2017). We suggest that this may be due to:

- Business models that currently only describe closed, proprietary and custom applications, interfaces and protocols;
- A lack of legal framework concerning the security, privacy and transparency of systems dealing with self-collected health data. The European General Data Protection Regulation (GDPR) can provide partial answers to the questions cited in the results section, but will not be enforced before next year;
- The complexity of integrating international and external aggregators or applications in such system, and the complexity of assuring a semantic interoperability between all actors;
- The large amount of patient-collected data that re-quire more coordinated and efficient ways of analyzing and following up this new type of information.

However, the variety of data collected from sensors and wearable is expected to be important, from fitness activity to more advanced medical data such as ECG and blood values (glucose, lipids, etc.). Patients can now buy more and more sensors, which are not just limited to activities trackers and smartwatches anymore, but include a wide range of exotic solution like e-clothes (e.g. smart-bras, smart-socks, smart-caps) and medical sensors such as HRMs or CGMs. Unfortunately, most of the businesses manufacturing these sensors close their solutions using private protocols and standards forcing patients to use their in-house developed applications to consult the data. This has led to a situation where patients are not waiting for the businesses to open-up anymore, and hack the protocols to extract, share and use the data the way they find to be the best for their health challenges.

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7 ACKNOWLEDGEMENT

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Ref.	Data Sou. *	Data Coll. **	Data Type ***	Interoperability	Security Privacy	System
(Song and Qiu, 2016)	App	Aut.	S U	CDA, SNOMED, ICD-10, DICOM		Personal Mobile Health Record (PMHR)
(Rubio et al., 2016)	App, Man			ISO11073, X73PHD, HL7	Twofish, RSA2048, SHA512, RIPEMD256, ECDSA256	
(Pfiffner et al., 2016)	App, Man	Aut.	S	FHIR	OAuth2, AES 256, PKCS7, UUID, Explicit consent	End-to-End Research (ResearchKit, HealthKit i2b2)
(Park et al., 2016)	App, Man, Sen	Aut.	S	Continua-based	Continua-based	Self-management Mobile Personal Health Record
(Kumar et al., 2016)	App, Man, Sen	Aut. Man.	S	CCD-HealthKit	Explicit consent	End-to-End (Epic HER, HealthKit,Share2)
(Horder n, 2016)	App, Man, Sen, Cl				Transparency disclosure, Explicit consent, data access	
(Marceglia et al., 2015)	App	Man.	S	CDA2, SNOMED, LOINC	De-identified data, XPHR	End-to-End POC (OpenMRS, IOS app)
(Leijdekkers and Gay, 2015)	App, Man, Sen	Aut.	S	HL7 (CDD-HealthVault)	OAuth2	Android App (Healthvault, Google fit, Fitbit, Jawbone, Withings)
(Gay and Leijdekkers, 2015)	App, Man, Sen	Aut.	S	HL7 (CCD-HealthVault)	OAuth2	Android App (Healthvault, Google fit, Fitbit, Jawbone, Withings)
(Young et al., 2014)	Ehr	Aut.	U	CESR CDM, SNOMED, ICD		Portal network member

Table 1: Papers included in the review ordered by date.
*Patient-data source: App=mobile applications, Man=Managers/aggregators, Sen=Sensors, Ehr=EHR, Cl=Cloud. **Data collection: Aut=Automatic, Man=Manual. ***Patient data type: U=Unstructured, S=Structured. Empty field means the subject was not described in the paper.

Possible usages of smart contracts (blockchain) in healthcare and why no one is using them

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Abstract

Security, privacy, transparency, consent and data sharing are major challenges that healthcare institutions must address today. The explosion of the Internet of Things (IoT), the enactment of the General Data Protection Regulation (GDPR), the growing trend of patients self-managing their diseases and the eagerness of patients to share their self-collected health data with primary and secondary health organisations further increase the complexity of these challenges. Smart contracts, based on blockchain technology, can be a legitimate approach for addressing these challenges. Smart contracts define rules and penalties in an agreement, enforce those rules and render them irrevocable. This paper presents a state-of-the-art review (as of May 2018) of the possible usages of smart contracts in healthcare and focuses on data sharing between patients, doctors and institutions.

Keywords: smart contracts, healthcare, blockchain

Introduction

Since the enactment, in May 2018, of the General Data Protection Regulation (GDPR), the security, privacy, transparency and consent for patientowned medical data have been at the forefront of the concerns of healthcare institutions. The explicit consent of patients for processing health data and the transparency notice explaining what data will be collected, how it will be collected and patients' rights to full access to their health data [1] have greatly affected healthcare information systems.

In addition to the data generated by healthcare institutions, patients are increasingly active in managing their diseases by collecting health data using mobile devices and sensors [2]. Sharing patients' self-collected data with medical systems has a positive effect on disease management [3], and patients are eager to participate [4].

Blockchain technology is receiving extensive publicity in healthcare and has promised great improvements, such as smart healthcare management and patient empowerment [5]. Smart contracts implemented using blockchains, sometimes referred to as Blockchain 2.0, are protocols permitting the verification and enforcement of legal agreements between two or more parties and rendering them irrevocable. Interest in smart contracts has been growing ever since the creation of Ethereum, the first blockchain-based solution that integrated smart contracts, which was publicly released in 2015. Smart contracts can allow patients to manage access to their health records, secure data exchange and ensure privacy of those exchanges [6].

This paper presents a state-of-the-art review of the possible usage of smart contracts in healthcare, their objectives and their limitations, with a focus on data sharing, and discusses why no one is using them in a real situation today.

Methods

Scientific and grey literature search

The author followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology to perform a scientific and grey literature search. Figure 1 shows the keywords and the search query selected by the author. Three peer-reviewed online databases were searched: PubMed, IEEE Xplore and Web of Science, together with Google Scholar. The author tailored the search query for each online database according to its specific functionalities. The search query was limited to the metadata fields: title, abstract and keywords.

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smart contracts[Title/Abstract/Keywords] AND
(clinical[Title/Abstract/Keywords] OR
healthcare[Title/Abstract/Keywords])

Figure 1: Search query and keywords used for the scientific literature review.

The author imported all the results from PubMed, IEEE Xplore and Web of Science, as well as the results displayed on the first page of Google Scholar, to Rayyan [7], an online tool that facilitates the review process. The author chose Rayyan based on its lack of cost and flexibility compared to other tools [8]. The author first excluded results based on their metadata fields (title, abstract and keywords) using criteria listed in the next section. The author then reviewed the remaining results for inclusion based on the full texts.

Inclusion and exclusion criteria

The papers needed to meet several criteria to be included in this review. The papers needed to do one of the following:

- Describe a model or an implementation using smart contracts in a healthcare-related situation;
- Illustrate an idea for, or the potential effects of, smart contracts in healthcare systems or medical workflow.

Systematic or literature reviews that provided sufficient information regarding smart contract usages in healthcare were also included.

Papers focusing on the blockchain technology stack or smart contract algorithms, but without illustrating their uses in a clinical setting, were excluded.

Studies reported in languages other than English were excluded.

Data categorisation and data collection

The content of the papers has been organised according to a taxonomy defined by the author for presenting an overview of the usage of smart contracts in healthcare. The categories comprise the following:

1. *State of the presented work*: the part of the life cycle in which the described work is positioned (e.g. proof-of-concept [POC], prototype, production);
2. *Objective*: the situations in which the smart contracts can be used and what their goals are, or what challenges they are addressing;
3. *Content of the smart contracts*: the data or information that the smart contracts contain;
4. *Technology stack*: the frameworks, components, software or standards on which the smart contracts rely on;
5. *Concerned Actors*: the actors affected by the introduction of the presented work in healthcare (e.g. electronic health records vendors, clinicians, patients);

The author used these categories to evaluate and analyse the included papers. Each included paper was expected to address at least one of these categories.

Results

Reviews on literature

Figure 2 shows the selection of articles. In total, forty-three articles were identified from the literature search: thirty-three from peer-reviewed literature and ten from Google Scholar. Eight duplicates were identified and removed. The author reviewed titles, keywords and abstracts of thirty-five papers, and fifteen were excluded based on the criteria specified in the previous section, leaving twenty articles for full-text assessment. Ten further articles were identified for exclusion for the following reasons:

- Out-of-scope papers (8): five papers cited healthcare settings as potential examples but did not include them at any stage of their studies, while two others limited their trials to blockchain technology that did not involve smart contracts. One paper focused on metrics for assessing blockchain-based healthcare apps instead of describing a model or an idea.
- Inappropriate description (1): the description or testing of an idea included insufficient details that would permit solid reproduction of the claims made.
- Full article innaccessible for review (1).

Ten papers were included in the final collection and analysis.

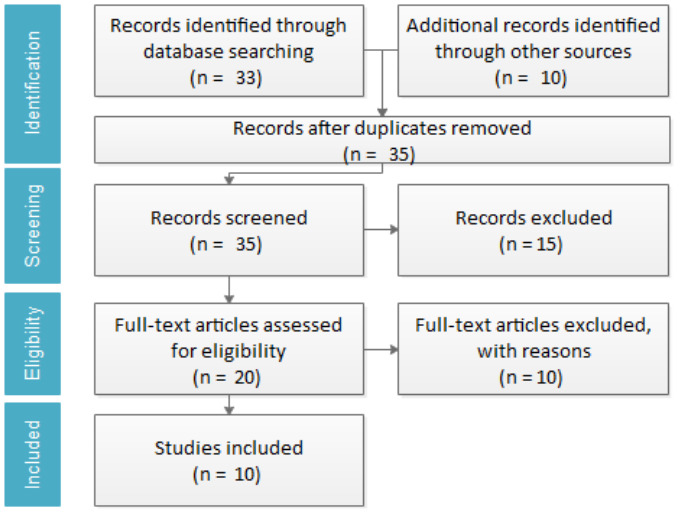

Figure 2: PRISMA flow diagram

Data extraction from included articles

The evaluation and analysis of the included articles (Table 1) are based on the categorizations described previously in the methods section.

State of the presented work

It is important to note that none of the nine studies (omitting one literature review) presented have reached the production stage. Of the nine presented studies, one is a model (i.e. a solution not entirely functional), three are POCs (i.e. demonstrating the feasibility of a concept) and five are prototypes (i.e. providing almost all features of an end product). None have been tested in a real-life situation.

Objectives of smart contracts, their contents and concerned actors

Six studies use smart contracts for managing data sharing. These studies concern patients, medical workers and healthcare institutions.

- Dubovitskaya et al. [9] defined a prototype using smart contracts for exchanging data between patients and doctors and to manage access permissions. The smart contracts contain three types of blocks: 1) patient-defined permissions for allowing doctors to access or share patient- or healthcare-generated health data. The permissions can specify a data category, particular rights (read, write and share) and a timeframe. They can also force the anonymisation of data. 2) clinical metadata, which contains all required information for accessing the corresponding data files stored off-chain (i.e. in a classic cloud solution). The clinical metadata also contains a hash of the data files to ensure the unforgeability of the data stored in the cloud. 3) patient private data directly attached to the chain by the patient, such as self-collected health data. This is the only prototype system that allows patients to exchange their data actively, without relying solely on data generated by healthcare institutions.
- Dagher et al. [10] proposed using six smart contracts as access controls for sharing medical records between healthcare and insurance providers. The first contract records the users and the mining operations. The second classifies users as patients, providers or third-parties. The third defines the relationships between users. The fourth defines the ownership of medical records, the fifth specifies the access permissions for those records and the last shares symmetric encryption keys (SEK). Patients interact with the blockchain by changing the access permissions, while the providers

use the SEKs to encrypt or decrypt medical records before sending or after receiving them via an off-chain communication channel.

- Azaria et al. [11] used several smart contracts in their data-sharing prototype for different purposes: 1) registrar contracts, which map participant (=patient) identification strings (e.g. social security numbers) to their public signing keys to be used in a blockchain. These contracts also contain policies regarding the creation or updating of identities, and only certified institutions can generate them. 2) patient–provider relationship contracts, which allow patients to fine tune the access rights of their providers regarding any portion of their medical data. These contracts also contain data pointers and can be used between providers. 3) summary contracts, which contain the history of all contracts signed by all parties. For instance, they include all the patient–provider relationship contracts of a patient, who can consult them. They also act as a backup.

- Xia et al. [12] used smart contracts for sharing medical data between cloud providers and medical and research organisations. The smart contracts are used for three main purposes: 1) encrypting medical reports, 2) identifying actions performed on sent data and 3) revoking access to violated data. The smart contracts contain a data sensitivity level, IDs of the owner and requestor (i.e. who is requesting the data), data IDs, permissions and the cryptographic keys.

- The POC defined by Ahram et al. [13] used smart contracts but for limited purposes compared to the previous studies. First, a smart contract ensures that a patient and only a patient is creating the initial version of their medical records during the first visit to a clinic. A second type of smart contract then ensures the update or transfer of the medical record by or to a provider.

- The POC by Saravanan et al. [14] used smart contracts for sharing health data with clinicians that has been self-collected using sensors. The contracts contain access logs and the shared health data. This solution requires patients to share their private keys with their clinicians off-chain before starting to use the solution.

Two other studies rely on smart contracts for improving medical trials. These studies concern researchers, participants in medical trials and research institutions.

- Benchoufi and Ravaud [15] proposed using two smart contracts to ensure the integrity and transparency of medical trials. The first ensures the irrevocability of the trial protocol by containing the protocol of the study and the statistical analysis plan and by defining the data monitoring committee. The second smart contract contains patient enrolment data (consent and information forms), data collection, trial monitoring, data management and data analysis. Using this approach, the authors claim that the reproduciability is improved and study reports and dissemination of results are impartial. Any public institution can monitor the flow and progress of a study and verify its validity.

- Nugent et al. [16] proposed similar usage of two smart contracts for improving the data transparency in clinical trials. The first is a regulator contract, containing clinical trial authorisation details, which is managed by public regulators (e.g. US Food and Drug Administration). The second is a trial contract, managed by the research organisations, which is used for storing trial protocols, consent forms and anonymised participant information.

