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Factors easing the transition from paper to electronic prescribing of multidose dispensed drugs (MDD)

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Abstract

Multidose dispensed drugs (MDD) is a machine-dispensed system packing drugs in unit-of-use disposable bags. MDD is still prescribed using paper and fax. There is now an ongoing national effort to introduce e-prescribing of MDD similar to ordinary e-prescriptions. In this paper, we analyse how some of the first GPs, nurses and pharmacists who started using the system in 2018 experienced the start-up. We found four factors affecting the transition. These were technical readiness; sufficient time to make the first medication list; appointed contact persons for support and questions; and, sufficient information and training in using the new system prior to start-up.

Keywords

Multidose dispensed drugs, e-prescribing, shared medication list

1 INTRODUCTION

One in three of the community-dwelling elderly have been exposed to errors and potentially inappropriate medications [1]. Lack of access to accurate information on patients' medicine use increases the risk of medication errors [2]. Medicine-related problems (MRP) such as side effects, inappropriate use and errors is a serious threat to patient safety. MRPs reduce quality of life, cause morbidity, death and increase health care costs [3, 4]. Ten percent of all hospital admissions to medical wards in Norwegian hospitals are due to medicine errors. This amounts to 490,000 additional bed-days and approximately 1000 deaths per year [5, 6].

To improve safety and effectiveness in the medication management process, multidose dispensed drug (MDD) have been implemented in Norway over the last two decades [7]. MDD is a machine-dispensed system packing the drugs in unit-of-use disposable bags, one unit for each dose occasion, usually covering a 14-day period. The MDD bags are labelled with the patient's name and birthdate, the names of the drugs and time for when the tablets or capsules should be taken. Only solid formulations such as tablets and capsules can be dispensed in MDD. Inhalators, liquids and creams are delivered in their original packaging alongside the multidose bags. MDD is assumed to improve medication adherence, reduce nurses' workloads and reduce the waste [8-10]. The scientific evidence to support these claims is limited [11, 12].

The use of MDD in Norway has grown extensively over the past decade, from 15,700 patients in 2006 to 90,500 in 2017 [13]. The majority of MDD patients (74%) receive home care services, 21% are residents in nursing homes

Figure 1 Multidose dispensed bags (Apotek 1).

and less than 5% have a private arrangement and pay for the MDD themselves [13]. Most MDD patients are elderly multi-medicine users that have difficulties managing their own drugs. This makes them at high risk of experiencing side effects, medication errors and other adverse drug reactions. MDD patients are even more likely to be exposed to MPRs than patients using ordinary dispensing [14-16].

Over 90 % of prescriptions in Norway are sent to the pharmacy electronically [17]. The prescribing of MDD has until recently been paper-based, and still is in most parts of Norway. All medications a patient is prescribed, is listed on a prescription card and sent to the pharmacy by fax or ordinary mail. This paper prescription is valid for multidose dispensing for one year. The pharmacy staff manually transfer the medicines information from the prescription into the electronic MDD-system. The machine pack the drugs and the multidose bags are sent to the home care service, together with a copy of the prescription card. The nurses then manually transfer the medication information from the card they receive from the pharmacy into their own electronic record system. All these manual steps in the medication process increase the risk of

medication errors. It has also been voiced concerns about duplicate prescriptions when general practitioners (GPs) prescribe electronic prescriptions in addition to MDD paper prescriptions [18]. There is now an ongoing effort to introduce an electronic MDD prescribing system, where the prescribing procedure will be similar for MDD and for ordinary electronic prescriptions.

Electronic prescribing of MDD is one of several political initiatives to improve medication safety and efficiency in the medicines management process [19]. The implementation effort is national and the Directorate for E-health is responsible for driving this process. The implementation of electronic prescribing for MDD patients began in 2018 after two years of pilot testing. The first MDD patients to get electronic prescribing are those receiving home care services. The GPs who started using electronic prescribing were two GP-offices in Rogaland, five in Hordaland and three in Oslo. GP-offices in Larvik and Bergen will follow in 2019. They all use the electronic patient record system from InfoDoc Plenario.

This paper is part of a lager study that explores and analyses how the implementation of electronic prescribing of MDD affect medication accuracy, efficiency, changes in work practice and collaboration in primary care.

In this paper, we present how the GPs, the nurses in home care services and the pharmacists that began using the electronic prescribing system in 2018, experienced the start-up phase. The aim is to identify factors that will ease the transition to support the national implementation effort that lies ahead.

2 METHOD

This paper presents a qualitative study investigating the transition from paper prescribing to an electronic MDD prescribing system. We conducted interviews with users of the new e-prescribing system. The users in this study are the health personnel handling e-prescribing for MDD in primary care. This involves GPs, nurses and pharmacists in the home care services, and employees at the pharmacy dispensing MDD. We invited users that started prescribing MDD electronically in the first half of 2018 to be interviewed. The Norwegian Directorate of e-Health provided contact details for the users. We sent emails inviting the GPs to participate in the study three months after start-up. We also consecutively sent invitations to contact persons in the corresponding home care services and the MDD pharmacy. The invitations briefly described the project and the main themes of the interviews. One reminder was sent to those who did not respond. We sent invitations for follow-up interviews 10 months after start-up. All users who agreed to participate were included as informants.

We conducted 16 interviews with 26 users in total. This included nine interviews with 19 GPs (two group interviews, and three individual phone interviews). We also received two e-mails from one of the GPs. We further interviewed two nurses and one pharmacist (individual interviews) in two home care services and one group interview with four pharmacists at the MDD pharmacy. We also conducted five follow-up phone interviews with

three GPs, one pharmacist in the home care service and two pharmacists at the MDD pharmacy. Two researchers completed the group interviews. These interviews took place at the workplace of the users. One researcher completed the phone interviews. We consider that our informants represent the experiences we sought. The GPs that agreed to participate came from five of the nine invited GP-clinics that started using electronic prescribing of MDD in 2018.

We used group and individual interviews. We considered that groups would provide sufficient depth to the information we wanted to collect, and in addition, the informants could stimulate each other to provide experiences and views. Differences in views and experiences were as interesting as uniform opinions among the informants. We also conducted 11 individual interviews, most of them by phone. The interviews were semi-structured, and included open and follow-up questions. The interviews focused on how e-prescribing of MDD affects the users work practice, the experienced benefits, risks, challenges, and measures to facilitate improvement. We further categorised the questions into prior to (preparation), during and after start-up. The interviews lasted 30-45 minutes.

For this paper, we have focused on the start-up phase and included themes and sub-topics relevant to factors that can ease the transition process for the nation-wide implementation effort.

The interviews were recorded on tape and transcribed by a professional agency. We anonymised the data in the transcription and stored audio recordings and person-identifiable identification information separate from the transcribed material.

An applied framework approach was used to assess the introduction of electronic prescribing of MDD [20, 21]. We explored the empirical data using a content analysis to break them down into analytical categories relevant to this study. We used the themes from the interview guide to define key categories. These were divided into three main groups. The first group included changes in work practices. The second included benefits, problems and risks they experienced with the system. The third included measures for improvements. Furthermore, we coded the empirical material in the following categories: the technology, safety, time use, communication, information about and training in how to use the new prescribing system. The results section presents quotes from those who used the system.

3 RESULTS

3.1 Medication safety and time use

The medical doctors experienced the transition from paper to electronic prescribing of MDD differently. Some experienced the start-up without any significant problems. Others experienced technical problems and errors that took some time to detect, creating extra work at the clinic. Others again, were unable to start using electronic prescribing and emphasised they still do not have a system that works. One GP describe the system as "*completely*

useless [...] It takes too much time and ends in a clear reduction in both overview and patient safety."

However, most GPs agreed that the electronic prescribing system increased medication safety. Some experienced that electronic prescribing was more time consuming. The electronic system requires that the GPs continuously keep the list up-to date and incorporate new prescriptions from other doctors. They must revise, reconcile, and renew prescriptions for the drugs listed in the medication list more often. How often depends on the type of drug and size of the packages. While the old prescription card was considered a valid prescription for one year for all medicines listed, the electronic system requires single e-prescriptions on each medication on the list.

The nurses we interviewed in the home care service experienced many errors in the medication lists at start-up. When they compared the first new medication list to the medication record in their own system, they discovered that some patients lacked multidose completely, some lacked specific drugs, while others had a different dosage. The nurses further experienced increased responsibility and workload, as they had to check and fix errors and discrepancies at every new MDD packing.

The pharmacist at the MDD pharmacy experienced that electronic prescribing was more time-consuming than paper and fax. Errors experienced in the e-prescriptions included too small pack sizes being prescribed so they did not have enough medicines to dispense in the bags, some patients lacked valid prescriptions or the prescriptions were empty (the patients had already collected the medicines at another pharmacy) and some prescriptions lacked reimbursement information. However, despite the challenges at start-up they agreed that when the system worked it was much better than paper prescriptions and fax.

Based on the interviews, we found four distinct factors that were essential to have in place to ease the transition from paper to electronic prescribing of MDD. These were technical readiness; sufficient time and resources to make the first medication list; appointed persons to call for support and questions; and, sufficient information and training in using the new system prior to start-up.

3.2 Technical readiness

The users agreed that the technology, that is, the prescribing module as part of the electronic medical journal at the GP-offices, must be as ready and mature as possible at start-up. If the GPs experience errors and problems, they get frustrated and the likelihood of someone dropping out and stop using the system increases.

"It was very frustrating, we spent a lot of time on it, and then I think some [of us], not just here but some of the others [GPs] dropped out." GP

A system that works will also motivate the GPs to do the extra work needed to review, reconcile, and make the first medication list for all MDD users.

"That it works technically from day one is important, [..] you are then motivated to do the extra work needed."

GP

Furthermore, the server must be able to handle all the new medication lists and prescriptions if many GPs start using the system simultaneously.

"[...] when we came on with a large volume it stopped working and then the whole project was delayed [..] the server crashed completely. " GP

3.3 Sufficient time and resources to make the first medication list

The users highlighted the importance of allocating sufficient time and resources to reconcile and make the first electronic medication lists for the MDD users. All paper prescriptions must be deleted and a new medication list and e-prescriptions on each drug must be created. The GPs we interviewed emphasised the importance of keeping the medication lists nice and tidy.

"And then the hustle and bustle to have clean and neat medication lists, that is important". GP

The nurses we interviewed experienced an increased workload as they checked every new delivery from the pharmacy. They allocated extra nurses to help check the MDDs on the delivery days.

"Before we had one nurse, [..], but at the last two deliveries we were four nurses [checking] approximately 100 users" Nurse

Both the GPs and the nurses stressed that they should be informed prior to start-up that the introducing electronic prescribing for MDD means extra work. They can then allocate more resources during start-up. They were not prepared for the time it took in the beginning.

It was also suggested that a meeting between GPs and staff from the home care service would be useful to ease and improve the reconciliation process.

3.4 Appointed contact/support persons

Some of the GPs had a direct phone number to one person for technological support. They also had one appointed contact at the pharmacy. In smaller municipalities, the GPs knew the pharmacist responsible for MDD and the nurses in the home care service. All users could easily make a phone call or arrange a meeting. In larger municipalities, this was more challenging.

The nurses we interviewed had trouble getting in touch with both GPs and staff working with MDD at the pharmacy when they had questions or wanted to report errors. Phone calls had to go through the reception and they did not always know whom to ask for.

"... it is very important that the pharmacy also has a person, [..] that the home care nursing [can contact]"
Nurse

The GPs also reported that having one contact person they could call for help to resolve problems was important. Some suggested that a super-user at the office would be most effective. They felt it was easier to ask a colleague.

"We don't have time to take that phone, so it's much easier to ask a colleague". GP

3.5 Information and training

Before start-up, the GPs received an information leaflet and a guide describing how to use the system. Some found this information sufficient and they received adequate support from the suppliers when needed. Others felt that this information and support was insufficient.

The GPs argued that the training should include a course, a short video and/or a written step-by step guide to explain

in detail how and what to do in the computer program. The most important was to have one person at the office who knew the system (one of the doctors). Such a super-user could demonstrate the steps and help others when they were stuck. The GP-offices that had a super-user emphasised this as valuable.

"Maybe a super-user should be able to take some responsibility for guiding the rest of the flock. I think maybe it would have been more successful than the way it was done." GP

The nurses did not get any information or training before start-up. They argued that training together with the other users would improve the transition. They believe that understanding the main features of the change can better equip them to handle errors and discrepancies in the start-up phase.

4 DISCUSSION

Most users agreed that when the electronic prescribing system for MDD worked, it was much safer for the MDD-patients than paper prescriptions and fax. However, the users experienced problems and challenges at start-up that, if addressed, could improve the implementation process. This study found four distinct factors that are essential for improving the start-up phase. These are technical maturity and readiness; sufficient time and resources to make the first medication list; appointed persons to call for support and questions; and, sufficient information and training in using the new system prior to start-up.

One measure to reduce medication errors and improve medication safety at start-up is to ensure that the technology works as planned from day one. Some of the GPs experienced the prescribing module immature with technical problems and errors that took time to resolve. Some GPs experienced so much trouble that they gave up and sent the prescriptions by fax to meet the packing deadline at the pharmacy. Spending time on tasks that is complicated in a hectic working day may be too demanding. Some might therefore give up on using the system until it works better. Others studies has also found that technical readiness, maturity and interoperability is crucial to successful implementations in health. For example a large study of shared electronic records in England found that the properties and attributes of the technology heavily influenced the implementation process [22]. The technical solutions, usability of systems, implementation strategy and routines are further affecting the accuracy of medication information [23].

Another reason for the different experiences at start-up might be MDD workloads. Those GPs with few MDD-patients seems to have less trouble than those with many MDD-patients. It is therefore important to plan and prepare GPs for the amount work that is needed to carry out the reconciliation process for the first medication list. Time is scarce at most GP-offices and the GPs have to review every medication for all MDD patients and decide whether to continue prescribing the drug or not. This is a time consuming, and sometimes impossible task since they do not have the patient in front of them. Sufficient time and resources must therefore be available. Difficulties in

allocating time and resources to implement e-health services within routine health care is a well-known barrier [24, 25].

The presence of a super-user also seems to affect how the GPs experienced the start-up. To have a colleague in the office that can show on the computer screen what to do, reduced frustrations and had a positive effect on how they experienced the implementation process. Providing extra training for one of the GPs at each clinic can improve the transition phase.

Sufficient information and training prior to the implementation is important. Most users agreed that more information on how to use the system such as videos and step-by step guides would have been useful. However, the information material should be easy to find and use in a busy GP-clinic.

Electronic prescribing of MDD is complex and involves a large number of different health professionals located at different health care facilities. The new prescribing system has the potential to improve medication safety and simplify the flow of information. Electronic prescribing can improve accuracy as it remove the tasks of manually transferring the medication information from paper prescriptions to the electronic systems at the MDD-pharmacy and the home care services. Automatic transfer can be a safer option as it has the potential to reduce the risk of human mistakes and errors. The communication patterns has also changed, as it is now possible to send messages in the electronic patient record at the GPs and the electronic prescription system at the pharmacy. This has the potential to make the prescribing process more efficient.

The providers in the home care service and the MDD-pharmacy experienced errors in the medications and the prescriptions at start-up. This resulted in a feeling of increased responsibility and workloads. The nurses we interviewed did not trust that the lists were correct, and they created new routines to check for every new delivery from the pharmacy. Trust is an important aspect when patient information is shared [26]. Building trust has to run in parallel with the introduction of new digital services [27]. This can be achieved by improving communication and cooperation between the different providers in the prescribing process.

A weakness of this study was the limited number of participants. We had in particular few interviews with the nurses involved. We cannot rule out that a larger number of participants would have put forward other views and experiences, and thereby included other important aspects. Furthermore, the GPs who agreed to participate might have been more positive towards the new prescribing routines than those who did not respond. One of the GPs pointed out that: *"I have been positive about this project all the time, so I am willing to overlook some bumps".* However, we believe that the views expressed by the informants in this paper capture the main aspects related to the start-up phase of implementing electronic prescribing of MDD.

Challenges in e-health implementation are an international phenomenon and have been widely reported [28, 29]. How e-health interventions are implemented is as important as

the features and functions of the intervention itself [30]. Understanding how best to implement new digital services is crucial to achieve its expected benefits.

5 CONCLUSION

Four factors reported to ease the transition from paper to electronic prescribing of MDD. These were technical readiness; sufficient time and resources to make the first medication list; appointed persons to call for support and questions; and, sufficient information and training in using the new system prior to start-up. Addressing these factors is important to reduce errors, improve medication safety, support up-take and facilitate the planned large-scale implementation.

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7 ACKNOWLEDGEMENT

Digital solutions for a shared medication list

A narrative literature review

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Abstract

Digital solutions for a shared medication list are important in order to provide correct medication information between health care providers and the patient. The objective of this review is to provide an overview of the existing knowledge of effects and experiences with digital solutions for a shared medication list. We conducted a narrative literature review and included nine primary studies. Most studies were qualitative, focusing on experiences of patients and health care providers. This review revealed a gap of knowledge on the effects of patient safety and quality of care related to digital solutions for a shared medication list.

Keywords

Digital medication management, primary health care, health care providers, patients.

1 INTRODUCTION

Correct information on a patient's medicine use makes it possible to cure and prevent many medical conditions [1]. Clinicians and other health care providers do not have immediate access to an up-to-date, complete and accurate list of the patients' prescribed medications which increases the risk of medication errors [2]. Medicine-related problems (MRP) such as side effects, inappropriate use and errors are serious threats to patient safety, as it may reduce quality of life, cause morbidity, death and increase health care costs [3, 4]. Patient safety is the foundation upon which all other aspects of quality of care are built, and are indistinguishable from the delivery of quality health care [5, 6].

The Norwegian Board of Health supervision describes that medication management within the municipalities' health and care services are not sufficient and concludes that health care personnel lack an overview of the patient's actual use of medications. Important information may be lost (observations, test results, documentation) and reduces the quality of services [7]. Further, one of the main challenges is that the digital systems do not provide health care providers or patients an overview of the medications the patient actually uses. Another challenge is the lack of reliable medication safety practices, particularly in patient transition between levels of care, which is recognized as a high-risk area for MPRs [8]. Several studies from Scandinavia [9-11] and internationally [12-14] show problems with correct information about a patient's actual medication list, and the impact on patient safety and quality of care. Polypharmacy patients and/or patients of high age are especially at risk when transitioning between levels of care. Some of the problems arise because different health care units are using different electronic health record (EHR) systems that are not connected to each other [15]. This may cause poor communication and lack of information between and within services and can lead to potentially harmful medication errors [16].

In Norway, the health authorities are investing in several digital innovations to improve patient safety, the quality of care and the efficiency in the medicine management process. To share updated drug information through the entire patient trajectory across organizations, is one of the prioritized areas in the Norwegian e-health strategy and a nationally shared medication list is the overall goal [17]. The Norwegian Directorate for E-health (NDE) is currently working on the implementation of e-prescribing, the summary care record (SCR) and a nationally shared medication list. The implementation of the summary care record in primary health care (nursing homes and home care) will begin towards the end of 2019, and is an important step towards the implementation of a national shared medication list in Norway. The Norwegian Centre for E-health Research is performing a longitudinal study in the period 2019-2023 on the effects and experiences on health care providers and patients of the summary care record and the nationally shared medication list in primary health care. Based on these ongoing projects, an overview and presentation of the current knowledge on digital solutions for a shared medication list is needed.

The main objective for this narrative literature review is to provide an overview of the existing knowledge on different digital solutions for a shared medication list in primary health care focusing on:

- Effects on patient safety and quality of care
- Experiences from health care providers and patients
- Digital solutions for a shared medication list

2 METHODS

2.1 Search strategy

The research team, consisting of two experienced researchers (TSB, USM) and a research librarian (KFL), identified relevant keywords and developed the search strategy. We systematically searched the databases PubMed, SveMed+, Cinahl, Embase, Cochrane and NORA (Norwegian Open Research Archive) to identify relevant literature. We did not apply a time filter on the search. Search terms used included "Electronic medication record", "Electronic shared medication list", "Shared electronic medication record", "Shared medication record", "Shared medication list", "National medication list", "Computerized National Medication List", "Digital medication management system", "Electronic medication management", "Electronic medication reconciliation (system)", "Online medication reconciliation", "Summary care record" and "Summary record". Depending on the database, we searched 'title/abstract' or 'all fields'.

2.2 Selection of studies and data retrieval

Each member of the research team independently screened the result and identified relevant papers based on title and abstract. Papers that met the following inclusion criteria were included:

- Primary studies on digital solutions within medicine management in primary care (GPs, nursing homes, home care etc.)
- Containing empirical material with a description of methods used for data collection and analysis
- Scandinavian or English language

We resolved any conflicts by discussion until consensus. The team further assessed the full-text articles independently and inclusion of papers meeting the inclusion criteria was determined by consensus. A manual search of the reference lists of included articles was done to identify any papers missed by the systematic search.

We used a predefined data retrieval form to analyze, categorize and systematize information of the included studies. This included information on first author, year of publication, title, digital technology, information sharing, design, population and setting, methods, number of participants (n), objective(s) and results. Further, we performed a thematic analysis of the results of the included papers. Thematic analysis is the most common method within narrative reviews to produce a synthesis of findings [18].

3 RESULTS

The database searches yielded 418 records after removing duplicates. The research team screened all 418 titles and abstracts, and we excluded 384 papers due to irrelevant titles and/or abstracts. Further, we considered 34 records for detailed assessment of full text, and excluded 25 papers not meeting one or several of the inclusion criteria. We included nine studies in this review, published in the period 2008-2018. The PRISMA flow chart shows the number of records/studies at each stage (Figure 1).
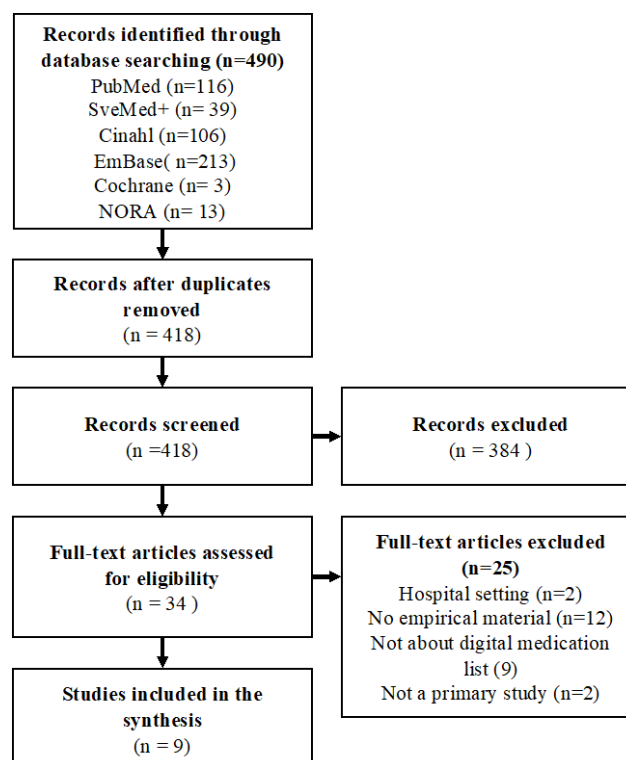
Figure 1 PRISMA flow diagram.

3.1 Characteristics of included studies

Countries represented in the included studies were Germany, Austria, Switzerland, Sweden, the US, Canada, UK and Norway. All settings were in primary health care. Study design varied from longitudinal evaluation studies, qualitative studies, multi-site/-level case studies and evaluation studies of larger e-medication implementations. Two studies used both qualitative and quantitative methods, five used qualitative methods, whereas two studies used quantitative methods.

The populations represented in the studies are mostly health care professionals (doctors, pharmacists, other) and patients. Most outcome measures relate to patient experience and satisfaction, and health care professionals experience with the use of digital technologies for sharing medication information. The digital technologies used for a shared medication list differs between the studies and are as follows: the summary care record (SCR), the eMedikation list, electronic health records (EHR, ELGA) and online personal health record (Shared Care Plan, HealthSpace). In each country represented, there are existing digital solutions for a shared medication list at a local and regional level, and plans for implementation at a national level. See Table 1 for characteristics of the included studies.

First author, year (country)	Digital technology	Setting	Study design and methods	Study participants	Main results
Dyb K, 2018 (Norway)	Summary care record (SCR)	Primary care (ER, GPS, Emergency ward)	Qualitative study. In-depth interviews	25 doctors	The doctors only used the pharmaceutical summary in the SCR for a few subgroups of patients. Reasons for not using the other components of the SCR was the need for manual updating.
Greenhalgh, 2008 (UK)	SCR	4 early adopter sites for the SCR in England	Multi-site, mixed method case study. Interviews, focus groups, ethnographic data	250 staff members, 170 patients/carers	Factors influencing the success of the SCR: Concerns about the workload, experiences from previous IT-implementation, attitude to the new system, the implementation process, the program's functionality and expected benefits.
Greenhalgh, 2008 (UK)	SCR and Health Space	3 primary care trusts	Qualitative study. Individual interviews and focus groups	170 participants	Many participants were not aware of the SCR, were not interested in recording and accessing their own medical data in the SCR and misconceptions of the content was common. Benefits when in need of emergency care, and for people with stigmatizing illnesses. SCR has a potential to support self-management.
Greenhalgh, 2010 (UK)	SCR	3 primary care districts	Mixed-method multi-level case study. Registry data, interviews, consultations, field notes.	Clinicians, patients, managers, policy makers	An increase in patients accessing the SCR was seen. The SCR may support better quality of care and potential to prevent medication errors. Risk for patient safety if the SCR does not contain updated medication information or critical information. Very low access in secondary care.
Gall, 2016 (Germany, Switzerland, Austria)	eMedikation Electronic health record (ELGA)	Germany, Switzerland and Austria	Qualitative study. Focus group interview and literature review	Expert groups from each country	For all three countries, a comprehensive national electronic infrastructure for the exchange of health data is planned but not yet available. Differences in whether it is mandatory or not for health care providers to use.
Hackl, 2014 (Austria).	eMedikation in ELGA eCard network	Austria	Quantitative study. 30-item questionnaire	61 physicians and 68 pharmacists	For physicians, the fear of improper data use, satisfaction with software support most crucial. For pharmacists the expected benefits and the system's functional aspects most crucial.
Hammar, 2014 (Sweden)	Electronic health record system (EHR)	4 counties in primary care	Qualitative study: Semi-structured interviews	7 physicians	Improved availability of information, more complete and accurate medication lists. Many non-current prescriptions, risk for violation of patient privacy. Responsibility for the list unclear. Not possible to share information between counties.
Janzek-Hawlat, 2013 (Austria)	eMedikation in ELGA eCard network	3 regions in Austria.	Quantitative study. Questionnaires, log-file analysis,	97 physicians, 58 pharmacies	Pharmacists and physicians satisfied with the potential impact on patient safety. Inefficient user friendliness and system performance. Recommends better training and support, mandatory nationwide roll-out, develop a patient portal.
Stock, 2008 (US)	Online personal health record (Shared Care Plan)	Ambulatory care clinics	Evaluation study. Mixed methods: focus group, survey, clinical data	486 patients 80 health care professionals	Patients more confident with own medication management, better communication with health care personnel, more active in own health care. Patient safety culture improved and medication list discrepancy decreased.

Table 1 Characteristics of the included studies.

3.2 Patient safety and quality of care

Four of the studies report on the impact on patient safety and the quality of care with a shared medication list: A study from the US evaluated the experiences from health care professionals on a local e-Medication list and the rate of medication list discrepancy before and after the implementation of a community-wide electronic shared medication list [2]. The authors reported an improvement in patient safety culture in 2 out of 3 ambulatory clinics, and a decrease in medication list discrepancy from 80 to 50% post-intervention. Greenhalgh et al evaluated the use, functionality and impact of the SCR and reported that health personnel experienced the SCR to support better quality of care and had the potential to prevent medication errors [19]. Further, the authors reported that incomplete or inaccurate data about medication information or critical information in the SCR was seen as a potential risk for patient safety. A quantitative evaluation study from Austria investigated physicians' and pharmacists' in a pilot study on a national medication list [20]. They reported that a potential positive impact from both professions was revealed for a shared medication list depending on the following factors: a mandatory nationwide roll-out, better user friendliness, system performance and better training and support. Gall et al. performed a structural comparison on the national e-medication approaches in Germany, Switzerland and Austria and reported that all three countries focus on improving medication safety but a national electronic infrastructure for exchange of health data is not yet available [21]. Further, there are differences between the countries as Switzerland has a decentralized approach of information sharing and a high degree of voluntariness for health care providers, , whereas Austria and Germany are planning a centralized approach mandatory for health care providers.

3.3 Experiences from health care providers and patients

Four studies from the UK, Sweden, Norway and Austria respectively, are describing factors affecting health care providers' use of the SCR. A mixed-method study by Greenhalgh et al. reported the following factors affecting health care providers' use of the SCR and a future national medication list: concerns about workload, experiences from previous IT-implementation, their attitude to the new system, the implementation process, the programs functionality and expected benefits [22]. A Swedish study explored doctors experiences with the implementation of a regionally shared medication list and reported that doctors experienced a more complete medication list and easier access to information going from a local to a regionally shared medication list [23]. Further, negative experiences included a number of non-current prescriptions, concerns about patient privacy, the lack of possibilities to share information between the regions, and the uncertainty of who is the main person responsible for a shared medication list. In a recent Norwegian study, Dyb et al. explored doctors' use and trust in the summary care record and reported that doctors only used the pharmaceutical summary in the SCR (as 1 of 6 functions in the SCR), and primarily only for a few subgroup of patients: unconscious patients, elderly with polypharmacy and patients with substance conditions [24]. Hackl et al. performed a quantitative study where physicians and pharmacists completed a 30-item survey identifying factors important for the acceptance of a national e-medication list. Among physicians, satisfaction with the software support and a fear of improper data use was most crucial, whereas the pharmacists pointed out the expected benefits and the system's functional aspect as most crucial [25].

Two studies describes patients' perspective concerning the use of a local e-medication list and the SCR: A study from the US reported that the patients felt more confident with a community-wide electronic shared medication list regarding their own medication management, they experienced better communication with the health care providers and became more active in their own health care [2]. A study from the UK reported a very low use of the SCR, many people were not aware of the SCR , its content or how to get access to it [26]. Further, Greenhalgh et al. found that people with stigmatizing illnesses were most positive about using the SCR. On the contrary, misconceptions of the SCR were common, especially about which type of data the SCR contained and who had access to the data. Greenhalgh et al. also revealed that many participants were not interested in recording their medical data or accessing their SCR through a web-interface, although some saw the potential for the technology to support self-management [26].

4 DISCUSSION

4.1 Principal findings

This narrative review provides an overview of current knowledge of digital solutions of a shared medication list. We found nine primary studies from seven different countries. The countries presented in this review, have different digital solutions and sharing of information at a local, regional or (future) national level. We found no studies investigating the effects on an implemented national shared medication list covering all institutions and levels of care. Digital health interventions are often complex with many different components and often with multiple aims. Therefore, evaluations of such interventions may present methodological challenges [27]. The studies included in this review have a range of different designs and methods used to explore, measure and evaluate digital interventions for a shared medication list. We found no intervention studies investigating the effect on patient outcomes with digital solutions for a shared medication list, and only one study measured and reported the rate of medication list discrepancy before and after the implementation of a single, community based medication list [2]. In addition, more qualitative studies exploring experiences from both health care providers and patients are important to provide an in-depth understanding on how the usability, availability, and efficiency of the digital solutions affects patient safety and quality of care. As new digital solutions for a nationally shared medication list are planned or in progress, there is a need to monitor and learn from their use.

4.2 Patient safety and quality of care

We found both positive and negative experiences affecting patient safety and quality of care [2, 19-21]. Patient safety is defined as the prevention of harm to patients, and emphasis is placed on the system of health care delivery that prevents errors, learns from errors that occurs and is built on a culture of safety involving health care professionals, organizations and patients [5]. Quality of care is seen as conceptual components of quality rather than the measured indicators[6]. Positive aspects of quality care are explained as achievement of appropriate self-care, health-promoting behaviors, health-related quality of life, whereas mortality, morbidity and adverse events are considered as negative outcomes [28, 29]. Qualitative studies on patient safety and quality of care before and after implementing digital tools for a shared medication list are important in order to guide health policy makers to optimize the process of implementation of digital solutions. Only one study used a questionnaire to measure the potential effect of a shared medication list regarding patient safety [20]. More quantitative studies are needed in order to measure the effect on patient outcomes, as well as measure experiences from health care personnel in a larger scale, eg. with validated questionnaires. A recent scoping review of quantitative and qualitative literature aimed to map research on the effectiveness, level of use and perceptions about e-medication administration records (eMAR) in long-term care facilities [30]. Further, the results revealed that the evidence of linking eMAR use and reductions in medication error was weak because of suboptimal study design and reporting inconsistent benefits and challenges as well as low levels of eMAR implementations. This review identified a gap of knowledge on the effects of patient safety and quality of care related to implementation of new digital solutions for a shared medication list.

4.3 Experiences from health care providers and patients

The studies report both positive and negative experiences from health care providers on digital solutions for a shared medication list. Hackl et al. shows that the groups of health care professional can be quite heterogeneous and different factors are important for the use and acceptance of new digital solutions [25]. This may show the importance of differentiating between the subgroups within "health care providers" as their use and requirements of a digital system for sharing medication information might be quite different. None of the studies explored nurses' experiences with the use of digital solutions for a shared medication list. There is a need to study nurses' experience in primary health care as nurses' involvement in the medication managing process includes dispensing and administrating medications, as well as monitoring efficacy of medications [31]. Studies exploring patients' experiences show that there are both positive and negative factors affecting the impact of digital solutions on their own medication scandanagement. Stock et al. reported that patients felt more confident with their own medication management, which made them more active in their own health care, is an important finding and shows how patients and people in general may be more involved in their own health [2]. As new digital interventions aim to involve patients and the general population to assess their own medication list, improve medication adherence, communication with health care personnel and their own health, patient and user experiences are crucial.

4.4 Strengths and limitations

We performed a narrative review in order to provide a synthesis of published literature on digital solutions of a shared medication list and describe the current state-of-art [32]. We used a systematic method in the literature search, assessment of studies and data retrieval, which is a strength of this review. Due to the scope of the project and the short time span, we did not systematically assess and report the quality of the included studies and this may limit the interpretation of our results. However, due to the more evaluative design of several of the studies included, using multiple methods, an assessment of the quality would be difficult to perform. Definitions of the digital solutions as well as the indicators used to measure effects and experiences vary between countries. This may have caused a limitation of the selection of keywords and search terms used in this study and may have restricted our findings.

5 CONCLUSION

This review found nine primary studies of different design and methodology investigating the experiences and effects of a digital shared medication list. The review presents current knowledge on the topic and presents a need for future studies especially with a quantitative design to measure the effects of digital interventions related to patient safety and quality of care. In addition, more studies exploring the experiences and effects on health care personnel's work practice, information sharing and communication before, during and after implemented digital solutions for a shared medication list are needed. This literature review may provide important information to the national health authorities responsible for the implementation of digital solutions for medication management. Furthermore, this review is an important step in planning and conducting the longitudinal study for the introduction of the SCR and the national shared medication list in Norwegian primary health care, especially according to the design and methodology used to investigate and explore the effects and experiences from digital implementations internationally.

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Pharmacists' Expectations and Perceptions of Electronic Medication Management

Lessons from Australia

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Abstract

Background: Implementing electronic medication management systems (eMMS) is likely to influence established work practices. ***Objective:*** To explore Australian hospital pharmacists' expectations of, or experiences with, eMMS. ***Methods:*** Semi-structured individual phone interviews with pharmacists from six Australian States and Territories were conducted in 2014. ***Results:*** A total of 18 pharmacists were interviewed. Pharmacists using what they perceived to be a well-designed eMMS appeared satisfied, reporting on increased work efficiency and improved medication safety, while pharmacists dissatisfied with the eMMS focused almost exclusively on negative effects of eMMS on time and patient safety. ***Conclusions:*** It is important to manage expectations and consider pharmacists' workflow when designing eMMS to increase satisfaction, perceived work efficiency and medication safety.

Keywords

Electronic medication management system; hospital pharmacists; qualitative study.

1 INTRODUCTION

The medication management process is complex and involves many different health professionals as well as the patient. Traditional paper medication charts are being replaced by electronic medication management systems (eMMS) that have been shown to reduce medication errors and adverse events [1-3]. However, studies have also found that these systems have major impact on health professionals' workflow [4, 5] and might lead to patient harm [6]. For example, Han and colleagues reported a significant increase in mortality rate due to delays in ordering of therapies and diagnostic testing [6]. The aim of the study was to explore Australian hospital pharmacists' expectations of, or experiences with eMMS, with a particular focus on how these systems will, or have had, an impact on work practices and care delivery.

2 METHODS

2.1 Recruitment

The Society of Hospital Pharmacists of Australia (SHPA) is a professional organization with over 3000 members. Information about the study was distributed via SHPA to all its members in a newsletter, on their Facebook page, Google+ and LinkedIn. Pharmacists interested in participating in the study were asked to contact the researchers directly. Everyone who responded to the invitation subsequently agreed to participate in the study and provided verbal consent before an interview was conducted.

This study was approved (2014-7-19) by the Medical and Community Human Research Ethics Advisory Panel at the University of New South Wales.

2.2 Development of interview guide

An interview guide was developed based on a literature search and consultations with a number of pharmacists working at one of the first hospitals to implement an eMMS in Australia. Two interviews with two pharmacists were conducted to pilot the semi-structured interview guide. The final list of interview questions appears in Table 1.

1. Which, if any, eMMS do you use? When was it implemented?
2. Tell me about the training you received when the eMMS was first introduced.
3. In what ways has/do you think the introduction has impacted/will impact on your work?
4. What are/do you think will be the major benefits with the eMMS?
5. What are/do you think will be drawbacks with the eMMS
6. How does eMMS compare to paper medication records in terms of quality of care and patient safety?

Table 1 Semi-structured interview guide

2.3 Data collection and analysis

All participants were interviewed over the phone by one researcher (ECL) in 2014. All interviews were digitally recorded, transcribed professionally and checked for accuracy by one researcher (ECL). Initial analysis was undertaken alongside data collection independently by two researchers (ECL, MTB, both trained in qualitative research methods) to identify emerging themes that needed to be further explored in subsequent interviews. The two researchers developed a coding scheme, applied it to a sample of transcripts to refine it before the coding scheme was applied to all transcripts. The researchers met regularly to discuss the coding progress and to ensure coding consistency.

3 RESULTS

A total of 18 pharmacists (three males and 15 females) from six Australian States and Territories were interviewed between June and October 2014. Interviews lasted on average 23 min (range 15 min (non-user) to 31 min (user)). Fourteen pharmacists had experience using one or more eMMS including CSC MedChart, Cerner, EPAS (Enterprise Patient Administration System), CHARM™, and MetaVision. Paper medication charts had been replaced by closed-loop systems for prescribing, administration and pharmacy review within the hospital. These systems are not linked to primary care services or community pharmacies. The decision support in the different systems varied. Examples of quotes are presented in Table 2.

3.1 Anticipated impact of eMMS on time and safety among non-users

Six pharmacists were working in hospitals that had not implemented an eMMS yet. Two pharmacists had previously worked in different hospitals thus had eMMS experience, but the other four pharmacists had no practical eMMS experience.

When asked to describe an eMMS, a common explanation was an electronic system that would replace paper medication charts and case notes, facilitate communication between different professions, and be a 'smart' system with alerts that would improve medication safety. The pharmacists were hoping that the eMMS would not negatively impact their workflow and thinking processes but rather facilitate their work and improve efficiency (for example, by not having to search for charts). Pharmacists were currently annotating medication charts and writing in notes but knew that this information was sometimes overlooked. There was an expectation that the eMMS would make this information more visible to others and alert prescribers and nurses to important medication-related information, for example, that therapeutic drug monitoring was needed before the next dose or that a particular medication should be given half an hour before food.

The ability to access electronic records and medication information from the pharmacy was seen as beneficial as long as it did not completely substitute face-to-face interactions. Reduced interaction between pharmacists and patients, nurses and prescribers was believed to be detrimental to patient care. Other benefits included improved legibility, notes documented in a more structured way, and the ability to easily extract and analyze data from the electronic system.

3.2 Users' perceived impact of eMMS on work efficiency

Twelve pharmacists currently using an eMMS reported both negative and positive impact of the eMMS on work efficiency. Positives included the ability to review a patient chart from anywhere in the hospital rather than having to physically locate the chart on the wards, and having all the relevant information stored in one place. Despite the potential to review a patient's chart remotely, almost all pharmacists stated a preference for reviewing the charts on the wards in order to maintain a presence on the wards and ensure high visibility of pharmacists, as well as to talk to other healthcare professionals and patients.

Pharmacists working in hospitals where the eMMS had been integrated with other digital systems reported added benefits including being able to review pathology results at the same time as reviewing medication charts. A number of eMMS were also linked to the pharmacy's dispensing program and this was perceived to facilitate faster dispensing.

Pharmacists with self-reported limited computer literacy, those who were still adjusting to the eMMS, and those using what they perceived to be a poorly designed eMMS reported that the eMMS had had a negative impact on their work efficiency. For example, medication lists displayed in a confusing manner (alphabetically regardless of current or ceased medications; different lists for regular medications, as needed medications, stat medications, and ceased medications) were perceived to slow work down. Some of the drawbacks with eMMS that Australian pharmacists reported were believed to be a result of implementing a system designed in the US without sufficiently tailoring the system to the Australian environment. Frequent tasks, such as documenting a medication history and reconciling a medication list, were perceived to take much longer in the eMMS than on paper charts.

3.3 Perceived impact of eMMS on patient safety

Pharmacists who were working with what they perceived to be well-designed and well-integrated eMMS reported numerous other safety benefits including a reduction in prescribing errors if a protocol, pathway or quick list was used. For example, patients receiving chemotherapy often have a suite of medications (combinations of chemotherapy and medications to ease side-effects for example antiemetics). Using pre-written order sets that included all these medications were perceived to improve safety as well as speed up the review process for pharmacists. Pharmacists could easily see when an order set had been prescribed, if it had been modified, and if so, how. Other safety benefits associated with eMMS included improved visibility and accountability. All medication orders and administrations had legible signatures making it easier to see who had ordered what, who had administered the medication, and at what time.

Some pharmacists mentioned that the eMMS had resulted in new types of errors, but there were inconsistent views about the severity of these new errors. For example, a new

error included using another prescriber's login to access the eMMS but this was perceived as less serious than the errors the eMMS had prevented, thus making it a safer option than paper charts. In contrast, other pharmacists believed that the new errors created by the eMMS were severe, would not have occurred when using paper charts, and therefore placed patients at unnecessary risk of medication errors. For example, one of the eMMS had an in-built 'safety measure' preventing prescribers from ordering warfarin for more than one dose at a time. This restriction had been put in place so that prescribers would monitor INR (international normalised ratio). In reality, this led to prescribers sometimes forgetting to order the daily warfarin dose, placing patients at risk of a serious adverse event. Another new type of error occurred in one eMMS which defaulted all medication orders to STAT (immediate) orders. This resulted in medication orders intended for regular use being ceased after the first dose had been given.

Pharmacists also described design features that did not align well with their work processes and as a result potentially impacted on safety. In one system, some medications had pre-populated directions (e.g. must be swallowed whole) and making changes to these directions had an unintended consequence. On paper charts, pharmacists could easily annotate this order (e.g. ok to dissolve a tablet, must not be crushed or chewed) but annotating a medication order in the eMMS resulted in a duplicate order. This was perceived as confusing and potentially dangerous.

Regardless of the eMM system, having a hybrid system in place (i.e. a combination of eMMS and paper charts) was considered to be a safety risk, minimising the benefits of eMMS. For example, pharmacists were not able to utilize the electronic drug-drug interaction check if some medications were prescribed on paper charts.

3.4 New or different work tasks following eMMS implementation identified by users

Pharmacists reported that recording a medication history was much easier to do on paper than in the eMMS. Some eMMS require the pharmacist to enter all information (medication name, strength, dose, etc) about one medication before moving on to the next medication. This way of documenting the information does not align well with how work is done because patients often first mention all the names of their medications, then how often they take them, and their strengths. Therefore, instead of wheeling in a computer-on-wheels to the patient's bedside (which was cumbersome, and involved asking patients to stop talking while documenting the relevant information) pharmacists would note down the information on paper and transcribe it into the eMMS at a later stage. This was time consuming and increased the risk of transcribing errors.

Another example of a changed task described by participants was requesting changes to orders. With a paper system in place, when pharmacists identified a component of the medication order that needed to be changed, they would take the paper chart to the prescriber and ask them to change the order. With eMMS, pharmacists had to locate the prescriber, ask them to go to a computer, log on and change the order. Pharmacists believed that this was inefficient and more disruptive for prescribers.

4 DISCUSSION

This study showed that some of the expectations pharmacists had before using an eMMS were realized following implementation, but the level of satisfaction with the eMMS was heavily dependent on how the eMMS is designed and how well it was perceived to support pharmacists in their work.

Pharmacists gave several examples of how the eMMS did not support their work, for example by creating duplicate orders when annotating a medication order. Workarounds, a temporary fix without resolving the problem, are common if a system does not support routine work [7] and may result in unintended safety threats such as delayed access to, or difficulty finding, clinically relevant information [8].

Some pharmacists reported that the eMMS was poorly designed and the result was that it took longer to document a medication history and reconcile a medication list. Previous research has shown that users' perceptions of time spent on different tasks may not reflect how they actually distribute their time [9]. We have therefore measured the impact of eMMS on pharmacists' work processes in a direct observational study and found that pharmacists indeed spend significantly more time on medication reviews and history taking post eMMS implementation [10]. However, it may not be that the processes take longer but rather that other tasks, such as supplying medications, are significantly reduced post eMMS implementation, and that this 'saved' time is allocated to important clinical tasks such as history taking and medication review.

Pharmacists in this study identified new errors post eMMS implementation, some of which were considered more serious than the errors the system prevented. The emergence of new types of errors post eMMS implementation is a well-known phenomenon [11-13]. Some of the new errors identified by pharmacists could be eliminated with system redesign. It is therefore important that commercially acquired eMMS are modified to local practices as the same system can produce different outcomes depending on where and how it is implemented [14, 15].

5 CONCLUSION

Electronic medication management systems affect pharmacists' work significantly. Managing expectations and involving pharmacists early in the process of choosing or designing an eMMS, may lead to greater acceptance of and satisfaction with the system. Incorporating safety features that disrupt routine workflows should be closely monitored to reduce the likelihood of unintended consequences.

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7 ACKNOWLEDGEMENT

8 APPENDIX

Themes	Quotes
Anticipated impact of eMMS time and safety	If there's legible writing we won't have to chase doctors around saying, "Oh, hey. What have you written there?" (#13, Male, non-user/previous eMMS user)
	If we've got easy access to their charts online I think that might be beneficial and advantageous (#14, Female, non-user)
	I guess being able to access the patient, the medication charts and their history and everything from the dispensary [would be time saving] whereas at the moment we've got a bit of a process for instance on discharge reconciliations (#8, Female, non-user)
Perceived impact of eMMS on work efficiency	We were able to link the [eMMS] software to our inpatient dispensing software… So the system knows whether the medication that's been prescribed for the patient is – whether it's kept on imprest or whether we need to get it from Pharmacy…So I suppose there's a time-saver there in that you don't have to go and photocopy the chart and then take the chart to Pharmacy and then put it back into the system and dispense it.)#5, Female, user)
	We also have our hospitals networked in the Northern Territory so any patient who comes into the hospital system, the public hospital system, we can view any of the medication history or any admissions across the whole Territory (#10, Female, user)
	If you wanted to write a medication history on a patient, on the paper chart you just write it. Whereas on the system you have to enter each drug and it's a lot slower… I can only type so fast (#Pilot 1, Female, user)
Perceived impact of eMMS on patient safety	Lots of incidents. What concerns me is Warfarin and insulin are very tricky, particularly Warfarin. I've seen a number of missed doses and I'm hearing that from all the pharmacists (#7, Female, user)
	Some of the errors that have happened with medication management that might not have happened in the paper system… And the ones I'm thinking of specifically are I've had three patients where Warfarin doses have been missed because the system is confusing the way Warfarin's ordered. So that's not been good. (#9, Female, user)
	There's a lot of safety features built in. And other things that are meant to be safety features on a paper chart that are automatically done on [eMMS], so like intermittent meds, like it only lets it be due every three days or every two days, if that's how it's charted, you don't have to just rely on someone drawing boxes or figuring it out. (#Pilot 1, Female, user)
New or different work tasks following eMMS implementation	If you don't have access to a terminal, I mean, you're still, essentially, writing it down and then having to transcribe it into the system later. (#13, Male, non-user/previous eMMS user)

Table 2 Quotes from interviews to support different themes

How Discrepancies in Medication Records Affect the Creation and Trust in a Shared Electronic Medication List in Norway

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Abstract
A shared electronic medication list is being piloted in Norway. By use of interviews and comparing medication records, we investigate how errors in current paper-based medication lists affect the creation of the shared electronic list. Of 367 patients, 88 % had discrepancies in their records between the GP, the home care service and dispensing pharmacy prior to start-up. Though the GPs experienced the medicines reconciliation and creation of the shared list very time consuming, the home care service and the pharmacy reported many errors in the first list created. Increased communication during the start-up will probably facilitate the trust in and use of the shared electronic medication list with further implementation.

Keywords
Patient safety, Medication reconciliation, Shared medication list, Multidose drug dispensing

1 INTRODUCTION

Medicines play an important role in the treatment and prevention of disease. However, medication errors, low adherence to prescribed treatment and adverse drug events can also cause increased morbidity and mortality [1-4]. In Norway, information about patients medicines use are stored in many different systems, with little automatic transfer of information between them. This is especially a challenge for clinicians, as they do not have immediate access to an up-to-date list of the patients' medications. Lack of access to such information increases the risk of medication errors [5].

Digital medicines management has the potential to increase efficiency and safety of medicines management by making information accessible. The Norwegian health authorities are currently piloting the use of a shared electronic medication list ("Pasientens Legemiddelliste" in Norwegian- hereafter shortened "PLL") [6, 7]. The first patients to get a PLL, are patients who receives home care services, and who get their medicines dispensed as multidose (e.g. patients who get medicines machine dispensed into unit bags for each dose occasion; a service commonly used by home care services in Norway. For more information about the multidose-system see [7]). These patients are typically elderly patients with difficulties handling and administering their own medicines, in addition to using several regular medicines [8-10].