The final study, by McFarlane et al. [17], focused on the adjudication of medical billing and the provision of medical access in case of emergency. In the first situation, a smart contract containing patient identification, institution denomination and the debt owed would be issued. The smart contract would be auto-updated once the patient has paid the debt. In the second situation, a smart contract containing a secondary private key (derived from the original private key) could be issued by the patient to allow emergency services to access medical records, should the patient be unresponsive, have their mobile phone present and have configured emergency access to that phone by bypassing the lock screen. The second situation is only an early model, and no more details are given.

Technology

While a comparison of the different blockchain technologies is outside the scope of this article, it is interesting to note that none of the studies are interoperable, even if they use the same blockchain "family". This is due to the use of proprietary data types, with different types of rules and custom codes for managing the automatic execution of smart contracts. In addition, only one addresses interoperability issues by proposing the use of the Fast Healthcare Interoperability Resources (FHIR) specification to represent medical data.

Five types of technologies are used in these studies. Ethereum, a permission-less blockchain (i.e. any user can create and run code, and its execution relies on miners), was the most used (6 studies of 9), together with specialised libraries or languages that targetthis blockchain, such as Solidity (a contract-oriented high level language targetting the Ethereum Virtual Machine). One of the studies relies on Hyperledger, which is a permissioned blockchain. The authors of that study claimed that Hyperledger is more suited for sharing data than Ethereum [9]. It is permission-limited, and the impersonalisation and risk of data misuse due to the anonymisation of permission-less-typed blockchains both increase the likelihood of a Hyperledger system being used and remove the need to pay for transaction execution (mining). Another study relies on IBM blockchain, and one proposes the usage of ErisDB (renamed Monax in 2017 - https://monax.io/2016/11/08/eris-0120-release/) as well as Ethereum.

Conclusion and Discussion

This paper shows that smart contracts could be used in healthcare in different situations, from data sharing to the improvement of clinical trials. Two studies presented allow patients to upload their self-collected data into a blockchain and share it with their clinicians.

However, the small numbers of studies included (n=9, omitting a literature review) and the fact that none of them were at a commercialisation or production stage raise questions about the usability of this technology in real-life situations. A wider systematic review of blockchain technology, conducted in 2016, showed the same limited results, with only three articles examining smart contracts and no production-ready services [18]. Several possibilities could explain this situation in healthcare:

1. Blockchain will not change how medical records are stored. Blockchain is usable as a registry only, because inserting vast amounts of medical data, such as computed tomography (CT) scans, would render the Blockchain bloated and difficult to manage. The challenges of medical data storageing are the same, whether blockchain is used or not.

2. Blockchain technology is not necessary when trusted parties or regulators control the decision-making processes (e.g. creating smart contracts or mining), as in healthcare. Moreover, private blockchains are arguably only a shared database with at best a journaling of the data, which has existed since the seventies [19]. However, blockchain has proved its usefulness in decentralized situations in which parties cannot be trusted, even if some security issues remain unaddressed today [18].
3. Accessing encrypted patient data in the blockchain requires the healthcare institutions to use the patients' private keys(the public keys being used for encrypting the data). The sharing of a private key renders it public, and therefore not secure. In addition, this raises the question of trusted parties, described in point 2.
4. The GDPR states that patients have full access to their data [1], meaning that they have the opportunity to both manage the access rights and to move any portion or all of their data from one provider to another. Moving data between providers implies the deletion of data held by the old provider. However, it is not possible to delete anything from a alockchain without voiding its integrity and recalculating all the hashes.
5. Some of the actors cited are vapourware. For instance, ErisDB (or Monax, as it is now branded) provides no documentation nor access to a single piece of code, but still advertises its products. These practices increase doubts about the usefulness of the technology.
6. There are contradictions regarding the potential impacts of the costs of using a blockchain-based solution by healthcare institutions; some suggest that cost savings could be made [20] while others point out probable cost increases due to the nature of blockchain itself (e.g. computational power and storage increase due to data replication) [21].

Based on these considerations, the author believes blockchain-based technologies are not adapted and not ready yet for usage in healthcare, at the time this study was conducted (May 2018). Moreover, another study has suggested that the usage of these technologies is extremely immature and lacks public or expert knowledge, making it hard to form a clear strategic vision of its true future potential [22].

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Table 1 Papers included in the review

Ref.	State	Objective of smart-contracts	Content	Technology	Actors
[17]	Model	1. Adjudication of medical billing 2. Emergency access of health records allowance	Patient (1) Institution (1) Debt (1) Secondary private key (2)	Ethereum FHIR Amazon Web Services ErisDB	Patients Institutions Debt collectors Insurances Emergency Services
[23]	Literature Review	---	Reference Paper [11]	---	---
[9]	Prototype	Data sharing between patients and doctors, with data generated from both sides	Permissions (patients to doctors) Clinical Metadata Patients' private data	Hyperledger Chaincode ARIA Varian Cloud Go	Doctors Patients
[15]	POC	Improving medical trials by managing consent and ensuring integrity and transparency of the trials	Trial protocol and setup (1) Patients enrolment (2) Data Collection (2) Trial Monitoring (2) Data Management (2) Data Analysis (2)	Ethereum Solidity Chainscript	Trial participants Researchers
[13]	POC	Consent of the patients Record transfer between healthcare networks	Any Protected Health Information Involved health networks	IBM Blockchain Bluemix NodeJS	Patients Doctors
[16]	Prototype	1. Capturing clinical trial authorization 2. Storing clinical trial protocols and collected data	Clinical trial authorization Protocols Collected data	Ethereum Javascript Solidity	Regulators Research Organizations Researchers Doctors Patients
[11]	Prototype	1. Mapping patients ID to their public keys 2. Logging patient-providers relationships, access rights and data retrieval pointers 3. Managing Medical Record history	Patients ID Patients Ethereum address Provider ID Patients-Providers relationships Access permissions Data pointers	Ethereum PyEthereum PyEthApp SQLite Flask	Patients Providers
[10]	Prototype	1. User registration and mining 2. Classify users as patients/providers/third party 3. Relationships of nodes 4. Ownerships of medical records 5. Permission access to medical records 6. Proxy re-encryption	Ethereum address Users ID Relationship status Access Conditions Hashes Symmetric Encryption Key	Ethereum QuorumChain Ethereum-Go	Patients Providers Healthcare Insurance
[12]	Prototype	1. Encrypt reports 2. Identify actions performed on sent data 3. Revoke access to violated data	Cryptographic keys Reports Permissions Data sensitivity level IDs	Undisclosed	Cloud providers Research organizations Medical organizations
[14]	POC	Share self-collected health data	Medical data Access logs	Ethereum	Patients Clinicians

Wearable Sensors with Possibilities for Data Exchange: Analyzing Status and Needs of Different Actors in Mobile Health Monitoring Systems

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Abstract

Background

Wearable devices with an ability to collect various type of physiological data are increasingly becoming seamlessly integrated into everyday life of people. In the area of electronic health (eHealth), many of these devices provide remote transfer of health data, as a result of the increasing need for ambulatory monitoring of patients. This has a potential to reduce the cost of care due to prevention and early detection.

Objective

The objective of this study was to provide an overview of available wearable sensor systems with data exchange possibilities. Due to the heterogeneous capabilities these systems possess today, we aimed to systematize this in terms of usage, where there is a need of, or users benefit from, transferring self-collected data to health care actors.

Methods

We searched for and reviewed relevant sensor systems (i.e. devices) and mapped these into 11 selected attributes related to data-exchange capabilities. We collected data from the Vandrico database of wearable devices and complemented the information with an additional internet search. We classified the following attributes of devices: type, communication interfaces, smartphone/PC integration, connection to smartphone health platforms, connection to health care system/middleware, type of gathered health data, integrated sensors, medical device certification, access to user data, developer-access to device, and market status. Devices from the same manufacturer with similar

functionalities/characteristics were identified under the same device *family*. Furthermore, we classified the systems in three subgroups of relevance for different actors in mobile health monitoring systems: EHR providers, software developers, and patient users.

Results

We identified 362 different mobile health monitoring devices belonging to 193 device families. Based on an analysis of these systems, we identified the following general challenges:

- Few systems have a Conformité Européene (CE) marking class II or above, or approval from the US Food and Drug Administration (FDA)
- Few systems use the standardized Bluetooth Low Energy GATT profiles for wireless transfer of health data
- Few systems support health aggregators/middleware
- Approximately 30% of the device families provide the user access to the source data. However, only 16% allow the transfer of data through direct communication with the device (i.e. without using a proprietary cloud-based service)

Conclusions

Few of the identified mobile health monitoring systems use standardized, open communication protocols, which would allow the user to directly acquire sensor data. Use of open protocols can provide mobile health (mHealth) application developers an alternative to proprietary cloud services and communication tools, which are often closely integrated with the devices. The emerging new types of sensors, often intended for everyday use, have a potential to supplement health records systems with data that can enrich patient care.

Keywords

Wearable device, health monitoring, data exchange, sensors, mHealth, EHR, pHR, health data aggregators

1. Introduction

During the last several years, we have witnessed an increase in various wearable health devices for the consumer market. Primary efforts have been aimed towards miniaturization and development of new features, and it has been less focus on data collection infrastructure, the use of standardized data transmission protocols, and providing sensor data for further use in various connected applications in areas of mHealth, gaming, industrial sector, etc. [1]. In a previous study we showed that for consumer-based activity trackers and smart watches, the number of new devices and brands appearing every year is high and increasing [2].

The fast-paced development of new health sensors, patient tools, and various types of electronic health records (EHR), Electronic medical record (EMR), Personal health record (pHR), and health data aggregators, in addition to patient empowerment supported technologies (e.g. using 3D printing and electronics prototyping tools), stimulates the need for improvements in interoperability and data-exchange capabilities. Such a need is also supported by the growing popularity of wearables, where

continuously collected data can have a significant value for both long- and short-term health monitoring purposes.

Interoperability, in terms of communication capabilities with other devices, is often influenced by different made-by-design constraints, and the full potential of devices may remain unutilized. Technically educated users can present, design, and implement their own solutions, tailored to facilitate living with a specific health condition (e.g. diabetes [3], obstructive apnea [4]). The core functionality of such solutions is often based on unofficial access to captured data from sensors, and wearable devices. Given the prototype nature of these solutions, they are also referred to as Do-It-Yourself (DIY) projects. Maintenance of these DIY projects is commonly provided by people who can personally relate to the disease or health condition. Existence of such technologically-focused initiatives, where the driver is based on an ability to freely operate with sensor data, supports the promotion of standardized and open access protocols.

The emerging various sensor technologies and its utilization in various self-management services, can have a positive impact on related functionality such as medical decision support, provisioning of alarms and remote caregiver monitoring [5]. However, manual logging and registration of different observations and measurements may become an everyday inconvenience for patients and can be facilitated by automatic transmission of sensor-based readings when the protocols are known and access is enabled.

Data protection laws, such as the EU General Data Protection Regulation (GDPR) and US Health Insurance Portability and Accountability Act (HIPAA), imposes eHealth application providers to address compliance and data security issues. In the context of cloud-based health monitoring systems, all of these responsibilities are divided in a transparent manner between cloud providers and application developers, who must relate to a new legal situation in the area.

The purpose of this review is to systematically describe and analyze the current data-exchange capabilities of wearables, with a particular focus on health monitoring systems and data transfer. We have analyzed important parameters and commented on each of these, describing how different actors in mobile health monitoring systems relates to these wearable sensor systems (i.e. mHealth software developers, EHR providers, and patients).

2. Methods

2.1. Search protocol

The search approach was based on searching through the grey literature, where we targeted all wearables with integrated communication interfaces for data transfer. We identified the Vandrico database [6] as the primary source of data.

The Vandrico wearables database is a structured summary of wearables, as of May 2018, the database receives 1,000,000 views annually, and holds 431 devices from 266 companies. The database is currently open for new device entries. Every device has to fulfill the following conditions in order to be accepted in the database. The device has to be wearable, controllable (i.e. device must be controllable by the user either actively or passively), enhancing (i.e. device must augment knowledge, facilitate learning or

enhance experience), and fully funded [6]. Once a device is inserted into the database, it is classified into one or more categories. The updates occur at irregular intervals, and can be initiated by a public contributor not affiliated with Vandrico.

We also performed a web search to complement the data from the Vandrico database. Searches were also done in cases where the provided information from Vandrico was incomplete, outdated, or inaccurate. For many device records, we were able to extract missing information directly from the manufacturer's website. Such additionally information was generally related to certification and sensor parameters, which are not recorded in Vandrico database.

2.2. Classification

Each included device was assigned one or more keywords to describe its purpose. Since manufacturers often release multiple generations of the same device with similar functionality, we documented the 'System variety' field, which lists models with similar functionality. In this article, we call such a group of similar devices a *device family*.

In addition to the original set of attributes tracked by Vandrico, we have added several new attributes with a focus on documenting data-exchange features of the devices in more detail. Three additional attributes were added to distinguish between data import options to different types of health data storages (E, F, G), see Table 1. Other attributes were added to indicate integrated sensors (I), set of collected health data types (H), and the possibility of data extraction (B, K). In addition, we also tracked whether the device supports transmission of data via open protocol (C), and which smartphone or PC applications the wearables is compatible with (D). We also reviewed the support for development of custom applications running on the device (L), which is a new characteristic with an increasing number of smartwatches on the market. Considering the focus of this review, we also included status of medical certification of the device (i.e. CE marking and FDA approval) (J). A list of these new attributes is shown in Table 1.