Before the implementation of PLL, there are at least three separate medication lists for each of these patients; one in the general practitioners' (GP) electronic medical journal, one in the home care service journal system, and one at the multidose dispensing pharmacy. Even though most prescriptions in Norway are electronic [11], the multidose prescriptions are still paper based. This creates an additional challenge for sharing medicines information for these patients. Previous studies have shown that up to 90 % of patients have one or more discrepancy in their

medication list when comparing the list in the GPs electronic medical journal and the list at the home-care-services [12-16]. When PLL is implemented, the PLL will be uploaded electronically to the Norwegian Prescription Mediator. This Prescription Mediator is a well established database, which is currently used for transferring electronic prescriptions. It is accessible for all doctors and pharmacies in Norway. In time of writing, the home-care services do not have access, though there are plans to give them access within a few years[17]. The PLL, though uploaded to the Mediatior, is not considered a valid prescription that can be used for dispensing of medicines. This means that patients who receive a PLL will still need electronic prescriptions in addition to the PLL.

The pilot testing of PLL for patients receiving home care services started in 2014. Further testing of PLL for other prescription recipients starts in 2020 [17]. The aim of this study is to investigate how errors and discrepancies in exciting medication records affect the implementation of PLL for patients receiving multidose drug dispensing in Norway.

2 METHODS

This study combines qualitative and quantitative methods with inspiration from mixed methods [18]. The main focus is on the quantitative part which investigates the occurrence of discrepancies in the medication records between the pharmacy, home care service and GPs before the creation of the PLL. With the purpose of expanding the results [19] we have also performed qualitative interviews with these three groups of health professionals about how the discrepancies affected the creation and use of PLL.

The official routines for creating the PLL was that the pharmacy sent a printout of their medication lists to the GPs, approximately 1 month prior to start-up. After comparing this list to their own record, the GP created and sent the PLL to the Prescription Mediator. The pharmacy

then deleted the medicines in their own system and started dispensing based on the PLL and the electronic prescriptions.

The data collection of the paper-based medication lists in this study was done approximately 2 months before the initial send-out from the pharmacy, while the interviews were preformed 3 months after the first dispensing based on PLL.

The study was approved by the Data Protection Officer at the University Hospital of North Norway (UNN), and the Regional Committee for Medical Research Ethics (REK) has given approval to collect the medication lists. Patient identifying data was stored separately from the anonymous medication list in a secure research server at UNN.

2.1 Discrepancies in medication records:

In the municipality which was about to start using PLL, we contacted 15 GP offices, the home care service and the delivering pharmacy, to ask for participation in the study. Those who accepted the invitation, received a list of patients and a generated serial number, together with instructions to print out the medication lists for these patients, replace patient identifying information with the serial number, and send the lists to the researcher via post. Lists from all three groups were collected within the same week.

Each set of medication lists were compared by two pharmacists separately. The number of medicines in each list, as well as any discordant information in the medication lists, was recorded. The categories of discrepancies was: Medication lacking from one of the lists, differences in dosage, prescriptions written as "regular use" in one list and "as required" in the other, lacking reimbursement information, different administration formula and others (see Table 1)

2.2 User's experiences

The Directorate e-Health provided contact details for the health care personnel who were piloting the PLL. Invitations were sent to the home care service, the pharmacy and all three of the GP-clinics, with brief information of the project and the main themes of the interviews. We conducted four interviews: One group interview with seven GPs, one group interview with four pharmacy employees and two individual interviews with nurses and pharmacist in the home care service. The interviews lasted about 45 minutes; they were recorded on tape and later transcribed by a professional agency.

The interviews focused on how electronic prescribing of multidose affected the users work practice, experiences with the transition, measures to facilitate improvement, and experienced risks and benefits with the system. The transcribed interviews were read by two researchers separately, and topics related to the medication reconciliation process (e.g. the process of using different sources of medicines information to create a complete and accurate list of all the medications the patient is using) and the use of the first PLL, were extracted.

3 RESULTS

3.1 Discrepancies in medication records:

In total, 36 GPs from seven doctor's clinics participated in the quantitative study, and medication lists for 367 patients were collected. For the GP, the home care service and the pharmacy, the total number of medications listed was 3723, 3740 and 3702, respectively. The median number of drugs was nine for all three lists, however, we see from Table 1 that the distribution of medicines listed as *regular* versus *as required*, differs between the lists. The home care service and the pharmacy had more medicines listed as *regular* and fewer *as required,* than the GPs.

	GP n (median)	HCS n (median)	Pharmacy n (median)
Regular drugs	2397 (5)	2757 (6)	2734 (6)
As required drugs	1066 (3)	773 (2)	759 (2)
Medical devices and consumables	260 (1)	210 (1)	209 (1)
Total	3723 (9)	3740 (9)	3702 (9)

Table 1 Number of drugs in the general practitioner (GP), the home care service (HCS) and the pharmacy medication lists. N= 367 patients.

If we disregard the dosage (including whether the medicine is listed *regular* or *as required)* there were 4519 unique medications in the lists. Of these, 2950 (65 %) were present in all three lists (Figure 1). From Figure 1 we also see that is a larger degree of overlap between the home care service lists and the pharmacy (3697/3800 = 97 %), than the home care service and the GP-lists (2958/4505 = 66 %).
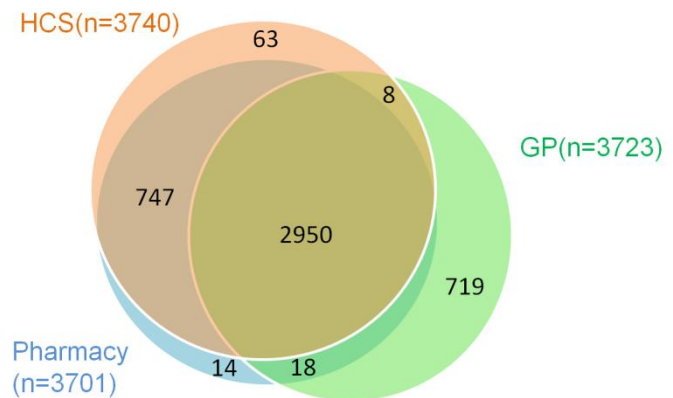
Congruence = 2950/4519 = 65%

Figure 1 Venn diagram showing the congruence of prescribed medications between the GPs medical record, the home care service (HCS) record, and the pharmacy medication list (N=367 patients, 4519 unique medications)

In addition to the medications lacking from one of the lists, there were also other types of discrepancies. In total, 1978 discrepancies were found between the home care service and the GP medication lists, affecting 88% of the patients. While 148 discrepancies were found between the home care service and the pharmacy lists, affecting 16 % of the patients. Table 2 shows that the most frequent discrepancy in all lists was that a medication was lacking, followed by differences in dosage.

	List comparison		
	GP - Pharmacy	GP-HCS	Pharmacy - HCS
Type of discrepancy	n (%)	n (%)	n (%)
Medication lacking from one of the lists	1474 (74.5)	1502 (77.8)	85 (57.4)
Dosage	223 (11.3)	253 (13.1)	49 (33.1)
Regular prescription versus as required	133 (6.7)	129 (6.7)	4 (2.7)
Reimbursement	71 (3.6)	NA	NA
Administration formula	31 (1.6)	28 (1.5)	3 (2.0)
Other	46 (2.3)	18 (0.9)	7 (4.7)
Discrepancies	1978 (100)	1930 (100)	148 (100)

Table 2 Frequency and type of discrepancy in the medication lists. HCS= Home care service. N = 367 patients.

3.2 User's experiences

Medical doctors:
The GPs expressed that the start-up had been somewhat challenging, mostly due to technical difficulties. The errors meant that they had to do certain tasks several times, some functions were not possible to perform, and the system was in general very slow. They also commented that they found the information and training prior to start-up insufficient for their needs.
Regarding the medication reconciliation, the GPs interviewed said that this had gone well and that the quality of the prescribing was improved after the transition because the steps in the prescribing process was more quality assured. Except for mentioning that the initial creation of the PLL took a long time, estimated 20-30 minutes per patient, the GPs did not mention any specific difficulties related to the discrepancies in the records.

Pharmacy staff:
The pharmacy staff expressed that the work during start-up varied greatly between the different GPs. Their impression was that the GPs did not get sufficient training beforehand, and that there was a lack of support during the starting phase. For the GPs that were thorough and experienced few technical difficulties, the pharmacy staff felt that the electronic prescribing was safer and more efficient than the paper-based. However, for those GPs who struggled, they reported using a lot of time and energy on trying to correct the medication lists. Even three months after the start-up, they reported that they were still struggling with certain patients.

We are more vulnerable if the GP makes an error, because on an ordinary paper [prescription] we could do the change ourselves and ask the GP to sign it afterwards [...]. but now, [...] we need a new e-prescription.

Regarding the first PLL, the pharmacy staff experienced many difficulties. Particularly, they reported that many prescriptions were expired, prescriptions had too few tablets left, or prescriptions were otherwise not possible to

use for dispensing. Some patients had completely wrong lists, where all the medications the patients had used, including those which had been stopped many years ago, appeared on the list. They also experiences problems when the GPs were trying to renew the prescriptions.

When renewing [...] instead of keeping the old [dose] they use the "standard dose; one tablet daily".

Straight after the start-up, they experienced many phone calls from the home care service, who were wondering whether patients had started with the new system, whether they had valid prescriptions, or were wondering why there were so many changes in the patient's drug regiments after the first dispensing. Though the calls had started to subside after three months, the pharmacy still experienced that the new system required more frequent contact with both the prescriber and the home care services.

Home care services:
The nurses and pharmacist in the home care service were the ones who reported the most problems with the reconciliation process, and the start-up in general. Since they did not have access to the PLL directly, they did not have the opportunity to double check the prescribing before the medicines were delivered to them. Since these multidose bags are usually delivered just a few days before the patients run out of medicines, this left the home care service with very little time to detect and correct errors in the dispensed medicines. They found the process of checking all the multidoses very time consuming due to many errors in the first delivery after start-up. When they received the first delivery based on the PLL and electronic prescriptions, they reported that some patients did not get medicines at all, some were missing certain drugs, and other had many unexpected changes in the doses

I experienced it as if the medication reconciliation had not been done, because when we got the multidose, [there were so many] differences between what they had been taking and what they were suddenly supposed to use.

However, also after the start-up, they still experienced many errors. After three months, they still felt that they had been given an increased responsibility with the new system, because they had to check the medicines dispensed more often and more thoroughly than before

We noticed in this project that we were the ones with the correct information about the dosage.

4 DISCUSSION
This study shows that there is a large degree of discrepancies between the medication records of the GPs, the home care service and the dispensing pharmacy, with 88 % patients having at least one discrepancy in their medication lists. Previous studies have shown discrepancies in 52 % to 90 % of the records [12-16]. The most frequent discrepancies we found in the records were that a prescription was lacking from one of the lists and different dosage, which is also consistent with findings from other studies [12, 15, 16].

As most previous studies have only compared the lists between the GPs and the home care service, our study is one of the first to compare the medication lists between the home care service and the pharmacy. We found that only 16 % of the patients had one or more discrepancy when comparing these two lists. The low number of discrepancies between these two might be because in the municipality included in this study, the pharmacy has an electronic transfer of their medication list to the home care service whenever there are any changes in the pharmacy records. The congruence might thus not be this high in municipalities without this system.

We know from previous studies that insufficient communication between health care personnel about medication use, especially in the transition between primary and secondary care, is a major cause of discrepancies in medication records [20-25]. In the current paper-based prescribing system for multidose, there are many manual processes that can lead to errors. We see from the pharmacy interview, that they report fixing problems on paper prescriptions and getting the change signed by the doctor afterwards. These kinds of procedures make it possible for the doctor to sign a prescription without updating their own medication record, which is a probable cause for some of the errors we find in this study. In the new electronic system however, it will normally not be possible for the pharmacy to change a prescription.

Since not all records were collected on the same day, some of the discrepancies found in this study might be intended changes in the patient's drug regimen, which happened in the days between the collections. However, data extracted from the pharmacy dispensing programme shows that normally 10-12 % of patients in a patient group, have changes every two-week period [26]. This means that even the frequency of discrepancies between the home care service and the pharmacy is higher than expected based on a normal rate of medication changes.

From our results, we only know that there are discrepancies in the medication information, and not in which list the error lays. Because these patients get their medicines dispensed in multidose bags and get help from the home care service to administer their medicines, the pharmacy or home care service list would probably be the list which best represents what the patients have actually been taking. However, from a medical point of view, it is not necessarily the most correct list. Also from the interviews, we see that the home care service feel that their lists is the correct one, and they experienced that the changes that happened in the patient's treatment when starting to use PLL, were errors that happened because the GPs had not done a proper medication reconciliation.

If the first PLL is not identical to the home care service-list, there can however, be several other explanations than the GP not having done a reconciliation. Either there can be normal changes in the patient's medication regimen, which happens to about 10-12 % of the patients each dispensing period. Another possible explanation could be that when doing the reconciliation, the GP also performed a more thorough medication review, which have led to many deliberate changes to the patient's regimen. If all that is communicated is the PLL, then the home care service would not be able to differentiate between these three reasons for changes. It might thus be necessary that more information is given at the very start, at least specific feedback or conformation that the reconciliation has been performed. Preferably, this report should also comment on why there are changes from the current treatment. Another alternative would be that the home care service was more involved in the reconciliation process. This alternative might imply some practical issues, as well as being quite time consuming. However, as the home care service already reported using a lot of time to double-check the PLL and the multidose bags, this might still be a better alternative.

It is interesting that the GPs in this study did not report reconciliation process as especially problematic, except for the time used to perform it, but that the recipients of the PLL experienced many errors and even commented that they thought the lists had not been reconciled at all. This might however, be due to bias in our interview material, as very few GPs accepted our invitation to participate. The ones included might thus be those with the most positive experience with the transition, and/or the most conscientious.

In our opinion, the discrepancies represent a patient safety problem. We see from Figure 1 that the home care service reported that the patients used 810 medicines that were not present in the GPs' medical record, and the GPs listed another 719 drugs the home care service did not know about. In addition, there were several discrepancies in the dosages of the medicines. The GPs thus risks making inappropriate decisions about the patients' medication therapy, if basing these decisions solely on the information in his or her own journal. The errors in medicines information we have found here have however, most likely been present for a long time, though the users do not seem to have experienced them as a particularly problematic in the paper-based system. With the implementation of PLL, these discrepancies become more visible, and the implementation process forces the users to perform a medication reconciliation. Though this study shows that the reconciliation process was not satisfactory, we see from the pilot of this system that the number of discrepancies seems to be reduced 1 year after the implementation, and the patient safety increased [27, 28]

Even if the discrepancies are reduced, there is still an issue with medication non-adherence, which we have not investigated in the present study. Medication non-adherence occurs for patients using multidose [29], though it seems to be even more common for patients not receiving multidose [30, 31]. We know from previous studies that there is a number of discrepancies between the GPs' medical records and what patients report taking [32-35]. These discrepancies are however more difficult to detect than the ones in our study, as it includes asking each patient about their actual medication use. Nevertheless, this issue should be addressed before PLL is implemented for all prescription users. For the patients in our study, the home

care service did a thorough control of the first PLL, which uncovered many errors. For other prescription recipients there is no formal control of the first list. Any errors in the PLL might thus go undiscovered and unrectified for a long time. We see from our study that the number of errors that were present in the first PLL seems to have reduced the home care services trust in the PLL. If this mistrust persists, it can reduce the use and the net benefits from the PLL.

5 CONCLUSION

Discrepancies in medication information between the GPs, the home care services and the dispensing pharmacy, are common, with 9 in 10 patients having at least one discrepancy in their medication lists. These discrepancies pose a challenge in the implementation of the shared electronic medication list (PLL). An unsatisfactory medicines reconciliation process prior to start-up seems to have reduced the home care services trust in the new system. When the PLL is implemented for other prescription recipients however, we risk that the errors go undetected because there is no formal control of the first PLL by the home care service. Before further implementation of PLL, the procedure for performing the medication reconciliation should be improved. The time from the reconciliation to the actual dispensing should be increased, and the communication between the health care personnel involved in the reconciliation process should be improved.

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7 ACKNOWLEDGEMENT

Design Research Themes for Mindful Interaction

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Abstract

The increasing excessive, automated or unaware use of smartphones calls for a better understanding and design of 'mindful' interactions with this device. In this 2-week study with 11 participants we focus on the influence of the operating system's interface in inviting for 'mindful' or 'mindless' interactions. Patterns of smartphone use were studied with a standard interface for the first week, and a reconfigured interface for the second week - the reconfigured interface being designed for more intentional use. Based on the study results we formulate a set of 5 design research themes for mindful interaction, and illustrate them in a conceptual proposal.

Keywords

Mindful interaction, mobile technology, interaction design, human computer interaction, user friendliness.

1 INTRODUCTION

Mindless consumption of digital media is recognized as a key research and development problem by health researchers, HCI researchers and IT industry alike. The effects of screen-time are broadly studied across various domains in the humanities and social sciences, while screen time management applications are gaining in popularity and recently became standardized features of operating systems [3]. One explanation for increased time spent on screens is that the success of game developers, news-sites, social media, video streaming and the like services depends on capturing the attention of new and current customers. This 'attention economy' [6] demands companies to use persuasive techniques in order to keep customers engaged with their services and outperform their competitors. Well-known and debated functions herein are the auto-play feature to be found on for instance Netflix or YouTube or infinite scrolling feeds such as employed by Instagram or Facebook. Such features contribute to a challenge for users to act mindful, and to the question of what screen-time value is in terms of lasting meaning and fulfilment.

The smartphone stands out as a smart technology that embodies the tension between mindless consumption and meaningful fulfilment, a tension known as the paradox of technology [15]. The plurality of functions offered by smartphones and the variety of use-situations create complex human-computer relations. Besides its obvious functional advantages such as instant communication, mobile connectedness, access to entertainment, navigation support, and facilitating productivity, smartphones are also increasingly recognized as a source for negative impact on health and social relations. Unaware and automated interactions with the smartphone can lead to screen time being twice as much than estimated by the user [2], while excessive use can lead to addiction [5], anxiety, irritation, frustration or impatience [13][14]. On the contrary, the smartphone can become such an extension of self that when separated it provokes fear, unofficially called *nomofobia* [23], or even a lessening of self [7]. The presence of the smartphone in learning environments can negatively influence cognitive performance and concentration [22].

In social situations, the phone can support or inspire the sharing and memorizing of moments, help inform one another, or help settle finances. Yet it can also create frictions in disrupting face-to-face interactions and conversations or reduce attention [17]. Social media makes teenagers in particular spend less time doing analogue free time activities and more time on their smartphone, which can be linked to increasing levels of unhappiness, loneliness, and even depression [20].

Design researchers and developers must take problematic mindless use of interactive technology seriously. They can contribute by developing knowledge about the role of design in situations of mindless use and its impact on users' health; by considering how users can be assisted and supported in creating a mindful relationship with the smartphone; and by proposing alternative designs so that users can integrate smartphones into everyday life in a thoughtful and reflective manner. Such new knowledge and design proposals can prompt debate and provoke reflection upon desired relations with the smartphone in situations of use, to contribute to a reduction of negative health impact. In this paper we study the influence of the operating system's interface on smartphone use by reconfiguring its interactive elements. Based on our insights we propose a set of design research themes for mindful interaction for future design research and to inspire development.

2 METHOD

In a study over a period of two weeks we explored the potential for more mindful interactions with the smartphone within the operating systems' constraints. We involved 11 participants between 20 and 34 years old. Participants were recruited through media channels at the IT university Copenhagen, which resulted in 9 out of 11 participants being local students. Beforehand we asked all participants to send us screenshots of their interface and to track their screen time during a week. In the following week of the study we asked all participants to reconfigure the interface on their phone following guidelines largely based by the *Center for Humane Technology* [6]. This is a project by former Google employee Tristan Harris to raise awareness about addictive aspects of designed technology [11]. The

Figure 1 Elements of the reconfigured interface. From left to right: all applications in one folder; the folder placed in the menu bar; notifications switched off for every application; use of the search function; and screen set to grayscale.

project encourages companies and designers to create products that are considerate towards users' time spent on digital products and services. The guidelines invite users to set up their smartphone interface to stimulate more intentional use of the smartphone, and reduce its distractions. This concretely meant switching off all notifications, except those from people, set the screen mode to grayscale, move all apps into one folder that is placed in the menu bar, move the social media apps into the last pages of this folder, and turn off audio input, while the suggested way of opening apps was through the search option (Figure 1). Through these relatively easy-to-make changes we aimed at finding out how the reconfigurations contributed to different interactions and use patterns with the smartphone. We conducted semi-structured interviews with each individual participant shortly after the second week of the study, each interview taking approximately 45 minutes. During the interviews we used the screenshots and screen time data as triggers for discussion, inspired by a media go-along [12]. Subsequently, we began a coding process, in which we moved from open to focused coding [19]. Based on this analysis, we formulated 5 design research themes.

3 REGULAR SMARTPHONE USE

The interviews revealed the tension between feeling supported and being dependent on the various functionalities offered by the smartphone. Smartphone applications clearly satisfied a need, yet the urgency of this need was debated. An overall matter of concern was the balance between perceived necessary and unnecessary use of the smartphone. The beliefs regarding a desirable amount of screen time differed, and ranged from less than 1 hour up to 3 hours of use per day. All participants expressed an overall aim to use the phone less.

3.1 Leaky, Habitual, Automatic Interactions

Most participants shared that much smartphone usage is unconscious and out of habit. P6 used the notion of a 'trigger finger' to describe this type of habitual interaction with the phone: *You don't even think about it. It's not a conscious choice* while P10 describes her experience saying that *one quickly gets to use super much time on just stoning, without thinking about it*, including the sudden realizations of such unconscious use. The multi-facetedness of the phone was often indicated as contributing to automatic interactions, or leaky interaction [11], e.g. P4 who notes that *I often take my phone to see what time it is and then I do something else* or P1: *Sometimes, I go into the phone to do something practical, and wind up surfing or sitting with the phone (...)*. The use of the applications in these situations is typically circular

meaning that the participants repeatedly go through a collection of apps: *You get through an app, and the next and the next and once you've gotten through all of them, you start all over again* (P10); *The hunger for something new or the reflex just does that you open the app again.* (P9), or the 'typical social media flow' where you need *to go through them all and check everything. Instagram, Facebook (...). But there you never arrive at a bottom* (P5).

3.2 Authorship of the Interface

Before the study, a minority of the participants left their interface untouched, whereas most of the participants organized their applications by arranging them and using folders. The standard operating system applications that were not used were typically still present, out of ignorance or out of possible future needs (e.g. P5: *there must be a reason for that they are standard*). P2 made a folder named 'shit', where she placed the unused standard applications such as *Stocks* and *Health*, out of frustration that they can't be deleted: *It's like there stands a sofa in your room that you do not use and that you don't like.* After the experiment, many participants indicated that they were not aware of the possibilities there were in reconfiguring the interface of the phone, for example in turning off notifications completely or setting the screen to greyscale. Upon revisiting the screenshots of the former interface, nearly all participants used the word 'messy' to describe it: *It looks bombastic (...) As if they all scream that I should click on them* (P6) or P7: *I can't figure out what I should focus on. There really is a lot that shouldn't be out on the frontpage*).

3.3 Notifications and Social Interaction

The notifications in the former interface, which typically included vibrations and sounds, evoked an urge to respond (e.g. P1: *I get stressed about these red thingies with numbers in them. If they are there, I need them to get resolved*). Especially in occupied situations these notifications were disturbing, as P5 emphasizes: *It's most intrusive when I am about to sleep. Then this 'ding' comes. I have just relaxed and then suddenly my 8ipulse is up again, and then I think: Ignore it, ignore it. But I can't, because it's in my head, and then I need to check it*. The social nature of the notifications is inherent to the urge to respond, e.g. P2, who switches her phone into silent mode in order to avoid being stressed by it, often finds herself being perceived as unreliable and hard to reach. For many, switching off notifications in the second half of the experiment caused a challenge in the risk that they were missing out on something. In our study, participants pointed to the homogeneity of notifications, which made it

difficult to differentiate between them without picking up the phone.

The role of the phone in social situations was addressed by all participants. For example, partners using the phone in the bed before sleeping (P1: *Shit, we are both lying here being on our phones. How stupid*); while watching a movie (P8: *it's difficult to discuss the movie because I am not 100% there. He thinks it is so annoying that I do that*); in one-on-one conversations (P6: *I don't want to talk to you if I am to compete with your phone*), or in group situations (P9: *(…) it is actually not appropriate because it conveys a disinterest and communicates that other things are more important*. Like P9, many would generally like to become better at putting the phone away, while P6 proposes the desire for established norms: *I would actually wish for a consensus about that it is just not something you do, just like you don't fart when eating with other people.*

The three categories above point to problematic instances when it comes to leaky interactions, lack of taken or possible authorship of the interface, and disturbances through notifications or in social situations. As such, and resonating with [4][11][16], it assured a call for reconsidered interactions with the smartphone.

4 SMARTPHONE USE WITH THE RECONFIGURED INTERFACE

The reconfigured interface revealed the tension between an increased feeling of freedom, and an increased fear of missing out. Feelings of freedom were evoked by the reconfigured empty home screen, where applications had to be opened through the search function, as it required participants to actively make up their mind. At the same time, a fear of missing out was evoked by the same emptiness, including the lack of notifications (e.g. P2: *You get a bit of FOMO when you look at an empty screen.)* And it sometimes indeed led to missing out (e.g. P8: *My friend had snapped me a picture of her newborn baby. And I didn't see it until a few days later where I thought 'oh no'. I would have wanted to congratulate her and show that I care. So I had to apologize that I did not see the snap until a few days later*). The tension between feeling freed from notifications and fear of missing out posed a dilemma, e.g. P5: *I think it's nice on one hand. On the other I think it's a bit annoying. I am not sure if I will turn notifications back on again or not*. Nonetheless, the use of the smartphone was articulated as more conscious, constructively unfriendly, including an increased awareness of screen time.

4.1 Fragmented Conscious Use

The reconfigured interface required participants to be more conscious about their use of applications. For P6 this meant getting rid of what she called her 'trigger finger' (*Those impulses are gone now, because you cannot click immediately*). This conscious use was shared by all participants: *I would say that I use my phone with more awareness* (P9); or *I am more aware of my use, I am not just sitting there like as if my brain is turned off, looking at a Facebook feed I have just checked five minutes ago,* (P8). The conscious choice for using in particular social media applications generated a sense of validity for P10 (*Now I*

may!), while P2 described the use of the search function in the reconfigured interface as responsively rather than gluttonously eating chocolate. For her the smartphone also presented itself much more like a toolbox: *What is it I need right now in this situation? Okay, I have to find the way. Which app helps to find way? Google maps*. For P11 the reconfigured interface turned the smartphone into *…almost just a phone. Before it was a protraction of my arm*. However, the actual interactions within applications remained the same, and evoked similar urges as before: *when you first are on Instagram, then I still get the urge to check Snapchat. So I think that hasn't changed much.* (P4). The reconfigured interface surely supported more conscious interaction with the phone, though it also left patterns of application use pretty much untouched.

4.2 User (Un)Friendly

The reconfigured interface was regarded as relatively user-unfriendly due to reduced efficiency and indirect accessibility of applications. However, participants experienced the intentions of a more conscious relationship with the phone relatively more user-friendly. As P10 states: *I like the idea of making it a bit harder to access social media, because we put them a bit further away*. The slightly increased distance, or micro-boundary [8] created a moment of reflection on intentions of use. For many participants this led to putting the phone away during the act of browsing towards a particular app.

The greyscale screen mode was consistently regarded as the most user-unfriendly. It hindered accessing functionalities where colors served as distinguishing elements and *it is exhausting for the eye* (P2). The greyscale screen mode stretched the notion of unfriendliness, by acting as a permanent boundary in use rather than a micro-boundary. As P10 states, *I have chosen to keep my interface with color, because it is needed to access things easily*. Two out of the eleven participants indicated that they would keep the greyscale screen mode, one of which believed that it would help her as she occasionally suffers from migraine, and P1 who believed it calmed her.

	Regular Interface	Reconfigured Interface	Difference
P1	0:40	0:58	+ 0:18
P2	1:04	0:45	- 0:19
P3	0:35	0:30	- 0:05
P4	1:03	0:43	- 0:20
P5	2:37	1:49	- 0:48
P6	2:40	1:35	- 1:05
P7	2:05	2:11	+ 0:06
P8	2:35	2:08	- 0:27
P9	2:30	2:40	+ 0:10
P10	3:10	4:05	+ 0:55
P11	6:06	4:55	- 1:11

Table 1 Average screen time per day (in h:mm) during first and second week of the study.
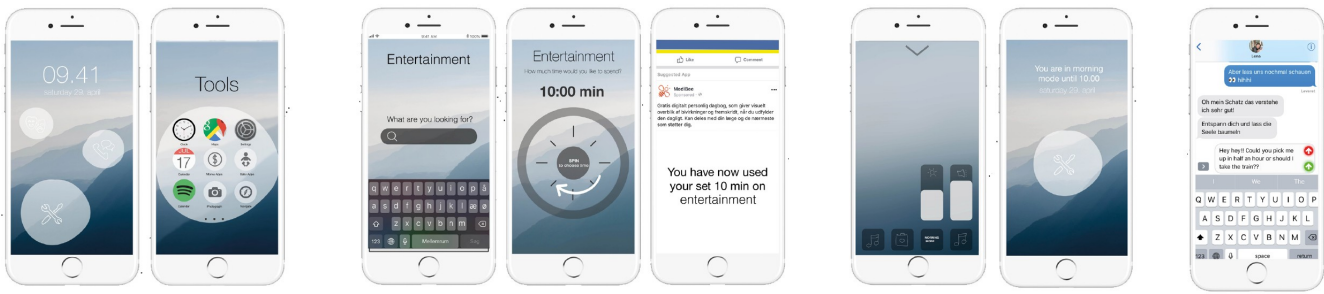
Figure 2 Conceptual smartphone interface elements inspired by design research themes for mindful interaction. From left to right: classification of apps in bubbles floating in different pace (a bubble for tools, communication, entertainment); search function and desired time frame for interacting with entertainment apps; different personalized modes; and prioritizing importance of messages.

4.3 Screen time & Interface Awareness

Tracking screen-time in combination with experienced micro-boundaries stirred an awareness of smartphone use, e.g. P11: The new interface has helped me to be more aware, that you use your phone so stupidly much, or P9: one also uses the phone out of boredom, or to bridge the time when waiting for the metro (...), which is a pity, because one could as well observe the environment. However, this conscious awareness of use is not consistently reflected in the differences of average daily screen time for all participants (Table 1). For P3, even though her average daily screen time was around 30 minutes, the experiences with the reconfigured interface worked as a first step towards a for her healthier relationship with the phone.

Overall, the short study showed participants the width of possibilities for organizing their interface, which was generally appreciated. In particular reducing the accessibility of social media applications offered a moment of reflection that could be enough to consciously continue or consciously withdraw. Other applications, for example for productivity, navigation and finance, were not seen to benefit from these breaks and were preferred to be easily accessible. A third class that sat in between, were news and weather applications, which participants experienced occasional unconscious interactions with. Not unlike the detour in [1], the functionality offered by the group of social media applications and the opportunity to momentarily draw back was regarded as valuable in terms of social connectivity and staying inspired. However, they were also the most alluring to mindless consumption. To recognize the complexity and individual preferences in reconfiguring the interface, P10 posed a personal ranking of groups of applications, each with their customized boundary as opportunity for reflection.

Many participants were particularly eager to reflect on those interactions that are triggered by the smartphone itself, such as notifications through sounds and vibrations and a strong visibility of icons. The experiment showed that these factors could be minimized, yet it also showed that the default settings were usually taken for granted. Generally, a more active authorship over the interface was evoked through the experience of the alternative reconfigured interface. The role of comparison and alternatives was essential in rethinking relationships with the phone.

5 DESIGN RESEARCH THEMES

Based on the analysis of the 2-week study, we now articulate design research themes. We combine these themes with contemporary literature to support design researchers and developers with key considerations when researching and developing intentional, conscious and mindful use of interactive technology.

5.1 Barriers

This theme refers to the leaky, habitual and automatic interactions, and overall experiences with the reconfigured interface, that there is a potential in making certain interactions with the smartphone harder, in order to create an opportunity for conscious reflection on immersive attentiveness. It points to appropriately preventing progress in interaction, to evoke a pause that redirects from ongoing activities. It is a broader consideration that connects user unfriendliness with a detour [1] and micro-boundaries [8] to lead to constructive unfriendliness. It is about carefully considering when accessibility, efficiency, or effectiveness needs to be reversed to break routine and prevent circular compulsive use and automated impulses.

5.2 Authorship

This theme points to enabling authorship over an interface and revealing possible alternative configurations, as we in our study have seen how this encouraged participants to be aware and act more conscious. It is a consideration that links to customization (e.g. notifications and visual layout), not to improve usability, but to improve intentionality. It is about offering, and making visible, alternative configurations that can be modified based on preferred hierarchies of importance. It is about setting goals for healthy consumption and sticking to them. Active authorship asks for a more aware consumption and requires unlearning habits of passive consumption.

5.3 Balance

This theme points to supporting the processual learning process between technology, self and other. It points to neither rejecting or blindly embracing technology, yet to relate to technology in a considerate manner by asking questions about how it impacts everyday life [21]. In line with the overall experience of the reconfigured interface in our study, and the paradox of freedom/enslavement [15], it is about asking which aspects could facilitate and foster independent conscious reflectivity, and which aspects could lead to addictive behaviour and raise irrational fears.

It is about considering that all technological functionality is not equal, and about considering the balance between fulfilling needs and creating desires.

5.4 Contrast

This theme points to creating relevant contrast between the designed object as part of self and the object as independent entity [9], while being aware of how user friendliness makes use transparent yet seductive [10]. It is about stimulating, what we in our study called, fragmented conscious use, with considerations of what meaningful fragments are. It is about creating relevant contrast between accessing functionality and performing that functionality in situ [18]. These moments of contrast can invite for actions to realign with intentions of use, to break temporal patterns or foreground grown routines.

5.5 Norms

This theme points to shaping technology in a matter that aids the development of, as our research hinted at, healthy norms. This means both providing means for evaluating appropriate use in context, and actively contributing to the negotiation of desired behaviour in context. It is about inviting for rather than forcing this negotiation. This theme also points to the shaping of technology to interrupt in culturally considerate manners.

6 CONCEPTUAL PROPOSAL

As an exercise in working with the design research themes for mindful interaction, we explored their usefulness in conceptually redesigning the operating system's interface. The resulting proposal is intended to make the design themes more accessible, and to spark imagination in what they can offer design researchers and developers. The proposal considers different kinds of micro-boundaries for accessing different kinds of applications; it considers authorship by allowing users to create hierarchies of importance; it considers balance by allowing users to create different 'modes'; it considers contrast by enabling the setting of time limits; and it considers norms by offering the setting of online and offline contexts (Figure 3).

To illustrate possible situated consequences of the design proposal, we developed a 7-minute long video (https://youtu.be/f5EXBMPAEhU). The contexts depicted in the video are inspired by the problematic instances that were identified through the interviews. However, we want to emphasize that the exercise of working with the proposed themes is not about developing technology that leads to mindful interactions. Instead, they are an invitation to research and contemplate how design can foster a more mindful, intentional, reflective, and conscious interactions with technology.

7 CONCLUSION

In this paper we have studied the role of the smartphone's operating system's interface on consumption of digital media. We synthesized the research contributions and the empirical findings in a set of design research themes for mindful interaction. They are meant as deliberately open formulations, to encourage design researchers and developers to explore opportunities for mindful interactions by considering barriers, authorship, balance, contrast, and norms. Following these considerations, *user-friendly* might not necessarily mean technologies that are convenient, comfortable, and usable, but might instead contain elements of desirable inconvenience. In the negotiation with these inconvenient encounters, users should be enabled to develop an intentional relationship with their technology that respects situated activities and aids the shaping of healthy norms.

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Do diabetes mHealth and online interventions evaluate what is important for users?

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Abstract
Research often presents patient needs from perceptions of healthcare professionals and researchers. Today, patients can formulate tailored questions and seek solutions for what they need to self-manage in many ways. We aimed to compare reported outcomes of mHealth and online intervention studies for diabetes self-management to patient-reported needs, from a systematic review and a literature review respectively. Although we found similarities between the reported outcomes and the patient-reported needs, research has yet to meet all patient needs. Comprehensive methods for development and testing of interventions should be explored to meet the specific needs of patients.

Keywords
mHealth, diabetes, online, evaluation, patients, needs.

1 INTRODUCTION

Evidence for models of diabetes self-management focus on medical devices and clinically relevant measures, and not those that are reportedly relevant for the patients who are the intended users [1,2]. Technology such as mHealth and online tools and services intend to aid patients' diabetes self-management (SM) and provide additional support and information to that from traditional diabetes care and medical technology. In fact, patients with diabetes, have expressed impatience and dissatisfaction with the medically approved technology-based solutions, leading to the rise of the Do-It-Yourself (DIY) movement of hacking technologies to provide the functions and support that patients need [3]. However, the tradition within health intervention research has been to mostly focus on addressing and reporting clinical evidence and outcomes such as change in hemoglobin A1c and cholesterol levels, and not so much on other patient-relevant factors [2]. This raises the question: to what extent is mHealth and online intervention research targeting what is important for the patient and their needs in diabetes care?

"Patient needs" are often described in scientific literature as activities or actions that patients have to take to achieve good diabetes health. In other words, it is often focused on what healthcare professionals (HCPs) and researchers, not patients, perceive as patient needs [4]. When reported, patient needs are usually inferred from patients' feedback about their experience with mHealth or online interventions as part of an intervention study [5,6]. However, these do not comprehensively cover the overall needs for aiding their self-management.

2 METHODS

We compare results from two reviews: Review 1 identified reported outcomes of mHealth and online intervention studies for diabetes SM, and Review 2 identified patient-reported needs and facilitating factors for diabetes SM. While performed separately, categorization of the results for each review were discussed and agreed upon by all co-authors.

2.1 Search strategy for Review 1 - reported outcomes of mHealth and online interventions

The first review was a systematic literature review, with the overall aim of identifying methods and evaluation criteria used during mHealth and online interventions for diabetes SM. Several categories of information were extracted from the resulting literature. However, for the purpose of this paper, we will focus on reporting only a selection of the extracted data, i.e. reported outcomes. The following are examples of terms within titles and abstracts of literature found in CINAHL, EMBASE, MEDLINE and Web of Science, and published between Jan 1, 2015 and June 21, 2018 for the search strategy: *[mHealth or web-based]* AND *[self-assessment OR self-care]* AND *[assessment OR guidelines]*. The detailed search strategy is published along with the protocol of the systematic review in PROSPERO (Registration number: CRD42018115246). Articles were included if: they reported a relevant framework, guideline, questionnaire or other relevant criteria for evaluating mHealth or online interventions for patients – with all types of diabetes. Articles were excluded if: the evaluation only included medical measurements or did not include patients. Articles with only abstracts available, reviews, and dissertations were also excluded. Data extraction was performed by two co-authors (PR, MB). The main author (DL) performed inductive qualitative analysis and grouping of the outcomes. All stages from search strategy to data extraction and synthesis were contributed to and approved by all co-authors.

2.2 Search strategy for Review 2 - patient-reported needs

The second review was a literature review aimed at identifying patient-reported needs related to the facilitation and performance of SM activities, including but not limited to those based on the use of mHealth technologies and online SM aids. Our search strategy included combinations of the following terms in titles and abstracts searched within Google (grey literature search) and PubMed that were published between Jan. 1, 2015 and August 17, 2019: *[patient-reported needs OR want OR information needs OR*

needs OR unmet needs] AND *[patients]* AND *[diabetes OR mHealth OR online]*. Literature, news articles and other resulting publications were included if they reported needs and wishes for SM and SM aids by patients with diabetes. Literature was excluded if the feedback was from non-patients, or from patients during development or testing of a specific app or online intervention only. This is because we aimed to identify unbiased feedback about needs for SM and factors that facilitated SM, without the context of development or testing of an app for a purpose that was chosen by the researchers, not the patients. Data extraction included patient-reported needs and facilitating factors related to diabetes self-management. Co-author (MB) performed inductive qualitative analysis and grouping of the needs.

2.3 Comparison of reported outcomes vs. patient-reported needs

We performed a comparison based on the individual topics, i.e. reported outcomes and patient-reported needs, independent of the previously established categories. Comparison of the individual topics was discussed and agreed upon by all co-authors. By comparing individual reported outcomes and patient-reported needs, we were able to identify which patient needs are addressed by intervention studies and which still need to be addressed in the future.

3 RESULTS

3.1 Results from Review 1 – reported outcomes of mHealth and online interventions

The search strategy resulted in the identification of n=1681 mHealth and online intervention studies. After removing duplicates, most were excluded because no evaluation was reported, the focus of the study was not on diabetes or apps and online interventions, was not in English, not peer-reviewed or published before 2015. The selection process is described in Figure 1.
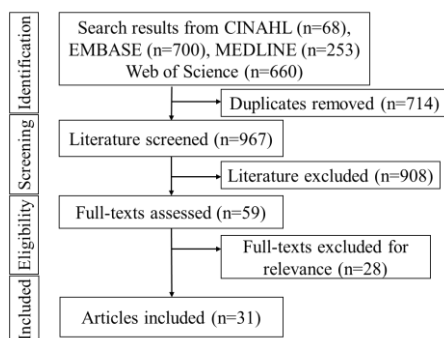
Figure 1 is a PRISMA flow chart diagram of Review 1.

The analysis of mHealth and online interventions studies resulted in six categories, each with outcomes reported from evaluations. The *Usability and Suitability of apps and interventions* category (see Table 1) had the most reported outcomes. Of these, the most commonly reported outcome was the Features and functions of an mHealth or online intervention. The Features and functions included the different types of tools for self-management such as diabetes diaries and glucose monitors, their characteristics and the users' experiences with these tools. mHealth and

online interventions tend to focus on their effect on self-management, self-efficacy and autonomy, and clinical health measures such as hemoglobin A1c and blood pressure. See Table 1 for the full list of reported outcomes.

Reported Outcomes	Refs
Usability and Suitability of apps and/or online interventions	[5, 7-32]
• Tailorability • Features and functions • Ease-of-use • Challenges of use (from HCPs and patients) • Suggestions for development and improvement • Feasibility of integration into care practice • User interface design	
Effect on patient empowerment and engagement	[5-7, 10-12, 14, 17-20, 22, 25-29, 31, 33-35]
• Self-management • Self-efficacy and autonomy • Motivation • Usage patterns • Adherence	
Effect on clinical health measures	[6, 7, 9, 12, 14, 16, 18, 20, 22, 26, 29, 34]
• Quality of life • Psychological symptoms • Physical symptoms • Clinically measured data • Changes in patient-recorded health measures	
Data protection	[11, 13, 15, 17, 22, 32]
• Security and privacy • Security regulations (or national standards)	
Support from and access to	[6, 9-11, 13, 14, 17, 18, 20, 24, 25, 27-29, 31, 33, 35]
• Peers • Family • Coordinated healthcare services • Relevant diabetes information	
Other	[9, 28]
• Cost of development • Recommendation of technical solutions to patients by HCPs	

Table 1 Results of Review 1, reported outcomes from mHealth and online interventions.

3.2 Results from Review 2 - patient-reported needs

The search strategy in PubMed and Google resulted in 160 manuscripts with references to "patients' needs" for diabetes self-management. Review of the titles, abstracts and brief descriptions, followed by review of full texts, resulted in the exclusion of 139 manuscripts, largely because the needs were not directly reported by patients, or were not related to diabetes. Figure 2 details the identification and selection of included literature.
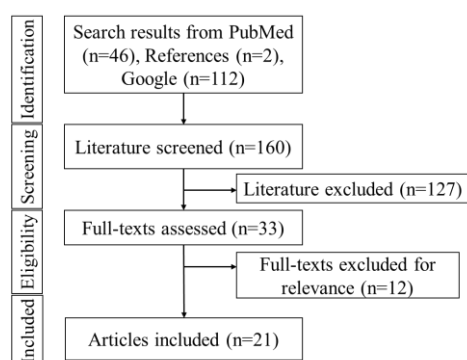
Figure 2 is a PRISMA flow chart diagram of Review 2.

Four categories of needs were identified from the qualitative assessment of reported patient needs. The most commonly reported needs were related to *Support and access to services,* including both Emotional and practical tailored support from family, peers and HCPs to encourage and guide SM. The second group of most common needs were related to *Coping, patient engagement and empowerment*. Patients saw the importance of being motivated and having confidence in their ability to perform SM tasks. This included being able to determine the best action in different situations, e.g. vacation, or if they needed to adjust how they managed their disease, e.g. because their metabolism and other factors changed as they grew older. While patients reported that they needed routines and more structure in their SM, they also wanted more relaxed and less strict SM goals, e.g. they did not like to feel ashamed or defeated by not reaching a diabetes-related goal. Because this review focused on general SM needs and facilitators of SM, fewer articles (n=6) described needs specifically related to mHealth or online interventions.

Further, many of the reported needs were inter-related. For example, patients wanted information about how their lifestyle choices affected their diabetes health, and vice versa. This information could be provided by HCPs' feedback about their SM performance, or from visualization of previously registered lifestyle and health data in an app (seen under *Support and access to services* and *Technology needs*, respectively, in Table 2). Table 2 provides more detail of the categorized needs that patients reported.

3.3 Comparing review results: Research foci vs. patient needs

When comparing the topics of the reported outcomes of mHealth and online interventions and the patient-reported needs (see Venn diagram, Figure 3), we found many commonalities. The green section of the Venn diagram (B) illustrates these commonalities, with some individual topics such as Relevant diabetes information, and Feasibility of integration into care practice, reported as outcomes of interventions covering a variety of individual topics from the patient-reported needs.

The yellow section of the Venn diagram (A) illustrates only reported outcomes from the mHealth and online interventions such as Cost of development, and Challenges to use from both HCPs and patients. The blue section of the Venn diagram (C) which illustrates only patient-reported needs, include individual topics such as Access to updated research results and policy changes related to diabetes SM, and How to cope with negative feelings and stress related to SM.

Patient-reported needs	Refs
Information needs	[36-46]

- Clinical tests and disease function
- Options, risks, symptoms of treatments and medications
- How lifestyle impacts disease
- How disease impacts life
- Population level disease info
- Information for family and friends
- Quality, reliable, tailored education and information
- Awareness of updated research and healthcare policies

Support and access to services (HCPs, peers, family) ***needs***	[36-45,47-56]

- Sharing data, e.g. from app to HCP, and from electronic health records to patient
- Emotional and practical tailored support
- Feedback on SM performance and reminders
- Variety of always-available health services/SM aid options
- Resources and services that facilitate SM activities, e.g. gyms

Coping, patient engagement and empowerment needs	[37, 39-42, 44-46, 49-53]

- Participation in own healthcare decisions
- Motivation
- Self-efficacy
- Self-control/discipline, e.g. daily routines
- SM plan/goals that are not too strict
- How to adjust SM to e.g. different situations, as disease progresses
- How to cope with negative feelings, stress, insecurity about disease
- Avoid burden of disease for self and family
- Balancing life and SM responsibilities

Technology needs	[36, 41, 47, 48, 50, 56]

- Simple and relevant visualization
- Automatic entry of different types of data
- Access to previous activity records
- Ease-of-use, e.g. always available

Table 2 Results of Review 2, patient-reported needs.
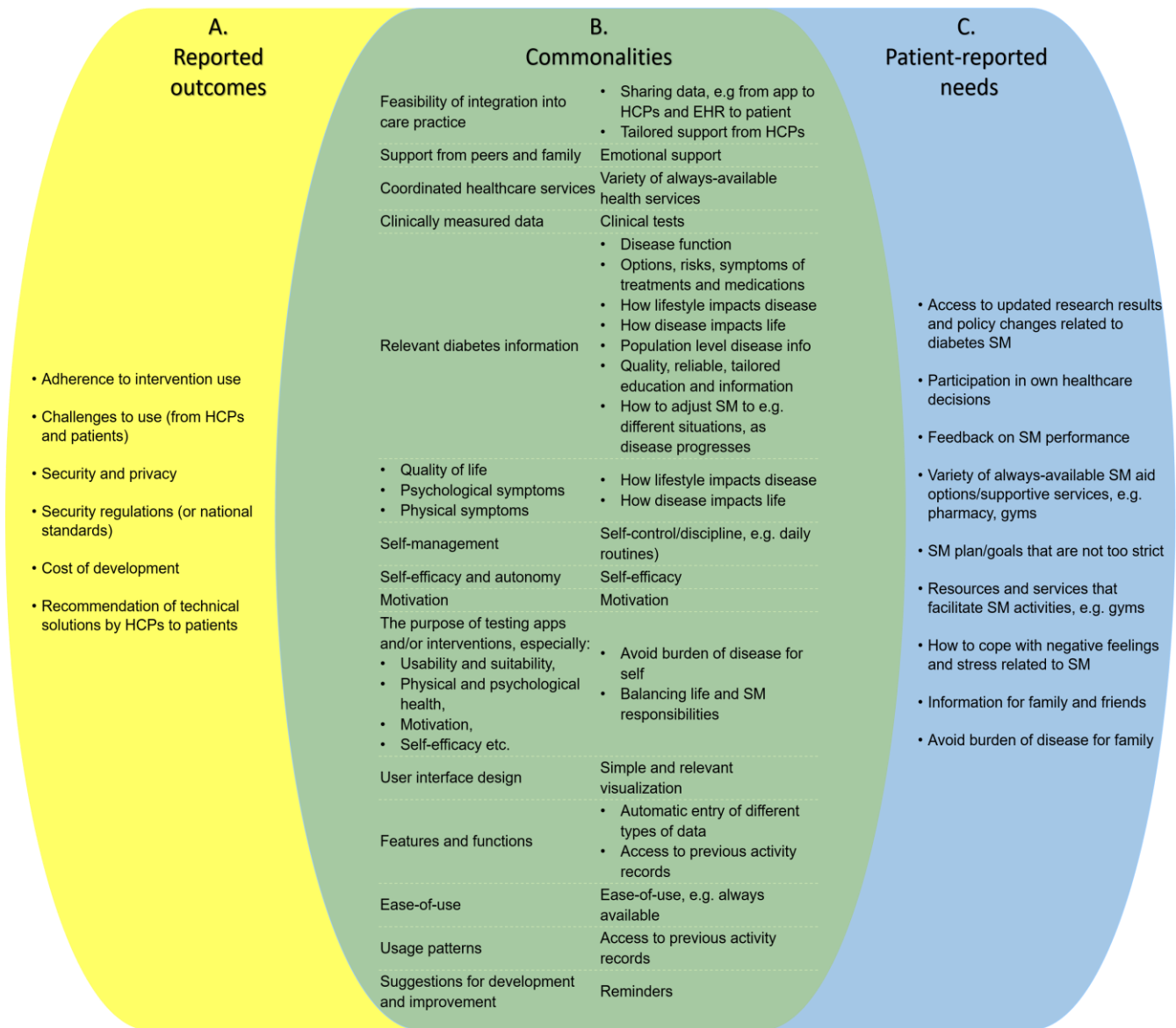
Figure 3 Venn diagram comparing results of both reviews, based on individual topics: **A.** topics that only appeared in reported outcomes, **B.** topics that appeared in both reported outcomes and patient-reported needs, and **C.** topics that only appeared in patient-reported needs.

4   DISCUSSION

The reported needs of patients and the reported outcomes of research did overlap a lot. There are still however, patient-reported needs that research has yet to address in order to optimize the self-management of diabetes patients.

4.1   Patients want to share data

The patients' need to share their own gathered health data from apps with HCP has little representation in research outcomes. Only recently have technology developers, health authorities and researchers accepted the need to address both patients' and healthcare practitioners' use of these technologies, for example in consultations [57]. As a new and emerging field, patient-generated health data integration faces challenges in the every-day clinical setting, as well as from continuous development and use [58]. In addition to its significant effect on patients' health, patient-generated data integration improves communication between HCPs and patients [58]. With input from HCPs

about this shared data, patients could receive more supportive and tailored services, e.g. medication advice, and tools for coping with emotional and psychological distress. With the continuous advancement in technology, more of the already existing and future diabetes interventions could incorporate this function to help improve SM activities. This is especially true for diabetes, which is the fastest growing target audience for both individual and integrated mHealth systems [59].

4.2   Patients want more information

The patient-reported need for Awareness of updated research and healthcare policies is among those needs not well-represented in the reported outcomes from mHealth and online intervention studies. Considering the importance that some categories of patients place in the digital sources of information [60], patients must be given the opportunity to access and understand research that pertains to their disease condition. We must also acknowledge that because

this information is published in a language and platform, e.g. scientific journals, that target researchers, not patients, it is understandable that patients do not feel that they have access to this information. If researchers would be more active in their production of popular science articles, participation in social media or blogs, this information could be more accessible and understandable for patients.

Patients also reported a strong need for evidence, information and support. Some important questions to ask regarding these topics are: for which patient group is the evidence, i.e. reported outcomes, relevant? And, are there factors or needs that precede patients' needs for SM? For example, Majeed-Ariss et al. report the needs of a group of British-Pakistani women who struggle with receiving health information and recommendations in English [51]. In this case, there was a fundamental barrier, i.e. communication, which needed to be overcome before these women could be expected to perform recommended SM activities, let alone to achieve diabetes health goals.

4.3 Involving Patients in SM interventions

Platforms or devices addressing the majority of the patient needs in mHealth and online interventions should be a priority for researchers. Similarly to Majeed-Ariss et al. [51], Berkowitz et al. [54] report that, in addition to healthcare services, patient needs include community resources and access to gyms that serve to lower the barriers to performing SM activities. Because patient needs relate to both medical and non-medical factors, research should involve patients from the beginning of SM aid-development to the identification and organization of a preventative or related service and support network, e.g. family and peers. Designing mHealth or online interventions that allow for personalization or tailoring based on each individual's needs at their stage of SM or disease progress, can be another way for research to significantly address patient-reported needs for SM.

4.4 Limitations

Based on experience in the field of mHealth development and evaluation, which iteratively involves patients, we know that data and personal security and privacy, as well as clinical efficacy of SM aids are both important to patients [61]. However, because Review 2 focused on general SM needs reported by patients, with less emphasis on needs from mHealth or health technologies, these were not included in the extraction of patient-reported needs.

Due to the differences in aims and the kind of data we hoped to extract from the two reviews used in this paper, the time span of the searches, the databases accessed, and the type of review (systematic versus non-systematic review) were different. In addition, the reviews were limited to articles published in English language.

5 CONCLUSION

There are many patient-reported needs not addressed in today's diabetes mHealth and online intervention studies. In order to meet the needs of patients, facilitate the expectations and treatment goals of care teams and improve overall health and wellbeing for those living with diabetes, comprehensive interventions and methods for developing and testing mHealth and online interventions should be further explored. With today's technologies, it is more feasible and possible to realize the potential of patient

empowerment and improved self-efficacy via mHealth and online interventions. Patients' desire to share information with their HCPs can reinforce the potential of collaborating with their healthcare teams as opposed to only following directions. Therefore, the more we know about the challenges that patients face, the specific needs for patients' self-management, and the ability of health services to support these needs, the more effectively we can develop tools and services, and provide relevant interventions for both patients and HCPs.

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7 ACKNOWLEDGEMENT

EDMON - A System Architecture for Real-Time Infection Monitoring and Outbreak Detection Based on Self-Recorded Data from People with Type 1 Diabetes: System Design and Prototype Implementation

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Abstract

Infection incidences in people with diabetes can create sever health complications mainly due to the effect of stress hormones, such as cortisol and adrenaline, which increases glucose production and insulin resistance in the body. The proposed electronic disease surveillance monitoring network (EDMON) relies on self-recorded data from people with Type 1 diabetes and dedicated algorithms to detect infection incidence at individual level and uncover infection outbreaks at population level. EDMON incorporates four major modules; patient modules, mobile computing modules, computing modules (cloud backend), and end user modules. This paper presents the patient and computing module prototypes along with various essential design choices and challenges together with their solution. At the time of writing, development of the EDMON infection and outbreak detection algorithms are already completed and the next phase of the study involves integration of the prototype along with the EDMON algorithms, developing end user visualization mechanism and performing a pilot study.

Keywords

Type 1 diabetes, Infection detection, Outbreak detection, Patient module, Cloud backend solution

1   INTRODUCTION

The Emerging and re-emerging infectious disease outbreaks are still a major threat to public health security requiring instant detection and response [1]. The transition from the classical surveillance to the syndromic surveillance has improved the timeliness for optimal public health response. Syndromic surveillance often uses clinical features that precedes diagnosis and various activities triggered by the onset of symptoms as an alert of change in disease activity [2]. Patient information is acquired from secondary sources of information primarily built for other purposes, which includes google searches, twitters, pharmacy drug sells, school and work absenteeism, and others. Due to the ever changing social and biological environment dynamics, new surveillance systems integrated with novel aberrant detection mechanisms are required to meet the demand of the rapidly changing world [2].

Diabetes mellitus is a chronic metabolic disorder, which results in abnormal blood glucose levels. Blood glucose control is mainly maintained through self-management practices involving active tracking of blood glucose levels, administering proper diet and medication, and performing balanced physical activity [3]. The number of people with diabetes was estimated to be around 425 million in 2017

and yet forecasted to reach 642 million by 2040 [4]. The incidence of infection in people with diabetes often creates sever health complications, mainly due to increased glucose production and insulin resistance developed in the body [5, 6]. This profound physiological alteration is occurred mainly due to the effect of stress hormones, such as cortisol and adrenaline, which in turn is triggered by the onset of infection in the host body [7-9]. As a result, it is common in people with diabetes to experience elevated blood glucose levels and increased insulin consumption upon infection incidences. The proposed Electronic disease surveillance monitoring network (EDMON) is an event-based digital infectious disease outbreak detection system, which relies on self-recorded data and dedicated algorithms to detect infection incidence at individual level (micro-events) and uncover outbreak detection at population level (macro-events) [10]. The EDMON system architecture mainly incorporates four major modules; patient module, mobile computing module, computing module (private cloud backend), and end user module, as shown in the **Figure 1**. The patient module is a standalone mobile health app that integrates different sensor reading including blood glucose levels, insulin injection, and diet information along with Global Positioning System (GPS) coordinate of the patient in terms of geographical latitude and longitude. The mobile computing module handles the communication and
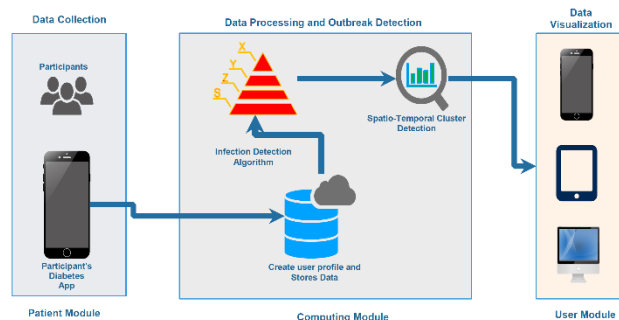
Figure 1 EDMON System Architecture.

transmit the user's collected data from the mobile health app to a remote private cloud for further processing. The main purpose of the computing module (cloud backend) is to securely store users' data and further processing of these data so as to uncover any potential threat of infectious disease outbreaks. The infection detection algorithm tracks individual diabetes patients and detect any incidence of infection using the key diabetes parameters; blood glucose levels, insulin injection and diet information. The spatio-temporal clustering algorithm scans the entire geographical region under surveillance looking for a group of infected people with diabetes within a specified time frame [11]. The end user module disseminates the status information for the concerned bodies and ordinary citizens under the surveillance regions based on both a standalone mobile application and through a dedicated website. It incorporates various means of information visualization techniques including maps, tables and graphs, where the end user can easily access through various devices including smartphones, tablets and desktops. To this end, this paper presents the patient and computing module prototypes along with various essential design choices and challenges together with their solution including standardization issues, privacy, security and data confidentiality compliance with General Data Protection Regulation (GDPR). Moreover, the paper presents different system design features including application programming interface, data transfer mechanism, authentication and access control mechanism, and system database. It worth mentioning that at the time of writing, development of the EDMON infection and outbreak detection algorithms are already completed and the next phase of the study involves integration of the prototype along with the EDMON algorithms, developing end user visualization mechanism (front end application) and performing a pilot study.

2 STATE-OF-THE-ART SYSTEMS

The widespread use of mobile devices, IoT devices and wearables and sensors have enabled people to collect vast amount of health data through quantified self and lifelogging for the purpose of personal informatics - self-tracking, self-quantifying, and self-surveillance [12, 13]. The amount of self-collected data is growing daily and is becoming apparent that it requires technologies such as cloud computing to process such a huge volume of data. However, collecting health related data to a central cloud brings various challenges including security, privacy, data confidentiality compliance, standardization issues, and

other related ethical and motivational issues [12, 14- 18]. The storage of sensitive information like health data in a cloud requires strict compliance to regulations like HIPPA and GDPR along with other related ethical issues. This demands strict mechanism to ensure authentication and authorization, identity and access control, de-identification and anonymization of user data, and encryption [14, 16]. Moreover, it is necessary to make sure the system is secured against any attacks by thoroughly capturing enough provenance information [14]. Furthermore, collecting of data from heterogeneous devices to the cloud brings standardization challenges, which calls to follow a certain standard such as HL7. There are fewer literatures, which describes a cloud (server) based solution in relation to people with diabetes [16, 19-27]. For example, Mougiakakou et al. [23] developed SMARTDIAB, which is a platform to support diabetes monitoring, management and treatment. The platform has relied on packet enciphering with Triple Data Encryption Standard (3DES) algorithm and data hashing by means of secure hashing (SH-1) algorithm to provide data privacy and data integrity [23]. Data exchange is performed based on Extensible markup language (XML) messages using the Simple Object Access Protocol (SOAP). A secured communication between remote server is ensured relying on IPSec on the network layer, secure socket layer (SSL) on the transport layer, and Hypertext Transfer Protocol Secure (HTTPS) for secure data transmission. Role-based access control along with an application layer firewall– intrusion detection system (IDS) is used to secure the central database [23]. Standardization is ensured following Health Level 7 (HL7) standard when designing the central database and also making the database ICD10 compliant [23]. Moreover, Al-Taee et al. [22] developed a platform to support self-management of diabetes based on internet of things (IoT). A communication between clients and remote server is secured using HTTPS protocol [22]. A Model- View-Control (MVC) pattern is adopted to design the application that handles users' related functionality considering the security and scalability aspects of the system. The central databased is based on SQLite and PostgreSQL database instance to store patients' data and other system related information [22]. Furthermore, Huzooree et al. [16] developed a platform to support remote real-time monitoring of people with diabetes based on a wireless body area network (WBAN). The proposed system relies on Bluetooth and ZigBee communication protocols to transmit the sensor data to the mobile phone. Further, the communication between the mobile phone and access point is based on IEEE 802.11 /Wi-Fi/GPRS [16].

3 MATERIALS AND METHODS

The prototype of the patient module and computing module (cloud backend solution) were developed using various tools, libraries, software and programming language. Both of these prototypes were developed bearing in mind the functionality required by each other during integration. The patient module was developed using TypeScript v3.4.5 [28], React-native v0.59.5 [29], and SQLite based on agile software development with an incremental approach. The prototype was run and tested using an Android-emulator running Android version 9.0(pie). The minimum functional

and non-functional requirement were derived directly from the existing diabetes mobile apps, especially Diabetes diary [30] and mySugr app [31]. However, a more advanced functionalities required by a disease surveillance system like the EDMON system were integrated.
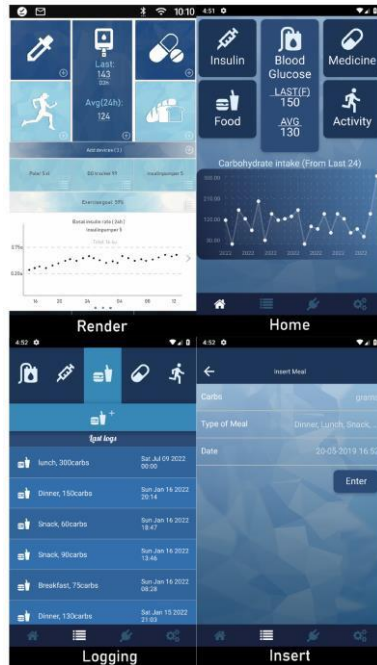
Figure 2 A prototype for EDMON patient module [32].

The development of the backend cloud solution relied on different service tools such as Vertelo [33] and Draw. Io [34], which were used to visualize the database and to design and illustrate figures respectively. Moreover, Golang [35], a programming language designed by Google, and Python programming languages were used. Apart from this, libraries and software were used such as Gin library [36], a framework used for HTTP requests and debugging, Postgres [37], an open source database used as the systems database, Gin-jwt [38], used as a middleware to handle JSON web tokens, and Openssl [39], which is used to create a certificate and public key for HTTPS requests. The performance of the cloud backend solution was evaluated using data from the Ohio T1 Diabetes datasets [40]. The Ohio T1 Diabetes datasets contains real datasets from six individuals with type 1 diabetes. It incorporates blood glucose, insulin, carbohydrate, physical exercise, sleeping time, heart rate, and other important physiological measurements. Performance evaluation was carried out for various features and functionality including the average time of execution for a user, average time of concurrent requests to the system, profiling in Golang, and system throughput. Moreover, the computational performance of the system was tested under the execution of the EDMON infection detection and cluster detection algorithm, assuming fetching and computing a very large dataset at a time from so many participants. The average performance of the system was calculated by running the task for a certain number of times. Different tasks such as creating user, login with user credentials, storing medical records

with location and timestamp, fetching and deleting all user medical records were used to test and evaluate the system performance. Average time of execution for a user was evaluated to determine the average time it takes to perform a given task while the server is under load. Average time of concurrent requests to the system was evaluated to determine the time it takes for a given concurrent requests from a given number of concurrent clients to the system. The throughput of the system was evaluated through spamming the server with requests from the Apache benchmark [41]. This is mainly performed to evaluate the performance of the server under heavy load and also to showcase the maximum number of requests per second the server can handle along with the maximum number of concurrent client requests it can handle.

4 THE PATIENT MODULE

The patient module has similar functionality with the existing well-known diabetes apps, such as Diabetes Diary and mySugr, as shown in the **Figure 2**. It can record key diabetes parameters such as blood glucose levels, insulin injection (both bolus and basal units separately), diet information, and physical activity load. However, it is designed to include additional functionality required by disease surveillance system like EDMON. The added functionality was capability to estimate and record the user geographical location along with the user log, recording weather information, and record events of infection and medication taken. Moreover, the prototype has a feature that enables to push newly created logs with added metadata to a remote EDMON private cloud, giving the user a freedom to pull out of the system at any time. Upon new event, the client can connect to the EDMON cloud, encrypt and transmit the added metadata along with the device GPS position and weather information. The user positional coordinates are collected through the Android API and requires post-processing in order to convert fine accuracy position to a course accuracy position.

5 THE CLOUD BACKEND SOLUTION

5.1 Functional requirements

The main functional requirements of the cloud backend solution is selected based on the necessary requirement for a digital infectious diseases outbreak detection system, such as EDMON, and include the following [42]:

- It should provide an open API so that an API call can be made to the system.
- A new participant could join the system at any time by creating a new account on the system.
- It should store the user's self-recorded data from the self-monitoring diabetes mobile app (patient module).
- It should store the user's location upon new data registrations.
- It should be able to fetch the individual user data and run the EDMON algorithm on each individual user's data at each hour of the day or at the end of each day to look for any infected individuals and mark them as sick.
- It should protect user privacy and confidentiality of the data by providing authentication and access control mechanisms for user's data.

- It should secure user data by encrypting all the data sent back and forth between the user and the system.
- Furthermore, it should let the user store small videos of medical recordings, which can be notes, and other important things the user wants to revise at later time.

5.2 System component design

Database design

To handle the stable storage of the medical data, a Postgres database is used. The database is designed focusing on being as general as possible to support later development of applications and exporting data from other applications into this system. The main goal is to support all types of medical data, while safely storing sensitive user information. All database access is done on individual user's credentials, which is based on JWT access control. The database incorporates three tables; User, Medical records, and locations.

User

User of the system are participants, who has type 1 diabetes. Each user is represented by a unique key identifier, and each user table contain many fields such as username, password, token, location, medical records, and health status. A user sets a password and username upon signing up a new account. The password is stored in the database and used for comparison purpose when the user tries to log in to the system or to fetch the JSON web token. The passwords are hashed and salted so as to ensure that the user security, privacy and data confidentiality are preserved at all times. As a result, whenever user tries to login to the system, their passwords are compared to the hashed and salted version stored in the database. For each user, once an account created a MedRecs ID is assigned, which is used to store and fetch user data upon request. Moreover, a field containing the health status of the individual is also assigned, which indicates the hourly and daily infection status of the individual.

Medical Record

A medical record in the system is a recording of health-related data at a given time. It is defined by its LOINC code, which has been called HL7 in the database. Each recording is unique but has a foreign key identifier to the user. The value of the recording is an integer which could be the heart rate per minute, blood glucose level, insulin injection, food intake or stress level recorded in scale from one to six. Upon registering data in the database, the data is tagged with a timestamp by the built-in now() functionality of Postgres. This time value is used to categorize the temporal aspect of the data and is required by the EDMON system to pinpoint the timing when an outbreak is detected in the surveillance region. For categorizing the spatial aspects of the data, each recording is assigned with geographical location coordinates used by the EDMON system to detect a cluster of infected people with type 1 diabetes on a certain geographical region. Each medical record also contains fields that let the user record and save either a picture or a short video showing how their condition and feeling at the time is.

Location

In the database, both the user and medical record table contain a reference to a location. The location holds information regarding user geographical location coordinates expressed in terms of latitude and longitude. The location table is separated from the user and medical record table for a security reason and also to give the possibility of changing the location format, if necessary, without affecting the other. Each user can have two different locations; static and dynamic location. The static location is defined as the user hometown, home address, and postal codes. The dynamic location specifies the approximate current location of the user upon registering a data as compared to the static location. These locations information are used by the EDMON algorithms to detect clusters of people based on geographical region. Moreover, this geo-information can also be used for other purposes such as to locate a patient with e.g. hypoglycemia (critical low blood glucose levels) and needs help, through alerting mechanism in the system.

Relations between the tables

The foreign keys in the database defines how each table interact with each other, as shown in the **Figure 3**. For example, a user has two different foreign keys to the location table; a static and dynamic location, which set the user geographical position at all times. However, even if the user has two different locations, he/she can only have one medical record ID. The relationship between a user and a medical record is a one-to-many relationship, which meant that a user can have many medical records. In turn, the medical record has a foreign key to a location, which indicates where the user is located at the time of recording the data.
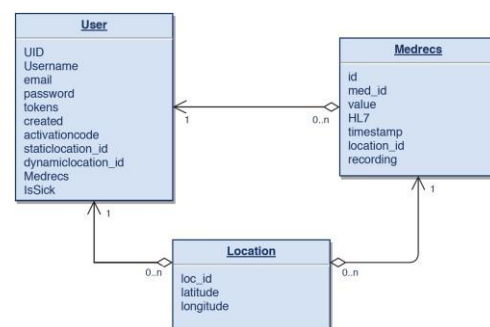
Figure 3 Database design.

5.3 Authentication and access control

Authentication and access control in the system is handled by JSON web tokens. These tokens are session-based, which mean that as long as they are refreshed before the expiration by the application, a user does not need to log in using their username and password. When joining the system, a user is expected to sign up and create an account by providing a username, email and password, which is used for authentication purposes. However, once the account setup is complete, the user email is automatically removed and deleted as part of the de-identification process and a unique key identifier is set in place. The token provided by the server is the users' way of authenticating all other HTTP requests.

5.4 Application programming interface

The application programming interface (API) is used to create an interface and connect the cloud backend solution with the necessary EDMON applications. Regarding the patient module, the API is designed giving a due consideration for the users to have a complete control of their stored data, where the user anytime can leave the system by deleting all the records. In connection with the data transfer design feature, the API is built with a RESTful design [43], which incorporates four different possible request to either fetch, delete and store data. These includes GET, PUT, POST and DELETE requests and the data sent from the user to the system is in JSON-format. For example, the transfer of data to the system is executed by the POST request, which contains JWT body with the JSON formatted data, as shown in the **Figure 4**. The authorization token should also be included in the header so that the user is given with the right privilege to edit the data. Upon completion of the data transfer, ID is created in the database to identify the object and the system acknowledges the user.
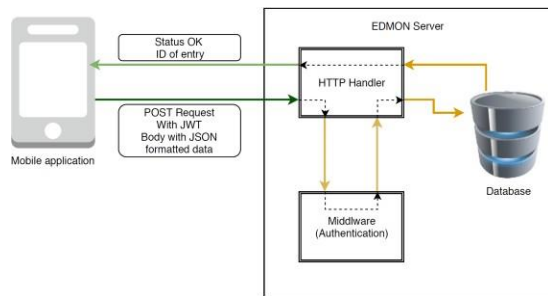
Figure 4 Example of a POST request to the system.

5.5 The overall system design

Generally, the designed cloud backend solution incorporates an API in which a user's patient module can initiate a send request to the system upon new data registration, a middleware that can authenticate the user, and a stable storage of database, as shown in the **Figure 5**.
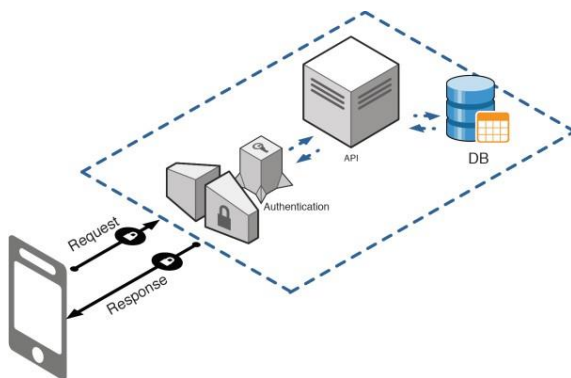
Figure 5 The overall system design.

Each request from a user goes to the systems through the authentication service which validates the token that is sent with the request. If a user has the correct authorization token the system will perform the requested task and send it back to the requester, as can be seen in Figure 6. On the

other hand, if the user cannot provide the correct authorization token, the middleware denies further access.

6 SYSTEM ILLUSTRATION

The interaction between different components of the designed system is illustrated, with an example, as shown in the **Figure 7**. The depicted example shows the component interaction, when a patient module application access request passes the authentication phase and initiates a request to fetch medical records stored in the system database. As can be seen, when a user places a request, it is first directed to the middleware for authentication through the HTTP request.
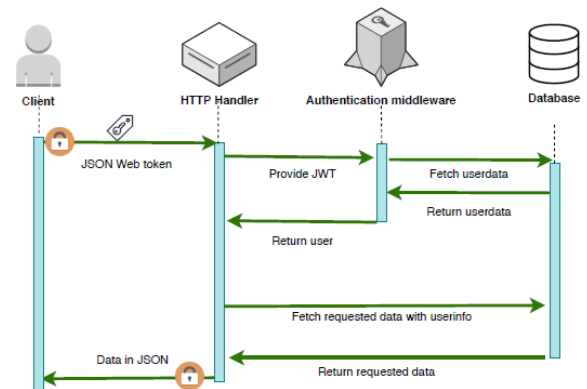
Figure 6 An example of granted access.

Here, the user access to the system is decided whether the user has provided the correct access token or not. If the user has provided the correct access token, then he/she will be granted access and the request goes through the user part of the API and directed to the model for the medical records. Then the requested data is returned to the user API, where it is parsed with JSON and sent to the requester.
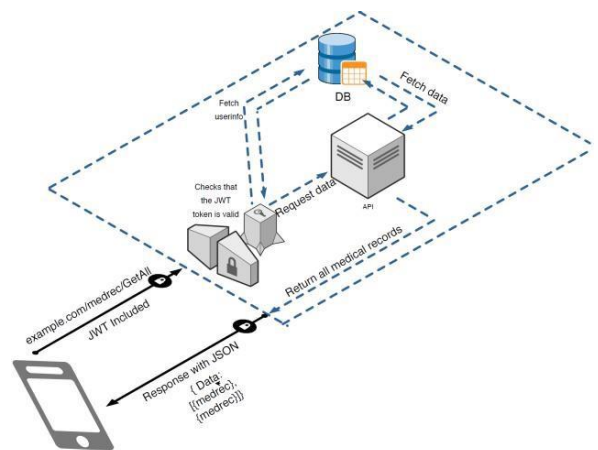
Figure 7 Example of a request to the system.

7 RESULT

The performance test, which is based on real datasets from OhioT1DM dataset, indicates that the server can handles up to 1000 requests per second depending on the request type and one can conclude that the requests per second are sufficient for a real-time system like EDMON with a lot of

participants. Moreover, the test conducted to evaluate the server performance during execution of EDMON detection algorithms performs well, however, the test reveals that an approach that could create a pool of workers in the form of Goroutines, that fetches the users' data continuously and spreads the workload over an hour is preferred, instead of having a heavy algorithm that run once per hour. Furthermore, the test conducted to evaluate the performance of the server in regard to execution time under a fair amount of traffic reveals that a user can upload 600 medical records along 300 different locations almost under seven seconds. Apart from these performance test, a stress test is conducted to measure the liability and maximal throughput of the server using Apache benchmark to create a small denial of service attacks. Almost close 7100 concurrent clients sent 10000 requests, which averaged around 800 requests per second. The test indicates that the server can withstand a high number of requests, only around 2% of the request failed.

8   DISCUSSION AND CONCLUSION

We have presented a prototype for a patient and computing (backend cloud solution) module, which are components of EDMON system towards infection monitoring in people with type 1 diabetes and detecting infection outbreaks based on a spatio-temporal cluster detection. Generally, the purpose of EDMON system is to collect diabetes related self-recorded data from individual with type 1 diabetes to a cloud and perform computation to detect infection incidences on an individual level and further use this information to spatio-temporal clusters for a possible confirmation of outbreak incidences. The system components are designed with due consideration of vital features and implemented in accordance with the state-of-the-art techniques of ensuring security, privacy, data confidentiality in compliance with GDPR along with standardization approaches. To secure the data transferred from the individual patient module, encryption, hashing and salting, and secure authentication is used on the server. In this regard, HTTPS is used to encrypt the data sent from a patient module to the server. This provides the security of a man-in-the-middle attack on the server where the certificates provide authentication from the server. Moreover, upon creation of new account user's password are hashed and salted before being added to the database so as to ensure optimal protection. As a result, there are no parts of the system that interacts with the password after a user is created. Furthermore, JSON web tokens are used to ensure the identity of a user upon authentication. This gives the user minimal interaction with the authentication part of a patient module application, where the application itself can refresh the token if used frequently.

As far as our knowledge is concerned, this is the first system that considers the use of self-recorded data from people with diabetes to detect the incidence of infection outbreaks. We believe such kind of cloud-based system might benefit other similar system built to provide decision support to the patient, diabetes patient monitoring and patient empowerment system, and most importantly provoke further thought in the challenging field of real time digital infectious disease outbreak detection systems.

9   FUTURE WORK

At the time of writing, development of the EDMON individual infection detection and spatio-temporal clustering algorithms are already completed and the next phase of the study involves:

- Integrating both prototypes; patient and computing module.
- Providing functionality such as automatic entry of sensors reading to the patient module.
- Integration of the computing module prototype with the individual infection detection algorithm and spatio-temporal clustering algorithm.
- Developing the end user visualization mechanism (dashboard) based on both a standalone mobile app and a dedicated website.
- Integration of the end user app/website with the computing module to fetch timely infection status of the region under surveillance.

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Food Recommendation Using Machine Learning for Physical Activities in Patients with Type 1 Diabetes

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Abstract

Physical activities have a significant impact on blood glucose homeostasis of patients with type 1 diabetes. Regular physical exercise provides many proven health benefits and is recommended as part of a healthy lifestyle. However, one of the main side effects of physical activities is hypoglycemia (low blood glucose). Fear of hypoglycemia generally leads to the patients not participating in physical activities. This paper shows a proof of concept that machine learning can be used to create a personalized food recommendation system for patients with type 1 diabetes. Machine learning algorithms were designed to improve glycemic control and reduce the overcompensation of carbohydrate. First, a personalized model based on feedforward neural networks is developed to predict the blood glucose outcome during and after physical activities. Based on the personalized model and reinforcement learning, optimal food intakes will be recommended to the patient. Simulation results show that the proposed methodology has successfully maintained the blood glucose in the healthy range on a type 1 diabetes simulator during physical activities.

Keywords

Type 1 diabetes, physical activities, feedforward neural network, reinforcement learning.

1 INTRODUCTION

Type 1 diabetes is a chronic disease characterized by the lack of insulin secretion due to the autoimmune destruction of pancreatic beta cells. This results in an uncontrolled increase of blood glucose level. High blood glucose (BG) level can lead to complications and eventually failure of various organs in the body. On the other hand, low BG level (hypoglycemia) is an acute complication of diabetes. Hypoglycemia is defined when the BG is dropped to less than 3.9 mmol/l (Seaquist *et al.*, 2013). Hypoglycemia causes symptoms from increased heart rate to mental confusion, and unconsciousness. Repeated episodes of hypoglycemia can also lead to brain damage. For many patients with diabetes, the hypoglycemia symptoms can be hard to detect due to a phenomenon, called hypoglycemic unawareness. Hypoglycemia unawareness is very dangerous as BG level may approach extremely low before any symptoms are perceived (Czyzewska, Czerniawska and Szadkowska, 2000; de Galan *et al.*, 2006; Schopman, Geddes and Frier, 2010).

Regular physical exercises have many health benefits and are therefore widely recommended for patients with type 1 diabetes. However, exercises alter significantly glucose homeostasis in patients with type 1 diabetes (Camacho *et al.*, 2005; Riddell and Perkins, 2009). Physical activities increase glucose uptake by muscles leading to a drop in BG concentration, which can reach the hypoglycemic values. Besides, increased insulin sensitivity effects are long-lasting after physical activities and have many negative impacts on daily activities of patients.

Since an automated solution in controlling blood glucose can bring tremendous benefit for patients with type 1 diabetes, various studies have been conducted to design algorithms for this purpose. For example, Marchetti *et al.* (2008) derived a proportional integral derivative controller for BG control. Soylu *et al.* (2013) proposed a Mamdani type fuzzy control strategy for exogenous insulin infusion. However, the glucose kinetics process is complex (Wang *et al.*, 2014) and depends on many factors such as food intakes, active insulin, physical activities, stress, and hormone changes. Furthermore, many of the techniques for BG control are difficult to be implemented since they either require extensive manual tuning for adapting to individual patients or assume that an accurate mathematical model of the patient BG dynamics is available.

Recently, machine learning algorithms have been widely used since they are able to learn and gain intelligence by utilizing a large amount of available data generated by the development of new technologies. For example, artificial neural networks (ANN) is an effective method that imitates how a nervous system works in a simple way and can be used for obtaining a personalized model of BG activities. Reinforcement learning (RL) is also a suitable machine learning tool for BG control. RL was developed and studied in control theory (Vrabie, Kyriakos G.

(Lanctot *et al.*, 2017), information theory (Leibfried, Grau-Moya and Bou-Ammar, 2018) and applied in many other applications including diabetes (Bothe *et al.*, 2013; De Paula, Ávila and Martínez, 2015; Ngo *et al.*, 2018). Through a series of experiments, Fox and Wiens (2019) compare the performance of different RL approaches to non-RL approaches and concluded that RL is a promising tool for improving blood glucose for individuals with type 1 diabetes. In this paper, novel, safe-for-patients machine learning techniques will be studied and developed in order to provide an estimation of food for patients with type 1 diabetes.

2 MACHINE LEARNING ALGORITHMS FOR FOOD RECOMMENDATION TO PATIENTS WITH TYPE-1 DIABETES

Depending on the length of physical activities, two alternatives for food recommendation can be provided to patients. For short physical activities, the system will recommend patients to eat only at the beginning of the exercise. The amount of carbohydrate (CHO) is recommended based on the prediction of the BG outcome from the feedforward neural network described in this section. For long physical activities, it is necessary to distribute food intake during the activities to keep the BG stable. RL is used to estimate the optimal distribution of food intake during the exercise for this purpose.

2.1 Model-Based Recommendation for Short Physical Activities Using Feedforward Neural Networks

A feedforward neural network (FFNN) is a type of ANN which is constructed by neurons organized into layers. The network can be used to estimate the blood glucose outcome from the information of the food that the patient consumes, the amount of physical activity and other factors. A structure of a simple FFNN demonstrated in this paper can be found in Figure 1.
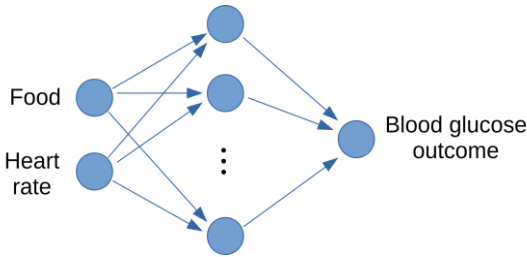
Figure 1 Diagram of the FFNN for estimating blood glucose outcome during physical activities

In this simple network, the inputs are the amount of CHO in food consumed by the patient before doing exercises and the average heart rate expected during the physical activity. The output is the BG outcome, which is represented by a score assigned for the average BG level during and after physical activities (Table 1). The score (ranged from -10 to 10) is designed such that it is high when the BG is closer to the healthy level and low when the BG is further away from the healthy value.

In FFNN, information flows from inputs through the hidden layer towards the output. Each node in the hidden layer is a rectifying linear unit function (ReLU) that mimics how the electrical impulse is fired from one neuron to another in the human brain. The output signal from each node can be represented mathematically as follows:

$$a_j^l = \sigma\left(\sum_k w_{jk}^l a_k^{l-1} + b_j^l\right) \qquad (1)$$

where σ is the activation function, a_j^l is the output value of node j in layer l. The notation w_{jk}^l is the weight of the connection from node k in layer l-1 to node j in layer l. b_j^l denotes the bias of node j in layer l. The task of training a neural network is to find the optimal set of w_{jk}^l and b_j^l such that the following cost function is minimized:

$$MSE = \frac{1}{N}\sum_{i=1}^{N}(\hat{y}_i - y_i)^2 \qquad (2)$$

where N is the number of training samples, $\hat{y}_i$ is the predicted value and y_i is the actual blood glucose score for each training sample i.

Upon trained, the optimal amount of CHO in food A^* that the patient should consume before the exercise can be obtained from the FFNN as follows:

$$A^* = \underset{a}{\operatorname{argmax}} f(a) \qquad (3)$$

where $f(a)$ is the mapping between the amount of carbohydrate in food and the blood glucose score.

2.2 Food Recommendation for Long Physical Activities Using Reinforcement Learning

The principle of RL is based on the interaction between a decision-making agent and its environment (Sutton and Barto, 2018). At certain times during the physical activity, the recommendation system evaluates the current BG condition and makes a recommendation of the amount of food that the patient should eat. The evolution of the BG as the results of the action by the patient determines whether the patient gets a positive or negative reinforcement (blood glucose score). Mathematically, the RL framework for recommending food for patients with type 1 diabetes during physical activities consists of the following elements:

• The state $s = S_t$ defines the condition of the patient at time t. It includes historical values of the blood glucose levels and the information about the physical activity intensity.

• The action $a = A_t$ (eg: type and quantity of food) that follows a policy $\pi(s, a)$. A policy is a mapping between the current condition of the patient and the probabilities of selecting each possible action.

• The score/reward $r = R_{t+1}$, which is the result (consequence) of action A_t at the state S_t.

The objective of the algorithm is to keep the BG level within the healthy level as much as possible during the physical activity. Hence it will search for an optimal policy that will maximize the accumulation of score/reward throughout the exercise. The accumulation of score/reward at state s when taking action a is defined as the action value function:

$$q_\pi(s, a) = \mathbb{E}_\pi\left\{\sum_{t=0}^{\infty}\gamma^k R_{\{t+k+1\}}|\, S_t = s, A_t = a\right\} \qquad (4)$$

With $\mathcal{S}$ as the set of all possible states and $\mathcal{A}$ as the set of all possible actions, the ε-greedy policy obtained from the action value function is defined as follows:

$$\pi(a,s) = \begin{cases} 1 - \epsilon + \epsilon/|\mathcal{A}| & \text{if } a = A^* \\ \epsilon/|\mathcal{A}| & \text{if } a \neq A^* \end{cases} \quad (5)$$

for all $s \in \mathcal{S}$, $a \in \mathcal{A}$, and A^* is the optimal food action:

$A^* = \text{argmax}_a Q(S_t, a)$.

The algorithm for controlling the BG during physical activity using RL can be summarized in Table 1.

Table 1: Reinforcement-learning algorithm for food recommendation during physical activity for patients with type 1 diabetes.

Initialize the estimated action value function $Q(s,a)$ for all $s \in \mathcal{S}$ and $a \in \mathcal{A}$.

Obtain the ε-greedy policy from the initial estimated action value function.

For each exercise do:

    For each break t during the exercise do:

        ○ Suggest and amount of food A_t based on the current policy $\pi(s,a)$.

        ○ Collect the dataset: $S_{t-1}, A_{t-1}, S_t, A_t$.

        ○ Update the current policy from the estimated action value function.

    end

  end

3 RESULTS AND DISCUSSION

In order to demonstrate how the algorithms work, we have built a glucose kinetics simulator based on the physical activity model suggested by Breton (2008) and part of the Hovorka's model (Hovorka *et al.*, 2004) which describes the CHO absorption process in the body. The mathematical description of the simulator can be found in the Appendix.

Table 2: Score/reward for different BG levels.

BG level	Score/reward
BG < 3.9 mmol/L	-10
3.9 mmol/L ≤ BG < 4.2 mmol/L	-3
4.2 mg/dl ≤ BG < 5.6 mmol/L	10
5.6 mmol/L ≤ BG < 7.2 mmol/L	5
7.2 mmol/L ≤ BG < 10.0 mmol/L	-1
10.0 mmol/L ≤ BG < 15.6 mmol/L	-5
BG ≥ 15.6 mmol/L	-8

3.1 Short Physical Activities

For short physical activities, the recommendation is based on the FNNN and is given at the beginning of each exercise. Training data for the FFNN was obtained by repeated simulations from the BG simulator under scenarios that a patient with type 1 diabetes performs physical exercises with different intensities and consumed different amount of food. The duration of physical activities is set to be constant at 30 minutes and the patient always eat at 15 minutes before the exercise starts. The outcome of each exercise is evaluated by measuring the average scores of the BG (defined in Table 2) over the

course of three hours starting at 15 minutes before the exercise. The BG is sampled every 5 minutes during the simulations, which is similar to the sampling time of many continuous glucose monitoring devices. Physical intensities are represented by heart rate values in the simulator. It is also assumed that during short physical activities, the heart rates are constant.

The result of the trained neural networks is shown in Figure 2 as a mapping from food amount and heart rate to the blood glucose outcome during each exercise. Based on this mapping, the optimal amount of food was calculated and given to the simulator.
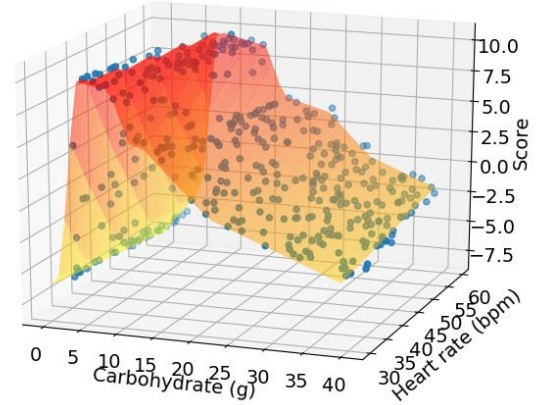
Figure 2 Estimation of the blood glucose score using feedforward neural network (blue dots represent training data).

A test scenario was carried out in which the average heart of the exercise is 100 bpm and the patient is provided with four different choices of food intakes before the exercise: 0, 10, 20, 30 and 40 grams of CHO. Figure 3 shows the comparison of the blood glucose responses within three hours when the patient does not eat anything, follows the recommendation from the algorithm (10 grams of CHO) or have the highest CHO portion (40 grams) at 15 minutes before the exercise. The result shows that by following the recommended food obtained based on the FFNN, the BG of the patient stays well within the healthy level for the duration of the simulation.

3.2 Long Physical Activities

In the long physical activity scenario, a patient performs an interval exercise with the heart-rate profile as shown in Figure 4. Three cases were simulated in this scenario. In case 1, the patient consumes food with the recommended CHO provided by the FFNN. In case 2, the patient is recommended by the RL algorithm the amount of food to eat at the beginning and at every 20 minutes during the exercise. The choices of actions suggested by the recommendation system include: eat nothing, one portion or two portions of food. Each portion of food contains 10 grams of CHO. In other words, at every 20 minutes during the exercise, the algorithm suggests the patient how much he or she should eat to keep the blood glucose level in the healthy level based on the blood glucose data (sampled at every 5 minutes) in the previous 20 minutes. After each time the patient eats, a reward or score is given based on the blood glucose responses in the next 20 minutes. The

value of the reward is assigned based on different blood glucose levels and is provided in Table 2. In case 3, the patient does not eat any food at the beginning and throughout the physical activity.

Figure 5 shows the BG responses proposed by the RL algorithm and the FFNN based recommendation in the same simulation scenario. Figure 6 shows the amount of food (CHO) recommended by the RL and the FFNN. From Figure 5, it can be seen that the BG has been well regulated. No hypoglycemia occurs in both scenarios. However, by spreading out and calculating the optimal food consumption throughout the period of long exercises as shown in Figure 6, RL has better performances compared to the FFNN.

4 CONCLUSION

This paper provides two algorithms that can be used in a food recommendation system for patients with type 1 diabetes: the model-based method based on feedforward neural networks and the reinforcement learning method. Simulation results show that the feedforward neural network based method is suitable for the scenario when the length of the exercise is short and data from past physical activities are available. However, reinforcement learning performs better in situations where physical activities are long and food intakes can be spread out during exercises.
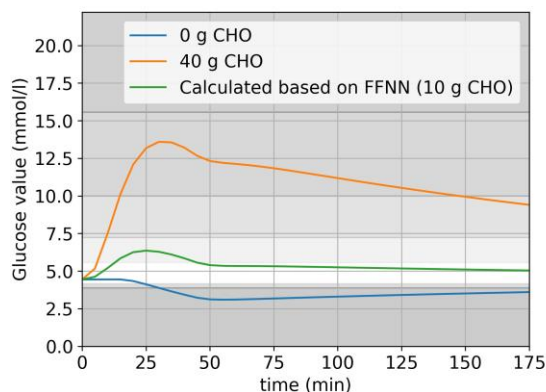
Figure 3 Blood glucose responses with different amount of CHO during a short physical activity (lighter shades indicate more desirable BG levels).
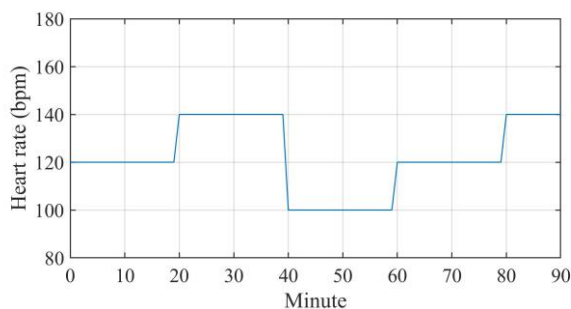
Figure 4 Heart rate during the exercise in the long physical activity scenario
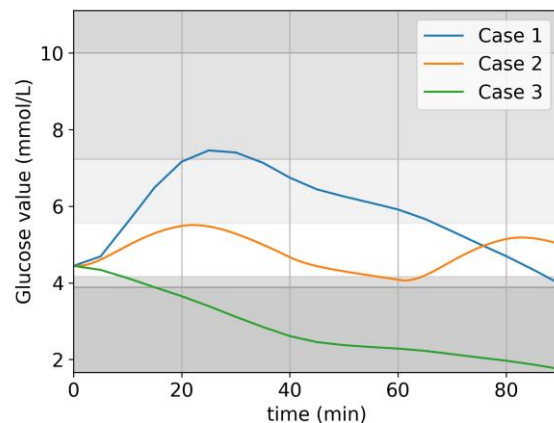
Figure 5 BG responses during the interval exercise in our simulations (Case 1: Food consumed at the beginning of physical activity using FFNN, Case 2: Food consumed throughout physical activity using RL, Case 3: No food consumption).
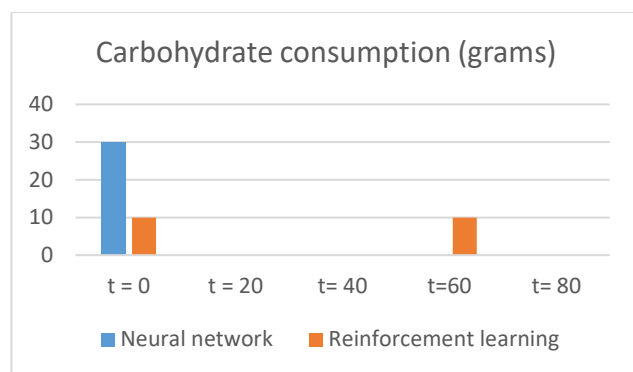
Figure 6: Food amounts recommended by the feedforward neural network (case 1) and the reinforcement learning (case 2).

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6 APPENDIX

The blood glucose simulator used in the paper was constructed based on the physical activity model suggested by Breton (Breton, 2008) and part of the Hovorka model (Hovorka *et al.*, 2004):

$$\frac{dD_1(t)}{dt} = A_G D(t) - \frac{D_1(t)}{\tau_D}$$

$$\frac{dD_2(t)}{dt} = \frac{D_1(t)}{\tau_D} - \frac{D_2(t)}{\tau_D}$$

$$\frac{dg}{dt} = -p_1 g(t) + \frac{D_2(t)}{\tau_D} - \chi(t)g(t) - \beta Y Q_1$$

$$\frac{d\chi}{dt} = -p_2 \chi(t) + p_3 V(i(t) - i_b(t))$$

Descriptions of the variables and parameter values can be found in **Table 3** and **Table 4**.

Table 3. Parameters of the blood glucose simulator.

Parameters		Value
p_1	Glucose effectiveness	0.2 min⁻¹
p_2	Insulin sensitivity	0.028 min⁻¹
p_3	Insulin rate of clearance	10^{-4} min⁻¹
A_G	CHO bioavailability	0.8 min⁻¹
τ_D	Glucose absorption constant	10 min
V	Plasma volume	2730 g
$i_b(t)$	Initial basal rate	7.326 μIU/(ml.min)

Table 4. Variables of the blood glucose kinetics model.

Variable		Unit
D	Amount of CHO intake	mmol/min
D_1	Glucose in compartment 1	Mmol
D_2	Glucose in compartment 2	Mmol
$g(t)$	Plasma glucose concentration	mmol/l
$\chi(t)$	Interstitial insulin activity	min-1
$i(t)$	Plasma insulin concentration	μIU/ml

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 sage 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 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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Dilemmas in Scaling up Telemedical Services

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Abstract

There is a strong drive for implementing technology in public health care to cope with the growing number of elderly. This paper studies the challenges in scaling up telemedical services and reports from the case of a large telemedical project, with cooperation between municipalities and hospitals, in Agder, Norway. The study applies dialectics as an analytical lens to make sense of the findings and discusses these dialectics and how the challenges may be solved.

Keywords

Scaling, telemedicine, sustainability, dialectics.

1 INTRODUCTION

There is a need for delivering health services in new ways in Norway and large parts of the Western world, due to demographic changes, increased expectations in the population, and cuts in public spending. In Norway, this has materialised in a strong drive for delivering services remotely through telecare and telemedicine. Telecare is an umbrella concept comprising several technologies to promote safety and security in patients' homes [1], whereas telemedicine (TM) implies the use of information, communication, and monitoring technologies for health care providers to remotely evaluate health status, provide educational intervention, or deliver health and social care to patients in their homes [2]. Our focus in this paper is on telemedicine and telemedical services.

There is a long history of telemedicine projects in different application areas in Norway and in several other countries (Denmark, Scotland, Canada, etc.). The project 'United4Health' (U4H) was one of the larger projects, running from 2013–2015 and involving 33 partners across Europe, including the Agder region and Tromsø in Norway [3-5]. From May 2014 to April 2016, a total of 94 patients with COPD were recruited and followed up by nurses employed at two telemedicine centrals (TMC) in Agder over a limited period of 30 days [4]. The purpose of U4H was to scale up the use of telemedicine. However, U4H showed some challenges in going from a pilot project to full operations [5] and in establishing telemedical services as part of the municipal health and care services. The recruitment of patients was one of the main challenges, despite the systematic work of the hospital in the project. Therefore, at the end of the project period, the service was terminated. However, a new project called TELMA started up in 2017, establishing TMCs in three municipalities (A, B, and C) to serve the 30 municipalities in the region. The goal of this project was to design a full service for chronic patients (COPD, diabetes, heart failure, and mental health issues), which

would be integrated into the existing service portfolios. This project has been run as a pilot in Agder but should be ready for full implementation as an ordinary service once the project period is completed.

Despite the strong drive and large investments in telemedicine, sustainability and scaling up has been difficult. Previous research shows that scaling up telemedicine projects often has been difficult [6-7], and this remains a challenge [8]. We therefore need to understand the challenges scaling involves and find measures to cope with these. This is the focus of our study. Hence, the research question is: What are the challenges in scaling up telemedical services?

2 METHOD

2.1 Design

To gain a deeper understanding of the challenges in scaling up telemedical services, a qualitative case study approach was used. According to Yin, 'A case study is an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context may not be clearly evident' [8]. A case study is limited in terms of generalisability; hence, our results cannot be generalised but give an indication of the possible general challenges faced. Managers and employees at the TMCs were included to develop a rich dataset. Individual interviews and observation studies were conducted to facilitate a holistic understanding of the phenomenon and to enhance data credibility.