Table 1 Collected attributes for wearables

Attribute	Attribute description	Label
Keywords	Keywords related to device	-
Owner	Name of the manufacturer/company producing the device	-
Short description	Short description of the device	-
Source of information	Source where the information about the device was obtained	-
System URL	URL of the system/manufacturer	-
System variety	Enumeration of models with similar characteristics	-
Type of wearable system	Device classification	A
Communication interfaces	Set of integrated communication interfaces for transmitting data	B
Data protocol	Indicates whether the device uses proprietary or standardized/open data protocols	C
Smartphone/PC integration	Types of systems the devices can be connected to	D
Direct integration with health platforms	Indicates whether device supports direct import of data to Google Fit and/or Apple Health	E
3rd party integration with health platforms	Device can be connected to one or more health platforms via 3rd party provider	F
Connection to Health Care System/Middleware	Device supports import of data to a health care system/middleware	G
Health data types	Enumeration of types of physiological data extracted from integrated sensors	H
Integrated sensors	Enumeration of sensors integrated within the device	I
Medical device	Indicates a certification or approval by corresponding agencies/authorities	J
User data access	Collected data are accessible either by directly inquiring the device or via cloud solution	K
Developer access	Indicates support for development of custom applications running on the device	L
Device availability	Indicates production status of the device	M

3. Results

The results section consists of two subsections. In the first section, we present each of the identified attributes specified in Table 1. In the second section, we present how different actors can utilize wearable devices in patient monitoring systems (i.e. mHealth software developers, EHR providers, and patient users).

3.1. Identified attributes

In the description of each attribute, numbers in parenthesis indicate the percent of device families classified within a specific identified attribute value.

Type of wearable system (Attribute A)

Summary: The majority of wearable device families in our review are Sensors (38%) and Smartwatches *(22%). We have also registered Trackers (11%), Gloves (5%), Glasses (4%), Insulin pumps (2%), Earphones (2%), Industry tools (1%), and Prosthesis (1%). Six percent of device families were sorted into the category Other.*

Communication interfaces and data protocols (Attributes B, C)

Summary: *Only a few producers are using standardized transmission protocols that enable 3rd parties to implement transfer of data from a wearable.*

The majority of wearables integrate Bluetooth interface (70%) for wireless communication with a remote device. Other interfaces include USB (21%), Wi-Fi (12%), RF Radio (5%), ANT+ (5%), and Near field communication (NFC) (4%).

Only a few devices (1%) that utilize Bluetooth Smart technology, use the standardized Generic Attribute Profile (GATT) specifications, adopted by the Bluetooth Special Interest Group (SIG) [7]. Use of standardized GATT specifications makes it possible for developers of smartphone/smartwatch/desktop applications to easily integrate wearable devices into their existing application. Only one Wi-Fi-enabled device supported open protocols. Furthermore, open protocols were not supported by any devices using NFC, Ant+, USB, and RF Radio. Currently most of the wearable devices manufacturers prefer proprietary data-transmission format. Consequently, only original software provided by the manufacturer can be used to use the data by communicating directly with the device.

Smartphone- and PC integration (Attribute D)

Summary: *Smartphone Bluetooth compatibility issues might hinder some Bluetooth-enabled device manufacturers to support interoperability among whole spectrum of mobile devices.*

The identified wearable devices can be divided into two main categories – consumer-level devices and research devices. Consumer-level devices often closely integrate with a smartphone device to provide advanced visualization of data, settings of personal goals, and in some cases further integration with other 3rd party services. The most commonly supported smartphone ecosystems are iOS (138 device families (71.5%), 271 devices (75%)) and Android (130 device families (67%), 263 devices (72.5%)). One of the main factors causing a slight dominance of the iOS platform, is a strong control of the whole platform, hardware, and application quality by a single company (i.e. Apple). With Android, the platform

and hardware diversity may cause compatibility issues when integrating Bluetooth-enabled devices. Only a few of all devices integrates with Windows-based phone OS (covering Windows Mobile, Windows Phone 8.1, Windows 10 Mobile), the 3rd player on the smartphone market, although holding only 0.15% market share (15 device families (7%), 46 devices (12%)).

Support for desktop operating systems can be found mostly among devices aimed for research purposes. Desktop operating systems which provide such support include Windows (45 device families (18%), 95 devices (26%)), OSX (28 device families (14%), 64 devices (17.5%)), and Linux (17 device families (8%), 49 devices (13%)).

Direct- and 3rd party integration with health platforms (Attributes E, F)

Summary: *Our results show that Google Fit integrates directly with slightly more devices (22 device families (11.5%), 45 devices (12.5%)) compared to Apple Health (16 device families (8%), 32 devices – 9%). However, these numbers make up approximately only 13% of the total amount of wearables we have covered in our research. The remaining 87% does not support any health platform (neither Google Fit nor Apple Health).*

To provide a better understanding of possible communication channels, we created the diagram in Figure 1. to visualize how data flows between the identified systems. The ultimate desirable transfer of data is a full link between the wearable device (Figure 1.-I) and EHR (Figure 1.-VII).

Google Fit [8] and Apple Health [9] are two major health platforms (also known as 'fitness platforms' or 'health-tracking platforms') associated with the Android and Apple ecosystems respectively. Health platforms represent types of health data storage, which can be effectively used to store collected data from wearables equipped with health sensors. Both platforms, as indicated in Figure 1.-IV, are supporting two-way transfer of data between device's associated cloud services, smartphone consumer applications, and 3rd party services. Several 3rd party cloud-enabled fitness services, which act as a collectors of fitness data, with the ability to combine data from multiple devices, exist on the market (Figure 1.-F). MyFitnessPal [10], MapMyFitness [11], WorkoutTrainer [12], Strava [13], and myFitnessCompanion [14] are some examples. These applications collect data from different device cloud services (Figure 1.-III) and can transfer them further to middleware/aggregators (Figure 1.-V) or health platforms (Figure 1.-IV).

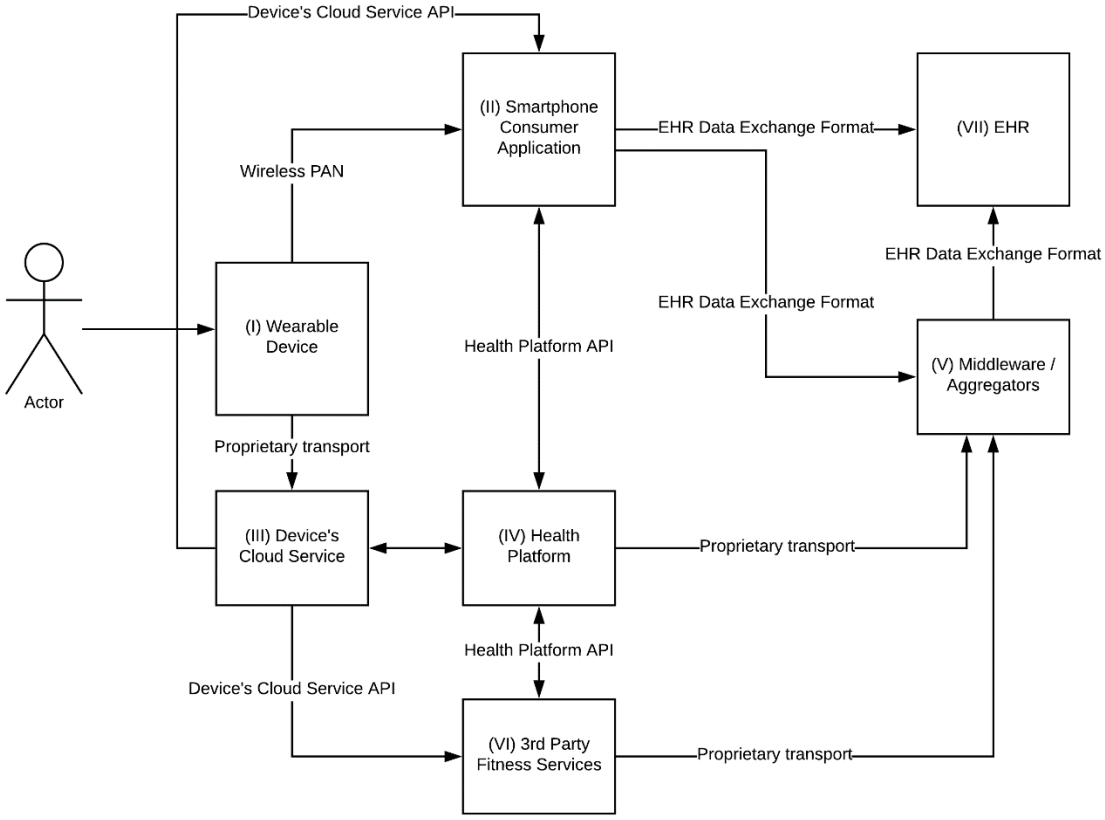

Figure 1. Data flow between different components in the identified wearable devices; arrow and text denote the way data is transferred.

Connection to Health Care System/Middleware (Attribute G)

Summary: *Middleware/aggregators are sparsely supported; only 26 device families (13%) support at least one of the identified aggregators. This situation is partially caused by the limited access to user data for many wearables on the market, which hinders further use of the data.*

Besides smartphone health platforms, several other server-based solutions are being utilized by different patient groups. The purpose of these solutions, often called aggregators or middleware (Figure 1.-V), is to capture, analyze and process data from 3rd party API providers and Health Platforms, and to provide it in a standardized format, readable by an EHR. In the review, we identified Shimmer [15], Tidepool [16, 17], and Glooko [17], as representatives of supported middleware software. Shimmer is supported by 18 device families (9.5%) and 37 devices (11%) in our review. Similarly to another aggregator, Tidepool (supported by 6 device families (3%)), set-up has to be done individually per user. Therefore, administration of these systems requires a certain amount of technical knowledge. Both Shimmer and Tidepool are open source projects, which are constantly improved by a group of project developers. A third identified system called Glooko is supported by 8 wearable devices families (4%) and 19 devices (5%). Glooko is a proprietary solution targeting diabetes patients.

Health data types (Attribute H)

Summary: *Accelerometer sensor-derived data (physical activity, sleep data) represent the majority of identified health data gathered by wearable devices in our review. Advanced physiological-data sensors are usually integrated within devices that are made for research purposes.*

We found the following physiological health parameters and derived parameters gathered by wearables covered in this review: Physical activity data (65 device families (33%)), heart rate (43 device families (22%)), sleep data (36 device families (18%)), blood glucose (11 device families (10%)), temperature (10 device families (5%)), heart rate variability (6 device families (3%)), blood pressure (4 device families (2%)), breath rate (3 device families (1.5%)), EEG (3 device families (1.5%)), ECG (3 device families (1.5%)), and excess post-exercise oxygen consumption (2 device families (1%)).

Integrated sensors in wearables (Attribute I)

Summary: *Few wearables in the review have advanced sensors of physiological health parameters integrated (ECG, EEG, blood pressure etc.)*

For each device, we counted integrated sensors. We found that accelerometers integrated with most device families in our list (107 device families (54.5%)). Together with gyroscope (57 device families (29%)) and magnetometer (17 device families (8.5%)), they are often integrated in wearables providing physical activity tracking capabilities. In some cases, this main set of physical activity related sensors are accompanied by a GPS (34 device families (17%)), compass (12 device families (6%)), and heart rate (13 device families (6%)) sensors. Accelerometers, together with gyroscopes and magnetometer, usually integrated within a single unit called inertial motion unit (IMU), also find a wide use in virtual reality accessories (e.g. gloves and head-tracking devices).

The remaining sensors (listed in attachment 1) include: Temperature sensors (10 device families (5%)), ECGs (8 device families (4%)), Barometers (7 device families (3,5%)), Respiratory sensors (7 device families (3,5%)), Cameras (4 device families (2%)), EEGs (4 device families (2%)), Galvanometers (2 device families), Humidity sensors (2 device families), UV sensors (1 device family), and one Proximity sensor (1).

Medical devices (Attribute J)

Summary: *The wearable devices consumer-market comprises of a small number of certified medical devices. The demand for more certified devices with validated/tested measurement methods is steered by an expanding portfolio of associated health data analytics services.*

Only 21 devices out of the 364 reviewed devices (5.7 %) are classified as a medical device (i.e. have CE-marking class II or above, and/or FDA approval). The need for more devices with validated measurement methods increases with the inclusion of advanced methods of health parameters monitoring (e.g. heart rate) and integration of capabilities to share data with health care systems/middleware [2]. In addition, many associated companion applications provide advanced statistics, suggestions, and prognosis, which can be used by many users as a recommendation for future medical-related actions, and therefore should be classified as medical devices.

Access to user data from sensors (Attribute K)

Summary: *There is a need to use standardized data exchange format to improve interoperability. There is also a need to produce more devices, which support direct transfer of data via local connection.*

A total of 61 device families (30%) and 137 devices (37.6%) provide electronic (machine-readable) access to user-gathered data. Among these, 34 device families (17%) and 79 devices (21%) use a local area network connection for data transfer (including Ant+, USB, Wi-Fi, NFC, Bluetooth and RF radio transmissions). Furthermore, 35 device families (18%) and 91 devices (25%) support data transfer via its associated cloud-based web service. The combination of both of these options is offered by 11 device families (5%) and 36 devices (9.8%).

Possibility to develop applications (Attribute L)

Summary: *Few devices provide developer-tools to create applications running directly on the device. The possibility to create applications running on the device is beneficial for software developers to fully utilize the capabilities of the device*.

We have identified 28 device families (14%) and 62 devices (17%) with the capability to run custom-developed applications. This means that these manufacturers provide software for developers and the necessary tools to create 3rd-party software running directly on these devices. The portfolio of devices supporting developers access include smartwatches (e.g. Android Wear-based smartwatches), VR gloves (e.g. CyberGlove), and recently also smart headphones (e.g. Bragi).

Advantages of 3rd party applications include addition of user-interaction capabilities, such as custom display user-interface, and further utilization of integrated sensors for various purposes (e.g. development of games working with data acquired in a real-time).

Availability of the device (Attribute M)

Summary: *In total, we have covered 193 wearable devices families consisting of 362 devices.*

In our search we included devices which are currently in production (154 device families (80%), 315 devices (86%)), discontinued (16 device families (8%), 25 devices (6.5%)), or in a design phase (22 device families (11%), 24 devices (6.5%)). We also identified one fraud company that pretended to sell nonexistent physical activity trackers.