2.2 Research context

The main goal of TELMA is to establish a common telemedicine solution for the remote follow-up of patients with chronic disorders and comorbidity in the Agder region, which can provide good health services with less use of health care resources.

In TELMA, telemedicine (distance follow-up) is defined as the use of technological solutions that allow patients to be followed up by the health and care services in their own homes. Patients perform their own measurements and answer simple questions about their health using a tablet. The results are transferred to the TMC (response or follow-up service), which then contacts the patient around signs of deterioration or if the measurements are outside the normal values. The TMC provides medical professional support and guidance based on the patient's needs and assesses if there is a need for contact with a GP or emergency services. The TMCs are open on weekdays during the daytime and are staffed with one nurse each. Patients are assigned to the service by the health administration in their home municipality and are given equipment and training by the staff at the TMC.

The TMC provides services to patients with chronic diseases such as COPD, heart failure, diabetes mellitus type 2, and mental illness. The follow-up consists of either a telephone or a video call. Some messages and questions and answers are also conveyed through text messages. Patients with mental illnesses answer an online questionnaire. Based on the patients' responses, the nurse at the TMC provides contact with a municipal follow-up service, which in turn contacts the patients.

The nurses have access to the electronic health records (EHRs) for the patients from the municipalities where the TMCs are located. All information exchanges with other municipalities, GPs, and the hospital are transferred via electronic messages. During the intervention period, various models for follow-up have been tested, including different frequencies of contact and duration of the follow-up period, but also different types of interactions. To monitor and assess the patients' clinical data, a computerised decision support system (CDSS) is used.

The goal of TELMA is to recruit a total of 200 patients during the project period 2017–2019. In total, as of August 2019, approximately 150 patients have been followed up during the project period, of which 94 were followed up simultaneously at the three centrals as of August 2019. The majority of patients have COPD, as this group of patients was included in the first phase of the project (based on experience from U4H). During the past year, patients with diabetes mellitus type 2 and heart failure have also been included, as well as some patients with mental health problems.

In many ways, this project has been successful in that new patient pathways have been developed, interviews show that the patients are satisfied with the quality of care, and algorithms for comorbidity and machine learning for decision support have been developed. However, scaling up has been challenging, and our focus is on its particular challenges.

2.3 Participants and data collection

This study is based on interviews with various stakeholders throughout the project period, and it involved employees from municipalities, the hospital, GP offices, and TMCs. Patients were also interviewed, but these interviews are not included in this study. In addition, data were collected through observations of work practices and attendance in meetings from 2017 to August 2019. Table 1 below shows an overview of the participants in the interviews.

Semi-structured interviews were conducted during 2017 and 2018. The questions focused on general experiences, beyond the research questions. The interviews were audio-recorded and transcribed before deleting the recording.

In addition to the interviews, we conducted four observations in June–October 2019, one at the TMC in municipality A, two at the TMC in municipality B, and one at the TMC in municipality C. The first observation at the TMC in municipality B was done with a nurse following up patients with COPD and diabetes, whereas the second was done with a social worker specialised in mental health, who followed up patients with mental illnesses. The third observation was done in municipality C, also with a nurse following up patients with COPD and diabetes.

During the observations, we took field notes and asked questions. We also took formal minutes from most of the project meetings that were held every second week over Skype, and informal notes from some meetings. Table 1 shows the work roles of our informants.

N	TCM	Admin	Hospital	GP office
1		A		
2		A		
3		A		
4	A			
5		B		
6		B		
7	B			
8	B			
9	B			
10			X	
11				X

Table 1 Overview of participants in interviews. A denotes employee in municipality A; B denotes employee in municipality B, X employees from other institutions.

2.4 Data analysis

Data were analysed using a thematic analysis [10], with a focus on scaling and on the dilemmas encountered in the pilot project period related to implementation of a full service. Two of the authors collaborated on the analyses to ensure validity. The theory of dialectics guided the analytical process, which followed the six phases of thematic analysis: familiarisation with the data, generating initial codes, searching for themes, reviewing themes, naming themes, and, finally, building the construct [10].

In this process, we applied dialectics as our analytical lens. Dialectics has been applied previously in research to understand the dilemmas involved in the public procurement of information systems [11] and the resistance towards implementation of information systems [12, 13] and change processes in general [14]. The term 'dialectics' originated in ancient Greece, referring to a discourse between two or more people holding opposite

views, and dialectical thinking can be explained as a way of thinking that considers the contradictions between irreconcilable goals, or thesis and antithesis. The result of pondering these opposites could be that either one of the two goals (the thesis or the antithesis) dominates and wins out, or that elements from the two are combined in a synthesis.

Applying dialectical analysis has the advantage of raising awareness of the inherent challenges or dilemmas between incompatible goals and the need to choose either one or the other, or to find a synthesis. There is also the possibility of choosing differently over time [11].

2.5 Ethical considerations

This study was approved by the Norwegian Centre for Research Data (NSD, project number 50421). The participants were given written and verbal information about the study. They were also guaranteed confidentiality and the opportunity to withdraw at any time, and patients were ensured that withdrawal would not affect the health care services they received. Employees in the municipalities, hospitals, and TMCs were first contacted by the project manager for TELMA.

3 FINDINGS

The study shows that several dilemmas arise when integrating telemedicine services into the regular service portfolio. Some of the dilemmas are related to the actual transition from a pilot project to ordinary operations, while others are of a more general nature and are related to the kind of service to be offered.

The study shows that in the transition between a project's pilot phase and ordinary operations, a dilemma may occur related to developing an effective pilot project and preparing for large-scale operations. In our case, this dilemma became evident within three areas.

3.1 Development of routines versus anchoring

One of the goals in this project was to prepare for implementation a full telemedical service later. Hence, the development of routines for the municipal health care services was a focus.

A consequence of this focus was neglecting the need for the anchoring and enrolment of stakeholders from the start. The involvement of people outside the project team who were needed for scaling up was neglected until quite late. Poor anchoring among key partners in the first phase of the project made it difficult to recruit enough users to take it into operation, as the following comments show:

'I am somewhat doubtful about how much the hospital knows about this service ... so there are many nurses in hospitals who do not know our services ...' (informant no. 5)

'The inhabitants of municipality ... do not know that there is such a service.' (informant no. 5)

'I think you have to go to the GPs again, and I don't think patients will come from the hospital, so I think you have to go to them [the GPs] a bit more, too, because they are the ones who recruit.' (informant no. 6)

Another consequence was that considerable time was spent developing templates and routines instead of

scaling, for example, by ordering equipment, establishing all the TMCs, and hiring and training staff.

During one of the observations, we understood from the answers to our questions that the employee at the TMS had 'spent a lot of time developing new routines and forms' (social worker at TMC B). In a similar manner, the vendor of the measurement equipment spent considerable time developing routines handling logistics, routines that are helpful if the number of users increases, but this does not in themselves increase the number of users.

However, the project group decided to shift focus, and, in March 2019, a nurse responsible for recruiting was appointed (from the meetings minutes in the project group and steering group). Hence, in this project, there was a transition from focusing on one goal only (or on the thesis) to also including a goal which was somehow conflicting (an antithesis).

3.2 Results orientation for the pilot period versus developing a full service

Another dilemma in this project concerned the goal of achieving good outcomes during the pilot period to convince decision-makers, as opposed to developing a service that could be implemented directly after the project period.

As a consequence, there was disagreement on the choice of target groups and whether the service should primarily be provided to patients who were already recipients of health services (COPD patients), so that TM could replace other services and save money, or offered as a preventive service to diabetes patients who had not previously received health care. By choosing to provide TM as a preventive service in the pilot phase, financial savings were hard to identify during the project period. However, previous research [15] shows that individual counselling programs can reduce risk factors significantly for diabetes patients. The following citations illustrate this dilemma:

'Now we provide an extra service to most, so this is ... more expensive for the municipality.' (informant no 6)

'If it turns out that this has had a good effect five years from now, …., then we may receive fewer admissions and fewer medical consultations.' (informant no 6)

'For those who get preventive care [from TMC], it is years before they would have received our services [from the municipality]. [Disease] development needs to slow down a lot ... for this preventive care to be profitable.' (informant no 6)

The project group in TELMA chose both goals at the same time. This resulted in spending a lot of resources on developing routines for diabetes patients, and since the patient pathway was developed fairly late in the project, there was little time for recruiting patients; hence, only a few were recruited.

The project further shows that establishing new telemedical services, with the required quality and routines, is resource intensive; therefore, it is hard to achieve benefits during the project period.

Another consequence of this dilemma was disagreement about the frequency and duration of the follow-up of patients. In the first part of the project period, an evaluation of patients' progress and needs was conducted

after three months, and the service was planned to last for a maximum of six months. However, there was a disagreement concerning the resources needed to promote lifestyle changes for some of the patients, as well as the need to watch the resource use. One nurse was concerned that long-term follow-up was required to achieve lifestyle changes. The same concern applies to patients with mental disorders. For many patients, it may therefore be problematic to offer the service for only a short period.

The discussion related to this dilemma also concerned the amount of service, the frequency of measurements, and the duration of follow-up conversations. For example, when scaling up the service, it may be necessary to reduce the amount of follow-up each patient receives. A relevant question was how much the service could be downscaled without reducing the quality significantly:

'.. it is a luxury edition [of the service] they receive; if we could cut down the follow-up, it would still be good enough.' (informant no 6).

In the TELMA project, choices made were to increase the duration of the service each patient received to more than three months and to include diabetes patients. These two choices were in line with the goal of developing a full service but in conflict with the goal of results orientation. At the same time, the project group reduced the frequency and duration of each interaction, in line with a goal of results orientation. Hence, a synthesis was reached.

3.3 Introducing new services vs. further development of well-proven existing services

As part of the TELMA project, a new service was established. However, the telemedical service was not the only possible service for the patient groups, as there were other well-proven existing services. In all three municipalities, the GPs were still responsible for the follow-up of their patients. In addition, several COPD patients with severe symptoms (grade 3 or 4) received visits from the home care services independent of the telemedical service.

In municipality B, there was a 'Frisklivssentral' offering advice, guidance, and various activities for persons with chronic diseases. A possible choice could have been to develop these services further. Hence, in some cases, the development of the telemedical service competed with existing services, and this was a recurring topic of discussion, especially among GPs, as the following comment indicates.

'And the thing about telemedicine is that some GPs are sceptical, because they want some of them [the patients] themselves.' (informant no 6)

As a consequence, there was opposition to the project, which was energy-intensive for the organisation. In this context, it was discussed whether TM would be competing with the existing services and become an unnecessary and expensive service for the municipalities. There were a number of discussions on this issue. This made anchoring and scaling more difficult, especially as the GPs have access to the patients and are important for recruiting.

In the TELMA project, the choice was from the start to introduce a new service, hence; to choose an 'antithesis' (a new service). However, for mental illness patients, the service was planned to be integrated with the existing services, so the project could be said to be moving towards a synthesis.

4 DISCUSSION

A possible consequence of dilemmas involving two opposing goals is that neither goal is chosen and therefore neither is met. How can this challenge be solved?

One way to deal with this is to select one of the goals, either the thesis or the antithesis; however, this requires awareness of the contradiction between the two goals, and, anchoring a decision in both a project group and among important or salient stakeholders [16]. One other way is to develop a synthesis, or a reconciliation, of the conflicting goals over time (i.e. one goal is chosen for part of the project and the opposing goal for other parts).

The first finding, the dilemma between the development of new routines and anchoring is a difficult one, even more so because scalability may depend on routinisation. Without clear and efficient routines, it is hard to scale up the usage. However, if the focus is solely on development of new routines, then scaling is hampered. This became evident in the project, as there were only 40 patients by the start of January 2019. When this was observed, the project switched to the goal of anchoring and enrolment of stakeholders; however, this was late in the project.

A consequence was that the project did not meet the goals of recruiting 200 patients and enough patients with diabetes, heart failure, and especially mental illness. Due to this there will be too little experience with these groups to achieve the learning from treating patients over time, as well as valid results regarding the outcomes of the service. Another implication is that operations has not been tested at full capacity, and the project owners therefore do not know how many they can operate simultaneously.

If the project group had switched to the goal of the anchoring and enrolment of stakeholders earlier, more patients would likely have been recruited. Would this have harmed the development? If the focus had shifted back to development again later in the project, then the end service could have been of the same quality. Enrolment of stakeholders could have benefitted the development, as input from different stakeholders (GPs, patient groups) could have been useful.

The second dialectic concerned results orientation for the pilot period versus developing a full service. The project partly tried to meet both goals by including patients that most likely would not show any effect during the project period, and, at the same time, by tailoring the resource usage in terms of the length of intervention and the duration and frequency of interaction with each patient.

As a consequence, the benefits of the project may be hard to identify, making a decision towards full implementation difficult. At the same time, the service may not be ready for full implementation.

The third dialectic concerned whether to develop a new service in competition with existing services, or to further develop services that are well-proven.

Faulkner [17] shows the difficulty in doing this, as '"measuring" success is a crucial element of the policy

shift towards health technology assessment and so has a potent "politics" of its own.' Moreover, the study shows how different sets of players operationalised diverse sets of reflexive practices that contested the authority of the other(s) in the project.

In all three municipalities, the focus was on the development of a new service, and, as a consequence, the GPs were sceptical and felt this as a competition, which made it more difficult to recruit more patients and scale up. However, in municipality B, the plan was to run the service for the mental illness patients as an add-on to an existing service, hence as a further development.

5 CONCLUSION

In this study, we identified three challenges related to the scaling up of telemedical services: the dialectics of 'development of routines versus anchoring', 'results orientation for the pilot period versus developing a full service', and 'introducing new services vs. further development of well-proven existing services'. There are definitely more challenges than these; however, through applying dialectics as an analytical lens, we see that these are dilemmas that require careful consideration, and that selecting one of the goals without adhering to the conflicting goal can limit scaling.

The development of efficient routines is needed for scaling; however, as there is a danger of neglecting anchoring in this process, both goals need to be focused on (synthesis). Furthermore, the discussion shows that it may be possible to shift the focus over time from one goal to the other. We found that a synthesis was applied for the second dialectic, the patients received the service for a longer duration, while, at the same time, the frequency of interactions and length of each interaction were reduced.

However, our findings have certain limitations. The dialectics may be context-specific and therefore need to be validated both through structured interviews with the project participants and through following the process of scaling up the service once the project phase is terminated. Other telemedical projects should also be studied with the same analytical lens to see if the results are generalisable and if the dialectics are generic. Our findings do not show whether shifting goals over time, as in dialectic 1, or synthesis, as in dialectic 2, lead to better outcomes. Further research should therefore try to answer this question. However, these findings on dialectics and the way TELMA attempted to solve them carry important implications for practice.

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Innovation Readiness in Healthcare Information Infrastructures

Key Resources to Enable Collaborative Digital Innovation

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Abstract

This paper describes key requirements for digital innovation readiness in the public healthcare sector. Collaborative innovation models, where internal and external innovators contribute their ideas and solutions put certain requirements to the organization and ICT infrastructure of health organizations. To explore these requirements, we conducted an empirical case study of a collaborative digital innovation project from its concept stage towards implementation. Our study identifies key technical and organizational resources needed to facilitate innovation, and it therefore has implications for what resources and capabilities need to become part of the healthcare information infrastructure to enable collaborative digital innovation.

Keywords

Innovation, collaborative innovation, digital, healthcare, information infrastructures, innovation readiness.

1 INTRODUCTION

During the last decade, a dynamic innovation ecosystem has emerged outside of the public healthcare sector. Entrepreneurs develop digital healthcare that utilizes e.g. wearables, self-monitoring and tele-health. Ideally, hospitals should relate to and benefit from this thriving innovative environment. Nevertheless, the transformative potential of innovation with digital technologies is difficult to realize in hospital settings [1] [2] [3] [4] [5]. Hospitals traditionally have siloed information systems catering for different functional areas with an immense number of localized and cross-cutting dependencies [6] [7].

Despite challenges in managing their existing digital infrastructures, hospitals need to foster innovation to meet the triple aim of improving health, enhancing care experience, and reducing per capita costs of healthcare [8]. This could happen by leveraging the dynamics of so-called open or collaborative innovation [9] [10]. Collaborative innovation is motivated by the assumption that active participation of a wide range of actors will increase the quantity and quality of innovations [11]. However, this entails accommodating third-party contributors in existing infrastructures. This may require changes to current ICT architectures, processes and governance arrangements. In this paper we seek to articulate the various aspects of opening up hospitals' ICT infrastructures to innovation, through examining the research question: "what does it take to foster collaborative innovation in established health information infrastructure?".

We draw on insights from the information infrastructure stream within information systems research. Digital infrastructures, and particularly digital platforms, are pivotal for collaborative innovation as they allow opening-up to third parties [12]. In the next sections we present related research, our empirical study, our key findings and their implications.

2 RELATED RESEARCH

2.1 Enabling Innovation in Digital Infrastructures

Complex, interconnected networks of systems have been called "system-of-systems" [13], "ultra-large scale systems" [14] or "coalitions of systems" [15] in order to emphasize their specific characteristics and challenges. We call them "information infrastructures" and draw on research that have studied the evolution trajectories of interconnected, distributed collections of systems comprised of both local systems and shared components.

The notion of infrastructure emphasize that these systems are shared, providing support to multiple different activities. They need to cater for a wide range of potential users and uses, both currently and in the future [16]. Moreover, they are open and evolving over time, as the pre-existing solutions, routines, and structures – the "installed base" – continuously evolve [17]. The solutions therefore have to be adaptive to the developments of practice [18]. At the same time, they have to be stable enough to reliably support activities that make use of them [19]. Balancing the need for flexibility and stability is a central dilemma for information infrastructures.

Aiming for innovation in existing large-scale infrastructures such as the ones that are in place in hospitals, entails conceptualising new technologies not as standalone objects, but as elements in larger infrastructural arrangements [20]. Working with infrastructures within healthcare is especially challenging because novelty has to link to historically built landscapes that are the outcome of intensive digitalization efforts undertaken during the last decades [21]. Furthermore, taking an infrastructural

perspective means paying attention to durability, permanence and to the investigation of strategies for effectively managing future evolution. The concept of the "long now" help us understand the forward looking concerns of infrastructural development, realizing that today's planning will effect tomorrow's sustainability and evolvability of infrastructures [22] [23]. This requires what Steinhardt and Jackson labelled "anticipation work" [24]. Anticipation of the future is not only about accommodating contingencies, it is also about providing the means for advancement, resources for "encouraging mutations, branching away from the status quo" [25]. Such an anticipatory or forward-looking orientation are thus crucial for ensuring innovation readiness of the information infrastructure.

## 2.2 Sources of Innovation in Healthcare

Hospitals are complex and risk averse environments that have traditionally struggled to innovate in networked information exchange and communications [26] [27] [28] [29]. Bygstad studied four cases in the health sector and found that: "the solutions of the future are not only hard to plan but also hard to envision, and emerge through interactions of diverse actors. That is why a third-party ecology is more innovative than a heavyweight IT department" [30]. Bygstad´s study articulated a distinction between "heavyweight" and "lightweight" information technology (idem). He suggested the use of the qualifier "lightweight" for mobile apps, sensors and simple solutions and the use of the qualifier "heavyweight" for large systems, and sophisticated solutions with advanced integration. Bygstad proposed that IT departments should focus on heavyweight technologies, letting external actors innovate with lightweight technologies.

King and Lakhani [31] (as cited by [32]) argued that open innovation is to be found when the knowledge needed to create or to select appropriate solutions to a problem is broadly held, while when such knowledge is concentrated internally we find intrafirm innovation to dominate. In a similar vein, Salge et al. argue that internal actors (from the clinical side or from the IT department side) may be well placed to identify problems related to clinical practice, to work out suitable solutions using digital technologies and to bring them in use, while external actors may be better placed to identify problems related to patient experience having the flexibility to experiment with different solutions. Overall, both third-party and internal initiatives are needed for hospital digital innovation [33].

2.3 Technological Innovation Potential

Current digital technologies allow modularization and decoupling, which can facilitate multiple contributors to expand established digital infrastructures. Specifically, the widespread use of web service protocols and APIs increase the level of decoupling, creating new opportunities to put together the initiatives of different parties [34]. The potentialities of technology allow conceptualising innovative solutions, moving quickly to proof of concept and small-scale piloting. Nevertheless, the transition to fully fledged implementations in hospital settings has proven to be very difficult. We aim to contribute to a better understanding of what such transition processes entail and require.

Currently the dominant model to map innovation processes includes a number of "maturity levels" or stages in a scale (technology readiness levels - TRL). This scale was introduced by NASA in the 1970s, but was modified since then (and extended from 7 to 9 levels) becoming a *de facto* standard for technology assessment in many industries [35]. It is widely used for innovation policy and governance. It is for instance central in EU's research program Horizon2020. Figure 1 presents the 9 different maturity levels.
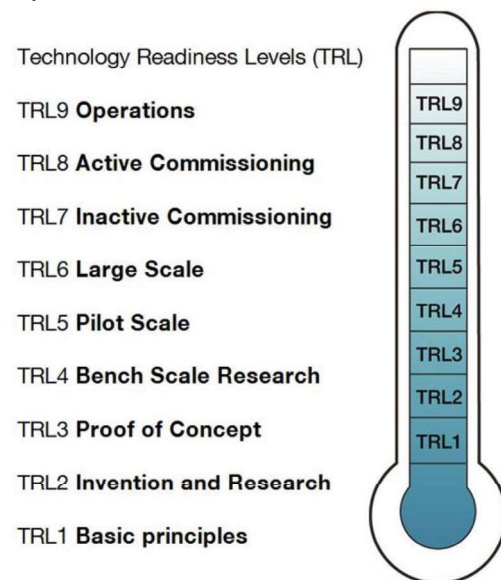
Figure 1. Technology Readiness Levels. Source: https://www.gov.uk/government/news/guidance-on-technology-readiness-levels

We will use this scale to give a temporal structure to the analysis of innovative collaborative projects.

3 METHOD AND CASE BACKGROUND

3.1 Case background

We conducted a case study [36] of the trajectory of a digital innovation initiative where a start-up company and a Norwegian hospital collaborated. The hospital offers multidisciplinary rehabilitation to patients following illness or injury and has a strong emphasis on research and innovation. The hospital is part of a regional health trust, where IT services are offered by a regional IT provider that we will here call HospitalPartner. The innovation initiative was initiated by a third party; an ICT company that was established by healthcare practitioners with the vision of facilitating and streamlining information flows in hospitals. Specifically, the initiative is about developing and introducing point-of-care information access tools enabling clinicians to read and register patient data on the move. These tools can improve efficiency of documentation work and support work optimization. The two main founders of the company conducted a proof of concept trial in 2015. The subsequent development of a prototype in the form of a mobile phone app was supported from different innovation support programs. In November 2016, the company contacted the rehabilitation hospital to present the concept and investigate the possibility of testing the prototype in the hospital. In December 2016 an initial test took place and hospital employees gave feedback towards adjusting the app to fit rehabilitation needs. During a

workflow simulation exercise, clinical workers performed different tasks measuring the time needed for task completion with and without the use of the new tool. This yielded evidence used to calculate the potential for time savings, and the hospital decided to work towards the deployment of the tool. This took more than two years (2017-2019) and revealed issues with the innovation readiness of the existing information infrastructure. In the Findings chapter we describe this phase in more detail.

3.2 Data collection and analysis

We gathered qualitative data through interviews, document analysis, as well as observations during meetings and presentations. We interviewed staff in the hospital's IT department (5 interviews) and staff in the ICT company (4 interviews), seeking to document key events along the process trajectory. We especially focused on the challenges of moving from conceptualisation, to proof of concept and then towards implementation in actual operations. In addition, we analysed status reports, project documents and presentations. Information on the existing ICT infrastructure was also gathered in a 4-year project between 2014-2018, where the hospital and HospitalPartner were partners (RFFHF no. 239050). Data collection was performed during the 2014-2019 period. The data analysis was performed from an infrastructure perspective informed by the literature on innovation (see section 2). Our concern has been to let empirical detail guide the development of insights. Thus, we started from the trajectories of the initiative studied and sought to understand how the initiative aimed to move from concept to prototype to pilot (i.e., from lower to higher readiness levels on the TRL scale), the challenges met along this trajectory and the infrastructural resources needed along this trajectory. Our analysis led to the identification of specific types of technical and organizational resources and capabilities that are required for innovation readiness, especially as regards facilitating the work of digital entrepreneurs.

4 FINDINGS

4.1 The innovation trajectory

The company's initial prototype was developed based on the start-up company initiators' work experience in the health sector and a series of observations at emergency wards in several hospitals. When the collaboration with the rehabilitation hospital started, the app was adjusted to better fit with the specific hospital's needs. During prototype testing, the mobile network was used instead of the hospital's network. Moreover, the app worked with mock data and without connection to any other IT system. When the hospital decided to work towards the deployment of the app, integration with the existing information infrastructure was needed. Specifically, it was important to exchange patient data between the Electronic Patient Record (EPR) system and the new app. A description of the EPR's API was provided by the EPR vendor on request, and the start-up company was able to develop an interface.

In January 2017, the company and the hospital sent the first formal request to HospitalPartner, concerning a test server for running the further development and testing within the region's ICT environment and with real data. This required first that HospitalPartner prepared a Solution Design

document and a Risk and Vulnerability Analysis, which were not generated until after the summer of 2017. The delays had several reasons. The major concern of HospitalPartner was to ensure secure operations for the existing infrastructure, and there was not sufficient capacity, nor adequate procedures in place to serve requests from this kind of innovation projects. In addition, large-scale infrastructure modernization programs and several critical incidents took up significant resources in the organization. While a test server was eventually granted (ready in October 2017), access to test data was more challenging. For internal testing, HospitalPartner would use copies of real data. This was legal since HospitalPartner is the formal data processing entity for the hospitals. However, such data could not legally be made available to an external actor such as the start-up company that had no formal role as vendor to the regional information infrastructure. The hospital made a decision to purchase the app and then enrol the company as a data processing partner in legal terms. Beyond getting access to test data to verify the integration, the app also had to be integrated with the regional solution for identification and access management (IAM), and the recently implemented enterprise mobile management solution (EMM) had to be used. Separate orders were sent for each of these, but the project again experienced long delays in getting responses. The orders were handled by several different sections within HospitalPartner (more than 10 groups and sections were involved). In the beginning of 2018, HospitalPartner revised its internal organization and processes and appointed a coordinator to oversee the various order processes. It was also decided that the hospital and not the company should be communicating with HospitalPartner, e.g. around the change requests emerging from testing. During the summer of 2018 testing could commence. Due to the legal status of test data as the hospital's data, the tests had to be conducted on-site in the hospital rather than on the company's premises, and with clinical staff present. This phase saw the need for a closer collaboration also with the EPR vendor. This brought a fourth actor into the collaboration and lack of timely and correct information delayed the project further. Traditionally, change requests to applications running in HospitalPartner's production environment were handled by the Change Management Board which met every three months. This governance model did not fit with the agile way the company's solution was developed, with frequent (often daily) changes. In the later testing stages, involving additional users also revealed new requirements, but due to concerns related to the formal process, several desired functionalities were postponed. Close to the final go-live, a critical problem with the interfacing of the EPR solution was discovered. A new change request was sent to HospitalPartner, who at that time had a two-months' change freeze period. However, half a year later (summer 2019), the solution was finally in small scale pilot use.

4.2 Infrastructural resources required

The trajectory shows a stretched-out process which has been frustrating for all participants. However, it also reveals what third-party innovation using mobile devices require from the existing information infrastructure. The trajectory shows how moving from "proof of concept"

towards operations requires an increasing scope of infrastructural resources. Some of these were related to technology: Information about current systems in use, access to a test setup including a system installation and test data, access to run on the internal infrastructure of the hospital, integration with the Identity and Access Management solution of the hospital, and information about updates happening to the infrastructure, which may have implications for the prototype. In addition, organizational arrangements to facilitate coordination among the actors were needed, as well as new governance arrangements matched to the agility and uncertainty of innovation projects.

As the solution transitioned from being just a concept to becoming a prototype and moving towards a pilot in actual use, new sets of such infrastructure resources were required. In Table 1 we mapped the resources against the readiness levels.

TRL	Use cases	Access to APIs of standard systems	Test Data (synthetic, masked or actual data)	Servers for test & development	Security services	Process mngt. Incl. formal agreements	Agile change mngt	Identity & Access Mngt.	Risk and Vulnerability analysis tools
1									
2-3	x								
4-6		x	x						
7-9		x	x	x	x	X	x	x	x

Table 1 Infrastructural resources mapped to the Technology Readiness Levels.

We see that most of the requirements for resources emerged in the later phases of the project. These requirements were related to the porting of a stand-alone prototype into a pre-existing information infrastructure. In our case study, the required resources were not in place as the innovation moved from stage to stage. The project (along with other innovation initiatives) stimulated the development of (some of) the required resources in HospitalPartner, who developed a proposal for building capacity, expertise and technology. The proposal suggests establishing a single point of contact and a standardized process for innovators, additionally to a set of technical resources.

The proposal sketches a development environment with servers, tools, databases, storage, and data access. Secure access to data from the central information systems (EPR/PAS, medical chart system, personnel system, and demographic information) is seen as crucial, however, for some projects, access to fictional or synthetic patient data is sufficient, while others need to interact with real data (e.g. if they seek to build up or verify data analysis capabilities). It is emphasized that the test platform (with real patient data) must have a sufficient security level. Also, a technical verification regime is needed to ensure that the third-party solutions adhere to the established procedures and that adverse security and performance aspects would not emerge when the solutions are scaled.

In sum, the proposal (which is not yet operational) aims to introduce a timely, flexible and needs-oriented procedure for handling collaborative innovation projects while adhering to information security and privacy demands.

5 DISCUSSION

5.1 Need for test facilities beyond 'sandbox'

The Technology Readiness Levels model stipulates that an innovation needs to move through stages where it is further developed and concretized. Testing is the core activity that yields the required insight for this development. Also for digital innovation in the healthcare sector there is widespread agreement that a test facility is required. Often such test facilities are setup as so-called "sandboxes", i.e. as test environments that are self-contained and isolated from the production environment. While such an environment may be helpful for early-stage testing, our case shows that this is not sufficient for moving further. In the process of connecting to the actual production environment several new issues need to be addressed. For instance, access to existing patient data requires integration with other information systems. Also, access-handling is important – not only on routine use but during the development phase of a collaborative innovation project. The ongoing interaction with users is crucial, and this requires an ongoing experimentation with the new technology in a real-life or realistic setting. Thus, the test and development facilities need to be connected to the actual information infrastructure.

Collaborative innovation requires flexibility and ability to handle gaps in planning, since innovation exhibits more uncertainty than operations, and frequently unfolds through exploratory small volume solutions. Procedures are needed for granting and revoking access to the test environment. Furthermore, support is needed for handling agreements and contracts, and for ensuring adherence to public sector procurement regulations General API management processes, such as e.g. key distribution, activation and revocation, are also required. Even more importantly, the distribution of costs and benefits associated with development, publication and usage of APIs must be addressed, both among vendors offering APIs and innovators using them.

Not all digital health innovations are the same. Our case concerns an application intended for daily clinical work with patients requiring a tight integration with the existing information infrastructure. While this was not the first mobile device based project in the region, it was the first where patient data were accessed via mobile phones and thus required the highest security level. Still, we will argue that most of the needs that emerged were not specific to this particular application. Any digital innovation to be used in a hospital context will at some point require resources such as use cases validated in work settings, test data (either synthetic, masked production data, or actual production data), APIs to interface with existing applications, secure communication networks and encryption, identity access management (IAM). Furthermore, collaborative innovation requires a project setup that ensures adequate communication and coordination between the project and infrastructure provider and appropriate governance mechanisms.

5.2 The Infrastructure's Innovation Readiness

An information infrastructure perspective helps us to take the existing infrastructure into account when thinking of innovation. It indicates a perspective shift: from a concern with the innovation initiative as a standalone project that needs specific types of support, to a concern with how the pre-existing information infrastructure can accommodate novel additions [20]. The findings from this case correlate with earlier studies that emphasize how information infrastructures grow by extending the installed base [17]. However, this study goes beyond the majority of previous studies on the evolution of the installed base, by focusing on the shortcomings of the installed base that hinder its ability to evolve. The case revealed that the ability of the existing information infrastructure to accommodate extensions resulting from the collaborative innovation project was limited. Establishing test facilities of the sandbox variety is only a partial solution towards acceleration of innovation. Beyond that, a core concern of the regional healthcare trust should be to consider the "innovation readiness" of its information infrastructure. In order to accommodate innovation and to "future-proof" the critical information infrastructure there is a need to have in place the resources required, including capacity, expertise and technology. Innovations, both from internal and external sources require a deliberate facilitation that is not achieved without explicit and strategic action.

6 CONCLUSION

We expect that more innovative solutions will find their way into healthcare, such as mobile solutions, data analytics, sensor-based innovations and also, patient-oriented solutions. More attention to the infrastructure's innovation readiness will therefore be necessary. Facilitating the ongoing experimental utilization of these possible solutions, while not exposing the infrastructure to unnecessary risks, requires attention to the offerings of the existing infrastructure in terms of both technical and organizational capabilities and services. Increasing the innovation readiness of the public sector, including its ICT infrastructures will be crucial in order to meet future challenges.

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8 ACKNOWLEDGEMENT

Immersion and Perspective Taking in Healthcare Technology

Supporting Healthcare Professionals with Daily Tasks and Clinical Procedures

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Abstract

A core of the education of medicine and nursing students is to understand, learn and train the use of clinical procedures. Health professionals are required to apply existing clinical procedures and acquire new ones as they are developed and incorporated into clinical practice. In order to improve clinical effectiveness and increase patient safety, these clinical procedures would ideally be easily accessible and provide a didactic explanation of the steps to be followed. In this way, digital clinical procedure libraries provide health professionals and students a useful tool for learning and practice. In this context, the International Bilateral Research and Innovation Cooperation (INT-BILAT) project on evidence-based interactive clinical systems aims at studying the usability and learnability of clinical procedures libraries in a health transnational context. This paper presents early stages of the research including the results of a survey among health professionals about using electronic clinical procedure libraries or guidelines at work. The research argues that electronic procedure libraries are a steppingstone of experiential learning in healthcare education and practice, where clinical procedures are learned through experience, reflection and conceptualisation. The analysis of the survey's answers and interviews showed the need for an enhanced digital clinical library with interactive features, drawing from immersive techniques and perspective taking (e.g., video guidelines, self-paced video instructions). The next steps of the research include a game design framework outline using immersion techniques for learners and practitioners.

Keywords

Clinical library, clinical procedure, immersion, perspective taking, gamification, usability, human-centred design, eHealth.

1 INTRODUCTION

Healthcare technology systems that aim at improving safety and quality of care and clinical workflows are increasing in number and complexity [1]. Among the different types of healthcare technologies, electronic clinical procedure libraries (eCPL) are meant to support healthcare professionals during their training, daily routines and continuous professional education. An important component of eCPLs is the clinical procedure. A clinical procedure is defined as "any practice of a health practitioner that involves a combination of special skills or abilities and may require drugs, devices, or both" [2]. In an eCPL, the explanation of a clinical procedure's objective and steps, content and visualisation, are key to healthcare professionals (e.g., eCPL users) being able to understand and successfully perform it.

Existing research (in German and Norwegian) about current versions of eCPLs [3] [4], showed that pictures and short animations were used to demonstrate specific steps of several procedures. The authors of this paper previously researched stakeholders' needs for digital technology support (research question (RQ) 1), looking into how to adapt the presentation of clinical procedures and improve outcomes (RQ2); both in a health learning context [5]. Stakeholders' needs (RQ1) varied depending on several factors, such as skill level, role as a health professional and context in which a procedure guideline was used. The optimal visualisation (RQ2) depended on evidence-based guidelines as a source for content but also on visualisation

options such as video, picture and re-creation of procedure-steps in visual and/or auditory ways to support the understanding and accuracy of procedures.

The aim of this paper is to follow-up the study of the usability and learnability of clinical procedures libraries in a health transnational context. The authors created a survey based on the preliminary investigation of stakeholders' needs and background knowledge, educational and professional requirements and gamification potential. We describe the results from such survey and the gamification analysis, focused on learning and professional use in the context of eCPLs.

2 METHOD AND RESULTS

The survey was designed based on literature review and preliminary interviews with healthcare professionals with ethical approval under review by the Norwegian Centre for Research Data (reference number 111924).

2.1 Survey Results

The survey's questions addressed the early stages of a human-centred design process [6], including the analysis of users' needs and inclusion of end-users into the design process. The selection of the methods was guided by their feasibility in the context of the project to comply with the user-centred design, usability and technology adoption in healthcare settings. Nineteen participants from 6 different countries (Germany, Norway, Denmark, Switzerland, United Kingdom, Iceland), answered the questionnaire with 19 questions (Table 1), with a gender distribution of

15 female and 4 male participants. Participants' education background ranged from master and PhD students to professor, including retired health professionals.

Table 1 Survey questions.

#	Question text
1	How old are you?
2	What is your nationality?
3	What is your gender?
4	What is your educational background?
5	What is your profession?
6	How many years of work experience do you have as a health professional?
7	In which country do you currently work?
8	What technologies do you use in the hospital on a daily basis?
9	Any additional comment regarding the technologies you use at the workplace?
10	Where do you look things up to follow the steps on a clinical protocol/procedure/instrumentation or medical device?
11	How often do you encounter procedures that you may not know by heart (e.g. that you have to look up the steps on how to proceed)?
12	How do you keep yourself up to date with new or updated clinical procedures, medicine, etc?
13	Please could you mention a complicated procedure that you had to look up recently to be able to conduct it?
14	Do you have a digital library/ a computer system to look up how to do certain procedures? E.g. what materials are needed and what to do in which order?
15	How did you learn (and remember) clinical and medical procedures?
16	Have you heard about evidence-based procedure libraries?
17	What support would you like to have to help you in your daily work related to clinical procedures?
18	Can you imagine using a mobile device (e.g., smart phone, tablet) dynamic situations (accident, outdoors injury, ...)?
19	Additional information about your needs, ideas, and wishes in case you want to say anything else

Q11 asked about frequency of use of clinical procedure guidelines and/or protocols. The majority answered that they had to look up information related to clinical procedures. Participants answered that they had to look up procedures "weekly" (47.3%), "monthly or twice a month" (36.8%) and "less than monthly", "varying" or "did not answer" (15.9% the sum of the three categories). Most of the participants had heard about evidence-based procedures (63.2%), however less than half of them do not use them at work ("know about them, but do not use them": 15.8%; "do

not use them": 52.6%). Q8 asked about types of technology used daily at work. Most participants selected "electronic health records (EHR), calculators, clinical procedure libraries". However, some participants stated that they did not use anything (at least not regularly), neither digital nor paper-based information collections such as books, folders and personal notes. Q17 asked about the ideal support in their daily work related to clinical procedures. More than half of the participants (52.6%) stated that updated and easy-to-access information would serve as a good support. One participant argued "up-to-date videos could instruct how to perform a procedure". Q15 asked about learning and remembering clinical procedures. Participants underlined the importance of revisiting the procedures learned, mentioning repetition as one of the key methods to remember them: "I learned by reading or seeing the procedure, and by performing it repeatedly myself".

2.2 Gamification Analysis

The authors found several issues during the research on the usability and game-design elements in the context of electronic procedure guidelines. A context analysis and a scope review of the literature were carried out focused on the usability and learnability of the eCPL. They resulted in the first steps of a gamification framework based on game-design elements to increase engagement, motivation and help solve existing issues from a different perspective. The analysed game-element categories (Fig. 1.) include aspects of the framework, such as immersion, support for interactivity and progress [7]. Immersion can enhance retention and knowledge transfer from simulated environments [8] [9] to the real-world using elements such as animations, pictures and procedure descriptions. Immersion is a complex concept with different levels, or degrees, of involvement. Those degrees can be categorised ranging from lowest to highest level of immersion as: engagement, engrossment, and total immersion [10]. The goal is then to search for any improvement of degree of immersion that can potentially lead to improved healthcare quality, learning and information retention in healthcare. For a meaningful research outcome, the level of immersion and quality improvement will be evaluated at a later stage.
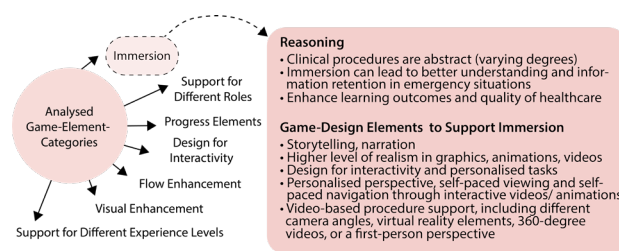
Figure 1 Framework of analysed game-element categories with further details for the category "immersion" [7].

2.3 Immersion in Game Design

Immersion in games can be created by high interactivity [11], storytelling, realistic graphics, and identification with (main/own) character. These elements can be perceived differently and with varying intensity by the users. It can be differentiated between (1) sensory (visual and/or auditive

aspects) immersion; (2) personalisation, narration (or plot) and story-based immersion; and (3) interactive-based (e.g. tasks) to improve immersion possibilities [10]. In games, these aspects do not usually exist without the others but can be used to different extents. However, a player's immersion derives from more than only the visual presentation, it is also influenced by a complex playing experience [12].

(1) Sensory (visual and auditive) immersion:

This type of immersion is described by [13] as sensory immersion, which is related to the audio-visual design and experience of games. Elements to enhance the sensory immersion are "audio-visually impressive design", and "three-dimensional and stereophonic worlds" [13]. Aspects of this type of immersion can also be related to the realism of the "game world" or to the atmospheric sounds [10]. Realism is not always necessary to create immersion but can be a contributing factor. These aspects can further be enhanced through blocking of sensory information from the real-world using headphones, headgear or other overpowering types of technology.

(2) Story, narration or plot-based immersion:

Narration-based immersion, or "imaginative immersion" can be seen as separate immersive qualities from sensory qualities [13] [14]. Story or narration can be designed separately from their sensory aspects, but often complement each other.

(3) Interaction-based immersion:

Interaction-based immersion is described in [14] as related to ludic pleasure ("challenge-based immersion") [14], since the flow state [15] can only be achieved through the "active collision of challenge and skill". This includes active participation (interaction with the game) and decision making [14]. Games usually offer various types of interaction; they can include interaction with objects, non-player-characters (NPCs) or other players. They may also require decision making in different situations such as: direction taking, to follow or not follow a given task/quest, path, tactic, role, alignment of the character or group, goal orientation and difficulty level. Games also often offer different interaction possibilities and decision making in the designed interface or other meta-level parts of the game that are not directly part of the story, such as: skills, secondary skill, or a profession. Player-NPC or player-player interactions can include interaction-feedback mechanisms such as reputation or friendship-level.

2.4 Immersion through Video and Perspective taking in a Health Context

Perspective taking consists of viewing a situation or becoming aware of something from a specific alternate point-of-view. Thus, a given situation may be recorded and presented from a first- or third-person perspective, differing in the perception, attitude or experience of each of the perspectives [16]. There is evidence that health perspective is useful in certain health contexts, such as reduction of racial disparities in pain management [17]. In this research, perspective-taking aims at providing successful retrieval of critical information for the clinical decision making in the future. For it, it is necessary to visualise the perspective of one's own self and learning cues that will be useful in the procedure [18]. First-person perspective of video recorded clinical procedures was used to analyse clinician's activity in an experiment somewhere else [19]. Clinicians retrospectively observed the steps followed in a radiological clinical procedure and investigated the information necessary to accomplish the task. Radiologists wore high-definition recording spectacles for a first-person experience evaluation.

All procedures were audio-visually recorded from a third- and first-person perspective, the latter using high-definition recording spectacles. Oral descriptions by clinicians while simultaneously visualising their own audio-visual recordings of the operations in first-person (i.e. HD spectacles camera) and third-person perspectives (i.e. front, rear and bore) were used to provide a concise description of the task at hand visualised in the recordings. The material collected through the experiment sessions were considered by the radiologists as a primary source of learning tools for radiology students. The video explanations would allow a new student to firstly observe the behaviour of an expert in a first-person perspective and secondly, learn why, how and when the actions should be performed during an intervention. In addition, observers could learn from the visualisation of errors, potentially increasing the error prevention rate.
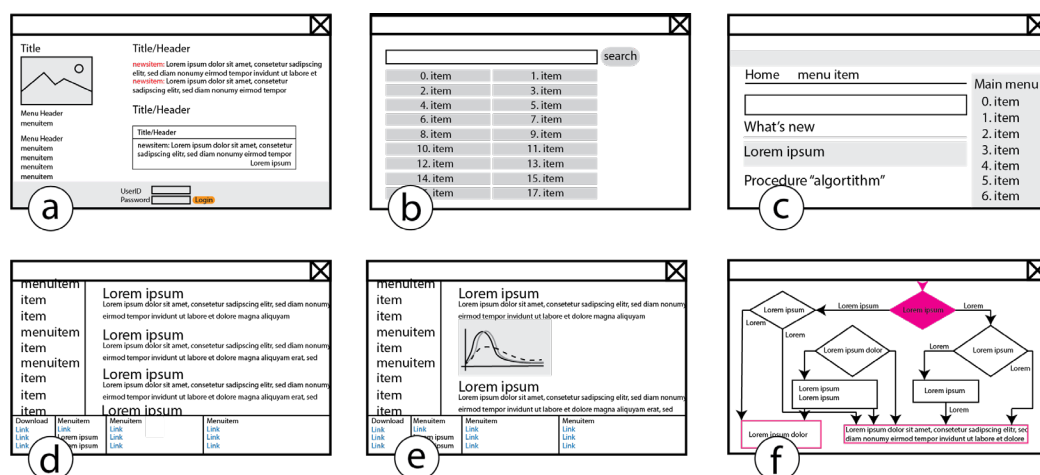

Figure 2 Wireframes representing the OU system.

2.5 Implications for eCPL

Following the summary of immersion and perspective taking aspects in games from previous sections, we revisit them by discussing how they can be integrated into eCPLs.

Sensory Elements to Improve Immersion

Improvements of visualisations may inform redesign for healthcare systems [20]. Appropriate visualisations can increase the quality of patient-centred care, support safe care, decision making, continuous learning and minimize information loss [20]. Pictures and other graphics in existing eCPLs are noticeably abstract, presented in various forms such as textual description or still pictures and schematic animations. Procedure guidelines often focus on textual descriptions with occasional graphics, still pictures, tables (medicine related) and graphs. An example of the latter is the procedure guideline system used at the Osaka University Hospital that shows graphs for medications (Figure 2. f). Another eCPL example is a system called VAR, currently deployed in several European countries (e.g. Norway, Denmark, Germany), which uses basic visualisations. The visual structures analysed are summarised in Figure 3. One finding of the analysis of the VAR system is that the text descriptions are separated from their visual representations (see Figure 3. d). In other cases, procedure steps are directly linked to a picture or a short animation where the next step features the next picture. Based on game visuals that draw on a direct connection between a story and its visual representation, the latter is a preferred option that could be populated across the entire eCPL. Another element is an increased level of perceived reality in pictures, animations or videos. Abstract and real presentations both have their advantages; being able to choose between visualisations can support the information transfer from the eCPL to the real environment. For the level of perceived reality, video and perspective taking can play a relevant role. That means, including different camera angles, virtual reality elements, 360-degree videos, and a first-person perspective can improve video-based procedure learning.

Story and Narrative Elements to Improve Immersion

A story or narrative can be represented by adding the context to clinical procedures or their steps. Procedures do not feature frequently made errors, nor how to prevent or spot them. Neither do they feature related, easily confoundable symptoms present in more than one clinical procedure. Learning from common errors and, more importantly, knowing how to prevent them are key information that could be incorporated into an eCPL. This could be done by health professionals themselves who perform and record a specific clinical procedure offering their first-person perspective and their own narration of why to select that specific clinical procedure and how to avoid common mistakes. Another way, not mutually exclusive with the previous one, could be a specifically designed immersive experience as described in [13] [14]. The difference to the previously described narration-based immersion is that this one transports a user/player into the world through identification with characters and other story elements. This type of immersion can be built through (real or fictive) patient stories connected to procedures and their outcomes, providing a new space for patient education [21] and involvement [22]. Another game-design element that is strongly connected to imaginative immersion is the element of interactivity, to feel and be part of the story and to be in charge of the character's experience.

Interactive Elements to Improve Immersion and self-paced interaction

Perspective and interaction can enable healthcare professionals with an option of switching between first- or third person perspective in a self-paced manner, adding control and immersion. Animated elements, interactive video elements, and instructional videos showing procedure details on request would contribute to self-evaluation and self-paced learning.

3 SUMMARY AND CONCLUSION

Existing eCPLs provide a useful tool for health professionals and scholars. However, a recent survey among 19 health professionals from 6 different countries showed that there is a potential to enhance the visualisation, user experience and human-computer interaction of eCPLs. This paper presents the results of the survey and describes two game design elements relevant for such enhancement:
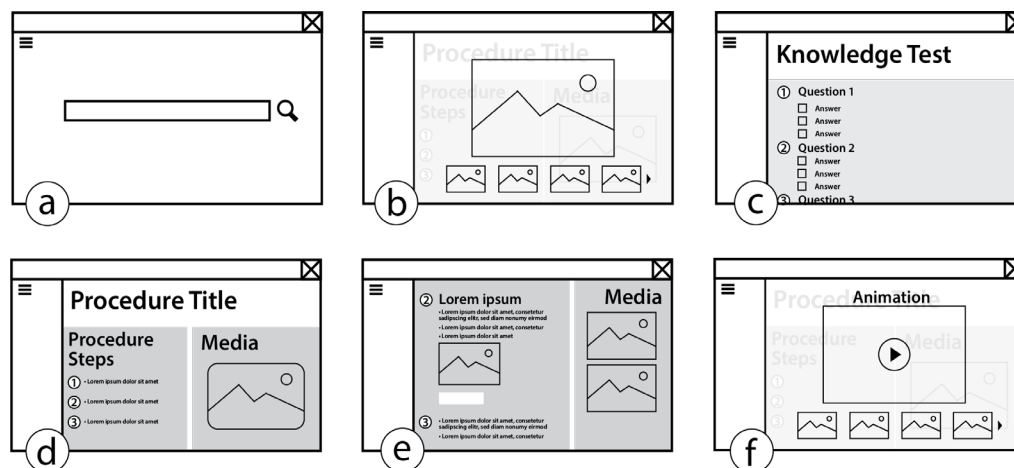
Figure 3 A wireframe summarising visual structures in the VAR eCPL.

immersion and perspective taking. The immersion has previously been successfully used in a learning context. Enhanced visualisations, improved narration and increased interactions can improve immersion. However, they are closely interconnected and therefore require an informed selection, so that an effective level of immersion (i.e. for enhanced learning and in-situ collection of information) can be achieved. Perspective taking has been used in early research for learning of clinical procedures and for common error prevention. Alternating between first- and third person perspective in videos can provide sense of control, and, more importantly, a tool for learning procedures from a different and own perspective, helping to prevent common errors. Follow-up interviews with the respondents will provide a deeper understanding of the results presented here. This research is the second step of a research project that aims to improve the learnability and usability of eCPLs in an international and professional health context. Future research includes evaluation of the elements described in this paper inside an existing eCPL.

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5 ACKNOWLEDGEMENT

The Dynamics of a Global Health Information Systems Research and Implementation Project

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Abstract

The Health Information Systems Programme (HISP) is a sustainable and scalable research project enabling and supporting health information systems implementation in more than 100 developing countries. In this paper, we present the historical roots, the status, and discuss the future of HISP and its software (DHIS2). We also reflect on factors contributing to the project's global success and find the open and participatory approaches to HISP and DHIS2 software development, and implementation in countries as key. For the future, we discuss strategies to stabilise as well as grow the HISP and DHIS2 community into a sustainable ecosystem.

Keywords

HISP, DHIS2, health information systems implementation, participatory action research, open-source software.

1 INTRODUCTION

Health information systems (HIS) are designed to manage different kinds of healthcare-related data and are one of the foundational building blocks of every health system [1]. These information systems (IS) enable data generation, collection, analysis, communication and use for decision-making at individual, facility, population, and public health surveillance levels [2]. While individual-level data serve as the basis for clinical decisions, facility aggregates and administrative data enable community-level resources planning and service delivery. The health service data, when combined with non-routine data such as household surveys, support population-level decision-making, and data from all sources combined enhance a country's ability to monitor, detect and respond appropriately to public health emergencies.

In many developing countries, appropriate and well-functioning HISs are either not available or fail to scale or be sustained [3]. Problems of institutional disparities, lack of proper technological solutions and constraints on resources in the public health sector are typical factors contributing to failure. In this context, we present the Health Information Systems Programme (HISP) and the District Health Information System (DHIS) software as a global success story in terms of being a sustainable and scalable project providing and supporting the implementation of HIS in developing countries. As a large-scale longitudinal international action research programme coordinated from the University of Oslo (UiO), HISP has engaged in the development and implementation of the DHIS software for more than two decades. The DHIS2 (second generation DHIS since 2005) is a generic open-source software system with data warehousing functionalities and customizable modules for integrated health data management[4]. Ministries of Health and Non-Governmental Organizations (NGO) in more than 100 developing countries are using DHIS2, covering an estimated 2.28 billion people (www.dhis2.org/inaction).

In this paper, we explain the historical roots, the status, as well as discuss what we see as the future of HISP and DHIS2. As participants in HISP at the University of Oslo, we provide an insider view of the organisation, its software and software innovation approaches, the research and education component, capacity building strategies, sources of funding, and the broader global community dynamics.

This paper is a retrospective study on activities the authors have participated in. As action researchers, we have carried out HIS strengthening activities through HISP totalling over 30 years. Data collection methods used for this particular paper include analysis of published HISP research and related IS literature, project documentation, semi-structured interviews, and own notes and memos based on our direct involvement in DHIS2 implementation projects. We aim in this paper to contribute by providing a detailed description of HISP and DHIS2. In addition to this, we offer relevant reflections on the factors contributing to the scalability and sustainability of this project. Accordingly, we have organised the paper as follows. First, we trace the early stages of HISP and DHIS2 and describe the key events and enablers in the establishment phase. Next, we describe the status and evolution of the project over the years, related to the organisation and the software. We provide an outlook on what we see as the future for the project and then discuss the community dynamics and what we see as accounting for the successes achieved so far. We conclude with our reflections on the future.

2 THE EARLY STAGES

2.1 The Organization and the Software

As part of the political processes of change in post-apartheid South Africa in 1994, strategic management teams were set-up to develop plans for the reconstruction of the health sector in different provinces [5]. With the government's priority to establish an integrated and decentralised health system, a district-based health system supported by a district health management information system was identified as a key element [6]. In 1995, the

HIS subcommittee for the Western Cape Province which included HISP founding members proposed to develop a district-based health information system. HISP started through this initiative and based on action research in two 'coloured' townships created during apartheid [7].

HISP was set up as a collaborative project involving the University of Cape Town, the University of Western Cape and a Norwegian PhD candidate from the University of Oslo (UiO). The initial aim was to contribute to addressing the information management challenges of the then highly centralized and extremely fragmented health system in South Africa. The strategy adopted to achieve this aim was through tools and data standardisation, development of essential datasets and a software application to support its implementation. This strategy led to the development of the first District Health Information Software (DHIS) prototype based on Visual Basic and Microsoft Access. The development team was located at the University of Western Cape (UWC) and consisted of two core software developers and a group of HISP members acting as mediators between users and the developers[8]. After testing and piloting in three districts in the Cape Town area, they scaled the system to the entire Western Cape Province by 1998 [7]. By 2001, the Department of Health in South Africa adopted DHIS, and associated HISP standardisation strategies. They further implemented it as the national standard in all districts of the country.

From the start, the project invested significant resources in building expertise in HIS in the countries where DHIS was implemented. In South Africa, formal DHIS training courses were made part of UWC's master in public health. The training received from UWC was cascaded down to the provinces by the trainees, and through this, nearly 2000 health workers were trained [7]. With success in South Africa, HISP pursued similar initiatives in other countries, including India and Mozambique. As the project expanded, challenges emerged with the two-person software development team and software architecture not suited for distributed development. Even if open source, DHIS used the Microsoft Access database and thus required full MS Windows and MS Office stack. The standalone installation of DHIS at each health facility, requiring a large maintenance team travelling around to keep all installations functional, virus-free and up-to-date was also challenging. To address these challenges and at the same time try to bridge software development and user context gaps, parallel development of a DHIS version 2 (DHIS2) started at the University of Oslo in 2005 [9]. Developed as open-source software and with client-server architecture, DHIS2 supports distributed software development, broad user participation and centralised maintenance.

2.2 Research, Capacity Building and Growth

Founded on research and development HISP was a synergetic collaboration between public health activists in the post-apartheid South Africa, and information system developers coming from the Scandinavian tradition of participatory design and action research (AR) [10]. Participatory design emphasises user participation [11] and AR has its basis in cyclical interventions in the research settings to accomplish change while reflecting and learning from the change processes [12]. In Mozambique, with funding from the Norwegian Council of Universities' Committee for Development Research and Education, HISP, the Universidade Eduardo Mondlane (UEM) and the Ministry of Health partnered up to pilot DHIS in 3 districts in 1999 [7]. A group of PhD candidates from Mozambique enrolled at UiO was the driving force in this implementation. They led user engagements in system customisation, training and translation to Portuguese. This university-based model [13] of HISP and DHIS capacity building was later replicated in India, Tanzania, Ethiopia, Malawi, Sri Lanka, and Bangladesh, and has resulted in more than 500 Master and 55 PhDs from HISP countries graduated and more are at various stages of completion.

Another institution for training is DHIS2 Academies established in 2011. Based on periodic regional gatherings and training of DHIS2 users, the Academies offer practical sessions on topics ranging from system development, implementation, maintenance, and system use. More than 4800 participants have attended the 87 Academies arranged so far. Since 2017, an online Academy is also offering free and self-paced courses on the fundamentals of DHIS2. Additionally, DHIS2 experts and community members from around the world, including implementers, developers, ministry representatives, technical partners, and donors meet in Oslo every year to share experiences on DHIS2 implementations at the DHIS2 Annual Conference (formally Experts Academy) since 2012.

In 2006 DHIS2 was first implemented in the state of Kerala in India after which it rapidly became the preferred option to the earlier DHIS [14]. The rapid global spread of mobile Internet at the time was a key factor in this. For example, in 2010, the Ministry of Health in Kenya decided to implement an online DHIS2 server [15]. Due to uncertainties regarding internet coverage and doubts regarding whether its 200 districts could use an online system, the decision was to go for a hybrid approach with one central online server for online offices supplemented by standalone installations where the Internet was not available. An offline data entry feature based on HTML5 was also developed to deal with cases of fluctuating internet connectivity. Such a centralised approach introduces common failure points and related risks to system availability. However, the advantages of improved data access and reporting timeliness inspired countries like Ghana, Uganda, and Rwanda to follow suit with their online national deployment of DHIS2[16].

2.3 Funding Sources

In the beginning, the funding of HISP came from the Norwegian agency for development cooperation (Norad), the University of Oslo, the Norwegian research council, the Norwegian university council, donors and the governments in the countries where DHIS was implemented. Early HISP activities in South Africa and Malawi, for example, received funding and support from EQUITY/USAID and Dutch AID [7]. The financing of the activities at UiO came through research programmes, PhD- and Master-scholarships, support for establishing Master programmes in developing countries, salaries of Faculty members and direct implementation support.

Master students and PhD-candidates developed the DHIS2 software and piloted it at the beginning. Over time, the funding from Norad evolved into core funding for professional system developers [14].

Other agencies including PEPFAR, the Global Fund, UNICEF, GAVI, CDC, USAID, WHO, and Bill and Melinda Gates Foundation have also funded HISP and DHIS2 activities through various arrangements [17] [18] [19]. For example, since 2015, PEPFAR is funding the development of DHIS2 software features to support particular requirements they have related to their use of DHIS2 as their internal reporting system. When implemented, these features are also available to all other DHIS2 users. Another organisation using DHIS2 for reporting in their program countries is Médecins Sans Frontières (MSF). With their focus on using mobile devices for reporting, MSF is providing particular funding for the DHIS2 mobile solution. Another source of funding is regional organisations such as EMRO (East Mediterranean Regional Office, WHO), supporting regional implementations of DHIS2.

3 THE PRESENT STATUS

3.1 The Current HISP and DHIS2 Community

HISP is today a global network constituted of Independent HISP groups (like HISP South Africa, HISP India and HISP Uganda), Universities (like University of Dar es Salaam and Universidade Eduardo Mondlane), Ministries of Health, NGOs, global policy-makers, global donors, researchers, students, social entrepreneurs, individual consultants, and more. Together, they play different, but complementary roles, and form an organically growing ecosystem around the DHIS2 software with new roles developing and shifting between the different actors.

HISP UiO, which coordinates the development of DHIS2, is now also a professionalised software development organisation. Other core actors in this global ecosystem around DHIS2 implementations are the HISP groups with established and sustainable local expertise in developing countries (Bangladesh, India, Malawi, Mozambique, Nigeria, Rwanda, South Africa, Sri Lanka, Tanzania, Uganda, Vietnam, West and Central Africa region, and Colombia). They support the implementation of DHIS2 in their countries and regions based on their domain knowledge, technical and implementation expertise and experience. Their efforts include training of users at different levels, system implementation, maintenance, integration with other systems and software development of extensions and apps. They also contribute by arranging regional DHIS2 academies and share knowledge with other entities through, e.g. the DHIS2 annual conference.

3.2 The Research Component

HISP is a large-scale and international action research project with actors including Universities, Ministries of Health, NGOs, global donors, researchers, students and many others [20]. The focus of HISP is knowledge development and the impact and sustainability of its AR interventions [7]. These are mainly pursued within the public health IS space of developing countries and with diverse AR goals [21] including organisational development, system design, scientific knowledge, and training [20]. Practical research activities involve experimenting with new technologies, adapting the DHIS2 software to new use-cases in local contexts, improving the platform capacities of DHIS2 (including interfaces and ease of integration), capacity building approaches, institutionalising the use of the system and evaluations of its impacts. The foundation of HISP research is the spread of these best practices for enhancing the long-term sustainability of outcomes [7].

The growth of the community has allowed diversification and specialisation in research, implementation, capacity building and software development. Designated software developers, product managers and project coordinators at UiO, for example, are not necessarily directly involved in academic research. Still, implementation and software innovation projects typically include different roles.

3.3 DHIS2 Software

The DHIS2 software has evolved from a tool for collection, storage, validation, analysis, and presentation of aggregate health data to also support patient management and individual records. It is a platform that Ministries of Health rely on for monitoring and evaluating the health services and health status of the population. Capacity strengthening and platform development fuel the participatory action research core of this project. It enables local innovations necessary to ensure relevant systems for the users today, and flexible enough to meet the new and changing requirements of tomorrow, such as emerging patient-based use cases (e.g. [22]) and others in agriculture, education, e-government and logistics management (see www.dhis2.org/user-stories).

DHIS2 is a Java-based web application and runs on multiple platforms including Windows, Linux, Mac OS X and Solaris. It's rich RESTful Web APIs, enable Java Scripting, CSS and HTML5 apps and by using the W3C standard compatible with all major web browsers. DHIS2 runs on PostgreSQL, MySQL and H2 database systems and with minor development efforts, DHIS2 can run on any mainstream relational database. Using the BSD license makes DHIS2 free and open-source with its code available to be used modified and redistributed freely. It interoperates with other relevant applications such as OpenLMIS, iHRIS, OpenMRS [23] and the World Health Organization (WHO) tools in the public health domain [24]. DHIS2 interfaces with third party web portals and technologies, including SMS, E-mail, and Geographical Information Systems (GIS) to enhance its functionality. The software user interface and meta-data are internationalised and currently available in English, French, Spanish, Portuguese, Hindi, Vietnamese, Chinese and Norwegian. DHIS2 mobile supports offline operations in areas with a poor and fluctuating Internet connection, based on HTML5, SMS and Browser and Java-based clients. DHIS2 Android apps support offline data capture, including a Dashboard app for data visualization.

3.4 Community Support and Coordination

Since the inception of DHIS2, UiO has played a core role in coordinating the community and the capacity building around the software and its implementations. The core DHIS2 software development expertise and activities are located at UiO with some of the software development

efforts delegated to experts in the HISP groups. The platform architecture [25] of DHIS2 is supporting this distribution. The professional software team consists of more than 30 developers located at UiO and in Vietnam, Spain, the US and the Netherlands. It is organized into frontend and backend teams headed a lead developer with the management and coordination of these teams located at UiO while the developers are distributed. Another essential element of HISP is providing implementation support to strengthen local capacity. Global, regional and UiO implementation support are available and work with the different groups on activities including capacity building, defining requirements, managing the community (Discourse) platform (www.community.dhis2.org), organising academies, creating training material, training in academies, and more.

An online community platform supports the interaction between the UiO team, ministries of health, donors, HISP-groups, implementers, third-party developers, and so on. The platform includes mailing lists, source code repositories, a forum, and an issue tracker. The Discourse platform, now acting as both a forum platform and mailing list, is the primary tool used to communicate publicly within the community. Another core tool mainly used by the software team to document, track and manage issues (bugs, new requirements and features, use cases, etc.) is Jira (www. jira.dhis2.org). Beyond the software team, any user on Jira can view, create and participate in discussions regarding features, requirements and bug reports. Users can also follow the progress of issues solving, and see an overview of planned future changes to the software. Software developers are also using a source code repository based on GitHub. The repository stores the source code of projects, providing version control of the software code and making the project openly available.

3.5 The Current Funding Landscape

Today's funding of HISP comes from international and national organisations related to the development of the DHIS2 software and country support in terms of implementation and capacity building. The funding landscape has changed over the years. For example, Norad, the Global Fund and PEPFAR entered into a joint agreement to coordinate funding and leverage investments in 2012 [17]. Through this agreement, Norad continues to support UiO's core funding needs, including the management team, software development, and in-country implementation support. The Global Fund support for core resources are applied to in-country services only. PEPFAR supports their targeted reporting needs in their DHIS2 implementation (i.e. DATIM) being used in more than 50 countries and this funding also feeds into the generic core of DHIS2 features available for all. UiO is also supporting the project by supporting the contribution from faculty members. UNICEF and the World Health Organization (WHO) are also supporting the core resources at UiO as well as particular initiatives[24].

4 THE FUTURE OUTLOOK

4.1 Stability and Growth of the DHIS2 Platform

The sustenance of DHIS2, its growing number of new and more mature implementations, the human capacity

supporting it and the wider HISP community will require further investments. One of the strategies pursued by UiO to prepare for the future is the positioning of DHIS2 as a digital global public good in which each community member can contribute in its growth and evolution [18] [26] [27]. Some inherent tensions with this approach relate to the funding of public goods. As public goods allow unrestricted use, sustainability will depend on 'voluntary' and continuous support from core funders. The tension here is a need to balance between serving those who can pay for functionality and those who cannot. Another tension is between developing globally relevant and generic software and serving the particular needs of a specific user. Another tension relates to the adoption of DHIS2 in domains other than health, such as education and e-government. While the primary goal of HISP is to support the health system, there is a need to strike a balance between focus and stability on the one hand and innovation on the other to maintain an acceptable quality of the core platform [19].

Improving DHIS2 stability and performance presupposes a generic and reasonably open core platform to enable increased community participation [28]. A purer platform approach, strictly separating generic core services, boundary objects such as Web APIs, and apps will be necessary to allow stability and diversity in a demanding community. [29]. Towards this, further *control devolution* [30] may be required to delegate even more platform and app development activities away from UiO to others in the community. This will enable app development by developers closer to the users and thus better suited to drive locally relevant innovation. Open and standardised interfaces must also be continuously updated to allow for interoperability with third-party systems where necessary.

Additionally, system performance at implementation and use need to be improved. These will require well-defined system deployment specifications and guides for proper configuration and use of DHIS2 features. The emerging individual events and patient-level use cases, and the traditional aggregate data management functionalities need to be continuously improved. Considering that internet connectivity is a challenge in many DHIS2 country implementations, more attention is required to strengthen offline usage of core functionalities for data entry, tracker, reporting and analytics.

4.2 Research, Learning and Long-term Capacity

With maturing DHIS2 software platform and implementations, new research topics also emerge. For example, there is an increasing need to go beyond how to create functioning systems. Key research themes in this respect relate to assuring high-quality data collection and a better understanding of how to improve and strengthen information use and better decisions based on HIS. A side effect of the global success of the project is that DHIS2 is becoming increasingly generic. Together with the increasing number of users, the distance between the users and the developers is increasing. We need to revisit the participatory design and action research approaches that spurred the initial success of HISP in this novel context. Further, there is a continuous need to evaluate the success and impact of DHIS2 implementations, especially for ministries of health in DHIS2 implementation countries

who are the primary user base. A DHIS2 developer at UiO, for example, observes, "… donor interest in DHIS2 is largely driven by its acceptance and adoption by countries' ministries of health". The strategy must, therefore, include a relevant DHIS2, tailored and country-specific guidance, and capacity building programs. Further development and institutionalisation of country support teams are required. Where HISP nodes and University partnerships exist, these too must be leveraged to support in-country capacity development.

5 DISCUSSION

HISP and DHIS2 have sustained over two decades based on the vision to build the capacity necessary for developing countries to govern their HISs in a sustainable way and by so doing strengthen their health services. A key factor contributing to sustainability is the adaptability and the resilience of HISP and DHIS2. The project has always been *open*, at least for those accepting the principles of openness and outputs in global public goods, for innovations and prototyping in new directions, and for new community members to join, support, influence, change and contribute to the further development.

Where some projects fail (or stagnate for years before starting again) and some financing sources dry out, HISP pursues new projects in new places or with other use-cases and explores new sources of financing. This *flexible and pragmatic* approach shows as a successful approach in the context of development where there is a need for a long-term commitment, while funding typically comes in bursts as parts of time-bound projects. The funding of HISP activities at UiO thus has a long history of balancing incremental donor needs and incremental requirements with product development, market development activities, and academic goals.

Aside from funding, political empowerment of local stakeholders in health and practical learning through hands-on participation, i.e. participatory design approaches [31] are key to the success of HISP. In South Africa, these principles resonated with the government's policy of health systems decentralisation. In countries with more rigid centralisation of health systems organising, top-down engagements for political buy-in are complemented with bottom-up strategies for system learning [31]. Learning through hands-on participation also helps to develop local capacity and contributed to project acceptance at the early stages. During the expansion phase of HISP when the traditional participatory design approach based on the experience in South Africa became impracticable, new approaches were explored. For example, the *networks of action* approach [7], [20] was used to provide the needed implementation support across multiple pilot projects in different countries. When proved successful, this approach was further expanded in a distributed participatory approach along with the introduction of the fully open-source and web-based DHIS2 software [9] [31].

The HISP community has shown the ability to adapt DHIS2 to changing user needs, technologies and available infrastructure. The earlier and at the time standalone, offline and non-web based version is now entirely replaced with a centralised, integrated, and online version

(i.e. DHIS2). Design flexibility, extensibility, and modularity enable its customisation to fit various use-case requirements. While these factors and others are driving the adoption and growth of DHIS2 across continents, some challenges still need to be addressed. An immediate example is platform governance, which involves incentivising participation and at the same time balancing control within an ecosystem of independent app developers and the core development team at UiO [27].

In terms of research and education, HISP is pursuing new research themes towards quality assurance and data use. The country implementations of DHIS2 also continue to serve as projects where researchers within HISP contribute practically to system implementation while learning and sharing knowledge obtained from the processes.

6 REFLECTIONS

Maturing over 20 years, HISP is now active in more than 100 developing countries and has scaled to achieve global success. The success lies in sustainable and scalable software and a thriving community. The community supports the development and implementation of HISs used in the management and prevention of diseases and pandemics. The factors (see Table 1) that have accounted for success include project openness and participatory approaches for relevance, appropriateness, and innovation such as going online for scale and sustainability and scoping into other use-case domains. While the changing contexts of implementations and funding uncertainties make future events in the network difficult to predict, HISP must remain committed to open participatory approaches [31] and focus on balancing stability with growth towards sustainability.

Table 1 Summary of Factors Contributing to Success.

The early stages:
Open, participatory design approaches
Funding and political support
Focusing on the health domain
Shifting to online and mobile at the right moment in time

The present status:
In-country, regional and global capacity building
Career building, research and community support
Matured APIs for interfacing with other systems
Generic and flexible system expanding into new areas
Platformisation; allowing content and app development outside UiO: WHO, NGOs, private entities

The future outlook:
A sustainable ecosystem with new business models and funding schemes
Balanced focus on stability and growth
Global public good positioning for broad participation
Perhaps some tough choices about focusing on the core and towards 'control devolution'

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Evaluating Welfare Technology Implementation in Municipal Care Services

Contextual Adaptation of the Measurement Instrument for Determinants of Innovation

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Abstract

The Measurement Instrument for Determinants of Innovations (MIDI) was developed to identify facilitators and barriers during implementation processes in healthcare. Thereby the implementation strategies can be better targeted to obtain successful implementation. MIDI is theory- and evidence based, and provides a generic description of 29 determinants with suggested questions that need to be adapted to the specific innovation and implementation context. This paper aims to describe how MIDI can be contextually adapted; using welfare technology implementation in municipal care services as context. Based on this process we suggest operationalization of specific determinants on item-level in the MIDI adapted to the welfare technology context (MIDI-WT).

Keywords

Welfare technology, implementation strategies, determinants, contextual adaptation, questionnaire survey.

1 INTRODUCTION

Recent implementation research have called for improved methods for tailoring implementation strategies and for measuring implementation outcomes in healthcare [1, 2]. *Implementation strategies* represent the 'how to' in introducing and making use of an innovation in healthcare services [3]; the actions needed to make an innovation fit the organization and services, and to enable the organization, the healthcare providers and patients to use the innovation. *Determinants* are factors that act as *facilitators* for or *barriers* to achieve the desired outcomes of the implementation strategies [4]. *Implementation outcomes* are intermediate process results that influence the later production of *service outcomes*, such as increased efficiency, safety and patient centeredness, and *patient outcomes*, as increased patient satisfaction and function [5].

There is a multitude of theories, frameworks and models in implementation science [6], of which some are suitable for research, some for pragmatic implementation and some for both. The Measurement Instrument for Determinants of Innovations (MIDI) is a theory- and evidence based questionnaire in the latter category [7]. MIDI determinants and their underpinning theories overlap with other implementation frameworks [8-11], and are founded in Rogers' Diffusion of Innovations theory [12]. Healthcare organizations can use MIDI just prior to and/or during an implementation process. MIDI was designed to identify how healthcare providers evaluate the innovation and factors related to the implementation process. The care providers' feedback reveal the facilitating or impeding effects of the determinants, allowing for adjustments of implementation strategies in order to support successful implementation, achieve expected outcomes, and sustained use of the innovation. MIDI encompasses 29 determinants (D1-D29) related to the innovation, the adopting user, the organization and the socio-political context (table 1).

The innovation category consists of seven determinants associated with the welfare technology: procedural clarity (D1), correctness (D2), completeness (D3), complexity (D4), compatibility (D5), observability (D6) and relevance for the patient/resident (D7). In MIDI-WT, this category details how the welfare technology is delivered from the vendor and how it fits with the current practice, whereas integration of the welfare technology in the care workflow is detailed in the adopting user and care organization categories.

The adopting user category captures 11 determinants associated with the care provider who is using the welfare technology: personal benefits and drawbacks (D8), outcome expectations (D9), professional obligation (D10), resident satisfaction (D11), resident cooperation (D12), social support (D13), descriptive norm (D14), subjective norm (D15), self-efficacy (D16), knowledge (D17) and awareness of content of innovation (D18).

Ten determinants associated with the care organization or underlying unit implementing the welfare technology form the third category, the organization. This category includes formal ratification by management (D19), replacement when staff leave (D20), staff capacity (D21), financial resources (D22), time available (D23), material resources and facilities (D24), coordinator (D25), unsettled organization (D26), information accessible about use of innovation (D27) and performance feedback (D28).

The socio-political context determinant (D29) in the fourth category is related to legislation and regulations of the Norwegian municipal healthcare services.

The categories and determinants correspond well with factors associated with effective implementation of digital health reported in the literature [e.g. 13, 14-16].

A 5-point Likert response scale is applied to assess most of the MIDI items, with 1 representing the lowest level of agreement and 5 representing the highest level. D14 has a 7-point Likert scale ranging from 1 representing 'not a single colleague', to 7, 'all colleagues'. D18 has a 4-point Likert scale ranging from 1, 'I am not familiar with the (technology)', to 4, 'I am thoroughly familiar with the (technology)'. A dichotomous Yes/No scale applies to D19, D25 and D26.

According to the MIDI manual, the generic instrument needs to be adapted to the specific innovation and context, based on 'use as intended by the developers' [17]. Developers and vendors are challenged by the variety in users and needs when developing welfare technology instructions and guidelines. Firstly, a specific technology can be applied to solve a range of needs. Secondly, welfare technology implementation is characterized by various factors related to the care contexts, patients, organizational culture, infrastructure, work practices, and management practices [15]. Thirdly, implementations involve technical installation and service innovation processes related to training, clinical procedures, routines, and responsibilities [18]. Previous studies that used MIDI to assess health innovation implementations [19-21] have not described the contextual adaptation processes of the determinants and their items.

This paper aims describe the contextual adaptation of the MIDI questionnaire to the implementation of welfare technology in municipal care services. The research question was: Which welfare technology related items should be included to cover the determinants in MIDI-WT?

2 METHODS

2.1 Design and study setting

During 2014-2019, we performed an iterative evaluation of our adaptations of the MIDI questionnaire to the implementation of welfare technology in residential care services in eight municipalities.

2.2 Data collection

We collected and analyzed data in order to get deep knowledge about welfare technologies, service innovation processes, implementation strategies and outcomes by reading political documents, procurement protocols, technology manuals, instructions, and clinical routines. We interviewed healthcare managers, project managers, professional development advisors, care providers, vendors, IT service managers, and –staff, individually and in groups. We observed meetings between stakeholders, participated in and facilitated implementation workshops and co-creation activities. Moreover, we observed some care providers while they responded to the MIDI questionnaire. The data collection was integrated in larger implementation research projects that explored facilitators and barriers, implementation strategies and outcomes, types of resistance, co-creation as an overall implementation strategy, and the roles of different stakeholders, and their analyses and results are detailed in previous studies [18, 22-27].

2.3 Iterative evaluation of MIDI adaptation

The iterations included: 1) a cross-cultural adaptation of MIDI to the Norwegian healthcare setting [28] in parallel to piloting the MIDI during the first year of an implementation of digital night monitoring of persons with dementia in five residential care facilities [23]. 2) a cross-sectional study that used MIDI to assess the implementation of wireless nurse call systems in five residential care facilities [27]. In both iterations, the MIDI was contextually adapted and distributed to care providers, and their responses were analyzed. We documented and discussed our reflections related to the research question during each step of the iterative evaluation, resulting in an improved adaptation process over time, as detailed below, and recommendations for MIDI-WT determinants and items.

The adaptation of the questionnaire relied on contributions from stakeholders involved in the implementation, preceded by an agreement to undertake the MIDI-based measurement of the implementation of welfare technology. Through the iterative evaluation approach, we developed the following procedure for implementations that were new to the researchers, with novel technologies and contexts:

2.3.1 Interview with healthcare top management

The first step was an interview with a municipal healthcare top manager at the care institution level or higher. The interview addressed the long-term welfare technology implementation strategy and how the top management had prepared the implementation, including procurement of technology, delegation of responsibilities and allocation of resources. The interview was done by phone or in a meeting, and lasted for about 15 minutes. We made written notes of responses, reflections and concerns.

2.3.2 Interview with care unit management team

The next step was a meeting with the management team of the unit(s) in the care organization where the implementation took place. Following a brief introduction of the MIDI and the need for adaptation, the management team was asked about the same issues as the top management representative, in order to reveal familiarity with and any concerns regarding the procurement, planning, allocation of resources and responsibilities. The team was then encouraged to describe the welfare technology and how it would be used in the unit, as well as the implementation strategies in the order that they would be effected. We specifically asked about the responsibilities of and cooperation with the IT service and the vendors. The meetings lasted for 30 to 45 minutes and we made written notes of the team members' responses, reflections and concerns. Comments directly relevant for the adaptation of items, such as the expressions used to describe the welfare technology, were written directly on a printout of the MIDI questionnaire.

2.3.3 Interview with vendors and/or IT service

The vendors and the IT service employees were presented with the same questions as the care unit management teams. Both the vendors and the IT services provided detailing and contrasting information about all parts of the welfare technologies, technological infrastructure, and safety aspects, as well as the implementation strategies and the managers' and care providers' overall technological

competence level. We interviewed vendors and IT services in meetings or by phone for 20 to 30 minutes and documented as for the management teams.

2.3.4 Co-creating the adaptation of MIDI items with a super user

Succeeding the interviews, we discussed the questionnaire in an item-by-item manner with a super user of the welfare technology, based on a drafted version of MIDI-WT. Caution was taken to ensure that relevant items were included, detailing the welfare technology, the clinical use, the implementation strategies and the stakeholders involved, and that irrelevant items were omitted. Further, to ensure that the wording of the items was unequivocal and in line with the expressions used in the care unit. The meeting lasted for 30 to 45 minutes and notes were made directly on the MIDI-WT printout.

2.3.5 Additional sources of information

The implementations relied on the joint and coordinated efforts of a number of stakeholders; hence, we observed the interactions between them. This was particularly useful when the interviews indicated disagreements or resistance. The observations included status-meetings between the vendors, IT service and the healthcare service; training sessions for care providers; and information meetings for nursing staff or patients/residents/families. We arranged to do the interviews just prior to or after these observations, which eased the access for doing interviews.

Moreover, we asked all informants for available written material, such as implementation plans, technical data sheets, checklists, and clinical procedures. We received and analyzed the written material as the MIDI-WT adaptation progressed, and it added useful information.

2.3.6 Verification of MIDI-WT

We e-mailed the proposed MIDI-WT to the care unit management for verification and discussed their feedback in meetings or by phone, in which we also coordinated the practical details of distributing the questionnaire to the care providers. Finally, the MIDI-WT questionnaire adapted to the specific welfare technology was completed.

3 RESULTS

The results sum up determinants and items relevant to the MIDI-WT, based on the information collected and validated by the procedure described in section 2.3. Table 1 details MIDI-WT determinants and items.

3.1 Recommended determinants and items in the MIDI-WT, adapted to welfare technology

3.1.1 The innovation/ welfare technology category

The seven determinants in the innovation category was successfully presented as suggested in the MIDI manual, by replacing the word 'innovation' with the name of the technology, but with no further detailing. A short description of the welfare technology and related material/equipment, written procedures, and information was included in the introduction section of the questionnaire in order to prepare the respondents. In the cross-cultural adaptation of the correctness-determinant (D2), we used the expression 'knowledge based' in Norwegian instead of 'based on factually correct knowledge'. Managers and super users questioned the

relevance of D2, and we observed that some care providers who were non-native Norwegian speaking found the expression difficult. Hence, D2 can possibly be omitted.

3.1.2 The adopting user / care provider category

The care providers were grouped as nurses (registered nurse), healthcare workers (nurse assistant) other healthcare professions (e.g. physiotherapist and learning disability nurse) and unskilled (lack of formal education), in the background section of the questionnaire, which also asked for gender, age and number of years of professional experience.

Their anticipated or experienced personal benefits (D8) included how the welfare technology made their work better, more efficient and safer; and how the welfare technology implied more benefits than drawbacks, overall. One personal drawback (D8) was included, regarding how demanding it was to learn how to use the welfare technology. The outcome expectations (D9) were based on how the care services had defined the aims of the specific welfare technology with regards to the patients/residents, modified by the information collected in the interviews. D9 was detailed with a probability and an importance item for each expected outcome, as recommended in the MIDI manual. We found outcome expectations related to enhanced safety for patients/residents, faster detection of their need for assistance, and decreased response time to calls.

We did not adapt the professional obligation determinant (D10) to all tasks related to the welfare technology, but included an overall statement: 'I feel it is my responsibility as a professional to use the (welfare technology)'.

During the implementations of welfare technology, the care providers cooperated closely with families of residents who had dementia. Hence, 'families' were added to all items related to the residents (i.e., D11, D12, D15 and D16).

We found the unit manager, the implementation project manager (if appointed), the care providers (we included nurses and healthcare workers), the super users, the IT service, the vendors, and the patients and families to influence the implementation strategies (i.e. D13 social support and D15 subjective norm, including normative beliefs and motivation to comply items). The influence by municipal politicians, municipal top management, janitor and union representatives was of less importance and could be omitted in the questionnaire.

The self-efficacy determinant (D16) was tailored with items detailing the operation and use of the welfare technology, e.g. being able to operate all the parts, charge the technology, troubleshoot if something does not work, prepare the technology for a patient/resident, and inform and instruct patients/residents/ families. We also included tasks related to the implementation process, such as participating in training and communicating with the different actors responsible for the implementation.

The knowledge determinant (D17) was detailed with items related to the current status of knowledge, background knowledge, and training. We included items regarding practical demonstrations of the welfare technology and acquisition of skills in relation to training.

Determinant	Item specification
Innovation: welfare technology	
D1 Procedural clarity	WT clearly describes all activities and their order
D2 Correctness	WT is based on factually correct knowledge
D3 Completeness	Information and materials provided by WT are complete
D4 Complexity	WT is too complex for me to use
D5 Compatibility	WT is a good match for how I am used to working
D6 Observability	The outcomes of using WT are clearly observable
D7 Relevance for resident	I think WT is relevant for the residents
Adopting user: care provider	
D8 Personal benefit	WT implies more benefits than drawbacks; makes my work performance better; more efficient; more interesting; safer
D8 Personal drawback	WT is too demanding to learn
D9A Outcome expectation	It is important that WT…. (e.g. increases safety for residents; gives faster assistance; increases safety for families)
D9B Outcome expectation	It is probable that WT …. (e.g. increases safety for residents; gives faster assistance; increases safety for families)
D10 Professional obligation	It is my responsibility as a professional to use WT
D11 Resident satisfaction	Residents/families will be satisfied when I use WT
D12 Resident cooperation	Residents/families will cooperate when I use WT
D13 Social support	To use WT, I can get support from the manager, a super user, a nurse, a healthcare worker, the IT service, the vendors
D14 Descriptive norm	The proportion of my colleagues that use WT as intended
D15A Normative beliefs	I'm expected to use WT by the manager, a super user, a nurse, a healthcare worker, the IT service, the vendors, the residents, the families
D15B Motivation to comply	I comply with opinions of the manager, a super user, a nurse, a healthcare worker, the IT service, the vendors, the residents, the families
D16 Self-efficacy	I can teach residents/families to troubleshoot if WT doesn't work; operate each part of WT; provide feed-back to the manager or super user
D17 Knowledge	I know enough to use WT; I had sufficient prior knowledge; I was offered training; I participated in training; I need more training; WT was demonstrated during training; I practice in idle time; I understand instructions by super users, managers, IT-service, vendors; I need to discuss my experiences and reflections
D18 Awareness of content	The extent to which I am familiar with WT
Organization: care unit	
D19 Formal ratification	Use of WT is integrated in plans
D20 Staff turnover	New colleagues are prepared to use WT
D21 Staff capacity	We are enough people to use WT as intended
D22 Financial resources	WT is supported by sufficient financial resources
D23 Time available	I have enough time available to use WT
D24 Material resources	I have enough equipment to use WT
D25 Coordinator	Responsible for WT implementation: Manager/super user, IT service
D26 Unsettled organization	Major changes are ongoing in parallel to WT implementation
D27 WT use information	I can easily find information about WT use
D28 Performances feedback	We get regular feedback about WT implementation
Socio-political context: Norwegian legislation	
D29 Legislation and regulations	WT activities fall within current regulations

Table 1 MIDI determinants and detailing items adapted to welfare technology implementation in municipal care services
Abbreviations: D; determinant, WT; welfare technology.

Further, items were included to specify whether the care providers understood instructions by all actors responsible for training. Finally, we included items about the need for repeated training and for discussions of experiences and ethical reflections.

The awareness of content determinant (D18) was presented with the following alternatives: 1) I'm not familiar with the (technology), 2) I'm familiar with the (technology), but have not explored it, 3) I'm familiar with the (technology) and have some experience with it, and 4) I'm well acquainted with and use the (technology).

3.1.3   The organization / care unit category

The coordinator (D25) determinant was detailed with items for the actors who had specific responsibilities in the implementation, i.e. the care unit manager, the implementation project manager (if appointed), and the IT service. We included 'I don't know' to the response scales of the formal ratification of management (D19), the replacement when staff leaves (D20), the staff capacity (D21), the financial resources (D22), the coordinator (D25) and the unsettled organization (D26) determinants. The recommendations during the interviews indicated that the care providers were not concerned with these issues and that some of the determinants could be omitted.

3.1.4   The socio-political context / Norwegian municipal healthcare service category

We included 'I don't know' to the response scale of the legislation and regulations determinant (D29), in line with recommendations during interviews.

4 DISCUSSION

By contextually adapting the MIDI to welfare technology implementation as proposed in the methods section of this paper, we have found the MIDI-WT useful for evaluating welfare technology implementation in research as well as in clinical practice. The item scores indicate whether the implementation strategies are functioning well or need adjustments [27]. Applying MIDI is an implementation strategy in itself. As suggested by Powell and colleagues, it 'Assesses various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort' [29].

As implementation strategies are applied over time, various determinants come to play in the early, mid- and late stages of welfare technology implementation [18]. Hence, the adaptation of MIDI may very well include a smaller selection of determinants, customized to the strategies or outcomes that one seeks to evaluate [17]. Likewise, for well-known implementations, the process of adapting the MIDI could possibly be less extensive than the procedure for novel technologies and contexts previously described. We would like to urge the importance of including the perspectives of multiple stakeholders, as both the language and expressions used, as well as the detailing items of the determinants tend to be perceived as more relevant and easier to comprehend by the intended respondents by this approach.

MIDI-WT aims to support *successful implementation*. However, defining success in implementation is a complex notion to make. The digital monitoring technology implementation included in this paper was regarded successful because the new service was sustained in all municipalities 1.5 years after the implementation was completed. Even if a number of service- and patient outcomes were realized [24], numerous barriers were encountered and many participants did not perceive the implementation as successful [18]. Whereas the municipalities are motivated by and frequently define service- and patient outcomes prior to the implementation of welfare technology, it will be useful to look further into implementation outcomes in future research. Proctor and colleagues [5] classified the intermediate implementation outcomes as adoption, acceptability, appropriateness, feasibility, penetration, cost, fidelity and sustainability.

4.1 Recommendations for implementation practice

MIDI-WT can be applied to evaluate implementation-, service- and expected patient outcomes, as far as they have been realized, in relation to the following implementation strategies: 1) WT adopted as part of strategic development of care unit. 2) Management plans implementation, defines roles and responsibilities, and allocates resources. 3) Disturbances from other ongoing processes in municipality/unit are avoided. 4) Implementation coordination team established: unit/project manager, super users, IT service and vendors. 5) End users (patients) selected/recruited. 6) Information meetings for care providers and for patients/residents/families prior to implementation. 7) WT tested before integrated in workflow. 8) WT implemented as complete system or stepwise, introducing more parts and functionalities over time. 9) WT manuals available to care providers. 10) Written clinical procedures related to technology use available to care providers. 11) Training sessions, supervision and support offered to care providers by unit/project manager, super users, IT service and vendors. 12) Care providers can operate WT and instruct residents/patients/families. 13) Unit manager is actively involved in implementation and can operate WT. 14) Implementation issues, technological issues and clinical/ethical implications discussed during care providers' meetings on regular basis. 15) New clinical procedures, tasks and/or responsibilities developed/adjusted and integrated in workflow. 16) Service outcomes measured for care providers and care unit, and patient outcomes measured for patients/residents and families.

5 SUMMARY

This paper presents a recommended procedure for the contextual adaptation of the MIDI questionnaire to the implementation of welfare technology, MIDI-WT, including the order of collecting information from useful sources and settings, practical issues regarding planning and documentation of the process and the final adaptation of each MIDI-WT determinant with detailing items.

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Why is it so Hard to Integrate Telemedicine as a Part of Municipal Health Care Services?

Experiences from a Norwegian Municipality

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Abstract

Telemedicine has a broad scope in Norway supported by the national authorities. As a part of the research project 3P- Patients and Professionals in Partnership, a telemedicine service was established in the municipality of Risør, Norway for patients with chronic obstructive pulmonary disease. The aim of this paper is to summarise and share the experiences from Risør. A qualitative research approach was used. The telemedicine service was an integrated part of the health services, having a close collaboration with general practitioners. Despite a detailed planning of the operation, administrative and economic challenges made the service closed after two years and replaced by services from an inter-municipal telemedicine centre.

Keywords

Telemedicine, remote monitoring, chronic obstructive pulmonary disease, collaboration, team work.

1 INTRODUCTION

Innovation and implementation of technology is a national focus area in Norwegian health care services and digital health services have been highlighted in the National Health and Hospital Plan [1]. The Norwegian Parliament has granted funding to the Directorate of Health through 'The national program for development and implementation of welfare technology 2014-2020' and approximately 340 Norwegian municipalities have participated in welfare technology projects [2]. 'The national telemedicine-project' was a part of this program with four national pilot arenas across Norway [3]. The World Health Organization (WHO) has defined telemedicine as the use of telecommunications to diagnose and treat diseases and ill-health [4]. There are in year 2019 several on-going projects in Norway focusing on telemedicine and remote monitoring [5]. '3P- Patients and Professionals in Productive Teams' is one of the on-going projects, with an overall aim of validating and verifying the prerequisites that support the transformation of a classical profession-centred health care system to a digitally supported patient-centred team-work approach [6]. There are four pilot sites enrolled in the 3P-project, which all have developed new care models, and taking advantage of new leading technologies and radical organisational redesign inspired by the Chronic Care Model [7]. The 3P-project is four-year long (2015-2019), led by the Norwegian Centre for E-health Research (NSE) and funded with a grant from the Norwegian Regional Hospital Trusts.

1.1 Aims of the 3P-project

Because of demographic changes in society with an increasing ageing population, the prevalence of long-term conditions and multi-morbidities is also rising [8][9]. These changes threaten the sustainability of todays' health care system [10][11]. Patients, health care professionals and authorities express a need for radical reorganisation of the health care service for patients with long-term conditions and multi-morbidities. There is a demand to place the patient's need in focus and develop service models that are patient-centred, integrated and proactive [12].

The 3P-project aims to support the development of a safe and integrated health care service model. A patient-centred health care service is based on the patient's own defined goals and encourages patient involvement and empowerment. The project has the aim of understanding how to reorganise the health care service model towards the triple aim of improved patient outcomes, improved care experience and reduced costs. Digitally supported communication- and work processes between providers and patients is a central part of an integrated health care service model. The 3P-project has five research-based work packages that collect data at the pilot sites. The research questions are related to patient experiences, the digital individual care plan, patient safety, digitally supported teamwork and implementation of new services.

1.2 The municipality of Risør

This paper describes the 3P pilot site Risør municipality, Norway, with around 6800 inhabitants [13]. Risør municipality established a telemedicine centre for patients with chronic obstructive pulmonary disease (COPD) and aimed at integrating this with the other municipal health care services. The technology used is described in details elsewhere [14]. The aim of the new telemedicine service was to increase the quality of care, patient safety and clinical outcomes for COPD patients in the municipality.

Several stakeholders were involved in the pilot site. The local project group was led by Sørlandet hospital, Risør municipal health service managed the telemedicine centre and University of Agder was the research partner in collaboration with the research department at Sørlandet Hospital.

The aim of this paper is to summarise and share the experiences with the telemedicine project in Risør municipality. The research questions (RQs) that were stated:

RQ1: *How can telemedicine in municipal context be operated with a patient-centred care model?*

RQ2: *How can technology support the teamwork regarding telemedicine in a municipal context?*

2 METHODOLOGY

Qualitative research methods were used in this study to map and evaluate team organisation, collaborative work and challenges that arose [15]. Two semi-structured focus group interviews were made in June and December 2018 with the local project group consisting of five people with background from health service, technology and administration. The same individuals participated in both interviews, two male and three females. The interviews were led by two researchers that were observing the group from the project start in 2015 and until project end. The interview guide consisted of three parts. The first part collected information about the project; organisation, administration, recruitment of patients, training of employees and the follow-up procedure. The second part systematically targeted challenges during the project; organisation, technology, economy and collaborative work. In the third part, a summarisation was made of the present status in the project, the achievements so far and the next step/the future of the project. Each focus group interview lasted for three hours, with a total of six hours of audio-recordings that were made. In addition, annotations were made by the researchers. The recordings were transcribed verbatim by one of the researchers and a content analysis made with categorisation into three thematic sub-groups. This study is a part of a larger project that was approved by the Norwegian Centre for Research Data (NSD) with project number 51408 [16]. All the participants signed an individual informed consent.

3 RESULTS

The results presented are divided into three main categories: Organisational issues, Challenges and Sustainable operation.

3.1 Organisational issues

The municipality of Risør was requested to participate in the 3P-project in 2015, by the project management (NSE in Tromsø). At that time, Risør already had experiences with telemedicine through the United4Health-project where a telemedicine centre was established in Risør and operated during 2013- 2015 [17]. When the local project group was composed, the members from the previous project were asked to contribute again. All members from municipality of Risør, Sørlandet hospital and University of Agder accepted to join the local project group. This project group was stable throughout all the project. The decision of

establishing the telemedicine centre was approved by both the political and administrative leadership of Risør.

For the operation of the telemedicine centre, the 'Risør model' was constructed. It is based on a patient-centred model where a team of relevant health care providers is established for each patient with focus on 'What matters to you?' and with the patient as an important partner of the team. It was emphasised that the General Practitioner (GP) was a mandatory member of the team and when relevant, persons from the occupational therapy, physical therapy and rehabilitation service were included. Digital technology that supported the information flow for collaborative teamwork was desired to be implemented, with access for all team members to the patient's information. The telemedicine centre was established as an integrated part of the municipal health service in Risør. The remote monitoring was primarily intended for the COPD patients in the municipality, mainly because at that time a telemedicine algorithm was already developed and verified in the United4Health project, but also because the municipality was experienced with this patient group. However, it was also discussed to open the remote monitoring for other diagnoses as well.

At the project start in 2015, the intention was to operate the service with the technical solution developed by University of Agder and used in the United4Health project. But the municipalities in the Agder-region were working towards joint procurement of welfare- and telemedicine technology [18][19]. There was a procurement process where the Danish system OpenTeleHealth was chosen as a vendor for telemedicine in the Agder-region [20].

In the 'Risør model' attention was made on how to collaborate and share information about the patient, in a patient-centred team. A solution would be to store documents in a document database instead of sending e-messages containing information, a link could be sent to members of the team. But those functions were not available in the chosen system. In the collaborative work of Risør several e-messages are sent daily between team members, and several systems are in parallel use. A constraint with the e-messages are lack of answers or confirmation that the message was read by the receiver of the message. In Risør there are regular collaborative meetings between the municipal health service and the GPs. The municipal health service would like to have two-way digital communication with the hospital to be able to discuss with diagnose experts. The municipal health care service can be characterised as 'allrounders' that focus on long-time follow up of patients that might have need for medical advices from time to time in addition to medical support and care services at home.

The telemedicine centre was placed at Frydenborgsenteret in Risør, which is an elderly centre/nursing home. Two nurses were responsible for the daily operation of the remote monitoring service, but also having other tasks in the municipal health services. The GPs of the municipality had the medical responsibility for the patients. The aim of the project was to recruit patients that already received services from the municipal health care, and they could also be referred from the GPs and the hospital. For inclusion, each patient received a home visit from one of the telemedicine nurses for information, written consent, user

training and registration forms. As a part of the 3P-project a study is made on eHealth literacy and patient safety, the research protocol is described elsewhere [21].

A case with a Tablet communicating with a pulse oximetry device and sending measurements to a telemedicine data storage was placed at the patient's home. The patient made measurements of pulse and oxygen saturation in blood (SpO_2) and filled in a questionnaire on the Tablet, with wireless transfer of data to the technical platform OpenTeleHealth. At the telemedicine centre, a nurse logged in to the platform to evaluate the measurements that were colour-coded with green, yellow and red alarm in a triage system. The technical system had included a videoconference function. In the case of acute deterioration, a home nurse could attend the patient using the tool TILT (early warning score). The municipal electronic health record (EHR) system Gerica was used in parallel with the telemedicine system for statutory documentation.

3.2 Challenges

Even though a detailed planning was made for the organisation and operation of the telemedicine service, there were some challenges.

One of the challenges was to find the patient group for inclusion to telemedicine intervention. The initial plan had the goal of 15-20 COPD patients recruited from established users of the municipal health care services. The home nursing service had two zones/groups in Risør. Both group leaders concluded that there were very few COPD patients receiving services at that time, in contrast to a few years ago when many patients had frequent hospital admissions. An agreement was made with Sørlandet hospital to help recruiting patients. But at that time the technology procurement was not finalised, and necessary equipment was not available, so the agreement had to be delayed. In addition, very few patients were referred from the GPs.

That led to an effort in recruiting patients that did not receive municipal health services but could benefit from remote monitoring services. This patient group often has contact with the municipal physical therapy and a formal collaboration was established. In addition, patients with respiratory aids at home were contacted for request about the interest of a telemedicine intervention.