3.2. Analysis of the identified attributes from the perspective the various stakeholders

Developers of mHealth-enabled applications

While many devices are shipped together with a smartphone companion application, that provides additional support and adds more functionality, the full potential of the devices may remain unutilized. Devices with access to user data enable mHealth software developers to create more comprehensive applications, that can make better use of the wearable devices. As examples, applications using data from wearable devices can be utilized within areas of chronic disease self-management, remote monitoring, fitness and wellness, education and other purposes.

Our review of wearable sensors indicate that few devices support transfer of data via local wired or wireless connection, and even fewer use standardized protocols such as Bluetooth Low Energy health

profiles and services. Therefore, the portfolio of devices that can be integrated into 3rd party mHealth software without a supporting cloud-based data collection service, is limited.

Several research projects [18], have investigated data-exchange capabilities of wearable devices via reverse engineering methods, and have been initiated as a response to an overall lack of options for standardized data transfer. One of the best known open-source project in this area, Nightscout [3], supports transmission of real-time, sensor-based blood glucose readings of the users to a cloud-based storage, from where it can be remotely monitored by a caregiver.

In order to provide system-wide, platform-independent support, mHealth software developers often have to rely on associated cloud services, or aggregators and health platforms. Unfortunately, the diverse format of data output hinders generic integration in mHealth software, and might force developers to put additional effort into incorporation of each additional service.

Health platforms providers

Multiple factors have to be considered when integrating a wearable device into an EHR system. In this context we identified 3 critical features – data reliability, device certification, and data transmission risks.

When data originating from wearable device sensors are involved in clinical decision making, clinicians need to know its reliability [19]. This could be achieved by ensuring that standardization, privacy and security issues are considered [20], which can be further ensured by a certification process handled by a regulatory authority. While wellness devices do not require such certification, devices providing health data analytics are regulated and has to be cleared prior to their introduction to a market [21]. Pilot programs, such as a Digital Health Software Precertification (Pre-cert) program, have been established to facilitate the device entire clearance process, and speed up the delivery process of these devices and services to patients [22]. Currently, the Pre-cert program comprises of 11 companies including Apple [23], Fitbit [24], and Roche [25].

Special considerations also come into place when patients transfer data from wearables into EHR. Specific types of sensor readings (e.g. steps, and blood glucose levels), can be more easily understood together with a patient's activity, when compared to other sensors data, and therefore make patients with chronic conditions (e.g. diabetes) benefit from integrating such data into EHRs.

Lately, several devices with new types of integrated sensors (e.g. Galvanic skin response (GSR), Peripheral capillary oxygen saturation (SpO_2)) have appeared on the consumer market. Both developer- and user-level access to measurements made by these new sensors are often disabled due to hardware requirements, missing verification of a data prediction model, or unsatisfied requirements of regulatory authorities. An example of such device is the new Fitbit Ionic and Apple Watch smartwatch with an integrated SpO_2 sensor where the access to sensor readings is currently disabled and is expected to be re-enabled in a future software update.

Data protection laws and regulations significantly affect operations with data provided by wearable health devices. According to *Processing of special categories of personal data*, Article 9. of EU GDPR regulation, mHeath data are being considered as *Sensitive Personal Data* and implies explicit user consent to be collected and processed. Furthermore, *Data Protection by Design and Default* (Article 23.) imposes the data controller to *implement appropriate technical and organizational measures* using

various restriction politics, techniques and rules. The US HIPAA Privacy rules apply to health plans, health care clearinghouses, and health care providers, collectively called *Covered entities,* working with protected health information (PHI). *Covered entities* do not include wearable devices, as they are usually directly purchased by a consumer, and not being prescribed by a physician. Also, commonly collected physiological health and derived parameters, such as number of steps and heart rate, are not considered to be personal health information. However, once the data is transferred to the EHR, it automatically becomes covered by HIPAA as part of the patient record.

Patients

Smartphones are our new personal digital assistants, running various types of mHealth tools. Patients are therefore essentially interested in whether wearable devices are compatible with the smartphone they are currently using. In this context, Bluetooth-enabled devices have the biggest potential to be connected and to communicate the information to a smartphone, where the data can be further processed and interpreted by a companion application.

In a situation where patient carries multiple devices capable of data collection, a direct integration of with health platforms, aggregating data from multiple wearable devices to a single place, becomes more and more important. Health platforms, capable of providing such functions, can advanced health data analytics and detailed insights into patient conditions. Today, patients can relate to Personal Health Record (pHR) in a form of tethered pHRs (e.g. MyChart [26]) or interconnected pHR (e.g. Microsoft Health Vault [27], Apple Health [9], Validic [28]) and these tools are become more frequently, bundled with smartphone software.

Physiological sensors, like heart rate sensor and blood oxygen saturation (SpO_2) sensor, can serve as continuous monitoring tools of different health parameters, which can provide indications of various diseases. As an example, continuous monitoring of hypoxemia for detection of sleep apnea, which in normal conditions requires use of continuous positive airway pressure (CPAP) device, can be integrated in a relatively cheap consumer wearable devices equipped with SpO_2 sensor.

The wearable form factor is becoming more and more important for many patients when considering a new wearable device for purchase. More and more functionalities are being integrated into different types of wearable devices of daily use (e.g. headphones and wristbands). However, a new trend among wearable devices is using modular accessories [29]. Modular accessory system allows the extension of existing functionality by adding new sensors, and might also influence customers' decision process when buying a new device.

4. Discussion

We have covered 193 device families to make an overview of data-exchange possibilities of existing wearable devices. In the current situation, where new devices are constantly introduced to the market using various financing schemes (e.g. crowd funding, startup, traditional funding), it is challenging to cover the whole spectrum. We have made a review identifying major challenges and status of such devices, and find this representable for the situation today.

In many cases, the user is locked within a limited-options ecosystem of device manufacturers, which raises concerns about secondary use of personal data. Furthermore, application developers are usually not able to utilize the potential of the device.

Support for communication with both Android and iOS-based companion applications is sometimes provided, however applications may differ in the set of implemented functionalities. Differences in the implementation of Bluetooth Low Energy stack between Android OS versions tailored to individual smartphone device models is one of the main reasons to this.

It is expected that Bluetooth, which is receiving strong support across the whole spectrum of device manufacturers, and is the most utilized wireless interface for transfer of data, will become integrated to even more devices. At the same time, proprietary wireless management protocols through radio frequency communications will still be used by a specific subset of devices (e.g. blood glucose meters, insulin pumps) as demonstrated by several devices (e.g. Medtronics [30], Animas [31]) in our review. The reason given by the vendors are often related to security and privacy.

Cloud-based web services extensively utilize Representational state transfer (REST) technology to support interoperability with various 3rd-party client applications. Due to a massive use of REST in most resource-oriented web services (i.e. services supporting internetworking of resources), such services can be easily implemented in client applications on many platforms. However, utilizing REST APIs does not imply use of standardized data format (e.g. Open mHealth) for data-transport. Device manufacturers often design their own proprietary data-schemes, which are used for transferring data. This represents a challenge when integrating multiple devices into one system.

Only a small number of devices have been CE marked (class II or above) or are FDA approved. A large number of uncertified devices raise questions about the reliability of data, since the algorithms running inside the device are proprietary.

Some consumer health wearables have been used in multiple scientific studies and have established partnerships with EHR providers. An example of such a device is Fitbit, which has been used in multiple studies targeting different types of patients (e.g. diabetes patients [32, 33], patients with obesity [34]) and integrated into existing infrastructure. Fitbit has also established partnership with the EPIC EHR system [26].

A relatively small percentage of devices support smartphone health platforms (e.g. Apple Health and Google Fit), for import of user-captured data. In addition, health aggregators/middleware as a next data-storage instance with rich data-mining capabilities is seldom used. Support of health data aggregators could enable easier and more secure data sharing with health care providers, without the use of 3rd party cloud-based services. In order to allow users to take advantage of modern smartphone health platforms (i.e. combined data view from multiple resources, standardized storage, etc.), such support should be integrated in more devices.

Advanced sensors, like heart rate sensor and UV sensor, are getting integrated into more wearable devices for daily use (e.g. wireless headphones). Consequently, higher-resolution metrics and continuous monitoring of different physiological parameters (e.g. continuous heart rate and SpO2 monitoring) will become more commonly accessible feature in upcoming wearable devices.

With an increasing data-ownership awareness among wearable devices users, it is important for device manufacturers to clarify secondary use of data. This include the possibility to use such devices without the need for transferring data via a cloud-based storage, by letting users opt-out from such data-collection service and rather access data directly. Introduction of GDPR and HIPAA regulations will likely enforce manufacturers to clarify the set of data being collected by the device, and allow developers and users to exchange and use data in an easy but secure way.

5. Conclusion

We propose a wider use of standardized, open communication protocols, which would allow to directly acquiring user data from a wider range of wearable devices. Use of open protocols can provide mobile health (mHealth) application developers an alternative to proprietary cloud services and communication tools, which are often closely integrated with the devices. The emerging new types of sensors, often intended for everyday use, have a potential to supplement health records systems with data that can enrich patient care.

Summary points

What was already known on this topic

- Wearable devices with an ability to collect various type of physiological data are increasingly becoming seamlessly integrated into everyday life of people
- Interoperability, in terms of communication capabilities with other devices, is often influenced by different made-by-design constraints, and the full potential of devices may remain unutilized
- The emerging various sensor technologies and its utilization in various self-management services, can have a positive impact on related functionality such as medical decision support, provisioning of alarms and remote caregiver monitoring

What this study added to our knowledge

- Few devices support transfer of data via local wired or wireless connection, and even fewer use standardized protocols such as Bluetooth Low Energy health profiles and services
- Lately, several devices with new types of integrated have appeared on the consumer market. Both developer- and user-level access to measurements made by these new sensors are often disabled due to hardware requirements, missing verification of a data prediction model, or unsatisfied requirements of regulatory authorities
- Only a small number of devices have been CE marked (class II or above) or are FDA approved
- A relatively small percentage of devices support smartphone health platforms (e.g. Apple Health and Google Fit), for import of user-captured data

Limitations

Vandrico database holds a considerable amount of records, some of them are not fully up-to-date and many recently released devices are not listed.

Conflicts of interest

The authors have no conflicts of interest to declare

Acknowledgements

Appendix A. Table of devices

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Abbreviations

API – Application Programming Interface
CE - Conformité Européene
CPAP - Continuous positive airway pressure
DIY – Do-It-Yourself
eHealth – Electronic Health
EHR – Electronic health records
EMR – Electronic medical record
FDA - Food and Drug Administration
GDPR – General Data Protection Regulation
GSR - Galvanic skin response

GATT - Generic Attribute Profile
HIPPA - Health Insurance Portability and Accountability Act
IMU - Inertial motion unit
mHealth – Mobile health
NFC – Near field communication
PHR – Personal health record
PHI- Protected health information
Pre-cert - Digital Health Software Precertification
REST - Representational state transfer
SIG - Special Interest Group
SpO_2 - Peripheral capillary oxygen saturation
USB - Universal Serial Bus

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
1	Artificial pancreas	DIY, artificial pancreas	AndroidAPS	1	-	Not applicable	OpenSource	Yes (Android)	No
2	Smartwatch	Smartwatch	Apple Watch	2	Serie 1, Serie 2	Bluetooth, WiFi, NFC	Proprietary	Yes (iOS)	Yes (Apple Health)
3	Artificial pancreas	DIY, artificial pancreas	Loop	1	-	Not applicable	OpenSource	Yes (iOS)	No
4	Artificial pancreas	DIY, artificial pancreas	OpenAPS	1	-	Not applicable	OpenSource	Yes (Android,iOS)	No
5	Tracker	Physical activity, tracker	Phyode	1	W/Me	Bluetooth, USB	Proprietary	Yes (iOS, Android)	No
6	Tracker	Physical activity, tracker	Pivotal Living	1	Life Tracker 1	Bluetooth	Proprietary	Yes (iOS, Android)	No
7	Smartwatch	Smartwatch	Qualcomm	1	Toq	Bluetooth	Proprietary	Yes (Android)	No
8	Earphones	Wireless, earphones, heart-rate	SMS Audio	1	Biosport	Bluetooth	Proprietary	Yes (iOS, Android)	No
9	Sensor	CGM, FGM	Abbott	2	Freestyle Libre, Navigator 2	RF Radio, NFC	Proprietary	No	No
10	Insulin pump	Insulin pump	Animas	3	Ping, 2020, Vibe	RF Radio	Proprietary	No	No
11	Sensor	Electroshock, punishment, bad habbit	Behavioral Technology Group	1	Pavlok	Bluetooth	Proprietary	Yes (Android, iOS)	No
12	Sensor	Gait analysis	Biosensics	2	LegSys, LegSys+	Bluetooth	Proprietary	Yes (iOS, Windows Mobile, Android)	No
13	Sensor	Activity sensor	Biosensics	1	PamSys	Bluetooth	Proprietary	Yes (Windows, OSX)	No
14	Sensor	Balance analysis	Biosensics	1	BalanSens	Bluetooth	Proprietary	Yes (iOS, Windows Mobile, Android)	No
15	Glasses	Dreaming, night	BitBanger Labs	1	Remee	None	None	No	No
16	Earphones	Earphones	Bragi	1	Dash	Bluetooth	Heart rate service (Bluetooth Smart)	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
17	Glasses	Glasses, bone-conductivity	Buhel	4	G31, G33, SG04/SG05, D01/D02	Bluetooth	Proprietary	Yes (iOS, Android, Windows Mobile, Blackberry)	No
18	Tracker	Elderly, monitoring	Carepredict	1	Tempo	Wifi	Proprietary	Yes (OSX, Windows)	No
19	Sensor	Shirt, e-textile	Carré Technologies	1	Hexoskin	Bluetooth, USB	Proprietary	Yes (iOS, Windows, OSX, Android)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
1	No	No	None	None	No	Yes
2	No	No	HR	Accelerometer, Gyroscope, Compass, GPS	No	Yes (REST API)
3	No	No	None	None	No	Yes
4	No	No	None	None	No	Yes
5	No	No	HR, HRV	Heart Rate Monitor, Respiratory Monitor	No	No
6	No	No	PA (ST + EE), SL	Accelerometer	No	No
7	No	No	None	None	No	No
8	No	No	HR, HRV	Heart Rate Sensor	No	No
9	Yes	Yes (Tidepool)	BG	None	Yes (FDA approved, CE marked)	No
10	No	Yes (Tidepool)	BG	None	Yes (FDA approved, CE marked)	No
11	No	No	None	None	No	No
12	No	No	Temporal and Spatial Gait parameters, Knee and Hip angles, Pelvis movement	Accelerometer, Gyroscope	No	No
13	No	No	Posture, Postural transitions, Gait, Falls	ECG, Gyroscope, GPS	No	No
14	No	No	Center of Mass (COM) motion, Anterior-Posterior motion, Medial-lateral motion, Ankle and hip angles, Sway velocity, Sway area, Reciprocal Compensatory index	Accelerometer, Gyroscope	No	No
15	No	No	None	None	No	No
16	No	Yes (Shimmer)	HR	Accelerometer, Gyroscope, Thermometer, Oxymeter	No	Yes (Bluetooth)
17	No	No	None	None	No	No
18	No	No	PA (ST + EE)	Accelerometer	No	No
19	No	No	PA (ST + EE), HR (Zones, Recovery, Resting), VO2Max, Minute ventilation, Breath Rate	Respiratory Monitor, Heart Rate Monitor, Pedometer, ECG Sensor, Accelerometer, Thermometer, Temperature Sensor, EKG Sensor	No	Yes (REST API)