Despite a zealous effort in the recruitment procedure, the municipality achieved only 50% of the initial goal of patients included to the intervention during the project time. In addition, the municipality had limited resources to provide telemedicine services to citizens not having municipal health services. There is a demand from the authorities to prevent disease in the municipalities, but no exact requirements on how or what to prevent. Telemedicine intervention is not only remote monitoring of symptoms, but also prevention through patient education [22][23].

Regarding the procurement process, several details needed attention. Who should evaluate the legal and privacy requirements and make the risk analysis? There were also issues regarding data storage and access control. In addition, a data controller agreement had to be made between the involved organisations.

Initially, there were legal and privacy issues to handle regarding the platform OpenTeleHealth [24] that delayed the technical implementation with more than a year. The main challenge was lack of secure authentication (2-factor on level 4) for log in to the telemedicine portal and log in was only allowed from registered addresses with Virtual Private Network (VPN) connection. To solve this issue an agreement was made with Siemens Healtineers Norway, regarding storage, operation and management of the technical solution, through the project funding.

The telemedicine platform did not have an integration with the municipal EHR system, Gerica. The GPs and the other municipal services involved in the patient's team did not have access to the medical information in the telemedicine system, so manual input was made into at least two systems. This caused some additional workload for the responsible nurses at the telemedicine centre in Risør. The nurses experienced technical challenges regarding the videoconferences with patients and chose in some cases to use the telephone instead.

The two-way communication between the telemedicine centre and the patient was an important function in the technical platform and was a highly appreciated function and important for the safety of the patient. With his function, it was possible for the telemedicine nurse to send a written confirmation to the patient's Tablet regarding verbal instructions made in the video consultations or by telephone, and the patient could reply with questions.

Regarding the technical platform, Bank-ID with 2-factor authentication was implemented to make the authorisation and log in procedure easier for health care professionals in field use. In addition, the same authentication method is being implemented for patients to access own health data.

3.3 How to manage sustainable operation?

The municipality of Risør managed to systemise the telemedicine intervention for COPD patients with the recruitment procedure, and implemented the technology fulfilling the privacy requirements. The main benefit of the intervention was to provide personalised remote monitoring in close collaboration with the health services of the municipality. However, it became difficult to integrate the telemedicine centre as a sustainable municipal service. One of the reasons might be that remote monitoring focuses on patient education and prevention of complications, which is not always a defined and prioritised task in the daily operation of municipal health care services.

Another reason is that the telemedicine centre generated more workload and with increased costs, related to inclusion of patients that did not receive municipal health care services. The outcome of telemedicine interventions should be economic benefits for the municipality, but there were no other services that could be reduced or replaced and this new service was recognised as a new unwanted increase in workload and costs. It is difficult for a municipality to measure the economic benefits in reduced hospital admissions or increased patient involvement and ability to stay longer at home because of the new remote support. During interview one of the project members expressed 'How to evaluate that the patients have an increased feeling of safety?'

Each municipality can distribute their budget for health services based on own priorities. An argument against telemedicine, is the cost of the intervention, focusing on prevention without knowing the long-term effects. This is competing with other priorities such as strengthening the staffing of each shift. An argument for telemedicine is the hypothesis of delaying the need for other municipal services, but again, with an unknown time aspect. A third reason for the difficulties in the operation of the telemedicine service were the different administrative levels in the patient-centred team as it had members from different organisations. It was expressed 'Who will pay for the technical equipment or the related user training? Unclear responsibilities and different administrative levels complicates this kind of collaborative work across organisational borders'.

After two years of operation, the Risør municipality decided to close down the telemedicine centre, because of the expenses and the demand for human resources involved. Instead, an agreement was made regarding a similar intervention from an inter-municipal telemedicine centre in Kristiansand, and later on this was changed to be a payed service from a centre located in Arendal.

The 3P-project with telemedicine intervention continued, despite there was a radical change in the operation. Risør municipality continued to recruit COPD patients for remote monitoring, none of them received other municipal services. Because of that, the patient-centred team approach did not work as intended as there were no need of professionals to be involved in the team and neither would they have access to any medical information regarding an intervention provided from another administrative municipality. The telemedicine intervention became a standalone 'silo-function' beside the municipal services in Risør. However, the municipal health service in Risør received e-messages from the inter-municipal telemedicine centre when changes were made in the medical treatment or if the intervention was terminated.

In interviews made with patients in the project, there was a positive feedback and general satisfaction with the service. It was also experienced an increased feeling of safety and improved self-management.

4 DISCUSSION

This paper has shared the experiences with the establishment and the operation of a patient-centred telemedicine intervention in a middle-sized Norwegian municipality. The study showed that several challenges and obstacles in the operation caused the service to be terminated after two years and replaced by a payed inter-municipal service. The two research questions are answered based on the results.

RQ1 asked about how to run a patient-centred telemedicine intervention in a municipal context. The health services in Risør municipality are based on an integrated and patient-centred model. For instance, Risør has no administrative office for providing and making legal decisions for the services (*bestillerkontor*), instead the services provided are based on the evaluation by professionals in each zone/team taking necessary decisions. There was close collaboration between the zones, and for complex or emergency situations team members could be moved to the other zone.

Risør municipality has a strong focus on providing health services at patient's home, and there has been a significant reduction of beds in the elderly centres/nursing homes during the past 20 years. By discharge of patients from the local hospital, a short-time stay in elderly centre is often requested, but in Risør first priority is to try to provide necessary care at the patient's home. The size of the municipality and the organisation of the home care services allows to attend patients frequently and with a satisfying continuity of the staff.

Risør municipality established the 'Risør-model' addressing a team-based patient-centred telemedicine intervention, focusing on patient needs. It was decided that the patient's GP was a mandatory part of the team. The importance of this decision was shown later, when the national report on telemedicine intervention [3] concluded that the four national pilots in general had a lacking involvement of GPs. The following national telemedicine program 2.0 highlighted the important role of GPs.

Based on the experiences from Risør, it is recommended to integrate telemedicine intervention as a part of other already existing health care services, to enhance the patient-centred approach and promote digitally supported collaborative work. Even though the telemedicine service was terminated, the experiences are probably similar in many small- and medium-sized Norwegian municipalities. The approach showed the importance of planning an integrated patient-centred model and contributed to test out new ways of delivering health services. Many of the patients enrolled for telemedicine intervention have multiple diagnoses, and it is demanding for a small municipality to have all the required medical competence. Health workers in municipalities are in general 'allrounders', trained in focusing on the patient's activity, loss of self-care functions and the need of care and support, and not designed for complex medical follow up. This is slightly changed in a telemedicine intervention where the health workers provide remote medical advices and follow-up.

RQ2 targeted the digitally supported teamwork. When working with a patient-centred approach in a team, the sharing and having access to digital information is necessary for collaborating efficiently, avoiding verbal transfer of clinical information or manually enter the same information in several systems. The lacking integration of the telemedicine system and the municipal EHR was a constraint for the information flow and the collaborative work. This experience shows the importance of integration and standalone systems should be avoided as they limit optimal information flow in inter-disciplinary teams across organisations.

The manual input of information into at least two systems was an additional workload but had to be made to ensure the access to the information for other team members, as teams across organisational borders need shared access to information. Due to patient safety verbal communication has deficiencies.

E-messages played an important role for the information flow, but has the constraint of not knowing if the receiver has read the information and the sender of messages very seldom receives a response. Based on the experiences in Risør, we suggest for patient-centred teamwork to establish

a central storage of documents, measurements and corresponding advices/interventions and with a link to all the team members about new information available. Especially the e-communication with GPs has a potential for improvements and shared data access.

Telemedicine intervention is a service provided at day-time. For chronic patients at a severe stage, there should be one-point-of-contact 24/7 to avoid today's fragmentation of the service. This function could be placed at a municipal response centre for telecare alarms, as this is a 24/7 service. Many patients have a need of both services, and the splitting of those services into different centres enhances the 'silo' fragmentation.

For patients, the user interface of provided technology has to be easy to use. The patient at home should be able to use one single user interface in the Tablet for measurements and support functions with the patient-centred team, and also accessing the national health portal where the prescribed medication list is available. Such functionality is in-line with the national vision for 'One citizen- one health record' [25][26] 'We are still not there' was expressed by the local project team.

This paper has some limitations as it presents experiences from one single telemedicine centre that was a pilot site in the 3P-project. One of the strengths is the open sharing of experiences from almost four years of operation and the data presented is collected and analysed in a systematic way. The experiences are most likely similar and transferable to other small- and medium-sized municipalities testing out delivery of health care services in new ways with teamwork collaboration and supported by technology.

5 CONCLUSION

Through the 3P-project in Risør municipality, new ways of digitally supported service delivery and collaborative work were tested over time. For sustainable implementations and operation of telemedicine, a close collaboration is needed between municipal health services and GPs, which was well-planned and established in Risør municipality. However, new services are costly to operate, they often generate more working effort and it takes time for realisation of benefits and expenses are not always reduced in the organisation.

The reason for terminating the telemedicine service was a summarisation of many factors. In general, there are too many projects in the municipalities, with few enrolled patients and very few sustainable implementations. There has to be a large-scale operation for testing out new sustainable services and implementations with a focus of benefit realisation in order to gain evidence for the new services. Several years of operation is needed to show the long-term effects and potential benefits, and until the challenge of multiple levels of administration and complicated data access for inter-organisational teamwork are solved, large-scale operation remains complicated.

However, the patient-centred approach 'What matters to you?' has a close connection to the digital support. Standalone 'silo' solutions in organisations should be avoided and considerations have to be made if already existing and implemented technology can be used to collaborate and coordinate the patient's team.

The telemedicine project in Risør was not wasted, even though the execution did not follow the plan. In addition to telemedicine, the next step might be to test out other ways of delivering digital health services, such a virtual home visits or planning hospital discharge over videoconference together with the patient and the municipal health service. After the telemedicine intervention was moved to an inter-municipal centre, also heart- and diabetes patients can be enrolled for remote monitoring.

In the final phase of this research work within the 3P-project, the results from Risør will be compared with other telemedicine interventions in other health regions.

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7 ACKNOWLEDGEMENT

Healthcare personnels' experience with patients' online access to electronic health records

Differences between professions, regions, and somatic and psychiatric healthcare

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Abstract

The aim of this study was to investigate hospital professionals' experience with patients accessing their own electronic health records, some years after implementing the service. Data was collected through an online survey. The results are based on 4477 replies. A quarter of the healthcare personnel (HCP) asked, had noticed that patients were better oriented about their own health after online access to their health record. Around 20 % of the HCP wanted to use the journal in following up patients. Under 15% of the HCP used more time on explaining and calming patients after the implementation. However, one third of the HCP spend more time on - and have changed the way they write journal notes. The results revealed that there are significant differences between the professions, regions and somatic and psychiatric healthcare.

Keywords

Electronic health record, digital access, PAEHR, healthcare personnel.

1 INTRODUCTION

The Norwegian Patients' Right Act states that all patients own their health records and have the right to read them [1]. To date, all hospitals in Northern and Western Norway and some hospitals in South-Eastern Norway provide patients online access to electronic health records (EHR).

Patient accessible electronic health records (PAEHR) are implemented in many countries, with variable policies and systems [2]. PAEHR are reported to increase patient involvement, through supporting patients to better understand their medical issues, feel more prepared for future visits, and to increase adherence to medications [3]. In addition, PAEHR is shown to be convenient and timesaving for patients [4], leading to a more balanced relationship between patients and healthcare personnel (HCP) [5].

However, the feedbacks from HCP on the impact of PAEHR have been diverse, and several concerns have been raised. Studies have showed that HCP become less candid in their documentation and spent more time on writing in the journal after PAEHR [6], and with a consequent increased workload [7]. There have also been concerns that online access to EHR without guidance from HCP may cause unnecessary worry, confusion, or distress among patients due to potential misunderstandings or disturbing information [7].

A Swedish study reported differences in expectations with regard to professions, finding doctors and psychologists in psychiatric care to be more negative towards PAEHR than nurses [8] [6]. Experiences from Norway also indicate additional challenges with the PAEHR for HCP working in psychiatry, with some HCP being sceptic to whether the service is suitable and safe for the sickest and most vulnerable patients or not. Some HCP in psychiatry reported that they omitted information from the EHR, or wrote off-the-record information into a "hidden" journal (also referred to as shadow records or ghost charts)[9].

Based on these findings, we aimed to investigate HCP's experiences with PAEHR in Northern Norway and South-Eastern Norway some years after implementation. In particular, the following aspects were explored: (1) perceived impact on patient empowerment and follow-up, (2) impact on patient-provider communication, (3) changes in documentation practices, including duplicate medical records referred to as off-the-record reporting. In addition, we wanted to investigate whether there were any differences in experiences: (a) between health regions, (b) between HCP in somatic care and psychiatric care, and (c) between different professions.

2 METHODS

2.1 Data collection

We conducted an online survey in two of the four health regions in Norway: Northern Norway and South-Eastern Norway. In Northern Norway, a link to the survey was sent by e-mail to all hospitals in the region, in total 16,643 employees. In South-Eastern Norway, 16,330 employees at the Oslo University Hospital were invited through the salary and schedule system MinGAT. It was not possible to invite only HCP who work with the EHR. Consequently, the first question aimed at identifying and phasing out those who did not.

The questions could be answered on a five-level Likert scale: strongly disagree, disagree, neutral, agree, and strongly agree. Respondents could also refrain from providing an answer by selecting "not relevant" in case a question was not relevant to their work situation. Results were summarized by the proportion of respondents who disagreed with a certain aspect (strongly disagree and disagree) and those who agreed (strongly agree and agree). For each question, the answers "not relevant" were

excluded from the analysis. Four categories of occupations were created: doctor / psychologist/ psychiatrist, nurse, other clinical personnel, and administrative personnel.

This study is based on a selection of six questions included in a larger survey consisting of 14 questions. An additional question about informal ways of making information inaccessible for patients (off-the-record reporting) was added to respondents from Northern Norway, as former studies from this region indicated that this might occur.

The survey was written in Norwegian. Questions and answers used in this article were translated into English.

2.2 Statistical analysis

Categorical variables are reported as counts and percentages. A Pearson's Chi-Square test is used to explore statistically significant differences between groups for all variables. A P-value < 0.05 is considered significant.

3 RESULTS

There were 6,105 respondents to the survey, 1,405 from Northern Norway, and 4,700 from South-Eastern Norway. Of these, 4,823 worked with the EHR. A total of 4,477 respondents (963 from Northern Norway and 3,514 from South-Eastern Norway) from either psychiatric or somatic healthcare were included in the analyses. Employees from other fields were not included in the results. The majority of the respondents (79%) worked within somatic care, while the remaining (21%) worked in psychiatric care (Figure 1).
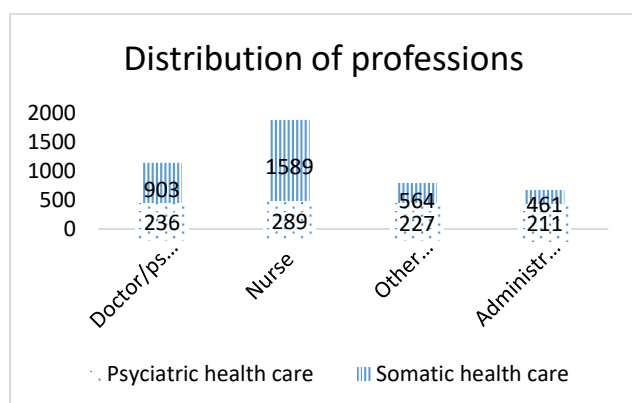
Figure 1 Distribution of professions.

Overall, there was a high number of "neutral" answers in all topics (Table 1, 2 and 3 in Appendix). The group with less neutral answers were doctors.

3.1 Better oriented patients and HCR's wish for using EHR in patient follow-up

About a fourth (24.7%) of the respondents found that patients were better oriented about diagnosis, treatment and follow-up, while a nearly equal proportion (28.3%) did not agree. There were statistically significant differences between regions and professions. Only 12.4 % of doctors found that patients were better oriented about diagnosis, treatment and follow-up. No difference was found between somatic care and psychiatric care. In both groups, around 25% of the respondents noticed that patients were more informed (Table 1 in Appendix).

Only 20.5% of the responding HCP wanted to use PAEHR more actively in following up patients. There were statistically significant differences between regions and professions. HCP from Northern Norway had a more positive attitude towards using the digital access in following up patients with over 28% wanting to do so, compared to only 18% in Southern Norway. Doctors were the least interested (15.8%) in using the service in patients' follow-up. No difference was found between somatic care and psychiatric care (Table 1 in Appendix).

3.2 Patient-provider communication

Only a small percentage of respondents declared that they spent more time on explaining the journal content (13.2%) or reassuring patients (14%) as a result of patients reading their EHR online. The results showed statistically significant differences between regions, health fields and professions for both questions. Doctors, in particular, spent more time on explaining the journal content (20.8%) and reassuring patients (22.8%) than the other professions (Table 2 in Appendix). Over 20% of HCP in psychiatric care reported that they spent more time on explaining the journal content and reassuring patients and relatives, compared to only 11% of HCP in somatic care.

3.3 Changes in documentation practices

Overall, 28.9% of the respondents felt that they spent more time writing in the EHR after patients gained online access. There were statistically significant differences between regions, health fields and professions.

Among HCP in psychiatric care, there was a higher proportion of respondents who used more time on writing in the EHR (38.6%) compared to HCP in somatic care (26.1%). Doctors and other clinical staff were the categories who reported that the implementation had resulted in more time sent on journaling (Table 3 in Appendix).

Almost a third of the respondents (29.8%) agreed that they changed the way they write in the EHR after the implementation of PAEHR. There were statistically significant differences between regions, health fields and professions. More than 40% of HCP in Northern Norway agreed to have changed the way they write in the EHR compared to only 26.7% of HCP in South Eastern Norway. There were more respondents who changed the way they wrote in the EHR among HCP in psychiatric care (39.1%) than in somatic care (27.2%). The highest impact in terms of changes in documentation practices, was measured for doctors (35.9%), while nurses, for instance, modified their way of writing in the EHR to a lesser extent (26.3%) (Table 3 in Appendix).

Results from the question about informal ways of making information inaccessible for patients, only available to HCP from Northern Norway, showed that 29% of HCP in psychiatric care had not report all relevant information (underreported) in the HER the last year. The corresponding number for somatic HCP were 18% (Figure 2). Among HCP in psychiatric care, over 8% of the respondents stated that they had written off-the-record journaling (also called shadow-records) the last year.This means that they had recorded patient information outside the official EHR system.(Figure 2)
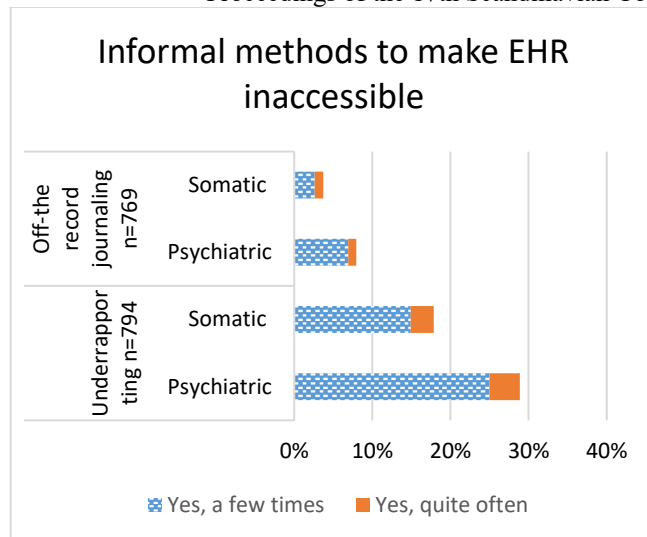
Figure 2 Frequency of HCP stating to have used informal methods to make EHR notes inaccessible.

4 DISCUSSION

Even though our main finding is that the implementation of PAEHR have not severely affected the HCP's work practices, PAEHR have had some impact for HCP in certain areas.

4.1 PAEHR's impact on different health care professionals

Some have explained the level of resistance towards EHR by the culture and nature of the professions. For example are physicians trained to perform with control and confidence in their work situations, and can have a stronger resistance towards PAEHR, as it is a system that provides augmented patient control and transparency. This can challenge the already defined relationship between patient and provider. [10]. Our study shows that doctors are the profession that least wants to use the digital access as a tool in following up patients. Nurses expressed a more positive attitude towards using access to the patient journal as a tool for communication in the future.

The percentage of doctors spending more time on explaining information and reassuring patients after the introduction of PAEHR were at 21-22%, were as the same corresponding numbers among nurses were only 8-9 %. This might be explained be the patients' behaviour pattern. We can imagine that patients who are disturbed, worried or confused about something they read in their EHR online would prefer to approach a doctor for explanations, rather than a nurse. A study from Sweden, however, showed that nurses experienced longer "in-depth discussions" with patients, as the patients came prepared with questions after reading their journal online. [11] A possible explanation for these contrary findings can be distinct organization of the healthcare system and differences in professionals' roles and responsibilities in Sweden compared to Norway. There have been shared opinion in the media were it is claimed that nurses are used in a more prevalence way and are expected to work more independently in the role as a nurse in Sweden compared to Norway [12].

4.2 Spending more time on documentations

A third of all doctors report spending more time writing information in the EHR after patient's digital access. Spending more time on a journal note could make the note more summarized and compressed, and if the extra time is used in described way, the journal could be consisting of more relevant information for other HCP and for the future treatment. This could make the communication among HCP better as the journal note would be more thought-through if the extra time spend would have an impact on quality. However, a previous study have showed that between 40% and 60% of all doctors in psychiatric care are less candid when writing journal notes after PAEHR[8]. A less candid way of writing can be harmful for the transparency and patient security of the health record. The exploration of potential positive and negative consequences in changed journal writing should be investigated further.

Most nurses, together with administrative personnel, did not spend more time on writing in the EHR nor change the way they write. A possible explanation could be that nursing notes are overall more pre-defined and based on schemes to fill in, while doctors' notes include more unstructured information.

4.3 Regional differences

PAEHR seems to have affected the work practices of HCP in South-Eastern Norway less than Northern Norway. Only 18.2% of HCP in South-Eastern Norway wanted to use PAEHR more actively in following up patients, compared to 28.2% in Northern Norway. While 40% of HCP in Northern Norway agreed to have changed the way they write in the EHR, only 26.7% of respondents in South-Eastern Norway agreed to the same. It is not clear what causes these differences. The time since implementation is more or less the same in the two health regions, so this cannot be the explanation. The differences could be caused by distinctive structures in organizational, resources used in implementing the service, training of HCP or internal communication. The exploration of these possible reasons requires further investigation.

4.4 Maturity of implementation

A study conducted in Northern Norway in 2016 showed that 67.5% of HCP *expected* more patients to gain better knowledge of their own health status in the future, thanks to the availability of the PAEHR. 21.4% of these found that patients were already more oriented on their diagnosis then earlier [9]. Our study conducted two years later, shows that 30% of HCP in Northern Norway agreed that patients are more informed about diagnoses, treatment and follow-up. Moreover, the proportion of HCP from Northern Norway who want to use PAEHR actively in patient follow-up increased from 19.6 % in 2016 to 28.2% in 2018. Such results confirm that the implementation of new digital services needs time to mature, and is in line with findings from Sweden where concerns and opinions were more positive after HCP gained more experiences with the PAEHR system [6]

4.5 Psychiatric care and PAEHR

There were significant differences between HCP in somatic and psychiatric care regarding both the impact on patient-provider relationship and changes in documentation practices. A much higher proportion of HCP from psychiatric care spent extra time writing in the EHR and on explaining and calming patients in consultations after PAEHR. HCP from psychiatric care also underreported information in the EHR and used shadow records to a higher extend than HCP in somatic healthcare.

The debate about the risks of giving digital access to patients has in particular been related to psychiatric care. Being exposed to threats or violence is more expected by HCP in this field [8]. The most negative opinion towards PAEHR believes that the patients with the most severe diagnosis in psychiatric health care can be worsen by reading details about their psychiatric health online[9]. Some hospitals in Norway have even closed the digital access for the sickest groups of patients, based on the risk of online information harming their healing process.

Studies show that clinicians change the way they write in the EHR after PAEHR because they feel a strong desire to protect their patients from potential harms, while also feeling vulnerable and exposed themselves [13]. It is also plausible to assume that HCP in psychiatric care omit information from the EHR, if they consider the information potentially damaging for the patient to read alone without guidance. However, under-reporting journal information or writing journal information in shadow records can harm patient security, prevent the provision of the best possible health care, and affect the communication among HCP by creating gaps in information [14] and there may be issues conserving confidentiality and privacy [15]. The law states that all documentation written about a patient should be made accessible, unless there is a risk to endanger the patient's life or serious damage to the patient's health [1]. Studies focusing on under-reporting and shadow recording as a result of PAEHR are lacking, we don't know what kind of information are most likely to be omitted, or the actual consequences of it. We would like to prioritize this question in futures studies.

4.6 Limitations

As participation to this survey was voluntary, the possibility of a higher proportion of respondents with a particularly strong opinion about the service in the data collection is present. If this would be the case, the answers might be biased. The survey was also sent out/made accessible to all employees, regardless of whether they worked with the EHR. Consequently, it is not possible to calculate the response rate. Further, due to the wide distribution of the survey, we could not take into consideration the heterogeneity of the healthcare sector in terms of routines and work situations, and some respondents might have received questions that are not relevant for their work situation.

5 CONCLUSIONS

Our main findings is that the implementation of PAEHR has not severely affected the hospital health professionals' work practices. However, PAEHR have made an impact in some areas. HCP noticed that patients were better oriented about their own health after online access to their health record. Around 20 % of the HCP wanted to use the journal in following up patients. Under 15% of the HCP used more time on explaining and calming patients after the implementation. One third of the HCP spend more time on - and have changed the way they write journal notes. The results revealed that there are significant differences between the professions, regions and somatic and psychiatric healthcare. HCP in psychiatric health care had in general experienced more effects of the PAEHR. An interesting finding that should be further investigated is that 25 % of psychiatric HCP stated to have under reported in the patients journal, and 8% reported to have kept a shadow record.

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7 ACKNOWLEDGEMENT

8 APPENDIX

		Health region		Health field		Profession			
	Total	North. Norway	South-Eastern Norway	Somatic care	Psych-iatric care	Doctor Psychol./ Psych-iatrist	Nurse	Other clinical prof.	Admin
I have noticed that patients and/or relatives are better oriented about diagnosis, treatment and follow-up plan then earlier.									
	n=3995	n=903	n=3092	n=3118	n=837	n=1038	n=1722	n=727	n=508
Agree	24.7%	30.1%	23.2%	25.2%	23.1%	12.4%	29.2%	24.2%	35.4%
Neutral	47.0%	44.3%	47.8%	47.1%	46.6%	40.7%	48.5%	50.9%	49.4%
Disagree	28.3%	25.6%	29.0%	27.7%	30.3%	46.9%	22.3%	24.9%	15.2%
I want to use patient's access to EHR more active in following up patients.									
	n=3466	n=804	n=2662	n=2693	n=773	n=1027	n=1464	n=656	n=319
Agree	20.5%	28.2%	18.2%	20.3%	21.3%	15.8%	21.0%	24.4%	25.4%
Neutral	44.8%	44.4%	44.9%	44.8%	44.8%	31.5%	49.7%	49.2%	56.1%
Disagree	34,7%	27.4%	(36.9%	34.9%	33.9%	52.7%	29.3%	26.4%	18.5%

Table 1 Patient empowerment and HCP's willingness to use EHR in follow up.

		Health region		Health field		Profession			
	Total	North. Norway	South-Eastern Norway	Somatic care	Psych-iatric care	Doctor Psychol./ Psych-iatrist	Nurse	Other clinical prof.	Admin
I spend more time on explaining journal content for patients and/or relatives because they read their health record online.									
	n=3332	n=829	n=2507	n=2614	n=718	n=956	n=1431	n=607	n=338
Agree	13.2%	19.5%	11.1%	11.3%	20.2%	20.8%	8.3%	10.7%	16.9%
Neutral	34.2%	29.0%	36.0%	34.5%	33.4%	28.9%	36.5%	31.5%	44.7%
Disagree	52.6%	51.5%	52.9%	54.2%	46.4%	50.3%	55.1%	57.8%	38.5%
I spend more time on calming patients and/or relatives because they read their health record online.									
	n=3357	n=826	n=2531	n=2636	n=721	n=957	n=1445	n=617	n=338
Agree	14.0%	20.5%	11.9%	11.8%	21.9%	22.8%	9.8%	10.4%	13.3%
Neutral	32.8%	27.1%	34.7%	33.2%	31.5%	27.5%	35.1%	30.3%	42.6%
Disagree	53.2%	52.4%	53.5%	55.0%	46.6%	49.7%	55.1%	59.3%	44.1%

Table 2 Patient-provider communication.

		Health region		Health field		Profession			
	Total	North. Norway	South-Eastern Norway	Somatic care	Psych-iatric care	Doctor Psychol./ Psych-iatrist	Nurse	Other clinical prof.	Admin
I spend more time on journaling now that I know patients and/or relatives can read what I write online.									
	n=3710	n=842	n=2867	n=2897	n=813	n=1048	n=1679	n=689	n=294
Agree	28.9%	36.5%	26.6%	26.1%	38.6%	32.5%	25.9%	33.1%	22.8%
Neutral	26.5%	24.7%	27.0%	26.9%	24.8%	22.9%	26.0%	26.0%	42.9%
Disagree	44.7%	38.8%	46.4%	46.9%	36.5%	44.6%	48.1%	40.9%	34.4%
I have changed my way of journaling after patients have been given access to their health record online									
	n=3763	n=842	n=2921	n=2947	n=816	n=1062	n=1722	n=691	n=288
Agree	29.8%	40.3%	26.7%	27.2%	39.1%	35.9%	26.3%	31.7%	23.3%
Neutral	23.6%	22.6%	23.9%	23.8%	23.0%	18.8%	23.0%	25.5%	40.3%
Disagree	46.6%	37.2%	49.4%	49.1%	37.9%	45.3%	50.7%	42.8%	36.5%

Table 3 Changes in documentation practises.

Ambivalently Awaiting: Norwegian General Practitioners' Expectations towards a Cross-institutional Electronic Health Record

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Abstract

A cross-institutional Electronic Health Record (EHR) where all healthcare workers can access a patient's record, is seen as an important means to improved access to information, better patient care, and increased efficiency. In Norway, the first EHR of this type (US based Epic EHR) is to be implemented in the Central Norway Regional Health Authority. General practitioners (GPs) are central actors in health service delivery, and consequently it is important that also they use the new system. However, we lack knowledge on GP's expectations and needs for cross-institutional EHRs. Drawing on interviews with 17 GPs, we discuss these topics and conclude that the GPs interviewed are ambivalent towards an EHR of this scale.

Keywords

General practitioners, Electronic Health Records (EHRs), Cross-institutional EHRs.

1 INTRODUCTION

Electronic Health Records (EHRs) are often presented as the cornerstone of a modernised health service, expected to make health care delivery better, safer, cheaper, and more integrated [1, 2]. The healthcare sector is information intensive and tasks and activities are distributed across professional, institutional and administrative boundaries. Collaboration and coordination of work and information are supported and shaped by the functionalities in digital systems, like the EHR [3]. Due to the nature of healthcare, there is a strong need for improved digital collaboration support.

Today, an increasing number of vendors are offering cross-institutional and interdisciplinary solutions, but they have not yet been tested in Norway. However, currently the Central Norway Regional Health Authority is about to implement the US based Epic EHR that will allow all health institutions in specialist and primary care, as well as general practitioners (GPs) to share data across administrative, geographical and institutional boundaries.

However, research literature reminds us that "failed" EHR programs are common, and that even "successful" initiatives are plagued by delays, escalation of costs, and technical glitches, including system crashes [4] and unintended organizational consequences [5]. A review in the field concluded that "EHR use will always require human input to recontextualize knowledge" and, further, that the efficiency gains are to be expected in secondary work (audit, research, billing) and not in clinical work, where "smaller EHR systems may sometimes be more efficient and effective than larger ones" [1].

Given the insight on such challenges, both from practice and research, it is of particular interest to explore the GPs attitudes and expectations towards such systems. Thus, the aim of the paper is to describe and discuss GPs expectations and reflections towards new cross-institutional EHRs.

2 METHODS AND MATERIAL

The paper is based on a qualitative, explorative study where the purpose was to gain knowledge on Norwegian GPs experiences with inter-organisational collaboration as well as their expectations on how a cross-institutional EHR may support such collaboration. The study is commissioned from the Health platform program in central Norway [6]. The Health Platform is responsible for the procurement and implementation of Epic in the entire Central Norway health region. The implementation is planned to start in 2021.

The study was approved by the data protection officer at the University Hospital of North Norway and the Norwegian Centre for Research Data (NSD) and conducted according to research ethical principles.

2.1 Data collection

Data was collected between January and April 2019. We conducted semi structured interviews with 17 GPs, which is a suitable method to capture people's reflections and expectations [7]. The interviews were conducted by LM, HKA, GS and LS. About half of the interviews were conducted face to face, while the rest were conducted on telephone or skype. All interviews were audio recorded and transcribed ad verbatim.

We used an interview guide, which covered the following main topics: examples of collaboration situations that currently work well, situations that do not work well, and reflections around how digital solutions could improve poorly working collaborations. We also asked more specific questions on attitudes towards information sharing, communication needs and privacy concerns related to information sharing. Background information, like working experience, current EHR-system, and satisfaction with IT-support was also included.

The interviewees comprised 11 men and 6 female GPs. They were recruited in different ways. Some of them were

suggested as potential interviewees from our contact persons in Central Norway Regional Health Authority, and a selection of these agreed to be interviewed after being contacted by the research team. Others were recruited through an open e-mail invitation from their respective district medical officers. A few others were contacted and recruited based on our knowledge on them as engaged in the study's topic. The interviewees consequently came from different health regions in Norway. Even though it is only the Central Norway Regional Health Authority that currently have decided to implement a cross-institutional EHR, Norwegian health policies and strategies recommend such an EHR on national basis. We therefore wanted to include GPs from all over Norway. Nine of the interviewees works in Central Norway Regional Health Authority, which has decided to implement Epic. All GPs had some working experience from specialist health care. The vast majority were self-employed.

2.2 Analysis

The interviews were analysed using an interpretative and eclectic approach, described by Kvale [7] as 'bricolage', in which the aim was to generate meaning and see connections across the material. the analysis was conducted stepwise. The first three authors read through all the interview transcripts and outlined several overall themes, covering collaboration challenges and digital support. These were discussed among the author group. The final themes presented in this paper were further developed by the first author, and they focus more strictly on expectations and reflection on a cross-institutional EHR.

3 RESULTS

Through the analysis we outlined six themes that represent the GPs expectations towards a common EPR-system. The themes cover both positive and negative expectations and reflections and highlight needs and concerns for such a system.

3.1 Shared information

Health care acts (e.g. [8]) state that healthcare workers should have access to information that is relevant for the treatment and follow up of the patient. A cross-institutional EHR has the potential to reduce the lack of information healthcare workers regularly experience today. Several of the interviewees see improved access to information through sharing the same EPR as the biggest benefit:

That vision is all physicians' wet dream. To be able to access a part of the hospital record, or the x-ray record… Not because we are curious, but because it eases the way forward. (GP1)

Interviewees further explained that it would be an advantage to have up-to-date basic patient data (address, next of kin etc.) through a common EHR. One common medication list across organisations was also on the top wanted list. The possibility for the GP to read running notes while the patient was admitted to hospital was also considered to be useful, even though not for all patients. A common system would also provide GPs with more detailed information about tests made at the hospital, which they currently only see the results from in the discharge letter. It could also give you access to tests and examinations that are not documented in the discharge

letter, like x-rays and some lab results, and thereby reduce the need for making tests twice.

3.2 The fear of information overload

At the same time as improved access to information is welcomed, many of the interviewees are sceptic and afraid that they will 'drown' in information. They described being over flooded by information in todays' practice and they express a need for being shielded from even more information:

The horror scenario is that it becomes too much information. How will you find what you are looking for? You drown in information that others have documented. Another interviewee said something similar. He was afraid that the essential information would vanish in the enormous amount of information potentially accessible and was concerned that the search functionality would not be good enough. (GP10)

A third interviewee problematised potential ethical challenges related to increased access to information. He argued that if all information is possibly accessible, then it becomes almost an active choice *not* to use it. Consequently, there can be formed an expectation that GPs must access and read the hospital information and act upon it.

3.3 A need for summarised information

A main result from the interviews is that GPs want relevant information. And relevant information (produced in the hospital) is put shortly summarised information – like discharge letters - that describe why the patient was admitted, status at discharge and how s/he should be followed up, and by whom. GPs explained that they were interested in hospital physicians' assessment of what had happened, and not so often the running documentation:

I really don't need access to the hospital's record. I need a good discharge letter. And we do have that today. (GP3)

The expressed need for summarised information, rather than access to *all* information is reasoned from the need for quality assurance. One interviewee said that if you access information in the patient's hospital record and there are notes that are not finalised, you do not know if the preliminary conclusion (if any) is for certain, and consequently, it would be difficult to trust the information. Another interviewee elaborates on this. He argued that today's practice has a built-in quality assurance. Information from the GP to the hospital and vice versa is not sent until the sender has thought through what s/he wants to accomplish with the information.

3.4 Digital dialogue

Several of the interviewees argued for the need for digital dialogue with their collaborating partners, e.g. in the hospitals. Some of them had experiences with communicating via electronic messages (PLO-messages) with physicians in the hospital and considered this as huge progress, compared to earlier. The possibility for digital dialogue was something that all GPs felt positive about, and some of them argued for it, based on a disbelief that you could make one common EPR that fits all user groups:

I don't really believe that there is one solution for all. I rather believe that good communication between systems is more important than designing one system that fits all. (GP8)

Another interviewee added that even though you may have access to a patient's hospital record, you will sometimes need to ask questions to the specialists on how to interpret the information. E.g. do you think this should be further investigated, or should we just leave it? Should we try adding a specific medication?

One of the GPs said he would like to work closer directly with the hospital physicians and this could be achieved through improved communication, like a digital dialogue functionality.

3.5 The different meanings of the EHR

Another theme that GPs addressed related to sharing EHR-information across GPs and hospitals, was what can be labelled 'working style reflected in documentation.' GPs argued that they use the record in a different way than hospital staff (physicians). For GPs the EHR is a personal working tool, as well as documentation of what has happened to the patient. Many of the interviewees had worked in hospitals and had experienced a different way of recording in the EPR. There was therefore a concern that hospital physicians would not understand their style of documentation, and one interviewee felt that 'culture would be a challenge.' Other GPs explained that they would not change anything in their documentation practice, and consequently it would rather be the hospital physicians' problem if they did not understand the information.

Another theme addressed was if GPs would need to change their documentation style considering the 'cultural difference', and in case of others making quality judgments of their work. The interviewees felt different about this. One GP said that he would need to work differently from today

…because I will have to adapt my notes… in case someone will read what I have written. That will be resource demanding for me. I will need to protect myself all the time. And the risk is that we start doing tests etc. just to make sure you have done everything possible. (GP4)

3.6 Privacy

The last theme we address is privacy and challenges related to this, a theme which was important to many of the interviewees. It was a concern that (sensitive) information meant only for the GP now would be shared with collaborating partners using the same common EPR-system. One GP gave an example:

How much information should the hospital have? And who will read it? We do not want to share information about the patient's chlamydia infections if the patient is referred for an MRI. So, we need to protect the information. (GP3)

Systems for securing information and making sure that only the essential information is shared was therefore crucial for the interviewees. Another GP in a small municipality had concerns if home care staff would be able to read his notes. If so, then he considered the record to be useless, because you would not be able to write anything, due to privacy concerns, as he argued. One interviewee also saw a potential situation where GPs would invent parallel documentation systems for supporting their own work, containing information that would not need to be shared. And one GPs suggested a routine where they could approve in advance what kind of information would be shared.

4 DISCUSSION

While a cross-institutional EHR may provide access to information for all health-related stakeholders, considerations on how to make the most out of the possibilities such a system represent remain uncertain.

The GPs in our study expressed limited interest for a cross-institutional EHR. More precisely, they were ambivalent towards it. They saw advantages, but also several disadvantages. The ambivalent attitude may be interpreted as a form of resistance towards the new EHR. Resistance towards health information systems are not uncommon and may range from apathy and passive resistance to active resistance and aggression. The resistance may be directed towards the system itself, the system's significance or the system's advocates [9]. Often, people are not completely supportive or completely resistive of a technology but may hold contrary positions [10]. It is too early to say how GPs attitudes towards the new EHR will evolve, but in line with Greenhalgh et al. [11] we argue that resistance should be interpreted as a highly complex phenomenon with socio-material and normative components. To fully understand resistance, one must therefore explore both the technology's material properties, the balance between bureaucratic means and professional ends, as well as implications for roles, relationship and collaborations.

The GPs reserved attitude in our study may also be interpreted as a relative satisfaction with the EHRs they already are using in their GP practices combined with a lack of imagination of a new system. However, the reserved attitude may also be interpreted as a potential loss of control of their personal working tool - the GP's existing EHR or a worry related to the organizational consequences of a cross-institutional EHR (i.e. they must do more work than today). We analyse these issues in three sections in the rest of the discussion.

4.1 The role of technology

Even though some GPs mentioned a fear of having to work through new computer interfaces developed mainly for the specialists, and not the GPs, the technology itself was to a lesser degree emphasised in the interviews. This is hardly surprising. Former studies on the implementation of IT underscore the difficulties of relating to something you neither have seen, tested or experimented with, nor actually used. In a study on the implementation of groupware in a large American organization, Orlikowski [12] pointed out how the users tried to understand the technology in terms of their existing technological frames - i.e. technology they already knew and used. Similarly, Silsand and Ellingsen [13] illustrated the challenges for developers of capturing user requirement from the users by asking them to formulate short user stories (2-3 lines) as a basis for a new system. Along the same lines, Ulriksen and Ellingsen [14] demonstrated that users have to experiment with system functionality in real life to see opportunities, as well as identify potential organizational problems. These issues are particularly relevant for a cross-institutional EHR such as Epic that commands a potentially huge impact on the different stakeholders, including the GPs. The Health platform organization in Central Norway is aware of this and to accommodate user needs it invited all the potential vendors in the acquisition process of a cross-institutional EHR. The vendors were invited to present technical

solutions to relevant users in the form of patient demonstrations and user scenarios that they have created. Based on this, requirement specifications and the public tender has been modified and refined accordingly.

4.2 The potential loss of a working tool

The GPs in our study emphasised that their existing EHR is their working tool in daily clinical work. Research has shown that GPs spend almost half their workday on the EHR [15], and it is therefore to be expected that they have concerns for how a new system may affect their job. GPs in our study used the record in ways suitable for their practice, for instance by their style of writing. Accordingly, they were not interested in changing the documentation style to adapt to other stakeholders' needs, for instance that of hospital physicians. However, others argued that due to privacy concerns, they might have to adapt their notes in order to make them suitable for a wider audience.

In this regard, Grünloh et al. [16] argue that one "interpretation of the physicians' view of the record as their work tool is that they see themselves as its owners" (p. 9). While the argument of ownership may stretch the point, it unmistakably underscores the importance of the GPs' current GP EHRs in their practices. Furthermore, the concern of a loss of their working tool is not totally unfounded. Ellingsen et al. [17] discussed how the experienced usefulness of the nursing classification system NIC and NANDA among nurses, increasingly was considered for management purposes, such as resource management. Nevertheless, it is evident that a new cross-institutional EHR needs to be able to support different domains and stakeholders, and not only one user group such as the GPs. Thus, Greenhalgh et al's [4] argument that efficiency gains are to be expected in secondary work (audit, research, billing) and not in clinical work, may sound familiar. On the other hand, we cannot say yet whether the GPs worry of a loss of their working tool will materialize or not. However, a status quo on this situation is hardly an option, as the EHR increasingly becomes a tool for multiple tasks, e.g. for communication between providers and for patient's updating on their own health situation. In turn, this may nonetheless enforce a different documentation style among GPs.

4.3 Work reconfigurations

A cross-institutional EHR provides the opportunity for extensive sharing of data among GPs, hospital physicians and municipalities. The GPs are ambivalent towards this. They entertain the idea that is might be both positive (access to all necessary information) and negative (information overflow). Without concluding too much on these issues at this stage, it is clear that a cross-institutional EHR (such as Epic) has a considerable potential for streamlining and transforming regional healthcare [18]. Andreassen et al. [19] use the concepts of reconnections and reconfigurations to characterize the potential effect of this.

The GP interviews reveal a concern that the reactions to reconnecting GPs sand specialist health care through a common EHR potentially can imply more work for the GPs. A cross-institutional EPR will mean a reconfiguration of work where new and old tasks will be distributed in new ways between the involved parties. E.g., today the important task of selecting and summarizing the relevant information about each patient is ascribed to the specialist, who does this in the discharge letter. The concern is that the reconnection of specialists and GPs through a cross-institutional EHR will alter this well-established routine, and the task of identifying and summarizing information from a comprehensive and potentially over-complex record be left to the GPs.

Another element in the reconfigurations of work practices, and an effect of a cross-institutional EHR in itself, is the large-scale sharing of patient data. Earlier studies have shown that privacy concerns are barriers for EHR adoption [20, 21]. Several of the GPs in our study were also concerned for the patients' and their relatives' privacy and considered changing their ways of documenting, which in turn could be a barrier for implementing the new EHR system. Other suggested to make private notes outside of the EHR, which would undermine whole idea of a joint EHR. Sound solutions for ensuring privacy is therefore necessary for getting GPs as users of a cross-institutional EHR.

While some concerns over reconfigured work among the GPs may be justified, they are also recognized as powerful and autonomous user group. Very few organizational changes will be put into effect without agreements from the GPs. To illustrate this in practical terms: in the Health platform program in Central Norway, the GPs are not required to participate in the Epic implementation, they have rather an option to buy-in to the program. And to make sure of GPs partaking, the system must be good enough and respond to the GPs' requirements.

5 SUMMARY

In this paper, we have described GPs' expectations towards a cross-institutional EHR. Interviews with GPs revealed both positive expectations and concerns for such a system, and in the paper, we have highlighted six themes: GPs reflections on sharing information across institutions, a fear of information overload, their need for summarised information, as well as digital dialogue. Furthermore, we have pointed to the possible different meanings of the EHR for GPs and hospital physicians and that a cross-institutional system challenges patient privacy.

Implementing an EHR system like Epic is a huge task that for certain will affect many actors, including the GPs. Since it is not mandatory for GPs to install Epic, the perceived benefits and drawbacks with the system become important for GPs potential buy-in. We have addressed some of the possible consequences. It is difficult for GPs to envisage how a cross-institutional EHR will look like, and consequently how it will affect their work. Research on implementations have shown that unintended consequences are like to occur [5, 22], a fact that furthermore increases the difficulties when it comes to predicting effects of a new system. Nevertheless, the interviewees were concerned that they will lose a valuable tool and that new work configurations will give them more work, even though they also see some advantages. GPs are therefore 'sitting on the fence', waiting for evidence that a cross-institutional EHR is better than their current systems.

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Managing Change of EHR Systems

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Abstract

This article analyzes the associations between four leadership styles, the implementation of renewed Electronic Health Record (EHR) systems in hospitals and performance. The four leadership styles are taken from the literature on change management and are: mobilize, guide, involve and adapt. The performance measure is inspired by the Technology Acceptance Model (TAM). The empirical context is the implementation of a new EHR system in a Danish multi-site hospital in 2015. We apply a mixed-method approach combining qualitative and quantitative data. Using a Structural Equation Model (SEM) combined with focus group interviews we find evidence for significant impact on performance of all four leadership styles.

Keywords

Implementation, EHR-system, Renewal, Leading Change, Hospitals, leadership style, Performance, Technology Acceptance Model (TAM), structural equation models (SEM)

1 INTRODUCTION[1]

For the past decades public sector services has undergone digitization and society has entered the digital era. As a consequence, one of the most important and permanent challenges of digital era governance is how to manage the implementation of new digital systems substituting old ones.

This paper examines if general theories of managing and leading change also hold in the context of hospitals implementing large EHR Systems? Does a leadership style that lives up to well-known recommendations for change management tend to imply a higher degree of performance than a management style that does not?

Both in the hospital system and in many other places, there have been massive challenges associated with the implementation of large information and communication technology (ICT) systems. This applies internationally in both the private and public sectors [1].

There are many reasons why such implementation processes often go wrong, but it is of the utmost importance that we develop knowledge of the various reasons and what can be done to increase the chances of success.

We are living in a digital age, and the question of how to ensure better implementation processes in connection with the introduction of new ICT systems is very likely to be on the agenda for several decades to come and will involve billions of dollars.

In this study, we focus on the importance of leadership, and our case is Electronic Health Records (EHR) in hospitals.

2 THEORY AND HYPOTHESES

Reviews about the impact of EHR systems has shown that good leadership and management, infrastructure support, staff training and focus on workflows and usability is important for the outcomes of implementing EHR[2].

Hospitals are not one single organization unit with one management but consist of a large number of clinical departments each with their own management team. Often a department includes more than 200 employees and is an organizational unit with its own local management, even though all departments have a superior management in the directors of the hospital.

Studies of the implementation of quality management systems and IT systems in Denmark and other countries has shown, that the management of the individual departments are quite different and can make a huge difference to the implementation process in terms of variations in management skills, management goals, organizational tasks and responsibilities [4] [3]. A Danish case study of an EHR development process in the North Denmark Region also found differences between wards in the implementation and use of EHR systems [5]

Based on the literature on leading and implementing change, we formulated four hypotheses about the importance of leading for performance. In the study, we focused on four well-known leadership styles that are generally recommended in the literature on leading the implementation of change processes [2] [2] [4]. We have called the four styles mobilize, guide, involve and adapt. Mobilizing and involving styles may be related to notions of

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[1] The article is based on research conducted and published in 2015 (see reference [8]). It elaborates further on findings previously published by two of the authors (see reference [5] [6]).

transformational leadership, while guiding and adapting styles are related to notions of situational leadership [4].

We formulated four hypotheses that were tested in the study:

2.1 Hypothesis 1 - Mobilize support before implementation.

There is a positive relationship between a management style that ensures support before the implementation process and performance after the implementation process.

2.2 Hypothesis 2 - Provide instructions, guidance and information in a timely manner.

There is a positive relationship between a leadership style that ensures that employees receive thorough instructions and guidance on using the ICT system, and performance following the implementation process.

2.3 Hypothesis 3 - Involve employees in local adaptation.

There is a positive relationship between a leadership style that involves employees in adapting the ICT system to the individual department's routines and procedures, and performance following the implementation process.

2.4 Hypothesis 4 - Adapt the implementation process to local conditions.

There is a positive relationship between a leadership style that adapts the implementation process to the specific characteristics of each department and performance after the implementation process.

3 RESEARCH DESIGN AND DATA GENERATION

We tested our hypotheses in an analysis of the implementation of a new Electronic Health Record (EHR) system. The implementation took place in 2015 at the Hospital Lillebælt, a multi-site hospital in the Southern Denmark region with several locations - in Kolding, Middelfart and Vejle .

We examined the hypotheses using a mixed methods design:

- we conducted survey studies of all approx. 4,000 affected employees before and after implementation. The surveys were conducted as a panel study where we could see exactly what the individual employee had answered before and after the implementation,
- we conducted qualitative interviews and focus group interviews during the implementation process to identify what challenges occurred along the way and how management and different groups of employees responded to these challenges.
- The time span between the pre- and post-study was approx. five months, so our findings reflect a short-term measure of performance three to four months after implementation was initiated [6].

On the basis of the quantitative data, the changes in support for the ICT innovation have been described, and four non-recursive structural equation models (SEM) have been constructed using a model build approach in order to test the overall hypothesis that local variations in the approach to leadership during the implementation affect the perceived performance after the implementation process.

4 FINDINGS

As Figure 1 shows, there was considerable support for the new system before implementation. However, this support had dropped significantly five months later after implementation. The figure also shows that there were major differences in the employees' perception of the system. There were major challenges along the way in the implementation process - technical challenges as well as challenges related to the content and use of the EHR system.
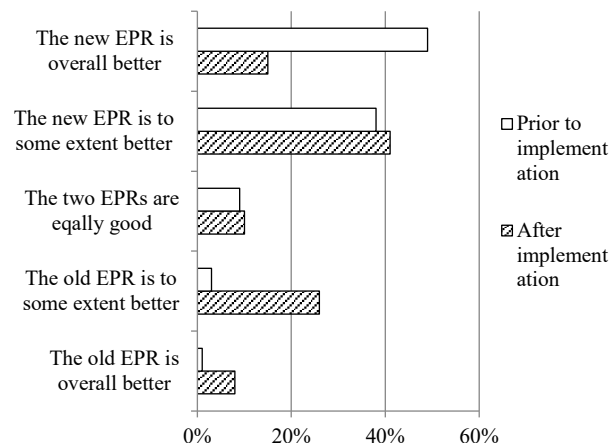
Figure 1 Overall support for the EHR system before and after the implementation (Source: Hansen & Nørup 2017, p. 856, [5]).

Furthermore, there were large differences in management style between the various departments.

The question here is whether differences in management style have a bearing on the performance of the system?

Inspired by the Technology Assessment Model [3] [2] [2], we measured performance on three dimensions:

- perceived ease of use (is it easy to use?).
- experienced usability (is it useful to use?).
- perceived impact (has services been improved?)

First, an initial model consisting only of the support for the ICT innovation before and after the implementation process has taken place is constructed. In the second model, two variables are added that measure the leadership style in relation to 1) providing sufficient information and training the employees (directive leadership) and 2) the degree of participative leadership of the local management.

In the third model, a variable is added measuring whether the management in the local hospital units has followed a locally adjusted implementation strategy or used the standardized strategy provided by the central hospital management. In the fourth model, a control for professional background is added (figure 2).

By gradually building the model, we investigate not only the direct effects of management and leadership style but also how these variables moderate the direct effects between initial support and perceived performance.
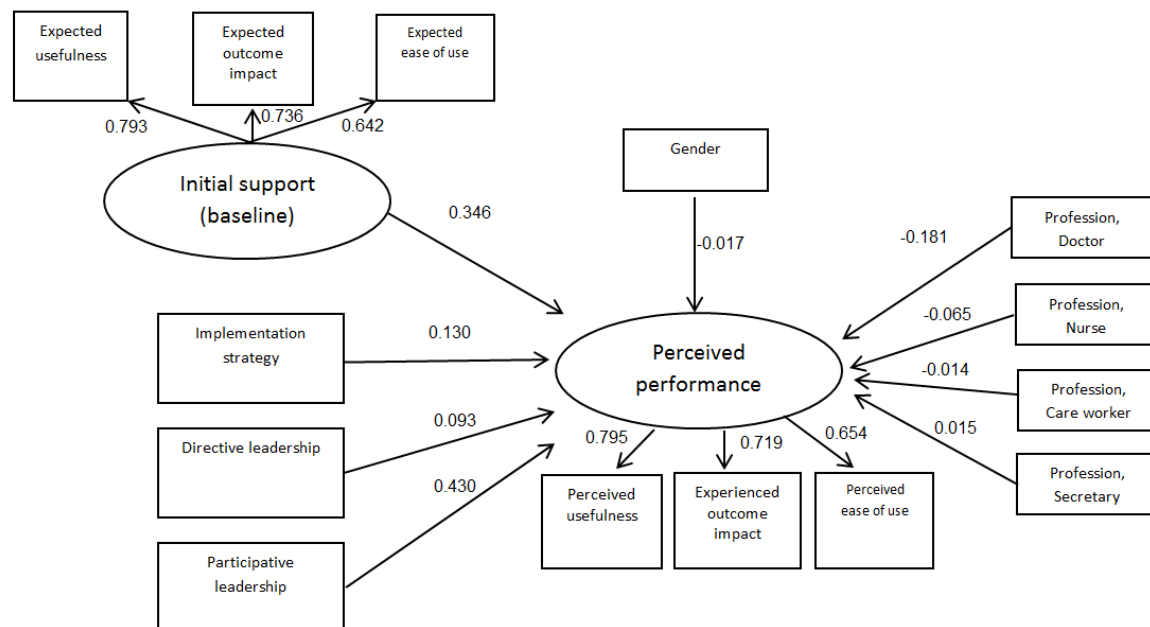
Figure 2 Model 4 – final model explaining variations in perceived performance, non-recursive SEM (Source: Hansen & Nørup 2017, page 857 [5]).

The study shows that all four leadership styles are significantly positively related to performance - all four hypotheses are supported by the empirical results, and management theory's recommendations for change management are thus confirmed by our study. The management style that has the most positive effect on perceived performance is employee involvement (Hypothesis 3). Employees at departments where the employees have been consulted to adapt the system to the department's routines experience higher levels of performance.

The management style with the second highest positive effect is support before implementation (Hypothesis 1). Employees who expected high performance before implementation tend to maintain this assessment, despite the experienced difficulties during the implementation. However, the study indicates that there is a delicate balance for management in mobilizing support before implementation. In addition to convincing that it is a good idea, it is also important to prepare employees for the difficulties that almost always arise when implementing large ICT systems.

The management style of local process adaptation (Hypothesis 4) had the third largest effect. In this case, it was a trial. Two departments were allowed to do an implementation process, where teaching and guidance were especially adapted to their department. At the other departments of the hospital, the employees received a generic introduction to the new system. Our findings indicate that the experiment was successful. The employees at these two departments experienced a higher degree of performance after implementation.

The management style of providing instructions and guidance (Hypothesis 2) had the least effect on perceived performance in this study. But there is an effect, and as expected, it is significantly positive. Employees who receive instructions and guidance when they need it experience a higher level of performance.

5 DISCUSSION AND CONCLUSION

The study has a number of implications for practice [6]:

- Prior mobilization of support for the new system among employees increases the likelihood of better results, even in the event of serious technical problems, but managers should strive for a careful balance between prior mobilization of support for ICT innovation and on the other to prepare employees for difficulties in the implementation process.
- Participative leadership involving employees in decisions on the practical implementation and adaptation of the ICT system significantly increases the likelihood of better results.
- Management that provides sufficient information and timely technical support during the implementation of the ICT system increases the likelihood of better results.
- Adapting the implementation process to the conditions in each department increases the likelihood of better results.

The findings of our study are clear and not surprising. Our study adds some nuances to theories of change management and it replicates previous studies within the field. Thereby the study contributes to a strengthening of the evidence for tested theories. Yet the above recommendations have been well known from management research for the past 15-20 years. These theories have been taught at many management education programs in Denmark during the same period.

It raises the question of why the recommendations are not being followed to a greater extent. We have not examined the implementation of the health platform in the metropolitan area and the Region Zealand, but according to media coverage and a recent government report , several of the above recommendations have not been followed - at least not sufficiently.

The paradox is well known and the problem is widespread. It is referred to in the international literature as the "knowing-doing gap" [6]. There is often a gap between what you do and what you know - between what people in organizations know and what they actually implement in practice. Thus, the study raises the question of how we increase the likelihood that the results of our and others' studies will have greater implications for practice.

The study does however have some limitations, which should be recognized, and its findings should be extended and tested in future research .

Perhaps the most important limitation is the short time horizon of the post-test measures. At the time of the post-implementation survey, the ICT innovation was not fully routinized and integrated in the organization. A research design including medium and long-term post-implementation measures would have been preferable, but was not possible due to lack of resources and access. Thus, our findings should be interpreted as especially relevant to the first stages of an implementation process.

The measure of performance is a subjective one as it measures perceived performance by the employees on multiple dimensions. How this performance measure may be associated with, for instance, actually delivered services, increasing errors in medical treatments or an increasing number of readmissions, has not been uncovered in the present study. On the other hand, from the point of view of management, the employees' perceptions of performance are crucially important to public service organizations.

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Efforts on Using Standards for Defining the Structuring of Electronic Health Record Data: A Scoping Review

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Abstract

Using a scoping review technique, this paper investigates approaches, challenges, and success factors when adopting highly structured Electronic Health Records (EHRs). Our findings are consistent with previous literature that reports that the most common methods for structuring patient data consist of a combination of codes, terminologies, reference information models, and standards. However, the review identified new factors and challenges previously not considered as critical areas for the successful implementation of highly structured EHRs; challenges related to human factors seem to be of paramount importance for the success of standard-based EHR adoption. The review revealed that main challenges are related to maturity of the technologies; methods for governance of clinical models; slow adoption of standards; high cost of running pilots; lack of standard compliance and validation mechanisms; and unclear terminology binding of information models. Key success factors are the availability of validated Clinical Information Models (CIMs) and value sets; properly leveraging and managing the complex technology stack; rapidly coordinating EHR implementers with governance bodies; performing agile requirements management; involvement of all stakeholders in the development of standard specifications; and implementing early pilots evaluating the adoption of structured EHRs.

Keywords

Structured EHR, health information standards, terminologies, decision support, review.

1 INTRODUCTION

Successful health care delivery is a service that requires efficient coordination and communication for both patient and provider benefits [1, 2]. Digitalization of work processes and the use of information systems such as the EHR has been though to alleviate some of these challenges [3]. However, the healthcare sector consists of a large number of actors – from highly specialized hospitals to general practitioners and home care providers – that often use different information systems [4]. The use of health information standards and structured data formats can through its common language and expectations provide semantic interoperability across organizational boarders and between different systems [5]. These concepts and technologies have been developed to define a standardized way of how health information should be structured and communicated [6]. The use of standards, terminologies and information models are also argued to be a prerequisite for realizing the potential in Clinical Decision Support Systems (CDSS), automatization of data reuse (secondary use) and efficient communication and information exchange [3, 7]. Currently, the adoption of shared and agreed-upon standards for EHR data structuring are being pushed through different initiatives internationally, both for the purpose of patient safety, accessibility, interoperability, privacy, and re-use of health related data [8].

There is a need for more comprehensive knowledge about experiences on using information standards for defining the structure of EHR data [5]. This paper investigates and discusses different approaches and related challenges to structuring patient data in EHRs.

1.1 Objective

This paper aims to identify and present methodologies and technologies used for structuring EHR data in general. The results of this scoping literature review will be used to inform recommendations and guide future research in the Norwegian medical informatics community on the adoption of standard-based EHRs.

Research questions (RQ) are:

1. What are current approaches to orientate the transition to structured and standard-based EHR data?
2. What are the specific problems and characteristics related to different methods of each approach for standardizing EHR data?
3. What factors are commonly predefined as crucial for a successful transition to a structured and standard-based EHR, and what is the relationship between the factors and actual implementation outcome?

2 METHOD

In this study, we used a scoping literature review for data collection. Scoping literature reviews are a well suited method to provide an overview of a broad and unfolding topic and for identifying relevant key concepts [9]. Argued to be as comprehensive as a systematic review, a scoping review allows for the treatment of broader research questions and provides greater flexibility in comparison [10]. In this study, we were interested in a diversity of relevant papers ranging across multiple methodologies and

disciplines and the scoping review technique is therefore well-suited.

2.1 Search strategy and study selection

In cooperation with a research librarian, we outlined the purpose and scope of the review in a search strategy document. In addition, we defined inclusion and exclusion criteria, as well as a concept definition. Search terms were identified using MeSH and through discussion among the authors. Search terms were subsequently categorized in one of four categories: i) IT system – electronic health records, medical records; ii) Terminology and classification – specific terminology or codes used; iii) Structure and standards – methods or standards used for structuring; and iv) Implementation and outcome – experiences or lessons learned. Categories were defined based on workshop sessions between the authors and project partners, as well as available literature and knowledge.

The search was performed in May 2018 using Ovid MEDLINE. The full set of returned publications were exported to Rayyan QCRI, a systematic review web application tool.

The included papers were randomly divided into three equal parts, and title and abstract were reviewed by one of three authors (LMR, ER, KMN). Papers were categorized as "INCLUDED", "EXCLUDED", or "UNCERTAIN". Papers could not belong to the same category at the same time. Any uncertainty or conflict was resolved by discussion until consensus was reached. The inclusion rate between the reviewing authors ranged from 20.1 % to 20.8 % in the first screening. The included papers were randomly assigned between three of the authors (LMR, ER, KMN).

2.2 Eligibility criteria

Publications were eligible if they met any of the following criteria:

1. The paper described experiences or lessons learned from transitions into a standard-based EHR by hospital senior management or medical head of departments.
2. The paper described how technologies were used in the adoption of, or transition to, standard based EHRs.
3. The paper described methodologies followed for the transition into standard-based EHRs.
4. The paper described data reuse methods/infrastructure and, at the same time, complied with one or more of the other eligibility criteria.

Exclusion criteria were applied: i) during the review in title and abstract for marking why a study was not included; and, ii) during the full text review to determine which papers would not be considered for the final analysis. Papers were removed after being revised in full text if they met any of the exclusion criteria:

1. The paper was excluded if it described a general interoperability strategy without organizational or technical details about the EHR adoption process. For example, the paper described a funding framework, a legal requirement, or a declaration of interest for adopting standard-based EHRs, but it did not provided organizational or technical details on how to perform it.

2. The paper was excluded if it defined the impact of a standard-based EHR on the clinical or patient side, but did not provided information about organizational or technological aspects used in the standardization process.
3. The paper was excluded if it did not report clearly on how the EHR was used to extract data and store structured data.
4. The paper was excluded if it only reported on impact for secondary use of data without complying with any of the other inclusion criteria.
5. Other- the paper was excluded if it did not meet any inclusion criteria during the review in title and abstract but could not be marked with any of the aforementioned exclusion criteria. In that case the reviewer wrote a small explanation about the reason for exclusion.

2.3 Data extraction and analysis

The included papers were randomly assigned to one of the authors (ER, LMR, KMN). A data extraction schema was designed as a tool to summarize the papers and justify either inclusion or exclusion by assigning them a corresponding pre-defined criterion. The authors extracted data during the full-text review process. The applied method resembles the scoping review stages proposed by Arksey et al. [11].

3 RESULTS

Approximately 24% (37/154) of the papers identified in the literature search were included in the final review. The initial search produced 377 potentially relevant publications. Of these, 223 publications were excluded due to duplications and age, as we restricted to papers published between 1st January 2010 to 21st May 2018. The 154 studies remaining were reviewed in title and abstract applying the eligibility criteria described in section 2.2. Forty-four remained after the review in title and abstract for being reviewed in full-text. After full text review, 37 publications were included in the review, and seven were excluded for complying with the exclusion criteria defined in the following section.

Figure 1 illustrates the literature search and article screening process.

3.1 Study characteristics

Through an inductive process of discussion between the authors, six main categories that encompass the dimensions involved in the implementation of structured EHRs were identified in the included papers: i) terminologies and decision support; ii) implementation of structured data; iii) technical infrastructure; iv) clinical information models governance and terminology binding; v) extraction transformation and load; and, vi) organization and management. Each category represents a specific approach, or use of standards, for structuring EHR data. Table 1 details a summary of the categories identified in the included papers. Note that the categories are non-mutually exclusive, meaning that the same paper can be plotted to multiple categories in the table.

Figure 1 Flow diagram of literature screening process.
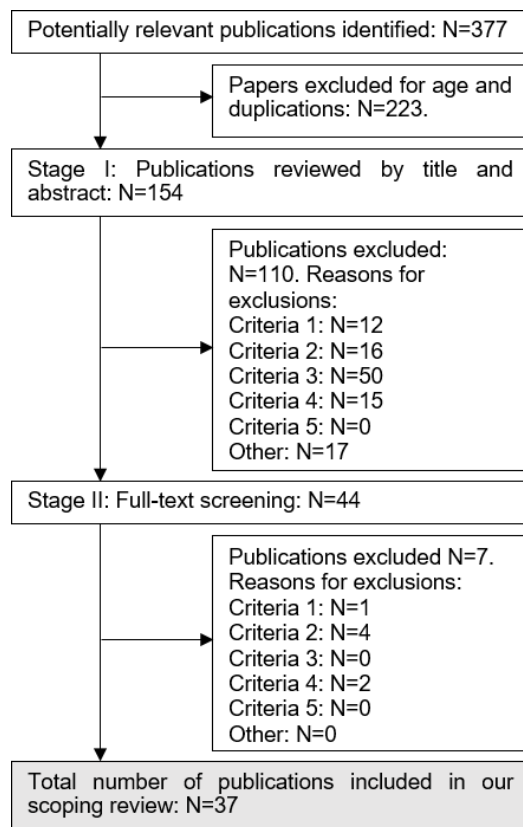
In the following, the paper describes the empirical material from the scoping review using the identified categories. Within each category, we will present the related challenges and critical factors described in the included papers.

Table 1 Categories identified after analysis of included papers.

Category	Reference	N
Terminologies adoption and management	[12-27]	15
Implementation of structured data	[13, 19, 20, 22, 25, 28-34]	12
Technical infrastructure	[14, 16, 24, 35-41]	10
Clinical information models governance and terminology binding	[14-16, 24, 26, 27, 31, 36-38, 40, 42-45]	14
ETL-process	[24, 39, 40, 42, 44, 46, 47]	7
Organization and management	[14, 25, 36, 38, 45, 48]	6

3.2 Terminologies adoption and management

A systematic literature review by Hyppönen, Hannele, et al. reported that the most common methods for structuring the patient data consisted of a combination of codes, terminologies, reference information models and documentation standards, standardized forms (templates), and post-hoc structuring using Natural Language Processing (NLP) [20]. Multiple papers discuss interoperability, mainly from a technical perspective,

reporting on ongoing efforts and challenges from an architectural and information standard perspective. Previous studies, both from research and practical application developments [12, 15, 16], focused on the use of terminologies and data formats for achieving information interoperability. Other studies [13, 22] discusses how the use of different terminologies for representing different clinical domains poses a challenge for connecting data elements if there lacks a homogenous system to support interaction, i.e. mapping between corresponding concepts in different terminologies, needed in some instances of decision support systems. Multiple studies [12, 21, 23] states that while terminologies and terminology services have proved effective for both direct-capture of data from live EHR for use in CDSS, for facilitating interoperability, and improve information management, Kuperman et. al. points out that unsolved challenges of version control and management of standards remain [14]. In addition, multiple papers discussed different architectural approaches best suited to serve multiple user sites or national solutions; two papers [14, 23] reported on successful projects using remote distributed terminology services. When comparing and evaluating different terminology services, Pathak, Jyotishman, et al., showed that there were significant differences in API performance between the services when performing queries that directly affected the quality and ability to support CDS, stressing the importance of thorough technical testing and API considerations in systems acquisition [27]. One paper [17] reported that a Data Management Strategy (practical user guidelines for documenting patient data) could improve both quality and quantity of coded clinical data from clinicians. Multiple papers [17-19] also identified clinicians to be important actors when developing coding strategies and templates for efficient use in clinical settings, as healthcare professionals were better equipped to see limitations in current coding systems based on the crucial clinical domain knowledge they hold.

3.3 Implementation of structured data

DeBlieck, et al. reported that documentation procedures of patient data using guidelines and templates developed by clinicians also partly improved clinical outcome in postoperative patients and resulted in more complete and reliable records [22]. Other papers [20, 29, 30] identified additional factors affecting implementation and adoption rate of clinical standards and structured data entry as system flexibility for customization and adaptation, systematic education and training, leadership support, and strategic planning , and that the introduction of a coding system for structuring clinical data improved both interdisciplinary collaboration and user satisfaction among healthcare professionals. User satisfaction with the implementation of structured EHRs were also showed to be affected by the perceived benefits and implications it would have on workflow, compliance, and reimbursement, and Jackson and Muckerman states that there need to be a sense of urgency for change among users [29].

3.4 Technical infrastructure

SOA architectures have been extensively used for better scalability and maintenance. Chipman et al. and Chronaki et al. presented a CDS functionality for risk assessment offered as a web service that relied on HL7 messages for

structuring the messages payload [16, 35]. Nagy et al. also relied on SOA to build a broker of HL7 v3 messages that allowed organizations in the Czech republic to share clinical data [36].

The use of standards and their importance in building effective regional and national health information networks has been acknowledged in several studies. Chronaki et al. presented the work towards the standardization of ePrescription in Greece and Finland using HL7 CDA, HL7 v3, and IHE profiles [16]. Multiple studies [14, 16, 37] found that the adoption of standardized structured health information systems is slower than originally planned, and that the reasons are the complexity of the HIT environment, the steep learning curve of the technologies, the time needed to become familiar with standard specifications, and the amount of resources needed to test new deployments before going live.

Standardization of extracts needs syntactic and semantic validation of the generated instances. Methods for validation are found in Goosen et al. who provided syntactic validation by using XML schemas to validate Care Provision Domain Model messages [38]; and, in Kuperman et al. that relied on Schematron-based validation of XML documents [14]. Microservices are earning momentum to deal with the complexity of HIT architectures allowing better scalability, evolution, and independence from large main frames [24].

Poulymenopoulou proposed a framework that combined the use of standards (HL7 CDA and IHE) with technologies such as NoSQL DBs and semantic web technologies for including both clinical and patient- reported data [39]. Rea et al. illustrated in their paper that the combination of different technologies are common to provide the functionality needed for each of the Extract Transform and Load (ETL) stages; they used a rich technology stack to approach a complex structuring and standardization process for data reuse [40], Mirth Connect was used to transform HL7 v2 messages into other semi-structured formats, and Apache UIMA as NLP technology for structuring free-text sections contained in the messages delivered by Mirth Connect into a relational database. A Drools rule engine was used on top of the for implementing phenotyping algorithms. It is also worth mentioning that Rea et al. had to deal with complex security layers in order to transfer information between different health institutions.

3.5 Clinical information models governance and terminology binding

The definition of CIMs is a complex process, and the same clinical concept may be modelled in different ways, all of them valid [15]. Thus, careful governance and participation of future users and implementers of the model is needed to ensure that their modelling pattern is correct [37, 38]. As with value sets, reuse of CIMs should always be attempted, provided that they are a corner stone for both syntactic and semantic interoperability [37], therefore implementers should leverage which standards offer reliable CIMs in an openly and transparent manner. However, depending on the clinical subdomain, the availability of validated CIMs may be different; Richelsson pointed to the absence of coverage

for psychological items in the standardization of psychological questionnaires [37].

Formal ontologies based on description logics are earning momentum for structuring complex biomedical vocabularies. In addition, they have played a role in integrating different vocabularies in projects that need to deal with equivalent terms from different coding systems [16]. Nowadays, many organizations rely on their own legacy coding systems and will need to map these to standard terminologies (LOINC, SNOMED-CT etc.) [14, 36]. However, terminology mapping is still a challenge due to the lack of appropriate tooling and the idiosyncrasies inherent to the design of each coding system (point of view, objective, amount of post-coordination etc.) [14, 36]. This results in imperfect matching and poor coverage of some areas when mapping from one terminology into another [42]. We found that the amount of information captured by the CIM and the terminology, and whether post-coordination should be used, is highly dependant on the maturity of the IT infrastructure [12]. The use of post-coordination is often avoided due to its complexity and requirements, but it results in data more consumable for clinical decision support than pre-coordination [15].

Another challenge related to terminologies is their management. Rea et al. warned about the costs involved in maintaining different versions of terminologies [40]. For example, obsolete codes need to be mapped to new ones when upgrading the terminology version [40]. Oniki et al. advocate for prioritizing clinical usefulness and "static" knowledge in the terminology and leave instance data in the CIM [15]. However, Bennett state that these decisions are highly dependant on the requirements of each individual organization [12]. Richelsson and Nadkarni state that it is necessary to emphasize the use of terminologies for semantic interoperability [37].

Peterson identified that matching of analogous terms between different terminologies requires a dedicated terminology service [24]. Relying on standards that count on specific tools for supporting the ETL process and allow the analysis of source and target data schemas and terminology mapping is important [24], in addition to pre-defining the value sets containing the codes that will be used by the EHR system. Terminology servers will need to provide an environment for the management of value sets and mapping between concepts from different terminologies with a GUI that supports these tasks [24]. Standards such as the Common Terminology Services 2 (CTS2) and FHIR terminology server API, are available and have the potential to help developers abstracting them from the complexities of terminology management.

The adoption of SNOMED-CT involves additional challenges. Even with expert terminologies, the choice of codes for creating value sets or coding CIMs, has proved to be ambiguous and requires careful consideration [37, 43, 44]. Some authors deal with these challenges using local guidelines. However, local guidelines cannot control terminology inconsistencies among different organizations, indicating that guidelines need to be provided and audited at a higher level in order to improve SNOMED-CT consistency. Also, few SNOMED-CT projects for large-scale adoption in large healthcare organizations are documented [43]. Several studies agreed on the necessity

to define best practices and experiences about the use of controlled terminologies in combination with CIMs [15, 24, 37, 40, 43].

3.6 Extraction Transformation and Load process

When migrating from EHRs that allow lots of free-text content, the pipeline often starts by Natural Language Processing (NLP) identifying the key sections that are likely to be structured [45, 49]. When information in the legacy (source) system is unstructured, or minimally structured, the task becomes an information extraction challenge where counting on a robust validated CIM can be of great help to act as target information schema during the NLP process [45]. Also, terminology codes and their synonyms can be of help in the process of identifying key words that allow for identifying which piece of information should populate each section of the CIM [45, 48]. When the ETL process involves several data sources and nested data structures that need to be integrated before transforming them into the standard form specified by the CIM, a canonical intermediate plain view is often created. That view is then used to map its fields to the elements of the CIM using transformation rules [42, 49]. That transformation can be carried out using ad-hoc scripts, rules languages, or tools specifically designed for such a task.

Paraiso-Medina split the process into data normalization and semantic harmonization [42]. Due to the complexity of the domain, many tasks need to be supervised manually and cannot rely on fully automatic processes [42]. In addition, once information is structured into a standard format, it is convenient to split different types of information into different repositories for privacy and management convenience. For example, Zhou describes how different types of information are structured in different tables (demographics, diagnoses, prescribing etc.) [44].

3.7 Organization and management

Goosen and Kuperman show the importance of pilots coordination for eliciting standards and CIMs, the importance of getting feedback from several stakeholders, and involve stakeholders with complementary views (government, health organizations, vendors etc.) [14, 38]. Further, they state that it is important to rely on standards that are balloted and piloted by different stakeholders before making them normative so reliable information about the challenges involved in implementing each standard can be understood [14, 38]. The local workflows of each organization establish a need for pilots in order to clearly understand the requirements of each implementation.

This is shown in Goosen and Kuperman where the HL7 CDA and IHE profiles are piloted before eliciting the final stable version of the standard [14, 38]. The management of requirements needs collaboration among all the stakeholders involved, thus working groups need to be multidisciplnar. For example, Kuperman reported on the organization of four different working groups in the implementation of IHE: IT infrastructure specifications development (Technical and Security Work Group), data specification development group, testing and coordination group, and coordination of participants for the data use agreements specification. Cooperative working among

members of different backgrounds (managers, vendors, technicians, and specially clinical users) have been pointed out as a key factor in the success of structuring and standardizing the EHR [14, 38].

4 DISCUSSION

Based on 37 included papers, this review identified and described six main categories related to critical factors, challenges and approaches to EHR data structuring and standardization. In the following, we discuss our results to the research questions defined in section 1.1. Objective.

4.1 RQ1: Common approaches for structuring

The findings in this review illustrate that there is a wide span in terms of technologies and approaches being used for structuring EHR data. Health professionals, governmental bodies, and hospital administrators are in general interested in the potential of structured and standard-based EHRs. The most common methods for structuring clinical data consisted of a combination of technologies and standards [20].

On top of EHRs, large regional and national health information networks also being deployed [16, 36]. These infrastructures can provide a greater landscape for information exchange and the possibility for local adaptability if validated standards and technologies are properly leveraged [35, 37, 40, 42, 46]. Service Oriented Architectures (SOA), and in particular RESTful-based microservices have been found useful for encapsulating software components of health information systems exposing them as web services that can be consumed remotely by several clients. This has allowed the re-use of complex components, thus reducing the cost of their deployment and maintenance tasks [50]. The latest developments in FHIR commit with these principles allowing developers to rapidly implement REST web services to exchange health information messages [41].

Few studies covered the importance of supplementing the implementations using clinical information standards with mechanisms for validating that the messages shared among stakeholders fully commit to the syntaxes defined by the CIM, and the semantics defined by the terminology. This is particularly needed when CIMs are refined to cover the needs of a specific scenario since their modification may result in the lack of interoperability [14, 38].

4.2 RQ2: Specific challenges when standardizing

There are several issues both technical and human that affect the successful standardization of clinical data. The first issue is the need for a proper governance of CIMs. HIT infrastructures are at this point not sufficiently mature for full-scale adoption of health Information standards, and organizations lack experience with the use of terminologies [7, 25]. The lack of effective governance of models is a main issue. For example, if FHIR profiling or openEHR archetypes development is not done in an ordered manner, i.e. with coordination from a national body, two systems operating in the same standard may not be able to interoperate seamlessly. In addition, some studies point out that legislation and management of the technologies reduces the possibility of exploiting the full potential of structured EHRs [32, 35], implementers shoud be aware of legal aspects at project design time.

The second factor is the proper use of terminologies customizing their use to the requirements posed by EHR users because currently there are many open issues when it comes to the adoption of reference terminologies [25, 27, 30, 31, 42]. EHR users are not only the direct healthcare providers (physicians and nurses), but also researchers and managers. Terminology binding of CIMs is highly dependent on the needs of different actors [12]. Requirements from all data users need to be clearly understood for determining the load of terminology codes that are bound to CIMs. For example, terminology requirements are different when only interoperability of EHR extracts is required and when enabling efficient data reuse is needed. In the former case, it is enough to bind some terminology codes to the main sections and values of CIMs; in the latter case, i.e. secondary use of data in research, the relationships among terms needs to be processed and expressive queries that deal with, for example subsumption, need to be enabled [12]. Also related to the use of terminologies is the complexity involved in managing the use of several terminology systems since mapping among concepts from different terminologies is not a trivial task and needs careful assessment by terminology experts [13, 22]. Despite the efforts in clarifying the best strategies for adopting terminologies, unsolved challenges in version control, management of standards, and terminology mapping remain [13, 14, 22]. Implementers need to carefully design terminology adoption strategies and aim for using standard terminology services that help to homogenize the access to value sets [14, 23, 27].

A third factor is the amount of work involved in structuring pre-existing clinical notes. Although NLP techniques have improved in the last decade, NLP is not a silver bullet that can directly establish equivalences between free-text and CIMs. Implementers need to take into account that in most cases, this task will need to be manually supervised by clinicians and NLP will be a helpful tool for them, but not a solution per-se. Implementers of structured EHRs should also be aware of the cost of the ETL stages involved in driving information from the free-text clinical notes to the standard structured CIMs [40, 42, 44].

4.3 RQ3: Crucial factors

Key success factors include both technical and human factors. Despite the technical advances, this review shows that practical use and real-life adoption of standardized HIT is slower than one might expect [14]. On the one hand, the slower adoption is due to immaturity of technologies and the complexity of standards. On the other hand, the slow adoption is caused by human and organizational factors such as lack of national and local competencies, lack of proper governance of CIMs and terminologies, poor management of requirements, and insufficient stakeholders involvement [29, 31]. Below we elaborate the findings about these success factors.

4.3.1 Technical factors

Technical factors are the best understood according to our review. They include the availability of validated CIMs and value sets, and the adequate management the complex technology stack [45].

Each organization must be aware of its limitations before starting the structuring process. Data quality of the legacy system may set boundaries for the completeness of CIMs that conform the first version of the structured EHR. Also, not all organizations will be able to code their information with some specified value sets [14]. The structured standard system may not be equivalent to the legacy data model (i.e. they may not be iso-semantic) leaving many attributes and sections of the target CIM unpopulated. This is something to take into account in order to avoid misunderstandings in a structured system. Projects producing a first structured version of the EHR may produce incomplete CIMs, but they will set the basis for a later project focusing on capturing clinical information with better quality and facilitate the adoption of clinical terminologies. This also applies to the amount of post-coordination allowed and the amount of information represented in the terminology space. In most cases, terminology binding of CIMs to clinical terminologies is crucial for appropriately specifying structured standard content [24, 40]. However, organizations with HIT infrastructures that are not mature and lack experience with the use of terminology servers should prioritize pre-coordination and capture of information in the CIM. More mature organizations may consider to increase the formality in the data they capture, making a heavier use of terminologies and post-coordination, but they need to be aware of the high costs involved both in terms of infrastructure and management [51].

4.3.2 Human factors

Human factors are less well understood and, at the moment, the most relevant when transiting to standard-based EHRs. They include the agile management of requirements by a rapid coordination with interoperability assets and governance bodies, proper system education and training, strategic planning, customization ability of the EHR, and early pilots evaluating the implementation of standards [6, 22, 38].

HIT is dependent on local workflows, this leads to requirements that can only be detected at implementation time. To minimize the risks derived from these local requirements, it is convenient to rely on standards that have formed traction among professionals that are able to report on the main challenges and aspects prior to implementation [14, 38]. Therefore, piloting any development is necessary to understand the risks associated with the structuring and standardization process and, often hidden by the complexity of the health domain. Also related with this finding is the need for involving stakeholders from the organizations that are part of a structuring and standardization process, thus including the perspectives from clinical users, vendors, standardization bodies, and health organization managers. Pilots that involve all these key stakeholders from an early stage will allow understanding the complexity and side effects of the standardization EHR project.

Every large implementation is likely to identify new requirements for information structures, and an agile management of requirements will be needed by the coordinating implementers and standardization bodies involved. Special attention must be paid to the structure of working groups and how the coordination with

standardization bodies will be achieved. Expert panels eliciting standards should contain representatives from the vendors and health organizations that are going to be using the standards for structuring their data [37, 43]. In a larger frame, local initiatives should, if possible, be coordinated if not nationally, at least with the surrounding organizational context.

5 CONCLUSION

Adherence to specific data formats was the main challenge related to interoperability and data exchange, including a lack of consensus on when different standards should be used [13, 14]. Incentives in the form of governmental enforcement, implementation funding and a shared implementation guide proved useful for increasing adoption of standards among EHR vendors [34].

In the review we did not find information about what was the best method to determine how to approach the period of transition where two systems (e.g. paper and structured EHR are used) and how long this period should last. Other studies should consider adding clarity in that regard.

Organizations considering adopting Health Information standards and structuring the EHR, should consider multiple approaches according to their specific needs. This assessment should carefully consider maturity of the technology, the extent of existing legislation and the need for governance models for management and control of the technologies.

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Method for Understanding Obstacles for Health Information Management in a Therapeutic Praxis

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Abstract

Focus on Collect Once Use many Times is essential and increasing in healthcare including occupational- and physical therapy. However, poor data quality and documentation praxis challenges this regime and compromises data reuse for quality assurance and research. Participatory Action Research (PAR) was applied to improve documentation praxis in a municipal therapeutic unit hence improve data quality. The method was validated through semi-structured interviews and findings revealed following barriers a) contextual practicalities, b) contradictions between professional experience and evidence and c) low involvement from organization managers. In conclusion, the implementation of new documentation praxis using PAR is relevant; however, successful implementation requires time and several loops of intervention.

Keywords

Health Information Management, Physical Therapy, Computerized Medical Records, Informatics, Information Science.

1 INTRODUCTION

Clinical praxis is in a continuous development process, as evidence-based clinical praxis (EBP) requires both professional experience and constant adaptations to changes in the organization and external demands [1,2]. To meet the demands for evidence-based praxis, high quality data suitable for research and quality assessment is needed. However, in a therapeutic point of view, data quality may be equivalent to the degree of relevance of the data for the individual therapist and consequently challenging data quality in the therapeutic Electronic Health Record (EHR) [3]. Hence, in clinical praxis, to ensure high data quality can be difficult and patient safety may be jeopardized [4].

An approach to making ends meet between research and clinical praxis may be to implement the Collect Once Use Many Times (COUMT) paradigm [3]. However, for the paradigm to be applicable in a therapeutic EHR, a thorough implementation process is needed to ensure that documentation criteria and guidelines are understood, accepted and met [5]. How this is done efficiently, is ambiguous, as every organization is different in culture, local organization, assignments and personnel [6]. One promising approach may be to apply Participatory Action Research (PAR), which is recognized as a useful method in domestic health research and implementation studies. PAR has the potential to involve and empower healthcare professionals to obtain increased control over their daily clinical praxis [6,7].This paper aims to investigate how PAR can be applied as study design and describes the method developed during an implementation project of a new documentation praxis

for optimizing data quality in the therapeutic EHR in a municipal therapeutic team in Jutland, Denmark.

2 METHODS

PAR design was used including a plan-do-study-act model (PDSA) and semi-structured interviews was performed to evaluate each loop of the PDSA. PAR draws on the paradigms of critical theory and constructivism and uses a range of qualitative and quantitative methods [7]. To investigate how PAR can be applied as study design, multiple loops of interaction and adaptation are required [8]. Thus, a collaborative, cyclical and reflective inquiry design is chosen that focuses on the improvement of work practices and understanding of the effect of the research or intervention chosen [6,7]. An illustration of the application of the PDSA method to improve quality in healthcare is shown in figure 1 [9].

2.1 The initial steps and formalization of the research process

When initiating at PAR, decisions regarding study terms and conditions for collaboration are necessary not only to formalize and plan the study, but also to create a solid base for collaboration, participation and reflection. Therefore the initiation phase of PAR is of upmost importance [8].

Poor data quality was previously revealed in the municipal therapeutic EHR by Toftdahl et al (2018) [10]. This study analysed both text-based and structural data of the EHR and data quality was defined as data being conform, accurate, complete, and valid [11,12]. The structured analysis revealed relevant documentation of outcome- and base-line measures in
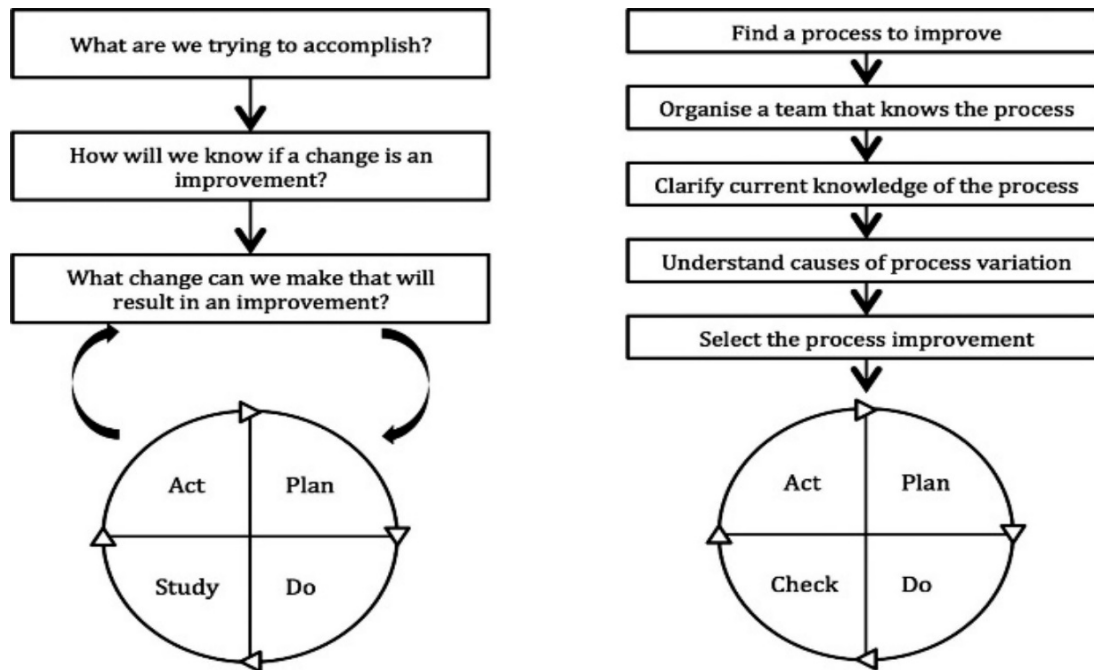
Figure 1 Plan-do-study-act model, used as model for every learning-loop in the implementation process [9].

approximately half the municipal therapeutic EHRs. Whereas, the text-based analysis revealed theese findings to be due to poor conformity, accuracy, completeness, and validity of the data, with data not reflecting the actual clinical assessments. These findings motivated the therapeutic unit to pursue improved data quality by initiating a collaboration with the research group.

The collaboration resulted in a plan for the process of implementation of a new documentation praxis, as illustrated in the left side of figure 1. The interests of the therapeutic team and the researchers were discussed, and common goals were defined leading to the four loops of actions. The research team and the therapeutic team agreed on the following foci in the implementation process; namely, to unify a) the use of validated outcome- and base- line measures according to best evident praxis and b) the data presentation in the EHR.

2.2 Plan - Do - Study - Act

The four PDSA loops were a mix of workshops and education. The loops were planned by the research team, but after every of the four workshops the process was evaluated through semi-structured interviews and evaluations, as illustrated in the right side of figure 1.

Example of a PDSA loop

The third PDSA loop focused on ensuring consensus regarding the outcome- and base-line measurements used in the municipal therapeutic EHR. This loop revolved around a workshop with the therapists, and the steps of the loop were as follows:

1. Plan: The relevant focus of this loop was based on the evaluation and analysis of the previous workshop and interview findings. In preparation the therapists were asked to list their current use of outcome measures and prepare for the workshop by reading relevant materials provided by the research team e.g. guidelines etc.

2. Do: Workshop:

    a. A brush-up session regarding guidelines and evidence of best practice within the field held by the researcher initiated the workshop.
    b. The therapists discussed in small groups the deviations and correlations between current documentational practice and recommended guidelines.
    c. The results of the group discussions were summarized and suggestions for future documentation practice were presented by the researcher.
    d. A group discussion lead to an agreement in the therapeutic team on future use of outcome- and base-line measures and documentational practice.

3. Study: The loop was concluded by interviews focusing on an evaluation of the loop and exposure of foci for the following loop.

Act: The analysis of the above-mentioned interviews guided the planning of the following loop and adjusting the implementation plan accordingly.
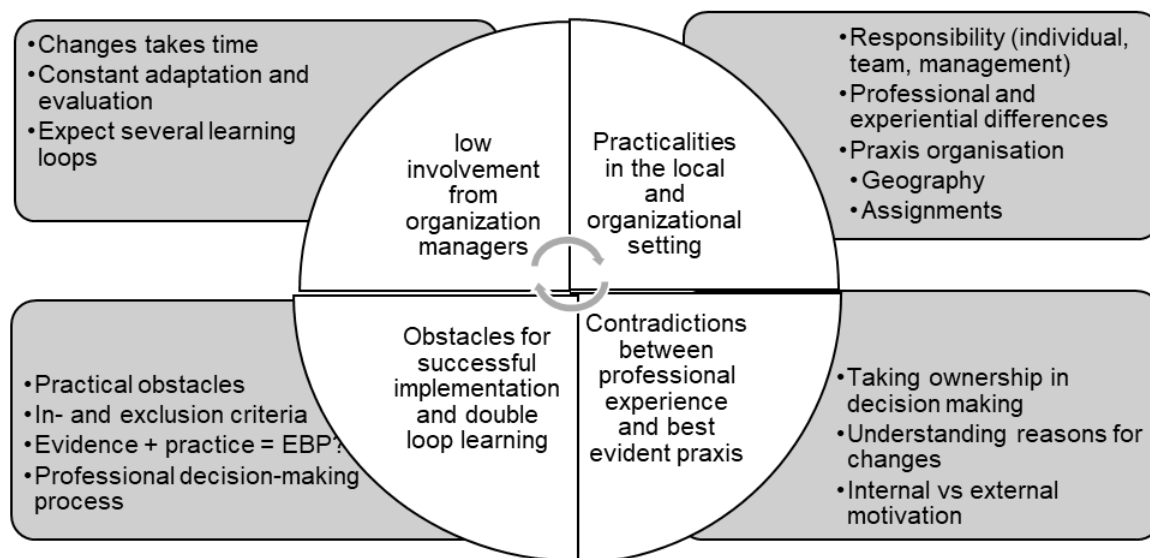
Figure 2 Thematic findings from method evaluation.

2.3 Interviews

Three focus group interviews (n =5-8) and three individual interviews were performed. Informants represented maximum diversity, i.e. both occupational- and physical therapists were included as well as therapists from the three geographical locations the team covered daily. Interviews and evaluations were analysed, and continuously integrated in the next loop of action. The content and focus of the four loops were as follows:

1. Barrier analysis to better understand the context, workflow and culture among the therapist team
2. Increasing the understanding of the COUMT regime among the therapist
3. Secure consensus regarding the outcome- and base- line measurements used in the municipal therapeutic EHR.
4. Revise the new documentational praxis to the therapists' experience according to loop three and unify the data presentation in the EHR.

Furthermore, the PAR design was evaluated in the therapeutic team according to the PAR characteristics [6,13]. The therapists were asked how they experienced:

- the collaborative design of the process
- the degree of internal control of the process
- the applicability of the new documentation praxis
- the extent to which the local environments were acknowledged
- if bias during the implementation process were adequately revealed
- the reflective process throughout the intervention
- the internal focus of the implementation process

3 FINDINGS

The findings of the semi-structured interviews revealed following four themes (figure 2):

1. Practicalities in the local and organizational setting, e.g. the therapeutic team is divided into three matrices and assesses patients both in- and out house
2. Contradictions between professional experience and best evident praxis, e.g. personal professional experience causes the therapist to exclude patient data based on personal experience or expectations.
3. Obstacles for successful implementation and double loop learning, e.g. double loop learning is challenged by a constantly changing clinical praxis, as high data quality requires that the therapeutic team independently and consecutively adapt their documentational praxis to their actual clinical praxis.
4. Low involvement from organization managers, e.g. consecutive adaptation requires resources and management involvement to ensure a relevant focus within the therapeutic team.

The evaluation of the PAR design revealed that the therapist team found the implementation process relevant. They emphasised the importance of an external facilitator that helped ensure focus and momentum of the implementation. External facilitation also ensured that the new documentation praxis was concurrently adapted and followed best evident praxis. The team; however, expressed frustrations regarding the practical barriers illustrated in figure 2. Barriers such as low management involvement and praxis organisation were regarded as contextual challenges that were beyond their influence.

4 DISCUSSION

The analysis shows an interaction between themes, and the evaluation following each loop revealed new barriers within the organisation, the team or the individual therapists. The barriers all created obstacles toward successful implementation of an improved data

quality within the therapeutic unit which are all well-known phenomena in double looped organisational learning [14]. The concurrent revelation of obstacles demonstrates the relevance of using the PAR design during implementation of new practices, as the application of the PAR method allows for continuous adaptation of the design and the methodology. By co-designing the implementation of a new documentational practice, the double loop learning is facilitated. Hopefully, the therapists are hereby better equipped to sustain and concurrently adapt their documentational practice, thereby ensuring future high data quality.

The present findings contrast with implementation studies using summative evaluation models where a deeper understanding of the obstacles towards successful implementation evades. Findings showed that practicalities such as geography, forgetting the new routine and 'who does what'; has a high impact on successful implementation of new practices or routines, e.g. therapists excluded patients from data collection, if they expected the patient to be unable to complete the examination form or when they disagreed with the collected data, based on their initial impression of the patient. Even though the therapists agreed on the challenges regarding the new routines no official agreement on exclusion criteria or handling strategies were decided on, until the next implementation loop (workshop four). This indicates that in a clinical setting with an ongoing professional decision-making processes, the professional decisions may conflict with the purposes of documentation and high data quality, unless the professional decisions are discussed forehand in a broader perspective.

The findings of this study accentuate the relevance of applying the PDSA method for implementation processes as well as the importance of consistency in user- involvement for successful implementation, as show in similar studies [6,7,15]. Therefore, the implementation process needs constant evolving in collaboration between participants, context and clinical setting as an ongoing process. The strength of PAR lies between researchers and participants collaborated effort towards resolving issues in a specific system and setting [6]. PAR requires that action and reflection always goes together, thus praxis cannot be divided into a prior stage of reflection and a subsequent stage of action [16]. The design focuses on three aims: (1) guiding the process of translating research into practice, (2) understanding what influences implementation outcomes and (3) evaluation of the implementation [16]. On these grounds PAR is highly relevant; however, as every step is evaluated and prioritised there is a risk of unintended learning processes or occurrences. In contrast, the ever- evolving loops allows and ensures re-evaluations and adapted actions to be initiated. In conclusion, implementation of new documentation praxis in a clinical setting using PAR is a relevant methodology; however, successful implementation requires time, resources and several loops of intervention throughout the entire process, as

even the most basic practical barriers might challenge a successful implementation.

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6 ACKNOWLEDGEMENT

Noise and Contraction Detection using Fetal Heart Rate and Accelerometer Signals During Labour

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Abstract

Fresh stillbirths and early neonatal deaths due to birth asphyxia are global challenges with an estimated 1.3 and 1.0 million deaths respectively every year. Adequate fetal monitoring during labour to prevent these deaths, is challenging, and regular assessment of fetal heart rate (FHR) in relation to uterine contractions is a key factor. A multi-crystal strap-on low-cost Doppler device, including an accelerometer, is recently developed to improve FHR monitoring in lower resource settings. In this work, we propose a method to increase interpretability of FHR Doppler signals by reducing noise, and a method to utilize accelerometer signals to estimate uterine contractions.