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
1	Yes	Modular, open source artificial pancreas app	Available
2	Yes	Smartwatch	Available
3	Yes	Automated insulin delivery system	Available
4	Yes	Open source artificial pancreas	Available
5	No	Heart rate monitor	Discontinued
6	No	Physical activity tracker	Discontinued
7	No	Smartwatch	Discontinued
8	No	Earphones providing body monitoring	Discontinued
9	No	Continuous blood glucose monitor	In production
10	No	Insulin pump	In production
11	No	Wearable device to make a user break from bad habbits	In production
12	No	Wearable sensor for quantitative gait analysis	In production
13	No	Wearable platform for long-term objective evaluation of physical activity during everyday life	In production
14	No	Wearable system for balance assessment	In production
15	No	Device designed to increase the frequency of Lucid Dreams	In production
16	Yes	Bluetooth-connected headphones with sensors	In production
17	No	Wearable smart glasses with speakers	In production
18	No	Wearable wristband that monitors seniors activities	In production
19	No	Fabric shirt with built-in sensors that measures fitness data	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
20	Gloves	Virtual reality, glove	CyberGlove Systems	6	CyberTouch, CyberTouch II, CyberGlove II, CyberGlove III, CyberGrasp, CyberForce	WiFi, USB	Proprietary	Yes (Windows)	No
21	Sensor	CGM	Dexcom	2	G4, G5	RF Radio, Bluetooth	Proprietary	Yes (Android,iOS)	No
22	Sensor	Cap, fatigue, awarness	Edan Safe Pty Ltd	1	Smart Cap	Bluetooth	Proprietary	No	No
23	Sensor	Wristband, watch	Empatica	2	E4 wristband, Embrace Watch	Bluetooth	Proprietary	Yes (iOS, Android, Windows)	No
24	Sensor	Security, alarm, bracelet	Everfind	1	Safelet	Bluetooth	Proprietary	Yes (Android, iOS)	No
25	Sensor	Heart Rate Monitor	Finis	1	AquaPulse	None	None	No	No
26	Tracker	Activity sensor	Fitbit	7	Zip, One, Flex, Alta, Charge HR, Blaze, Surge	Bluetooth	Proprietary	Yes (Android,iOS)	No
27	Tracker	Activity sensor	Fitbug	1	Orb	Bluetooth	Proprietary	Yes (Android, iOS, Windows, OSX)	No
28	Smartwatch	Smartwatch	Fossil	3	Q Marshal, Q Founder, Q Wander	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
29	Smartwatch	Smartwatch	Garmin	2	Approach S3, Approach S6	Bluetooth, USB	Proprietary	Yes (iOS, Android, Windows Mobile)	No
30	Smartwatch	Sportwatch	Garmin	1	Swim	Ant+	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux)	No
31	Smartwatch	Sportwatch	Garmin	5	Forerunner 15, Forerunner 910XT, Forerunner 920XT, Forerunner 620, Forerunner 220	WiFi, USB, Bluetooth, ANT+	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux)	No
32	Smartwatch	Smartwatch	Garmin	5	vivomove, vivofit, vivofit 2, vivofit 3, vivosmart	Bluetooth	Proprietary	Yes (iOS, Android, Windows Mobile)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
20	No	No	Motion analysis	IMU sensor	No	Yes
21	Yes	Yes (Tidepool, Glooko)	BG	None	Yes (FDA approved, CE marked)	No
22	No	No	None	EEG, GPS	No	No
23	No	No	PA (ST + EE), BVP, HR, HRV, GSR, TMP	Accelerometer, photoplethysmography sensor, EDA sensor, temperature sensor	Yes (FDA approved, CE marked)	Yes (Bluetooth)
24	No	No	None	GPS	No	No
25	No	No	HR	Heart rate sensor	No	No
26	Yes	Yes (Shimmer, Glooko)	PA (ST + EE), SL, HR	Accelerometer, Gyroscope	No	Yes (REST API)
27	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope	No	No
28	No	Yes (Shimmer)	None	Accelerometer, Gyroscope, Compass	No	Yes (Bluetooth, REST API)
29	Yes	No	PA (ST + EE)	Accelerometer, GPS, Altimeter	No	Yes
30	Yes	No	PA (Swim stroke + Laps + Distance)	Accelerometer, GPS, Altimeter	No	Yes
31	Yes	No	PA (ST + EE)	Accelerometer, GPS, Altimeter	No	Yes
32	Yes	No	PA (ST + EE)	Accelerometer, GPS, Altimeter	No	Yes

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
20	Yes	Glove for motion capture	In production
21	No	Continuous blood glucose monitor	In production
22	No	Smart cap developed to overcome the limitations of fatigue monitoring technologies	In production
23	No	Wristband for monitoring physiological signals in real-time	In production
24	No	Wirelessly-connected bracelet with a panic button alerting users caregivers	In production
25	No	Under water heart rate monitor	In production
26	No	Wrist worn physical activity tracker	In production
27	No	Wrist worn physical activity tracker	In production
28	Yes	Smartwatch	In production
29	No	Bluetooth connected smartwatch	In production
30	No	Bluetooth connected smartwatch	In production
31	No	Bluetooth connected smartwatch	In production
32	No	Bluetooth connected smartwatch	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
33	Smartwatch	Smartwatch	Garmin	1	vívoactive	Bluetooth	Proprietary	Yes (Android,iOS)	No
34	Sensor	Pedometer, Children	Geopalz	1	Ibitz	Bluetooth	Proprietary	Yes (iOS)	No
35	Sensor	Activity sensor	Healbe	2	GoBe, GoBe 2	Bluetooth	Proprietary	Yes (iOS, Android, Windows, OSX)	No
36	Smartwatch	Smartwatch	Hewlett-Packard	1	MB Chronowing	Bluetooth	Proprietary	Yes (Android, iOS)	No
37	Smartwatch	Smartwatch	Huawei	2	Huawei Watch, Huawei Watch 2	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
38	Tracker	Activity sensor	Huawei	3	TalkBand B1, TalkBand B2, TalkBand B3	Bluetooth	Proprietary	Yes (Android, iOS)	No
39	Tracker	Punch tracker, gym, boxing	Hykso	1	Hykso	Bluetooth	Proprietary	Yes (iOS, Android)	No
40	Sensor	Crash sensor	Icedot	1	Crash Sensor	Bluetooth	Proprietary	Yes (iOS, Android)	No
41	Tracker	Activity sensor	iFit technologies	4	Vue, Link, Axis HR, Active	WiFi, Bluetooth	Proprietary	Yes (iOS, Android)	No
42	Tracker	Activity sensor, watch	iFit technologies	2	Classic, Duo	Bluetooth	Proprietary	Yes (iOS, Android)	No
43	Tracker	Activity sensor	iHealth	2	Edge, Wave	Bluetooth	Proprietary	Yes (iOS, Android)	No
44	Tracker	Activity sensor	iHealth	1	Air	Bluetooth	Proprietary	Yes (iOS, Android)	Yes (Apple Health)
45	Insulin pump	Insulin pump	Insulet	1	Omnipod	RF Radio	Proprietary	No	No
46	Sensor	Earlobe, Non-invasive	Integrity Applications	1	GlucoTrack	USB	Proprietary	Unknown	Unknown
47	Smartwatch	Notifications, wristwatch	Intel	1	Mica	GSM	Proprietary	Unknown	Unknown
48	Smartwatch	Notifications, wristwatch	Intel	1	Runiq	Bluetooth	Proprietary	Yes (Android, iOS)	No
49	Other	Sleep mask, sleep analysis	Inteliclinic	1	Neuroon	Bluetooth, USB	Proprietary	Yes (iOS, Android)	No
50	Gloves	Glove, gaming	Iron Will Innovations Canada	1	Peregrine	USB	Proprietary	Yes (Windows, OSX, Linux)	No
51	Sensor	Heart rate, patch	Irythm	1	Zio XT Patch	Bluetooth	Proprietary	Yes (iPhone)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
33	Yes	No	HR	Accelerometer, GPS, Altimeter	No	Yes
34	No	No	None	Accelerometer	No	No
35	No	No	PA (ST + EE), SL	Accelerometer, Skin impedance, Oximeter	No	Yes (Bluetooth, REST API)
36	No	No	None	None	No	No
37	Yes	Yes (Shimmer)	PA (ST + EE), SL	Accelerometer	No	Yes (Bluetooth, REST API)
38	Yes	No	PA (ST + EE), SL	Accelerometer	No	Yes (REST API)
39	No	No	Motion analysis	Punch count, punch speed, intensity score	No	No
40	No	No	None	Accelerometer, Gyroscope	No	No
41	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope	No	No
42	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope	No	No
43	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope	No	No
44	No	No	SpO2	Oximeter	No	No
45	Yes	Yes (Tidepool, Glooko)	BG	None	Yes (FDA approved, CE marked)	No
46	Unknown	Unknown	BG	None	Unknown	Unknown
47	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
48	Yes (Strava)	No	PA (ST + EE), SL, HR	Accelerometer, Gyroscope, GPS	No	Yes (REST API)
49	No	No	EEG, EOG, Pulse, Motion, Temperature	Accelerometer, EEG Sensor, Thermometer, Oximeter, Temperature Sensor	No	No
50	No	No	None	None	No	No
51	No	No	HR	None	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
33	No	Bluetooth connected smartwatch	In production
34	No	Wearable pedometer for children	In production
35	No	Fitness tracker	In production
36	No	Smartwatch	In production
37	Yes	Smartwatch	In production
38	No	Wrist worn physical activity tracker / fitness monitor	In production
39	No	Fitness boxing tracker	In production
40	No	Crash sensor intended to be worn on a helmet	In production
41	No	Fitness tracker	In production
42	No	Fitness tracker with limited smartwatch functionalities	In production
43	No	Fitness tracker	In production
44	No	Wireless Pulse Oximeter	In production
45	No	Insulin pump	In production
46	No	Non-invasive BG sensor	In production
47	Unknown	Smart notification device	In production
48	No	Sport smartwatch	In production
49	No	Sleep tracking device	In production
50	No	Glove designed for gamers that works as a controller thanks to sensors located on the tip of the fingers	In production
51	No	Wearable patch analyzing heart rate	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
52	Glasses	Glasses, LED	Japanese Institute of Advanced Media Arts and Sciences (IAMAS) and Paris Miki Holdings Inc	1	Fun'iki Ambient Glasses	USB, Bluetooth	Proprietary	Yes (Android, iOS, Windows, OSX)	No
53	Sensor	Activity sensor	Jawbone	3	UP Move, UP2, UP3	Bluetooth	Proprietary	Yes (Android,iOS)	No
54	Sensor	Footbed, expert system	JumpStartCSR	1	IDM PERFORM	Bluetooth	Proprietary	Yes (iOS, Android)	No
55	Sensor	Position tracker	KMS	1	Kit Wristband	WiFi, GSM	Proprietary	Yes (iOS, Android)	No
56	Sensor	Activity sensor, shoe, insule	Lechal	1	Lechal Shoe	Bluetooth	Proprietary	Yes (iOS, Android)	No
57	Smartwatch	Smartwatch	Leikr	1	GPS Sport Watch	WiFi, USB, ANT+	Proprietary	Yes (OSX, Windows, Linux, iOS & Android)	No
58	Smartwatch	Smartwatch	LG	2	LG G Watch R, LG Watch Urbane	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
59	Sensor	Ring, gestures	Logbar	1	Ring	Bluetooth	Proprietary	Yes (iOS, Android)	No
60	Earphones	Earphones	Lumafit	1	Lumafit	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
61	Sensor	Posture, coaching	Lumo Body Tech	1	Lift	Bluetooth, USB	Proprietary	Yes (iOS, Android)	No
62	Sensor	Run, coaching	Lumo Body Tech	1	Run	Bluetooth	Proprietary	Yes (iOS)	No
63	Gloves	Virtual reality, glove	Manus VR	1	Manus VR	RF, Bluetooth	Proprietary	Yes (Windows)	No
64	Smartwatch	Notifications, wristwatch	Martian	14	AE01, PT02, PTL02, AE02, PT01, PTL01, Aviator B10, Envoy G10, Electra E10, Alpha T10, Electra T10, Passport, Victory, G2G	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No
65	Smartwatch	Notifications, wristwatch	Martian	9	CL04, CL05, CL06, CL03, CL07, CL02, SP03, SP01, CL01	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No
66	Sensor	Headset, awarness, fatigue	Maven	1	Co-pilot	Bluetooth	Proprietary	Yes (iOS, Android)	No
67	Sensor	CGM	Medtronics	2	Enlite, Minimed	RF Radio, Bluetooth (via adapter)	Proprietary	Yes (Android,iOS)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
52	No	No	None	Accelerometer	No	No
53	Yes (FitnesSyncer)	Yes (Shimmer, Glooko)	PA (ST + EE), SL, HR, GSR	Accelerometer, Gyroscope	No	Yes (REST API)
54	No	No	None	Accelerometer, Gyroscope	No	No
55	No	No	None	GPS	No	No
56	No	No	PA (ST + EE)	Accelerometer, Gyroscope	No	No
57	Yes (MapMyFitness, Strava)	No	PA (ST + EE)	GPS	No	No
58	No	Yes (Shimmer)	PA (ST + EE), SL, HR	Accelerometer, Gyroscope, Barometer	No	Yes (Bluetooth, REST API)
59	No	No	None	Accelerometer	No	Yes (Bluetooth)
60	No	Yes (Shimmer)	HR	Oxymeter	No	No
61	No	No	None	Undisclosed	No	Yes (REST API)
62	No	No	None	Accelerometer, Gyroscope, Magnetometer	No	Yes (REST API)
63	No	No	Motion analysis	Gyroscope, Accelerometer, Magnetometer	No	Yes (Bluetooth)
64	No	No	None	None	No	No
65	No	No	None	None	No	No
66	No	No	None	Microphone, Accelerometer, Gyroscope, Magnetometer, Compass	No	No
67	Yes	Yes (Tidepool, Glooko)	BG	None	Yes (FDA approved, CE marked)	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
52	No	Wearable smart glasses with LED diodes signalization	In production
53	No	Wrist worn physical activity tracker	In production
54	No	Intelligent footbed that collects physiological and biomechanical data	In production
55	No	Band for children and vulnerable adults for their safety in case they get lost	In production
56	No	Shoe insules providing navigation and physical activity tracking capabilities	In production
57	No	Sport smartwatch	In production
58	Yes	Smartwatch	In production
59	No	Ring with gestures recognition capabilities	In production
60	No	Interactive fitness coach headphones	In production
61	No	Posture coaching device	In production
62	No	Real-time run coaching device	In production
63	Yes	Virtual reality glove	In production
64	No	Simple smartwatch with notification functionalities	In production
65	No	Simple smartwatch with notification functionalities	In production
66	No	Wearable device designed to address truck driver fatigue and distraction	In production
67	No	Continuous blood glucose monitor	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
68	Sensor	Camera, Life camera	meMINI	1	meMINI	WiFi, Bluetooth, USB	Proprietary	Yes (iOS)	No
69	Glasses	Virtual reality, glass	Meta	1	META 2 Augmented Reality Headset	Proprietary	Proprietary	Yes (Windows, iOS)	No
70	Smartwatch	Smartwatch	Michael Kors	1	Access	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
71	Tracker	Activity sensor, Activity tracker	Mio	5	Alpha, Alpha 2, FUSE, VELO, Link	Bluetooth, ANT+	Proprietary	Yes (Android, iOS)	Yes (Google Fit, Apple Health)
72	Tracker	Activity sensor, Activity tracker	Misfit	6	Ray, Shine, Shine 2, Link, Phase, Flash	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
73	Sensor	Children, wearable	Moff	1	Moff	Bluetooth	Proprietary	Yes (iOS, Android)	No
74	Sensor	Children, monitoring	Mondevices	1	Monbaby	Bluetooth	Proprietary	Yes (iOS, Android)	No
75	Sensor	Fetal, prenatal, heart-rate monitor	Monica Healthcare	2	Novii Wireless Patch System, Monica AN24	Bluetooth	Proprietary	No	No
76	Other	Strap, watch, notifications	Montblanc	1	TimeWalker Urban Speed e-Strap	Bluetooth	Proprietary	Yes (iOS, Android)	No
77	Sensor	Foot pressure, motion analysis	Moticon	1	OpenGo	Ant+	Proprietary	Yes (Linux, Windows, OSX, Android)	No
78	Smartwatch	Smartwatch	Moto	3	360, 360 2, 360 Sport	Wifi, Bluetooth	Proprietary	Yes (Android, Blackberry, iOS, Linux, OSX, Windows, Windows Mobile)	Yes (Google Fit)
79	Tracker	Activity sensor	Mushroom Labs	2	Moov Now, Moov HR	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit, Apple Health)
80	Smartwatch	Smartwatch	MyKronoz	6	ZeWatch 2, ZeWatch 3, ZeWatch 4,ZeWatch 4HR, ZeRound, ZeSport	USB, Bluetooth	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux & Blackberry)	No
81	Smartwatch	Smartwatch	MyKronoz	2	ZeSplash, ZeSplash 2	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No
82	Sensor	Activity sensor	MyKronoz	5	ZeFit, ZeFit 2, ZeFit 2 Pulse, ZeFit 3HR, ZeCircle 2	USB, Bluetooth	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux & Blackberry)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
68	No	No	None	Camera	No	No
69	No	No	None	Undisclosed	No	No
70	No	Yes (Shimmer)	None	Accelerometer, Gyroscope	No	Yes (Bluetooth, REST API)
71	No	No	HR	Accelerometer	No	No
72	Yes (FitnesSyncer)	Yes (Shimmer)	PA (ST + EE), SL, HR	Accelerometer, Gyroscope	No	Yes (REST API)
73	No	No	None	Accelerometer, Gyroscope	No	No
74	No	No	Breat and movement patterns	Accelerometer	No	No
75	No	No	FHR, MHR, UA	ECG Sensor, EMG Sensor	Yes (FDA approved, CE marked)	Yes (Bluetooth)
76	No	No	None	None	No	No
77	No	No	Motion analysis	Accelerometer, Pressure sensor	No	No
78	No	No	HR	Accelerometer	No	Yes (Bluetooth, REST API)
79	No	Yes (Shimmer)	PA (ST + EE), SL, HR	Accelerometer, Gyroscope, Magnetometer, Compass	No	Yes (REST API)
80	No	No	PA (ST + EE), SL, HR	Accelerometer	No	No
81	No	No	PA (ST + EE)	Accelerometer	No	No
82	No	No	PA (ST + EE), SL, HR	Accelerometer	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
68	No	Wearable event-recording camera	In production
69	No	Accelerometer, Gyroscope, Magnetometer, Compass	In production
70	Yes	Smartwatch	In production
71	No	Wrist worn physical activity tracker / fitness monitor	In production
72	No	Wrist worn physical activity tracker	In production
73	No	Wearable device worn on the wrist that reproduces toys' sounds while children are playing	In production
74	No	Clip-on breathing and activity tracker for babies	In production
75	No	Wearable device designed for high BMI patients designed for monitoring of fetal and maternal HR	In production
76	No	Watch strap	In production
77	No	Wearable device that measures plantar foot pressure for motion analysis	In production
78	Yes	Smartwatch	In production
79	No	Personal physical activity coaching device	In production
80	No	Smartwatch	In production
81	No	Smartwatch	In production
82	No	Wrist worn physical activity tracker / fitness monitor	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
83	Sensor	Activity sensor	MyKronoz	3	ZeCircle, ZeClock, ZeRound	USB, Bluetooth	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux & Blackberry)	No
84	Sensor	Muscle, performance, training	Myontec	2	Mbody, Mbody Pro	Bluetooth	Proprietary	Yes (Windows, Windows Mobile, iOS, Android)	No
85	Tracker	Wearable camera, life camera	Narrative	2	Clip 1, Clip 2	USB	Proprietary	Yes (Linux, Windows, OSX, Android)	No
86	Sensor	UV sensor	Netatmo	1	June	Bluetooth	Proprietary	Yes (iOS)	No
87	Other	Therapy, ulcer, diabetes	NeuroMetrix	1	Sensus Pain Management System	None	None	No	No
88	Sensor	EEG, headset	Neurosky	2	Mindwave, Mindwave Mobile	Bluetooth	Proprietary	Yes (Windows, iOS, Android)	No
89	Smartwatch	Smartwatch, fitness, tracking	Nevo	1	Nevo watch	Bluetooth	Proprietary	Yes (iOS, Android)	Yes (Google Fit, Apple Health)
90	Smartwatch	Smartwatch	Nixon	1	The Mission	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
91	Sensor	Body area network	Notch	1	Notch	Bluetooth	Proprietary	Yes (Android)	No
92	Sensor	Wearable ECG recorder	Nuubo	1	nECG Minder	Bluetooth, USB	Proprietary	Yes (OSX, Windows, iOS, Android)	No
93	Sensor	Authentication device	Nymi	1	The Nymi Band	Bluetooth, NFC	Proprietary	Yes (Android, iOS)	No
94	Smartwatch	Smartwatch	Omate	1	TrueSmart	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)
95	Sensor	Smart bra	OMsignal	1	Bra	Bluetooth	Proprietary	Yes (iOS)	No
96	Sensor	Fatigue, Drowsiness, Glasses	Optalert	2	Eagle Portable, Eagle Industrial	Bluetooth, USB, WiFi	Proprietary	Yes (iOS, Android, Windows)	No
97	Glasses	Glasses, HUD, AR	Optinvent	2	Ora-2, Ora-X	Bluetooth, USB, WiFi	Proprietary	Yes (Android, Blackberry, iOS, Windows Mobile)	No
98	Glasses	Glasses, HUD, AR	Orcam	1	Orcam	Unknown	Proprietary	No	No
99	Other	Communication, PPT	Orion Labs	1	Onyx	Bluetooth	Proprietary	Yes (iOS, Android)	No
100	Sensor	Heads-up display	O-Synce	1	Screeneye x	ANT+, USB	Proprietary	Yes (Windows)	No
101	Sensor	Baby, remote monitoring	Owlet	2	Baby Monitor, Smart Sock 2	Bluetooth	Proprietary	Yes (iOS)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
83	No	No	PA (ST + EE)	Accelerometer	No	No
84	No	No	Multiple muscle metrics	Heart Rate Monitor, Altimeter, Accelerometer, Muscle Contraction Sensor	No	No
85	No	No	Image	GPS, Accelerometer, Magnetometer, Compass	No	No
86	No	No	UV	Ultraviolet Light Sensor	No	No
87	No	No	Therapeutic	Electrical nerve stimulator	Yes (FDA approved, CE marked)	No
88	No	No	EEG power spectrum	TGAM1 module	No	No
89	No	No	PA (ST + EE), SL	Accelerometer	No	No
90	No	Yes (Shimmer)	None	Accelerometer, Barometer, Altimeter, Gyroscope, Thermometer, Humidity	No	Yes (Bluetooth, REST API)
91	No	No	Motion analysis	Accelerometer, Gyroscope, Magnetometer	No	Yes (Bluetooth)
92	No	No	PA, ECG	Accelerometer, ECG sensor	Yes (FDA approved, CE marked)	Yes (Bluetooth)
93	No	No	HR	Accelerometer, Gyroscope, Biometric Authenticator	No	No
94	No	Yes (Shimmer)	None	None	No	Yes (REST API)
95	No	No	PA (ST + EE), BTH, HR	Heart Rate Monitor, Respiratory Monitor, Accelerometer	No	No
96	No	No	Eylid motion	LED sensor	No	No
97	No	No	None	Accelerometer, Gyroscope, Magnetometer, Compass, GPS	No	No
98	No	No	Unknown	Unknown	No	No
99	No	No	None	None	No	No
100	No	No	PA (ST + EE), HR	Thermometer, Temperature Sensor	No	Yes (USB)
101	No	No	HR, SpO2	Heart Rate Sensor, Oximeter	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
83	No	Wrist worn physical activity tracker / fitness monitor	In production
84	No	Wearable device that gathers and analysis muscles' activity data	In production
85	No	An automatic camera that continuously captures moments from persons life	In production
86	No	UV sensing bracelet	In production
87	No	Electrotherapy device designed for relief of chronic pain in the lower legs and feet	In production
88	No	Mobile EEG headset	In production
89	No	Watch with fitness tracking capabilities	In production
90	Yes	Smartwatch	In production
91	No	Set of wearable sensor for motion analysis	In production
92	No	Wearable activity monitor designed to record ECG signals	In production
93	Yes	Wrist worn authentication device	In production
94	Yes	Smartwatch	In production
95	No	High-performance sports Bra that records heart rate and physical activity data	In production
96	No	Fatigue management system that detects the physiological warning signs of early onset drowsiness	In production
97	No	Combined HUD and AR display in a form of glasses	In production
98	No	Artificial vision device that allows the visually impaired to understand text and identify objects	In production
99	No	Communication system designed to replace two way radios	In production
100	No	Wearable augmented-reality heads up display	In production
101	No	Owlet Baby Monitor is a sock designed for babies to detect heart rate, oxygen levels	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
102	Wearable	Safety, bracelet, location, awarness	PFO	1	Safety Bracelet	GSM	Proprietary	No	No
103	Other	Incotinency, urine analysis	Pixie Scientific	1	Smart Diaper	Image recognition	Proprietary	Yes (iOS)	No
104	Sensor	Heart Rate Monitor	Polar	15	A300, M200, M400, M450, M600, Polar A360, Polar Loop, Polar Loop 2, Polar Loop Crystal, V650, V800, RCX5, FT4, FT7, H7	Bluetooth	Heart rate service (Bluetooth Smart)	Yes (Android,iOS)	No
105	Tracker	Physical activity, tracker	Preventice	3	BodyGuardian Heart, BodyGuardian Verité, BodyGuardian Holter	Bluetooth	Proprietary	Yes (iOS, Windows, Linux, OSX)	No
106	Sensor	Armband, heart rate, blood pressure	Qardio	1	QardioArm	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit, Apple Health)
107	Sensor	Weight, scale	Qardio	1	QardioBase	Bluetooth, WiFi	Proprietary	Yes (Android, iOS)	Yes (Google Fit, Apple Health)
108	Sensor	Elderly, monitoring, panic button	Qmedic	1	Qmedic	RF	Proprietary	No	No
109	Other	Neurostimulation	Quell	1	Quell	Bluetooth, USB	Proprietary	Yes (iOS, Android)	No
110	Smartwatch	Wristband, notifications	Razer	1	Nabu	Bluetooth, USB	Proprietary	Yes (iOS, Android)	No
111	Other	Gaming	Razer	1	OSVR	USB	Proprietary	Yes (Windows, OSX, Linux)	No
112	Glasses	Smart glasses	Recon	3	Jet, Snow, Engage	Bluetooth, ANT, WiFi	Proprietary	Yes (Android,iOS)	No
113	Other	Safety, helmet, head injury	Reebok	1	Checklight	USB	Proprietary	No	No
114	Sensor	Elderly, monitoring	ReemoHealth	1	Reemo	Undisclosed	Proprietary	No	No
115	Tracker	Children, monitoring	Rest Devices	2	Mimo Activity Tracker, Mimo Sleep Tracker	Bluetooth, WiFi, USB	Proprietary	Yes (iOS)	No
116	Smartwatch	Smartwatch	Rip Curl	1	SearchGPS	Bluetooth	Proprietary	Yes (iOS)	No
117	Insulin pump	Insulin pump	Roche	1	G4Roche Accu-Chek Combo	Bluetooth	Proprietary	Yes (Android,iOS)	No
118	Prosthesis	Hand prosthetis	Rslsteeper	1	Be Bionic	USB	Proprietary	No	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
102	No	No	None	GPS	No	No
103	No	No	Urine analysis	Undisclosed	No	No
104	Yes	No	PA (ST + EE), HR	Accelerometer, Gyroscope, Heart rate sensor	No	Yes (Bluetooth, REST API)
105	No	No	HR, HRV	ECG Sensor, Respiratory Monitor	No	No
106	No	Yes (Shimmer)	HR, BP	Blood pressure, heart rate sensor	No	Yes (REST API)
107	No	Yes (Shimmer)	WGT, BMI	Weight scale sensor	No	Yes (REST API)
108	No	No	PA, SL	Accelerometer, Thermometer, Temperature Sensor	No	No
109	No	No	None	Accelerometer	No	No
110	No	No	None	Accelerometer, Altimeter	No	No
111	No	No	None	Accelerometer, Gyroscope, Magnetometer	No	No
112	No	No	PA (ST + EE)	Accelerometer, Audio Speaker, Barometer, Clock, DLP Display, GPS, Gyroscope, Microphone, Photo Camera, Video Camera, Touch Interface, Magnetometer & Thermometer	No	Yes
113	No	No	None	Accelerometer	No	No
114	No	No	None	Accelerometer, Gyroscope, Magnetometer, Compass	No	No
115	No	No	PA, SL	Accelerometer, Respiratory Monitor	No	No
116	No	No	SP	Accelerometer, Gyroscope	No	No
117	No	No	BG	None	Yes (FDA approved, CE marked)	No
118	No	No	EMG	None	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
102	No	Positioning device with a patented alarm mechanism	In production
103	No	Passive system that uses chemical marker that react with the child's urine and change color accordingly	In production
104	No	Wrist worn physical activity tracker / fitness monitor	In production
105	No	Heart rate monitor	In production
106	No	Arm-band which tracks and measures the users vital health signs	In production
107	No	Smart weight scale	In production
108	No	Elderly people monitoring device	In production
109	No	Wearable device designed to provide widespread relief from chronic pain	In production
110	No	Gesture driven wearable smart watch that uses data collection to provide a preference based user experience	In production
111	No	Open-source virtual reality headset kit	In production
112	Yes	Smart glasses for athletes	In production
113	No	Impact detection sensor	In production
114	No	Wearable device to assist elderly health status monitoring	In production
115	No	Physical activity and sleep tracking of children	In production
116	No	Smartwatch	In production
117	No	Insulin pump	In production
118	No	Intelligent wearable hand prosthesis	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
119	Smartwatch	Smartwatch	Samsung	4	Gear, Gear 2, Gear 2 Neo, Gear Fit 2	Bluetooth	Proprietary	Yes (Android)	No
120	Smartwatch	Smartwatch	Samsung	3	Gear S, Gear S2, Gear S3	Bluetooth	Proprietary	Yes (Android, iOS)	No
121	Tracker	Physical activity, tracker	Scribe Labs	1	Run Scribe Pro	Bluetooth	Proprietary	Yes (iOS, Android)	No
122	Gloves	Virtual reality, glove	Senso Devices Inc.	1	Senso	Bluetooth	Proprietary	Yes (Android, OSX, Windows, Linux)	No
123	Gloves	Golf, coaching, glove	SensoGlove	1	SensoGlove	USB	Proprietary	No	No
124	Sensor	Behaviour research, industry	SensoMotoric Instrument	2	SMI Eye Tracking Glasses, SMI Driver Machine Analysis Package	WiFi	Proprietary	Yes (Windows, iOS)	No
125	Sensor	Basketball, shot, sensor	ShotTracker	1	ShotTracker	Bluetooth	Proprietary	Yes (iOS, Android)	No
126	Other	Socks	Siren	1	Siren	Bluetooth	Proprietary	Yes (iOS, Android)	No
127	Sensor	Muscle, activity, electrode	Somaxis	1	MyoLink	Bluetooth	Proprietary	Yes (iOS, Android)	No
128	Smartwatch	Smartwatch	Sony	3	Smartwatch, SmartWatch 2, SmartWatch 3	USB, Bluetooth, NFC	Proprietary	Yes (Android)	Yes (Google Fit)
129	Insulin pump	Insulin pump	Sooil	1	DANA R Insulin pump	Bluetooth	Proprietary	Yes (Android)	No
130	Other	Wearable metronome device	Soundbrenner	1	Pulse	Bluetooth	Proprietary	Yes (Android, iOS)	No
131	Sensor	Breath	Spire	1	Spire	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Apple Health)
132	Sensor	Smartcap	Spree Wearables	1	Smartcap	Bluetooth	Proprietary	Yes (iOS, Android)	No
133	Smartwatch	Smartwatch	Suunto	3	Ambit, Ambit2, Quest	Bluetooth, ANT+	Proprietary	Yes (Windows, OSX, Linux)	No
134	Smartwatch	Smartwatch	Tag Heuer	1	Connected	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit)

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
119	Yes (Workout Trainer)	No	PA (ST + EE)	Accelerometer, Gyroscope	No	No
120	Yes (Workout Trainer)	No	PA (ST + EE), SL, HR	Accelerometer, Gyroscope, Barometer, GPS	No	No
121	No	No	PA (ST + EE)	Accelerometer, GPS, Gyroscope	No	No
122	No	No	Motion analysis	Multiple IMU sensors	No	Yes (Bluetooth)
123	No	No	Motion analysis	Undisclosed	No	No
124	No	No	Image analysis	Camera	No	No
125	No	No	None	Undisclosed	No	No
126	No	No	TMP	Temperature sensor	No	No
127	No	No	Motion analysis, EEG, EKG, EMG	6-Axis IMU, EEG Sensor, EMG Sensor, ECG Sensor	No	No
128	No	No	PA (ST + EE), SL	Accelerometer, Magnetometer, Gyroscope, GPS, Compass	No	Yes (REST API)
129	No	No	BG	None	Yes (FDA approved, CE marked)	No
130	No	No	None	None	No	No
131	No	No	PA (ST + EE), BTH	Accelerometer, Respiratory monitor	No	Yes (REST API)
132	No	No	PA (ST + EE), HR, TMP	GPS, Accelerometer, Plethysmograph	No	No
133	Yes (Strava)	No	PA (ST + EE), SL, HR	Accelerometer, Barometer, Altimeter, GPS	No	Yes (REST API)
134	No	Yes (Shimmer)	None	Accelerometer, Gyroscope	No	Yes (Bluetooth, REST API)

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
119	No	Smartwatch	In production
120	No	Smartwatch	In production
121	No	Wearable device that gives athletes data about training	In production
122	Yes	Gloves for virtual and augmented reality	In production
123	No	Smart glove designed for golfers	In production
124	No	Hi-tech pair of glasses used to record what is in the user's field of vision	In production
125	No	Wearable tech for the baller that automatically tracks shot attempts, makes, and misses.	In production
126	No	Diabetes sock with a temperature sensor preventing development of ulcer	In production
127	No	Muscle activity monitor of the arm for health and fitness purposes	In production
128	Yes	Smartwatch	In production
129	No	Insulin pump	In production
130	No	Wearable metronome device for musicians	In production
131	No	Breath and activity tracker	In production
132	No		In production
133	Yes	Smartwatch	In production
134	Yes	Smartwatch	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
135	Insulin pump	Insulin pump	Tandem Diabetes Care	3	t:slim X2, t:slim G4, t:flex	RF Radio, Bluetooth	Proprietary	No	No
136	Sensor	Gesture control device	Thalmic Labs	1	Myo Armband	USB, Bluetooth	Proprietary	Yes (iOS, Windows, Android, OSX, Linux)	No
137	Wearable	Communication	Theatro	1	Theatro	Wifi	Proprietary	Yes (Android, iOS)	No
138	Wearable	Headband, stimulation	Thync	1	Thync	Bluetooth	Proprietary	Yes (iOS)	No
139	Sensor	Activity sensor	Timex	3	Ironman Move x20, Ironman One GPS+, Ironman Run X50	Bluetooth	Proprietary	Yes (iOS, Windows, Android, OSX)	No
140	Tracker	Children, tracker	Tinitell	1	Tinitell	Bluetooth, GSM	Proprietary	Yes (Android, iOS)	No
141	Sensor	Golf, coaching	Voice Caddie	5	D1, T1, VC100, VC200, VS300	USB	Proprietary	No	No
142	Glasses	Smart glasses	Vuzix	9	1200DX, 1200DX-AR, 1200DX-VR, AR3000, Blade 3000, M100, M2000AR, M300, M3000	HDMI, USB	Proprietary	Yes (Windows, OSX, Linux)	No
143	Sensor	Activity sensor	Wahoo	3	Run Workout Tracker, Tickr X Workout Tracker, Tickr Heart Rate Monitor	Bluetooth, ANT+	Proprietary	Yes (Android, iOS)	No
144	Smartwatch	Smartwatch	Wellograph Co., Ltd.	1	Wellograph	Bluetooth, USB	Proprietary	Yes (Android, iOS, Windows)	No
145	Tracker	Wearable, activity tracker	Whoop	2	WHOOP Strap, WHOOP Strap 2.0	Bluetooth	Proprietary	Yes (iOS)	No
146	Tracker	Wearable, activity tracker, notification device	Wisewear	3	Duchess, Calder, Kingston	Bluetooth, WiFi	Proprietary	Yes (Android, iOS)	No
147	Sensor	Weight Scale, Smart Body Analyzer, Smart Scale	Withings/Nokia	1	Body	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
148	Sensor	Wearable blood pressure monitor	Withings/Nokia	1	Blood Pressure Monitor	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
149	Sensor	Activity sensor/watch	Withings/Nokia	2	Activité, Activité Pop	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
135	No	Yes (Tidepool)	BG	None	Yes (FDA approved, CE marked)	No
136	No	No	EMG	Accelerometer	No	Yes (Bluetooth)
137	No	No	None	Microphone	No	No
138	No	No	None	None	No	No
139	Yes (Strava)	No	PA (ST + EE)	Accelerometer, GPS	No	Yes (REST API)
140	No	No	None	Accelerometer, GPS	No	No
141	No	No	None	GPS	No	No
142	No	No	None	None	No	No
143	No	No	PA (ST + EE), HR	Accelerometer	No	Yes (REST API)
144	Yes (MapMyFitness)	No	PA (ST + EE), SL, HR	Accelerometer, Gyroscope, Magnetometer, Compass	No	No
145	No	No	PA (ST + EE), SL, HR, HRV, TMP	Heart Rate Monitor, Accelerometer, Touch Interface, Temperature Sensor, Thermometer	No	No
146	No	No	PA (ST + EE), SL, HR, HRV, TMP	Accelerometer, GPS	No	No
147	Yes	Yes (Shimmer, Glooko)	WG	None	No	Yes (REST API)
148	Yes	Yes (Shimmer, Glooko)	BP, HR	None	No	Yes (REST API)
149	Yes	Yes (Shimmer, Glooko)	PA (ST + EE), SL	Accelerometer, Gyroscope	No	Yes (REST API)

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
135	No	Insulin pump	In production
136	No	Gesture control device that uses arm and hand movements to operate.	In production
137	No	Wearable device providing communication between employees	In production
138	No	Headband using low level electrical signals for brain stimulation	In production
139	Yes	Fitness tracker with limited smartwatch functionalities	In production
140	No	Tracking device for children with a calling functionalities	In production
141	No	Voice coaching wearable device	In production
142	Yes	Augmented reality glasses	In production
143	No	Wearable physical activity tracker	In production
144	No	Wellness watch	In production
145	No	Fitness tracker targetting athletes	In production
146	No	Wearable fitness tracker and notification device	In production
147	No	Bluetooth Smart scale	In production
148	No	Bluetooth wearable blood pressure monitor	In production
149	No	Physical activity tracker integrated into wristwatch	In production

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
150	Sensor	Smart Temporal Thermometer	Withings/Nokia	1	Thermo	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
151	Sensor	Sensor, sports tracker	Xensr	1	Xensr Air	Bluetooth	Proprietary	Yes (Android, iOS)	No
152	Sensor	Sensor, swimming, sports tracker	Xmetrics	2	Xmetrics Pro, Xmetrics Fit	USB, Bluetooth	Proprietary	Yes (iOS, Windows, OSX, Android)	No
153	Sensor	Animation	Xsens	2	MVN, MVN Biotech	RF	Proprietary	Yes (Windows)	No
154	Smartwatch	Smartband	Zeblaze	1	ZeBand	Bluetooth, GSM	Proprietary	Yes (Android, iOS)	No
155	Smartwatch	Smartwatch	Zeblaze	5	Classic, Blitz, Rover, Crystal, Cosmo	Bluetooth, GSM	Proprietary	Yes (Android, iOS)	No
156	Industry tool	Tracking device	Zebra	1	Dart Tag	Ultra Wide Band, WiFi	Proprietary	No	No
157	Industry tool	Barcode, scanner	Zebra	2	RS6000, RS4000	Bluetooth, NFC	Proprietary	Yes (Android)	No
158	Industry tool	Personal computer	Zebra	2	WT41N0, WT6000	Bluetooth, NFC, WiFi, USB	Proprietary	No	No
159	Sensor	Activity sensor	Zikto	1	Walk	Bluetooth	Proprietary	Yes (Android, iOS)	No
160	Smartwatch	Smartwatch	TomTom	3	TomTom Golfer, TomTom Runner Cardio, TomTom Spark	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No
161	Sensor	Activity sensor	WOR(l)D Global Network	1	Helo	Bluetooth	Proprietary	Yes (Android,iOS)	No
162	Smartwatch	Smartwatch	Blocks	1	Blocks	Bluetooth, WiFi	OpenSource	Yes (Android,iOS)	No
163	Gloves	Virtual reality, glove	BreqLabs	1	ExoGlove	Undisclosed (wireless)	Proprietary	Unknown	No
164	Sensor	CGM, Patch, Non-invasive	Dia-Vit	1	Dia-Vit Tracker	Unknown	Proprietary	Unknown	Unknown
165	Gloves	Glove, fitness	Everyday Olympian	1	PureCarbon	Bluetooth	Proprietary	Yes (iOS)	No
166	Tracker	Activity sensor	Humon	1	Hex	Bluetooth, ANT+	Proprietary	Yes (iOS, Android)	No
167	Smartwatch	Smartwatch, accessory	Kiwi	1	Glance	Bluetooth	Proprietary	Yes (Android, iOS)	No
168	Sensor	Augmented reality, HUD, glass	Lumus	3	DK-40, DK-50, Sleek	Undisclosed	Unknown	Unknown	Unknown
169	Gloves	Music controller, glove	mi.mu gloves	1	mi.mu gloves	WiFi	Proprietary	Yes (Windows)	No
170	Sensor	CGM, Patch, Non-invasive	Nemaura Medical	1	SugarBEAT	Unknown	Proprietary	Yes (Unknown)	Unknown
171	Gloves	Glove, virtual reality	Noitom	1	Hi5 VR Glove	Undisclosed (wireless)	Proprietary	Yes (Windows)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
150	Yes	Yes (Shimmer, Glooko)	TMP	None	No	Yes (REST API)
151	No	No	None	Accelerometer, Gyroscope, Magnetometer, GPS	No	No
152	No	No	EE	Accelerometer, Gyroscope, Magnetometer	No	No
153	No	No	None	Accelerometer, Gyroscope, Magnetometer	No	Yes
154	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope, GPS, Heart Rate Monitor, Pressure Sensor	No	No
155	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope, GPS, Heart Rate Monitor, Pressure Sensor	No	No
156	No	No	None	None	No	No
157	No	No	None	Camera	No	No
158	No	No	None	None	No	Yes (Bluetooth)
159	No	No	PA (ST + EE), SL	Accelerometer, Gyroscope, Proximity sensor	No	No
160	No	No	PA (ST + EE), SL, HR	Heart Rate Monitor, Accelerometer	No	Yes (REST API)
161	No	No	PA (ST + EE), SL, HR, TMP, BP, Mood, Fatigue, ECG	Accelerometer, Gyroscope, Heart rate sensor	No	Yes (Bluetooth, REST API)
162	No	No	HR	Accelerometer, Gyroscope, Compass, GPS, Humidity Sensor, Pressure Sensor, Thermometer	No	Yes
163	No	No	Motion analysis	Ultrasonic tracking, IMU sensor	No	No
164	Unknown	Unknown	BG	None	Unknown	Unknown
165	No	No	Motion analysis	Accelerometer, Gyroscope	No	No
166	No	No	Unknown	Oximeter	No	No
167	No	No	None	Accelerometer, Gyroscope, Magnetometer, Barometer, Compass	No	No
168	Unknown	Unknown	Unknown	Accelerometer, Gyroscope, Magnetometer, Compass	No	No
169	No	No	Motion analysis	IMU sensor	No	No
170	Unknown	Unknown	BG	None	Yes (FDA approved, CE marked)	Unknown
171	No	No	Motion analysis	IMU sensor	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
150	No	Bluetooth personal temperature meter	In production
151	No	Sports tracker	In production
152	No	Wearable tracker for swimmers	In production
153	No	Wearable motion-capture device aimed at professional animators	In production
154	No	Smartband	In production
155	No	Smartwatch	In production
156	No	Device for tracking assets and personnel	In production
157	No	Wearable barcode scanner	In production
158	Yes	Multipurpose wearable computer	In production
159	No	Smartwatch	In production
160	No	Smartwatch	In production
161	No	Wrist worn physical activity tracker / fitness monitor	Marketing scam
162	Yes	Modular smartwatch	Not released yet
163	Yes	Virtual reality glove	Not released yet
164	No	Non-invasive BG sensor	Not released yet
165	No	Fitness gloves	Not released yet
166	No	Wearable system to allow endurance athletes to train smarter by monitoring the way their muscles are using oxygen in real-time	Not released yet
167	No	Smartwatch accessory	Not released yet
168	No	Wearable head mounted display with augmented reality capabilities	Not released yet
169	No	Gloves for the performance and composition of music	Not released yet
170	No	Non-invasive BG monitoring system	Not released yet
171	No	Virtual reality glove	Not released yet

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
172	Sensor	Chest strap, ECG	Qardio	1	QardioCore	Bluetooth	Proprietary	Yes (iOS)	Yes (Google Fit, Apple Health)
173	Other	Wearable computer	Rufus Labs	1	Rufus Cuff	WiFi, Bluetooth	Proprietary	Yes (iOS, Android)	No
174	Sensor	Electrodes, oxygen consumption	SenseCore	1	Sense Pro	Undisclosed	Proprietary	No	No
175	Gloves	Virtual reality, glove	SenseGlove	1	Sense Glove	Bluetooth	Proprietary	Yes (Windows)	No
176	Sensor	Wristband	Sensmi	1	Sensmi	Bluetooth	Proprietary	Yes (iOS, Android)	No
177	Earphones	Bone conduction, speaker	Sonitus Medical Inc.	1	SoundBite	WiFi	Proprietary	No	No
178	Sensor	Punch tracker, gym, boxing	Striketec	1	StrikeTec	Bluetooth	Proprietary	Yes (iOS, Android)	No
179	Prosthesis	Artificial prosthetis	Touch Bionics	1	I-limb Ultra	Bluetooth	Proprietary	Yes (iOS, Windows, OSX)	No
180	Smartwatch	Smartwatch	Unaliwear	1	Kanega	WiFi, GSM, Bluetooth	Proprietary	No	No
181	Sensor	Skin, sensor	Vancive Medical Technologies	1	Metria IH1	USB	Proprietary	Yes (Windows, OSX)	No
182	Sensor	Activity sensor	Wearit	1	Smartwatch	WiFi, Bluetooth, USB, RFID	Proprietary	Yes (Android)	No
183	Sensor	Ankle, Wearable system, Step impact	Xybermind	1	Achillex	USB	Proprietary	Yes (Windows)	No
184	Other	Contactless payment systém	Barclaycard	1	bPay Wristband	NFC	Proprietary	Yes (Android, iOS)	No
185	Other	Personal Health Information device	Code4Armour	1	Code4Armour	NFC	Proprietary	Yes (Android, iOS)	No
186	Smartwatch	Smartwatch	LG	1	Gizmopal VC100	GSM	Proprietary	Yes (Android, iOS)	No
187	Smartwatch	Smartwatch	LG	1	Lifeband Touch	Bluetooth	Proprietary	Yes (Android, iOS)	No
188	Smartwatch	Earphones	LG	1	Heart Rate Monitor	Bluetooth	Proprietary	Yes (Android, iOS)	No
189	Smartwatch	Notifications, wristwatch	Martian	1	Martian Notifier	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No
190	Smartwatch	Smartwatch	Microsoft	2	Band, Band 2	Bluetooth	Proprietary	Yes (iOS, Windows, Android, Windows Mobile)	Yes (Microsoft HealthVault)
191	Smartwatch	Smartwatch	MyKronoz	1	ZeBracelet2	USB, Bluetooth	Proprietary	Yes (Android, iOS)	No

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
172	No	Yes (Shimmer)	ECG, TMP	ECG, Thermometer	No	Yes (REST API)
173	No	No	None	Accelerometer, GPS, Gyroscope	No	No
174	No	No	PA (ST + EE), EPOC	ECG Sensor, Respiratory Monitor, Accelerometer, Temperature Sensor	No	No
175	No	No	Motion analysis	Multiple IMU sensors	No	Yes (Bluetooth)
176	No	No	GSR, SL	GSR, Accelerometer	No	No
177	No	No	None	Bone Conduction Speaker	No	No
178	No	No	Motion analysis	Accelerometer, Gyroscope	No	No
179	No	No	None	None	No	No
180	No	No	None	Accelerometer, GPS	No	No
181	No	No	None	Accelerometer, Galvanometer, Thermometer & Temperature Sensor	No	No
182	No	No	PA (ST + EE)	Accelerometer, Gyroscope, GPS	No	No
183	No	No	Impact force, degree of pronation, and orientation of the foot	Unknown	No	No
184	No	No	None	None	No	No
185	No	No	None	None	No	No
186	No	No	None	GPS	No	No
187	No	No	PA (ST + EE), SL	Accelerometer, Altimeter	No	No
188	No	No	HR	None	No	No
189	No	No	None	None	No	No
190	Yes (Strava)	No	PA (ST + EE), SL, HR	Accelerometer, Barometer, GPS, Gyroscope, Thermometer, UV sensor, Galvanometer	No	Yes (REST API)
191	No	No	PA (ST + EE)	Accelerometer	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
172	No	Chest-worn device measuring heart rate, temperature and physical activity	Not released yet
173	No	Wearable wrist computer	Not released yet
174	No	Wearable electrodes that compute post-exercise oxygen consumption (EPOC), speed/pace, distance, cadence, total steps and activity classification	Not released yet
175	Yes	Virtual reality hand controller with haptic feedback	Not released yet
176	No	Wristband for monitoring of stress levels	Not released yet
177	No	Wearable hearing aid designed to be worn on the inside of the mouth	Not released yet
178	No	Fitness boxing tracker	Not released yet
179	No	Wearable prosthetic hand	Not released yet
180	No	Smartwatch for elderly people with fall detection and voice control	Not released yet
181	No	Disposable wearable device that detects the user's skin temperature and activity	Not released yet
182	No	Smartwatch	Not released yet
183	No	Wearable system used to determine the ideal shoe for the user	Not released yet
184	No	Wristband providing contactless payment capabilities	Product discontinued
185	No	Wearable device and mobile app that gives First Responders instant access to critical Personal Health Information	Product discontinued
186	No	Wearable device which enables parents, guardians, and caregivers a simple method of keeping track of the wearer.	Product discontinued
187	No	Physical activity tracker	Product discontinued
188	No		Product discontinued
189	No	Simple smartwatch with notification functionalities	Product discontinued
190	Yes	Smartwatch	Product discontinued
191	No	Smartwatch	Product discontinued

#	A. Type of wearable system	Keywords	Owner	Family devices	System variety	B. Communication interfaces	C. Data protocol (device supports standardized protocol for data transmission)	D. Smartphone/PC integration	E. Direct integration with health platforms (Apple Health, Google Fit)
192	Smartwatch	Smartwatch	MyKronoz	3	ZeWatch, ZeBracelet, ZeNano	Bluetooth	Proprietary	Yes (iOS, Windows, Android, Windows Mobile, OSX, Linux & Blackberry)	No
193	Sensor	Activity sensor	Nike	3	FuelBand, FuelBand SE, Sportwatch GPS	USB, Bluetooth	Proprietary	Yes (iOS, Windows, Android)	No
194	Smartwatch	Smartwatch	Pebble	5	Pebble, Pebble 2, Pebble 2 SE, Time Steel, Time Round	Bluetooth	Proprietary	Yes (Android,iOS)	Yes (Google Fit, Apple Health)
195	Smartwatch	Notifications, wristwatch	Intel	1	Basis Peak	Bluetooth	Proprietary	Yes (Android, iOS)	Yes (Google Fit, Apple Health)
				364					

#	F. 3rd party integration with health platforms (Apple Health, Google Fit)	G. Connection to Health Care System/Middleware	H. Health data types (PA – Physical activity, ST – Steps, EE – Energy expenditure, SL – Sleep, HR – Heart Rate, TMP – Temperature, WG – Weight, BP – Blood Pressure, BTH – Breath Patterns, EPOC - Excess Post-Exercise Oxygen Consumption)	I. Integrated sensors (if applicable)	J. Medical device	K. User data access (access to data acquisitioned by integrated sensors)
192	No	No	PA (ST + EE)	Accelerometer	No	No
193	No	No	PA (ST + EE), GPS	Accelerometer, Gyroscope	No	Yes (REST API)
194	No	No	PA (ST + EE), SL, HR	Accelerometer, Gyroscope	No	Yes (Bluetooth, REST API)
195	No	No	PA (ST + EE), SL, HR, TMP	Accelerometer, Skin temeprature, Galvanic skin response sensor	No	No

#	L. Developers access (i.e. Add/modify existing functionality)	Short description	M. Availability of the device
192	No	Smartwatch	Product discontinued
193	No	Wrist worn physical activity tracker / fitness monitor	Product discontinued
194	Yes	Bluetooth connected smartwatch	Product discontinued
195	No	Smartwatch	Product discontinued/recalled