Keywords

Fetal Heart Rate, Doppler, Uterine contractions, Noise, Accelerometer

1 INTRODUCTION

Fetal heart rate (FHR) monitoring is a widely used method to assess the status of a fetus during pregnancy and labour. In high resource countries, cardiotocography (CTG) is normally used for all labours assessed as high risk. This measuring technique normally includes an external Doppler based FHR sensor and a tocometer to measure uterine contractions. In cases where the Doppler based sensor is insufficient in obtaining a good quality measurement, an alternative FHR sensor can be attached directly to the scalp of the fetus. In low resource settings, however, assessment of the FHR is often conducted manually using either a fetoscope or intermittent Doppler. As these techniques does not include information of the uterine contractions, the FHR is often not assessed in relation to the contractions.

Fresh stillbirths and asphyxia-related newborn deaths, meaning the fetus dies during labour or soon after birth, are global challenges with an estimated 1.3 and 1.0 million deaths respectively every year [1]. The vast majority of these, 98%, occurs in low resource settings [1], and the primary cause of these deaths is interruption of placental blood flow with ensuing changes in FHR patterns [1] [2] [3]. Optimal FHR monitoring should detect such changes at an early stage to facilitate adequate obstetric interventions.

The introduction of a portable, low-cost, multi-crystal Doppler continuous FHR monitoring device (Moyo, Laerdal Global Health, Stavanger, Norway) at several sites in Tanzania, provides the opportunity to study the FHR changes and patterns without relying on human interventions to conduct periodic measurements. Well-known problems with such continuous Doppler devices are both noise and missing signal data. This can be caused by sensor movement, suboptimal placement of the sensor, maternal heart rate, doubling and halving of the FHR signal caused by the Doppler principle. Missing data can be estimated to resemble the measured data using dictionary learning [4] [5]. Artefacts due to noise may affect the interpretability and should be removed for both visual interpretation and further digital analysis. Methods for classification and suppression of this noise [6] and removal of the maternal heart rate [7] have previously been used on electrocardiography (ECG) signals from CTG. A system utilizing the sampled heart rate is, however, desired for low-cost continuous FHR monitoring devices for increased visual interpretation of the FHR.

Interpretation of the FHR signal during labour is normally conducted in relation to the corresponding uterine contraction, if this measurement is available. Accelerometers have previously been used to monitor muscle contractions [8], and muscular fatigue [9]. Signals from an accelerometer attached to the abdomen during labour has been shown to correlate to uterine contractions [10]. By utilizing an accelerometer mounted in close proximity of the Doppler sensor, indications of when contractions occur can potentially be extracted. In this work, we have studied Doppler and accelerometer signals from Moyo and identified time periods in the measured FHR where the signal is likely to be noise. Using the three-

Figure 1 The Laerdal Moyo fetal heart rate monitor. Reprinted with permission [13].

axes accelerometer, we indicate the position where uterine contractions occur.

2 DATA MATERIAL

The data is collected as part of the Safer Births research project, which is a research collaboration between multiple international research institutions, and hospitals in Tanzania. Data is collected at two urban and one rural hospital in Tanzanian between October 2015 and June 2018. In total, 3807 labours were recorded. Of these, 3593 were classified as normal 24 hours after birth, 184 were still admitted to a neonatal care unit, 18 died during the first 24 hours, and 12 died during labour. Only labours which were assessed as normal on admission to the hospital were included in the study.

Data collection was done using the Laerdal Moyo fetal heart rate monitor [11], illustrated in Figure 1. The device consists of a main unit with a display presenting the measured heart rate to the health care personnel, and a sensor unit with a Doppler ultrasound sensor and an accelerometer. The sensor unit is attached to the mother using an elastic strap. If the detected FHR stays outside the 110-160 range for 10 minutes, or outside the 100-180 range for 3 minutes, an alarm will sound to alert the health care personnel. The FHR is measured using a 9-crystal pulsed wave Doppler ultrasound sensor operating at a frequency of 1MHz and an intensity of less than 5mW/cm². The FHR is computed from the Doppler signal twice per second, i.e.

equivalent to sampling rate 2Hz. This gives a discrete FHR signal $fhr(n)$, where $n \in \mathbb{N}$ refers to the discrete index. Movement of the sensor unit is measured using a three-axes accelerometer, sampled at 50Hz. This gives the discrete acceleration signals $Acc_x(m)$, $Acc_y(m)$ and $Acc_z(m)$ at the x, y, and z directions respectively, where $m \in \mathbb{N}$ refers to the discrete index.

The project was ethically approved prior to implementation by the National Institute for Medical Research (NIMR) in Tanzania (NIMR/HQ/R.8a/Vol. IX/1434) and the Regional Committee for Medical and Health Research Ethics (REK) in Norway (2013/110/REK vest).

3 METHOD

This section first introduces a method to identify regions in the FHR measurement where the heart rate is less trustworthy, and thus should be removed. A proposed method of estimating the point in time when contractions occur based on acceleration signal follows. An example of the recorded signals is shown in Figure 2. The upper plot shows the FHR signal, and the lower plot shows the corresponding accelerometer. In the following we will use the notation $\dot{x}(n)$ to denote the discrete derivative of the signal $x(n)$.

3.1 Noise detection

Noise introduced in the measured FHR, $fhr(n)$, can affect the visual interpretation conducted by medical personnel as well as introduce undesired artefacts in a continuous digital analysis. To identify time periods, hereafter called segments, where variations in the FHR cannot be explained from a physiological perspective, we first fill missing data in the FHR using forward replication, given by

$$fhr_{rep}(n+1) = fhr(n): fhr(n+1) = 0 \;\forall n \qquad (1)$$

Let s be a pair of indexes (t_s, k) representing the start point and length of a segment. Let A be a set of s,

$$A = \{s: |f\dot{h}r_{rep}(t_s)| > c \;\cap \qquad (2)$$
$$|f\dot{h}r_{rep}(t_s + \text{k})| > c \;\cap \text{k} < T_K\}$$

Where T_K is the maximum allowed segment length, and c a threshold for the change in heart rate. As the measured FHR is a result of a biological process, physiological limitations exist for how fast the heart rate can change, the threshold c is set to 30 beats per minute. The segments are thereafter checked in order from the shortest to the largest, to see if the large signal variation is a doubling or halving caused by a Doppler shift error. Let $fhr_d(n)$ and $fhr_h(n)$ denote the intersample variation, and be defined by:
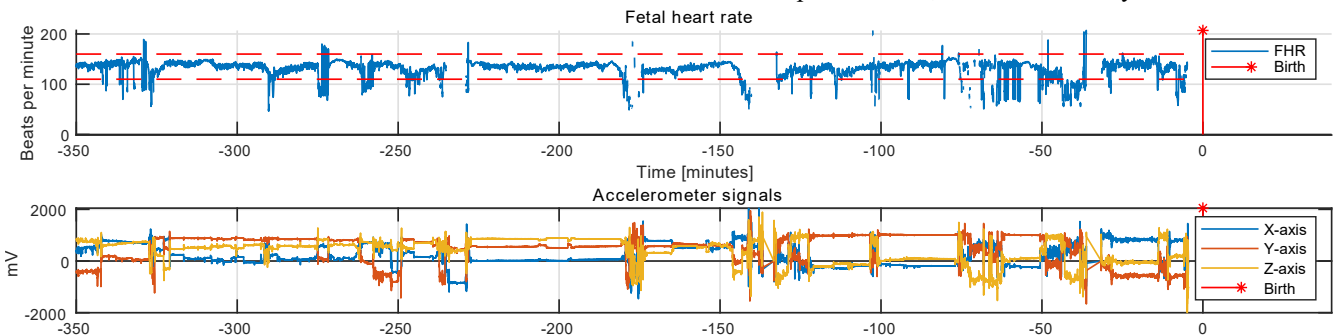
Figure 2 Signal example recorded using the Moyo fetal heart rate monitor. The red dashed lines indicate the normal region of the fetal heart rate. In the bottom plot, the three acceleration axes can be observed.

$$fhr_h(n) = |2 \cdot fhr(n) - fhr(n-1)| \qquad (3)$$

$$fhr_d(n) = |0.5 \cdot fhr(n) - fhr(n-1)| \qquad (4)$$

The shift errors are identified by comparing the intersample variation to a threshold T_D, allowing for some intersample variability. The shift errors are corrected using:

$$fhr_c(n) = 2 \cdot fhr(n) : fhr_h(n) < T_D \qquad (5)$$

$$fhr_c(n) = .5 \cdot fhr(n) : fhr_d(n) < T_D \qquad (6)$$

T_D is set to 5 based on empirical observation. If the sharp variations do not correspond to doubling or halving, the segment is considered as noise. When all segments of length $< T_K$ are checked, the process is repeated using backward replication as some segments may be $>T_K$ due to replication of missing data in the end of the segment. Based on findings from our previous work [5], the threshold T_K is set to 50 samples, equivalent to 25 seconds. A cleaned FHR signal is returned. An overview of the method is shown in Algorithm 1.

Algorithm 1 noisedetect

Input: fetal heart rate, fhr

Variation threshold, c

Maximum length of segment, T_K

Doubling/halving variation threshold, T_D

Output: cleaned fetal heart rate, fhr_c

$fhr_c = fhr$

for direction $\in$ {forward, backward}

$\quad fhr_{rep}(n) = $ fillGaps$(fhr_c(n),$ direction$)$

$\quad$ A $= \{s: |\dot{fhr}_{rep}(t_s)| > c \; \cap$

$\qquad\qquad |\dot{fhr}_{rep}(t_s + k)| > c \; \cap$ k $< T_K\}$

$\quad for \; all \; s \in$ A sorted from smallest k

$\qquad for \; all \; i \in \{t_s, t_s + k\}$

$\qquad\quad fhr_c(i) = 2 \cdot fhr(i) : fhr_h(n) < T_D$

$\qquad\quad fhr_c(i) = .5 \cdot fhr(i) : fhr_d(n) < T_D$

$\qquad\quad fhr_c(i) = 0: |\dot{fhr}(i)| > T_D$

$\qquad\quad fhr_{rep}(n) = $ fillGaps$(fhr_c(n),$ direction$)$

$\qquad$ end while

$\quad$ end for

procedure fhr$_{rep} = $ fillGaps (fhr$_{rep}$, direction)

$\quad$ if direction = forward

$\qquad fhr_{rep}(n+1) = fhr_{rep}(n): fhr_{rep}(n+1) = 0 \; \forall n$

$\quad$ else

$\qquad fhr_{rep}(n-1) = fhr_{rep}(n): fhr_{rep}(n-1) = 0 \; \forall n$

$\quad$ end procedure

3.2 Estimation of contractions

An advantage of indicating the positions of the uterine contractions based only on the acceleration signal, allows the algorithm to run on recordings independent of missing FHR. The accelerometer captures small movements in the abdomen muscle as well as larger movements due to the mother changing positions. The acceleration signal amplitude of these movements is, however, typically vastly different. As the sensor location and orientation may be different between each labour, a trend describing the movement is computed using the acceleration energy, $Acc_E(n)$, given by:

$$Acc_E(m) = \sqrt{Acc_x^2(m) + Acc_y^2(m) + Acc_z^2(m)} \qquad (7)$$

As the acceleration energy signal contains high frequency components, an upper envelope is computed to obtain the movement trend. The envelope of the acceleration energy, $Acc_{env}(m)$, is computed using a 20 second window. A set of positions, C, indicating contractions at time points, t_c, are found as local peaks of the envelope, given by

$$C = \{t_c : \dot{Acc}_{env}(t_c) = 0 \cap T_1 < Acc_{env}(t_c) \qquad (8)$$
$$< T_2\}$$

Where the thresholds T_1 and T_2 are set to 10^{-2} and 10^{-1} standard gravity, g_0, correspondingly, to avoid detecting small movements, and movements due to the mother changing position as contractions. As the intrapartum fetal monitoring guidelines from the International Federation of Gynecology and Obstetrics (FIGO) [12] states that <5 per 10-minute window averaged over 30 minutes is considered normal, the onset of two consecutive indicated contractions must occur at least 2 minutes from each other. The indicated contractions are hereafter called detected contractions. A pseudocode of the proposed contraction detection is depicted in Algorithm 2.

Algorithm 2 contractions

Input: Acceleration signals, Acc_x, Acc_y, Acc_z

Output: Set positions for detected contractions, C

$$Acc_E(m) = \sqrt{Acc_x^2(m) + Acc_y^2(m) + Acc_z^2(m)}$$

$$Acc_{env}(m) = envelope(Acc_E(m))$$

$$C = \{t_c : \dot{Acc}_{env}(t_c) = 0 \cap T_1 < Acc_{env}(t_c) < T_2\}$$

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4 EXPERIMENTS AND RESULTS

As the dataset does not include measurements or registrations describing when uterine contractions or noise on the FHR signal occurs, experiments were devised to utilize both visual interpretation and statistics from the complete dataset to assess if the results from the proposed algorithms are reasonable. Experiments with visual interpretation of detected contractions on signals with low, medium, and high amounts of energy in the acceleration signal were chosen. The visual interpretation is based on discussions with trained midwifes and the FIGO guidelines[12].

4.1 Noise removal

An example illustrating an example FHR signal, and the corresponding signal after noise removal is removed is shown in Figure 3. The method successfully identifies many of the outliers as noise, while some segments in the 75bpm region is kept. At the first stage of the data collection, the first generation Moyo was used. At a later stage, a second generation Moyo was used, and the percentage of missing data as well as noise was decreased.

The algorithm was run on the complete dataset. An overview of the amount of detected noise is shown in table 1.
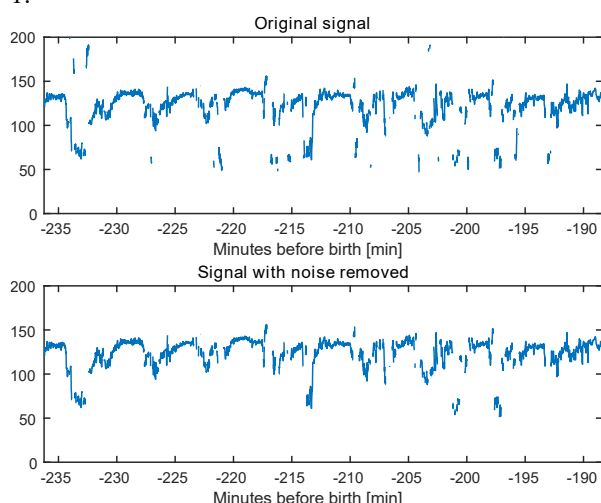

Figure 3 Example of noise detection and removal. Original signal on top, with some artefacts. Filtered signal on the bottom.

Number of episodes	3807
Total duration of all episodes	14201 hours
Percentage of all samples with detected, and corrected, Doppler shift error	0.22
Percentage of all samples removed	2.73

Table 1 Overview of the detected noise in the complete dataset.

4.2 Contractions on signals with low energy in the acceleration signal

Detection of contractions were conducted on a recording with low amount of energy in the acceleration signal extracted from the dataset, Figure 4. The FHR signal shows decelerations, which typically occur as a fetal response to a contraction. In the Figure we show the time points of detected contractions using red markers. It is easily seen that contractions corresponding to the 6 largest decelerations are detected. The contraction associated to the deceleration with a smaller drop in heart rate, at approximately 86 minutes before birth, is not considered to be caused by a contraction as it is too close to the previous
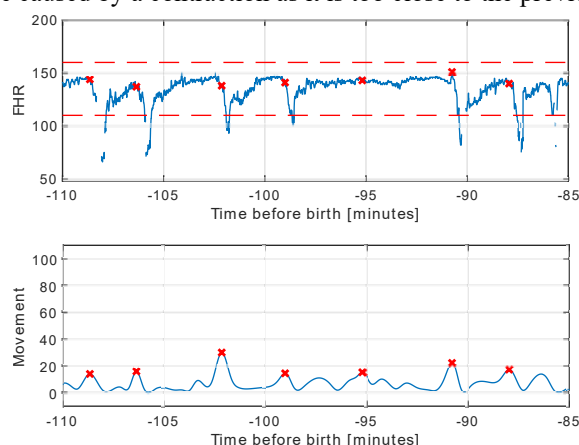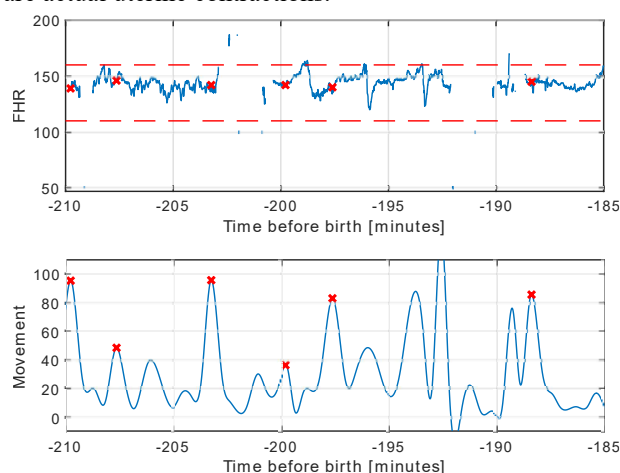

Figure 4 Detected contractions on a signal with low energy in the acceleration signal. The red dashed lines

indicate the normal range of the FHR. The red crosses indicate the detected contractions.

detected contraction. An additional uterine contraction is detected at approximately 95 minutes before birth, without a corresponding deceleration in the FHR.

## 4.3 Contractions on signals with medium energy in the acceleration signal.

Detection of contractions were conducted on a recording with medium amount of energy in the acceleration signal from the dataset, Figure 5. Contractions are detected periodically in the first half of the signal, while only one contraction are detected in the second half. Due to the quality of the FHR signal, it is challenging to assess if these are actual uterine contractions.

Figure 5 Detected contractions on a signal with a medium energy in the acceleration signal. The red dashed lines indicate the normal range of the FHR. The red crosses indicate the detected contractions.

4.4 Contractions on signals with high energy in the acceleration signal

Detection of contractions were conducted on a recording with high amount of energy in the acceleration signal from the dataset, Figure 6. Four uterine contractions are detected in the 25-minute window, but it is challenging to assess if these are actual contractions due to the FHR signal quality.
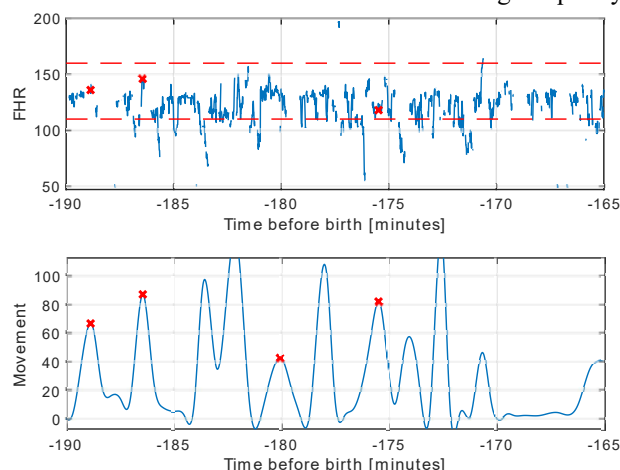
Figure 6 Detected contractions on a signal with a high energy in the acceleration signal. The red dashed lines

indicate the normal range of the FHR. The red crosses indicate the detected contractions.

4.5 Overview of contractions on complete dataset

The algorithm was run on all 3807 recordings in the dataset to indicate how many contractions were found, the mean time between contractions and other performance metrics. The results are shown in table 2.

Episodes with detected contractions	3753
Episodes without detected contractions	54
Median number of detected contractions per episode	29 [14, 51]
Median length of episode	171 [90, 304]
Mean time between contractions	6.27 minutes

Table 2 Overview of the detected uterine contractions in the complete dataset.

5 DISCUSSION

The noise-detection algorithm identifies many small sections of the FHR signal as noise. By removing these, a cleaner version of the FHR signal, and thereby the trend can be obtained. This may result in improved visual interpretation as well as it opens for automated signal analysis and feature extraction for future work. As it is difficult to determine with certainty which part of the measured FHR signal that is noise, only time periods where the signal is very unlikely to contain information of the fetal status is removed. This conservative approach results in that some periods containing noise may be kept.

Information of when uterine contractions occur can sometimes be found by studying the FHR signal itself, as the fetus might respond to a contraction by a deceleration. A challenge in this approach is that uterine contractions may cause increased movement of the mother and sensor, thus increasing the amount of missing data in the FHR.

The proposed method correctly identifies contraction waveforms corresponding to all six large decelerations in the example with low amount of movement, seen in Figure 4. These decelerations are confirmed by experienced midwifes to resemble typical examples of decelerations caused by uterine contractions. The detected contraction at 95 minutes before birth may still be an actual uterine contraction, even if it does not have a deceleration in the measured FHR. The time periods in between the detected contractions resembles typical labour, and it would be less typical if there was not detected a contraction at the 95-minute point. When the energy in the acceleration signal increase, as seen in Figure 5, less contractions are detected. As the number of contractions during a 10-minute window varies from labour to labour, it is difficult to do a direct comparison between recordings. In cases with a high energy in the acceleration signal, Figure 6, the movement create peaks with a higher amplitude than contractions. While the highest peaks, categorized as movement and therefore excluded, is not detected as contractions it is challenging to categorize remaining peaks as contractions and not artefacts due to the movement. In cases where the FHR signal contains a large amount of missing data, the corresponding acceleration signal often contains more maternal movement. That is resulting in a lower identification of uterine contractions. In addition, real

contractions may in some cases occur at a higher rate than 5 per 10-minute windows, known as tachysystole. In the proposed algorithm, a threshold of minimum 2 minutes between the onset of two concurring uterine contractions is used, and this may be a limiting factor to detect tachysystole.

5.1 Limitations

A limitation of this work is the lack of tocometer measurements and manual annotations of the positions where uterine contractions occur in the dataset. To overcome this challenge, discussions regarding noise removal and indication of likely uterine contractions has been conducted during the study with trained health care personnel.

6 CONCLUSION

The work presented indicates that a large portion of the noise present in the FHR signal from Moyo can be removed utilizing only the sampled heart rate. It also indicates that a three-axes accelerometer mounted in proximity of the Doppler sensor, i.e. Moyo Fetal Heart Rate Monitor, can be used to estimate the point in time where contractions occur when the maternal movement is low. Further work validating indication positions of contractions with the use of a tocometer or manually annotated data must be conducted to determine the real performance.

7 ACKNOWLEDGEMENT

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A Practical Methodology for Anonymization of Structured Health Data

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Abstract

Hospitals, as data custodians, have the need to share a version of the data in hand with external research institutes for analysis purposes. For preserving the privacy of the patients, anonymization methods are employed to produce a modified version of data for publishing; these methodologies shall not reveal the patient's information while maintaining the utility of data. In this article, we propose a practical methodology for anonymization of structured health data based on cryptographic algorithms, which preserves the privacy by construction. Our initial experimental results indicate that the methodology might outperform the existing solutions by retaining the utility of data.

Keywords

Anonymization, privacy-preserving data sharing, structured health data, data mining, cryptography.

1 INTRODUCTION

Hospitals, nowadays, are increasingly collecting data from patients as it allows to provide better treatment and precise diagnosis. Analyzing such data by sharing it with researchers can be useful for society. However, the shared data should not compromise the privacy of the individuals. Removing the identifier fields like name and address, is not enough for preserving privacy from certain attacks, e.g., linking attack [1]. Such attacks can re-identify the individuals and reveal specific information based on the raw data. One solution to this is that the data custodians, e.g., hospitals, anonymize such data before sharing.

1.1 Anonymization

Having access to high-quality data is a necessity for medical and pharmaceutical experts and researchers for facilitating decision making. Sharing healthcare data can benefit several parties, including hospitals, medical and pharmaceutical researchers outside the hospital, patients, and data mining researchers. Hospitals, more precisely, medical experts and researchers, can make use of the result of data analysis performed by external research centers. Medical practitioners and pharmaceutical researchers outside the hospital need the data for analysis leading to informed decision making. Patients, indirectly through this, will receive better services from hospitals and medical centers outside the hospital. Finally, data mining researchers will have access to real health data and use them as benchmarks for their methods. However, raw health data contains patients' sensitive information and can compromise their privacy. Therefore, health data holders are looking for anonymization techniques that prepare the health data for release, while keeping the quality of data and preserving the privacy of patients.

Patients consider hospitals as trustworthy entities, so they are willing to share their data with hospitals. Nevertheless, this trust is not transitive to other entities such as research centers outside the hospitals. Many believe that removing specific identifying information including name, telephone, and social security number, is sufficient for releasing the data. As several previous studies show [1, 2], merely removing the identifier fields is deficient for preserving the privacy of individuals. Sweeney [1] shows, an adversary by having limited information from an individual, say from another dataset, can match other attributes, called quasi-identifiers (QID), and reidentify the individual. Three prominent examples about this are provided in [1, 3-6, 7].

At some points, hospitals, instead of analyzing the data by themselves and sharing the analysis results, e.g., statistics or classifiers, need to share the data with external research centers, e.g., universities and pharmaceutical companies, in order to make use of other professional resources outside. Therefore, they should share the data with external researchers specialist in data analysis. Moreover, having the data give much freedom to external research centers for data analysis. Frequent requests from hospitals for providing statistical information and fine-tuning the data mining results is not feasible [2].

1.2 Motivational Example

Hospitals are considered to be the trusted party, and thus have access to the raw data. However, they, in general have limited resources for some specific data analyses. Therefore, it is common to delegate the analysis process to external research institutions. To preserve privacy of individuals, data should be anonymized in the hospitals, and only anonymized data can be shared with external institutions or released to the public. Note that any party external to hospitals can be the adversary, as illustrated in Figure 1.

After analyzing the published data, the results will be released to the hospital, which can be, for instance, a discriminator function as the outcome of the learning from anonymized data. With this function, the hospital can

classify new raw records as follows: firstly, the new record should be anonymized in the same way as the published data anonymized; secondly, the new anonymized record can be passed to discriminator function, shared by the external institutions, for classification. In this way, hospitals can make use of services outside without compromising the privacy of their patients.
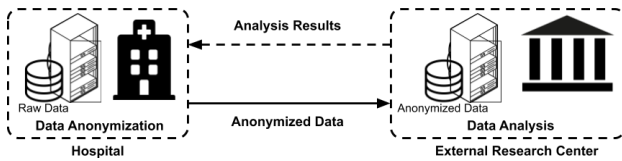
Figure 1 medical data anonymization and analysis.

In this paper, we propose a methodology to anonymize structured health data based on cryptographic algorithms and without assumptions on the characteristics of the encryption method. Adopting cryptographic algorithms guarantees privacy preservation by construction. Moreover, the comparison results of the data utility between raw and anonymized data generated based on our proposed methodology and the existing methods are promising. The proposed methodology can have a complementary role in combination with previous methods as well.

The organization of the rest of this article is as follows. In Section 2, a short review of previous methods for anonymization of the structured data is provided. Section 3 addresses the proposed approach for anonymization, along with providing some preliminary information. Section 4 presents the necessary information and settings concerning the experiments. Section 5 is devoted to the evaluation and experimental results. Finally, in Section 6, conclusions and future research directions are provided.

2 RELATED WORKS

For research purposes, data custodians need to release a version of data in a way that individuals cannot be re-identified. Statistical and multi-level databases are among the other approaches for addressing these kinds of needs. Despite the assumption made in [1], statistical disclosure control [8] is an active research area for addressing today's needs to provide accurate information while protecting the privacy of the various parties involved [9, 10]. On the other hand, anonymization techniques are between other solutions in this regard. For sharing the data records, microdata, in anonymization, we try to irreversibly alter the personal data until the re-identification of data subjects is no longer possible [11].

Anonymization methods provide a new class of acceptable solutions to this problem. Typically, anonymization techniques for structured data make use of generalization method. More specifically, such techniques modify or generalized the data records components in a way that a data record is hardly distinguishable from others. Some important related studies are k-anonymity [1], l-diversity [12], t-closeness [13], and LKC-privacy [2]. To date, k-anonymity remains the most widely known privacy model for anonymization during the past two decades. To thwart privacy threats, k-anonymity privacy model generalizes and suppresses data record components or features into equivalence groups so that any record is indistinguishable from at least k other data records [14, 2]. However, in this

method, when the dimensionality of data is high, most of the data must be generalized or suppressed for achieving k-anonymity; this negatively affects the utility of data and degrades it [2]. Other methods try to rectify the issue, for instance, by imposing limitations on the problem, such as the supposition of limited knowledge of the adversary about the patient. For example, in the LKC-privacy model, the adversary is supposed to have only the values for a part of the QID attributes of the victim's record, L attributes [2].

The proposed approach in this study described in Section 3 tries to provide a solution for the above problem, i.e., anonymization of structured data. The problem here is the same as the one described in the above research studies, while we formally define the problem in Section 3. The proposed approach of this study for the solution is completely different from that provided in the previous studies. This study investigates the application of cryptographic algorithms, which is distinguishing from previous works. The majority of previous studies consider performing machine learning over homomorphically-encrypted data [15-18], while in this paper we do not make such assumptions.

3 METHOD

In this section, we first define the anonymization problem and then propose a practical solution to this problem. Two main concerns for data anonymization is privacy preservation and data utility, discussed in the following subsection. There is often an inherent trade-off between these two metrics. At one extreme, all data can be released, for maximizing the utility, and as a result, violate the privacy entirely. On the other extreme, releasing no data can maximize privacy; however, there would be no data utility [14]. The proposed methodology in this section provides an approach for addressing this problem, which is based on cryptography for data anonymization.

3.1 Problem Definition

In the following two subsections we discuss the two criteria for this problem. We define the anonymization problem as guaranteeing the privacy while maximizing the utility of the data for the statistical and machine learning data analysis.

Privacy Preservation

This section explains the privacy threats for sharing the raw information through an example; there exist two types of privacy concerns, namely identity linkage and attribute linkage. Table 1 shows the raw patient data. The raw data does not have the identifier features but is still vulnerable to the violation of privacy. Education, sex, and age are quasi-identifying attributes [1]. Disorder is the sensitive feature that the adversary does not know about the victim patient and tries to infer it. Finally, there exists one class for every record in the dataset.

Based on the following assumptions about the adversary, there are two types of privacy concerns to address. As mentioned in Introduction, the adversary is assumed to have anonymous data for all the patients. Moreover, the adversary has parts of the victim patient's record, in its raw format; this information is part of or all the quasi-identifying attributes and is only for one patient. The extent

| ID | Quasi-identifier (QID) | | | Sensitive | Class |
	Education	Sex	Age	Disorder	
1	BSc	F	40	Depression	cat. #1
2	MSc	M	53	ADHD	cat. #1
3	HS-grad	F	40	Depression	cat. #2
4	PhD	F	31	Social Anxiety	cat. #1
5	MSc	M	31	Bipolar	cat. #2

Table 1 An example of raw data table.

of adversary's information about the victim patient is assumed differently in different studies. For instance, in [1] the author for k-anonymity model assumes that the adversary has all the values for quasi-identifying attributes, but in [2] in LKC-privacy model limits the adversary's information to only the values of L number of the quasi-identifying attributes. Finally, the adversary does not know about the sensitive information of the victim and is willing to infer it. Accordingly, hospitals face two common privacy concerns [2] described below:

- **Identity Disclosure:** If the record is highly specific, matching the records with the victim's information is simple, which lead to the inference of the patient's sensitive information. For instance, in Table 1, the raw data table, if the adversary knows that the victim's education and age are 'MSc' and '31', respectively, then s/he confidently identifies that record number 5 is the victim's and infers that the victim's disorder is 'Bipolar'.

- **Attribute Disclosure:** If with some quasi-identifying attributes, the sensitive value happens repeatedly, it makes the inference of the sensitive value easy, although the accurate data record of the victim is not identifiable. For instance, in Table 1, the raw data table, if the adversary knows that the victim's sex and age are 'F' and '40', respectively, then, s/he can match the victim's information to records number 1 and 3. However, since both sensitive values for record number 1 and 3 are the same, 'Depression', then, the adversary can infer with 100% confidence that the victim's disorder is 'Depression'.

Utility of Data

To make sure that the anonymization method is not degrading the utility of the data, a comparison of the utility of raw data with the anonymous data is essential. The classification performance is a valid criterion for making a comparison between the utility of data before and after anonymization. Since the main concern of this study is sharing the data for data mining purposes, the difference between the classification performance for the raw and anonymized data shows the excellence and efficiency of the algorithm.

Information gain [19] is another criterion that indicates how much a method may degrade or improve the data quality for every feature of the data individually. Information gain was first introduced for decision trees and is based on the information entropy [20]. Nevertheless, since it does not consider the correlation and combination of the attributes, it is not as reliable as the classification performance criterion.

3.2 The Anonymization Method

For the preservation of privacy, we seek a function to map each unique record of raw data to another unique record, different from the raw record and in the same feature space. The anonymized data records must be different enough to prevent identity and attribute attacks. The anonymized data must not allow the possibility for the adversary to map back to the raw data. Therefore, the utilized function for mapping the raw data must not be reversible, or in other words must be one-way, for those with whom the anonymized data will be shared.

Cryptography fulfills the privacy objectives by construction. Mapping a number to another unique number through one-way functions is the main purpose of cryptography. Therefore, by such intrinsic features of cryptographic algorithms, we can make sure of the preservation of privacy criterion without taking further actions. Since, after encryption, the values would be meaningless numbers for the adversary, and it is not possible for one without a key to map back to the raw data.

Due to the objective of this study for anonymization of the structured health data containing categorical and numerical features, encryption is entirely feasible. Since in both cases there are numbers, more precisely category numbers and numerical values, which are mapped to other numbers. The sensitive attribute is not an exception and is encrypted as well. Normalization of data is the second phase of anonymization. Normalization, in addition to the positive impact on learning, reinforces preserving the privacy as this is a hashing phase after encryption.

As described earlier the anonymization methods should fulfill two criteria, namely privacy preservation and data utility. Application of cryptographic algorithms guarantees the privacy preservation criterion by construction. However, we also need to make sure about the performance of this methodology in regard to the utility of data. In this study, we experimentally show that our proposed methodology for anonymization of structured data is also efficient regarding the data utility.

The utility of the data needs to be preserved and this is related to the correlation of attributes and labels in data samples and the algebraic distance of samples from each other. To ensure satisfying this criterion after encryption and normalization of the dataset, the utility of the data is compared before and after anonymization based on two measurements described previously in this section. If the results for raw and anonymized data are close, then in addition to the preservation of the privacy, there also would be a confidence about the utility of data. A loss to a limited extent in the utility of data is acceptable as there exists a trade-off between privacy and data utility in data anonymization [14].

4 EVALUATION SETUP

4.1 Dataset for Evaluation of the Methodology

Adult dataset [21] is the de facto benchmark for evaluation of anonymization models [2, 12, 22-27]. In this dataset, the samples belong to two different classes; the rates of the positive and negative classes are 76.07% and 23.93%. The total number of records is 48842 (train=32561, test=16281), and the train and test sets were separated when

shared. Each record has 14 attributes, including eight categorical and six numerical ones. Furthermore, the dataset contains missing values. This study considers all the attributes as QID, although it is possible to suppose part of them as QID, like in [2] which considers marital-status as sensitive and others as QID attributes.

4.2 Encryption Algorithms

For the evaluation of the proposed approach, four cryptographic algorithms, including two from symmetric and two from asymmetric encryption systems, are considered. The symmetric algorithms are Advanced Encryption Standard (AES) and Data Encryption Standard (DES); the input and output data and key size for each is 128 and 64 bits, respectively. The Asymmetric algorithms are RivestShamirAdleman (RSA) and ElGamal, which both are also homomorphic over multiplication. The key size for each is 2048 and 1024 bits, respectively. All the keys are generated randomly for every iteration of experiments, based on the toolbox.

4.3 Comparison with K-Anonymity

In order to evaluate the results of our methodology, a comparison between the results of the proposed and former methods of anonymization is necessary. K-anonymity is one of the most popular privacy models. In [28], the authors propose Mondrian for obtaining k-anonymity. This study considers this work for anonymizing the data based on the k-anonymity model for comparison with the proposed methodology. The corresponding parameters for these methods are k, set of QID, and the mode of the algorithm, which can be either relaxed or strict. In the experiments, k is set to 10 and QID are set to all the attributes, and the results for both relaxed and strict modes are provided.

4.4 Utility Measure

Two measures employed here for evaluation of data utility are information gain and classification performance. Information gain is based on information entropy and is being used to evaluate how well an attribute alone predicts the classes for samples in comparison to other attributes. In other words, every attribute is used to categorize samples, then the information entropy of the classes of the categorized samples are calculated. The lower the entropy of the samples' classes in each category of samples categorized based on that specific attribute, the higher the information gain of that attribute. The loss of information gain after anonymization can indicate the extent of deterioration of data. However, since this measure does not consider the combination of attributes, it is not as reliable as classification performance. For calculation of classification performance, we used the geometric mean of the ratios of correctly classified samples to the number of samples in that particular class. Geometric mean is the only correct average for normalized measurement [29].

5 EVALUATION RESULTS

To evaluate the efficiency of our proposed methodology, the Adult dataset [21] is sanonymized with the proposed methodology by this paper. Afterward, the information gain and classification performance for raw and anonymized data are calculated and recorded for comparison and evaluation. The closer the results of raw and anonymized

data the higher our confidence to the anonymization methodology regarding the preservation of data utility.

As mentioned earlier, after one level of encryption, we need to normalize the data in order to obtain the anonymized data. The normalization method used for our experiments is min-max normalization:

$$x_{new} = \frac{x - x_{min}}{x_{max} - x_{min}}, \qquad (1)$$

where x_{new} is the normalized value of x, the encrypted number, and x_{min} and x_{max} are respectively minimum and maximum values of the corresponding column in the matrix of encrypted numbers.

Furthermore, for more certainty, the experiments for every method iterates for ten times, and the average results are measured. In every, iteration the key for encryption algorithms are generated separately and randomly, to ensure the classification results are independent of the keys.

5.1 Information Gain

The encryption is particularly useful when the attribute is numerical since, concerning the learning results, encryption of the number of categories is similar to mapping each specific category number to another random number specific for that category; therefore, for such attributes, encryption is not a necessary process. However, in this study's experiments, we encrypted all the attributes and normalized the data afterward. Before and after anonymization by this methodology, the information gain of categorical attributes always remains the same, because of the characteristics of this measure, so there would be no points in reporting them here.

Table 2 presents the information gain of the numerical attributes of raw and anonymized datasets; the results are from the average for ten independent iterations. The results in this table show that our anonymization methodology does not reduce the information gain of the numerical attribute unless in attributes 1 and 13, albeit negligible. Considering the information gain, the proposed methodology preserves the utility of data to a considerable extent.

5.2 Classification Performance

In addition to the anonymization with the proposed methodology of this paper, for comparison, we also anonymized the Adult dataset with Mondrian multidimensional k-anonymity approach [28]. Then, the results of these methods, along with the raw dataset, are used for learning a classification function. The learning algorithm used in this research is the random forest algorithm [30]. The training and testing sets for the raw data and anonymized data based on our proposed methodology are the same as published in [21]. However, for Mondrian multidimensional k-anonymity approach for every iteration, we take 70% of randomly shuffled data as the training set and the remaining 30% as the testing set; splitting the train and test sets for learning and evaluation in this setting is conventional and valid, considering the studies in the field [31].

Table 3 exhibits the classification performance based on the geometric mean measure, i.e., geometric mean of the ratios of correctly classified samples to the number of samples in

DATASET	INFORMATION GAIN					
	Attribute 1	Attribute 3	Attribute 5	Attribute 11	Attribute 12	Attribute 13
Raw Data	0.09754	0	0.09328	0.11452	0.05072	0.05814
Anonymized Data (RSA Alg.)	0.096839	0	0.093379	0.118778	0.051108	0.057001
Anonymized Data (ElGamal Alg.)	0.097563	0	0.093507	0.118503	0.05157	0.056479
Anonymized Data (DES Alg.)	0.096581	0	0.093452	0.118688	0.051163	0.05713
Anonymized Data (AES Alg.)	0.096755	0	0.093434	0.118512	0.051061	0.057325

Table 2 Information Gain for numerical attributes of the Adult dataset [21] before and after anonymization.

that particular class, for raw and anonymized data obtained adopting several methods. All the results in Table 3 are the average of the results of ten independent iterations. The information gain table provided in this article is calculated using WEKA software [32]. The difference between the classification performance of anonymized data based on our methodology and the raw data is less than 3%; our proposed methodology, however, outperforms Mondrian multidimensional k-anonymity regarding classification performance for adult dataset as the results show that the geometric mean measure for our anonymization approach, in the worst case, is higher for at least 5%.

Dataset	Geometric Mean (%)
Raw Data	75.37
Anonymized Data (K-Anonymity Mondrian [21], Relaxed, K=10, QI = Attribute 1-14)	67.87
Anonymized Data (K-Anonymity Mondrian [21], Strict, K=10, QI = Attribute 1-14)	68.08
Anonymized Data (RSA Alg.)	73.30
Anonymized Data (ElGamal Alg.)	73.59
Anonymized Data (DES Alg.)	73.22
Anonymized Data (AES Alg.)	73.57

Table 3 Classification performance based on geometric mean for all methods for Adult dataset [21].

The results in Tables 2 and 3 show that our proposed methodology only deteriorates the data to a negligible extent depending on the application; this is justifiable as there exists a cost for preserving the privacy of individuals. A comparison between the classification results of the anonymized data obtained by our proposed methodology and Mondrian multidimensional k-anonymity approach, in Table 3, indicates that our methodology outperforms theirs as the prediction results, with the same learning algorithm, are more accurate. Moreover, the results suggest that maintaining the utility of data is not dependent on a specific cryptographic algorithm.

Comparisons of two data utility measures for raw and anonymized data show that this methodology preserves the relations of values in the data table to a considerable extent. Therefore, analyses dependent on the relations of the data attributes to each other, and the labels are feasible and supported, e.g., learning tasks through machine learning algorithms. Such analyses are not dependent on the exact values in raw data since the anonymization changes the range of values for each attribute. The anonymized data is a matrix of numbers, likewise to the raw data, and it can be used the same way as the raw data. Moreover, regarding the privacy concerns described in the Problem Definition Section, if one manages to change the values in the raw data

until the adversary cannot map it back to the original values, then the desired purpose is achieved. Using cryptographic algorithms for anonymization along with the fundamental property of these algorithms, i.e., mapping numbers by one-way injective functions, dismisses the described privacy concerns, in other words, matching data values from what the adversary has and what is published as anonymized data is not possible.

6 CONCLUSION

In this study, we investigated the approach of anonymizing the structured health data by utilizing cryptographic algorithms, which is, to the best of our knowledge, the first application of these algorithms in anonymization. Anonymization methods must fulfill two criteria, namely privacy preservation and data utility. We evaluated the presented methodology on the de facto benchmark dataset for anonymization. The results are promising and indicate that such an approach may be employed in real-world applications by the healthcare sector. However, similar to the majority of anonymization techniques, our proposed methodology impacts the quality of data mining results, even though we have shown that this degradation is less than the previous works in the data anonymization domain. This methodology is particularly practical for anonymizing the data for data mining applications. For future works, the applicability of this approach may be investigated for unstructured types of health data, e.g., physiological signals. Moreover, automatic de-identification of clinical notes and overcoming the particular challenges is another closely related research area that can be tied up with natural language processing [33, 34]. Further studies on the field mentioned above would be analogous to this study and worthwhile.

7 ACKNOWLEDGMENTS

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A Visual Analytics Dashboard to support iCBT Therapists

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Abstract

This research lifts Internet-based Cognitive Behavioural Therapy (iCBT) further by introducing visual analytics dashboard techniques to facilitate iCBT therapists in organising and carrying out their work in a potential more efficient way. Following a design science methodology we developed a web-app and dashboard that processes standardized mental health screening questionnaires and visualizes the result at both individual patient and group levels. The dashboard was evaluated through user testing and semi-structured interviews by two experts (one psychiatrist and one psychologist), who responded with great interest and enthusiasm, and gave suggestions for further development. Finally, scalability issues using HL7 FHIR are addressed.

Keywords

Mental Health, iCBT, Dashboard, Visual Analytics, Visualization, Decision Support, FHIR, Interoperability.

1 INTRODUCTION

Mental health disorders constitute the single largest source of health-related economic burden worldwide [1]. According to a recent Lancet Commission report, mental disorders are recognized as a continuously growing problem worldwide, and are expected to reach an US$16 trillion impact by 2030 [2]. The majority of these costs are indirect, such as social security and welfare, costs related to law and order, and loss of productivity. The minor direct costs relate to healthcare, medicine, and other therapies.

In 2018 an OECD report calculated the economic impact of mental illness to average more than 4% of GDP in the EU countries, with Norway placing 5th at 4,97% [3]. Furthermore, the WHO considers mental illness to be the leading cause of disability worldwide [4].

Cognitive Behavioural Therapy (CBT) is a well-documented therapy used to treat patients with a variety of mental disorders with good results [5]. CBT treats mental problems through challenging and actively changing dysfunctional emotions, behaviours, and thoughts, while promoting well-being. In a therapist-patient, one-to-one setting, the therapist's role is to assist the patient in finding and practicing effective strategies to address identified goals and decrease symptoms of the disorder. Despite CBT being acknowledged as a long-term cost-effective therapy when compared to the use of drugs, or in combination with drugs [6], it has been widely accepted over the last two decades that the healthcare system does not have the capacity to deal with the growing numbers in need for treatment through traditional CBT. This has been one of the main motivations for Internet-based Cognitive Behavioral Therapy (iCBT) [7], which makes CBT more accessible and efficient. Therapist guided iCBT has shown the same efficacy as regular CBT for some patient groups [8], while reducing the time required per patient for the therapist.

We propose that introducing visual analytics dashboards to guided iCBT is one area that has great potential for improving the cost-benefit ratio of CBT. Dashboards will provide the therapist with much needed visual decision support functionalities for dealing with individual patients, as well as supporting a better and more efficient organisation of their workflow.

2 BACKGROUND

2.1 Important variations in CBT and iCBT

iCBT can take the form of guided or unguided self-help programs [7] [9]. In guided iCBT, a therapist guides the patient through the treatment program using electronic asynchronous communication such as email or messages, typically through a patient portal. Systematic reviews of literature reporting on outcomes from the two types of iCBT conclude that unguided self-help, also referred to as "stand-alone" programs, are known to have poorer outcomes and higher dropout rates than guided programs [7] [9]. In another systematic review of iCBT for depression, it was found that the difference in the numbers completing iCBT was dependent on who provided the guidance, favouring therapists-guidance (72%) over administrative support (65,2%), although both had much better results than unguided iCBT (26%) [10].

Cost wise, unguided iCBT has the lowest cost per patient, while traditional face-to-face CBT is by far the most expensive therapy. With qualified psychologists and psychiatrists being a scarce resource and with traditional CBT having a high cost, iCBT and other Internet therapies will play an even more significant role in a future with a growing number of people suffering from mental disorders.

In recent meta-analyses on iCBT it is argued that unguided iCBT might be the most efficient way to scale up iCBT, also when looking at cost-effectiveness [11] [12]. We feel that there is an important aspect missing in these discussions. As guided iCBT is more effective, but more costly due to the involvement of a therapist – can we find innovative ways to improve and scale-up guided iCBT with respect to the quality of therapy, the adherence/dropout rate, and therapist capacity? These are important challenges that should be addressed in an attempt to improve guided iCBT and make it more cost-effective.

2.2 Looking at eMeistring for improving iCBT

eMeistring is a guided iCBT program addressing panic disorder, depression, and social anxiety through different modules, that has been in successful routine clinical use in Bergen since 2013 [13]. The program has shown the same outcome as regular CBT for some patient groups, while reducing the time required per patient for the therapist. Therapists working with eMeistring can help 10-12 patients per day, while therapists providing traditional face-to-face CBT had 3-4 consultations per day [14]. Due to its proven success, eMeistring is now in regular use in other regions of Norway as well.

Brainstorming ways to improve eMeistring, together with a psychiatrist with long experience as a therapist using the platform, revealed a weakness that could be improved. eMeistring does not provide therapists with an overview of their patient's current status, nor their activities and progress over time. This is in part due to eMeistring being built on a platform that relies on data being stored in pdf-forms, a data format that is not well suiting to handing and analysing patient data. This is a data representation that is basically an electronic paper format, with all the limitations of having data stored as typed letters and numbers on pieces of paper. If a therapist wants to see a patient's progress over time, this requires opening a corresponding *set of .pdf files* and processing the content on their own. A better data representation would open for new possibilities in making more efficient and better quality use of the data for the therapists. Some of these challenges are also described by Folker et al. [15] in their analysis of iCBT treatments in Europe. Looking for a suitable data representation also has to comply with general requirements of interoperability standards for health data [16].

2.3 Visual Analytics Dashboard functionalities in iCBT, can it make a difference?

The nature of the asynchronous patient-therapist communication in iCBT opens up for new therapist workflow options. Visual analytics dashboard techniques have the potential to enable therapists to choose their workflow based on decision support made available through suitable and well-presented information, as opposed to having a strictly synchronous workflow. Determining workflow based on prioritization, rather than a predetermined sequence, has successfully been applied in other medical domains [17]. In CBT, therapists use a range of qualitative and quantitative data to provide guidance for their patients. In this paper, we limit ourselves to quantitative numerical data (e.g., sleep duration) and standardized mental health screening questionnaires that provide an overview of the patient's mental health at any given time. An eMeistring patient produces over 20 filled-in questionnaires during the course of treatment. Thus, as each therapist has multiple patients (generally 15-20), the amount of data available for each therapist is too large to make optimal use of in its current raw format.

Better presentations of the data can improve therapist workflow by removing the need to manually consider each data point. Providing automatic processing of complex data sets can further optimize therapist performance. By being given an overview of a patient's state through the available data, the therapist can tailor the treatment towards each single patient. Therapists will also be better equipped to prioritize within their group of patients. Combined, this can lead to both higher efficiency and efficacy of guided iCBT.

Data visualization and Clinical Decision Support (CDS) tools can contribute to providing insight both within the context of a single patient, and for a group of patients. Therapists can more easily identify trends in the data for a single patient, which can provide opportunities to customize the treatment to the patient. For a group of patients, a fast overview based on the visualised data can provide faster help for those in special need, as well as freeing more of the therapist's time for patients needing it the most. This resembles the medical technique of triage, where treatment providers assign each patient degrees of urgency depending on their need for care [18], although on a different time scale. A better overview of a group of patients with summary or status variables presented to express the need of each individual patient might also contribute to help the therapist organize her workday in a better way.

2.4 Dashboards and Visual Analytics

Thomas and Cook [19] define visual analytics as the science of analytical reasoning supported by interactive visual interfaces. While visual analytics includes visualization, it also considers the disciplines of decision-making, human factors, and data analysis [20].

By leveraging multiple disciplines, visual analytics aims to reduce the effect of information overload, and achieve higher utilization of large data sets. Procedures to automatically process data can be implemented, and when further automatic analysis are intractable, the result can be integrated with visualization and interaction techniques [20]. The techniques of visual analytics can be combined with dashboard techniques to create tools for continuous data processing and visualization. Such techniques have proven valuable within other health domains. Dashboard applications can be categorised into administrative or clinical dashboards. Common places to see clinical dashboards in healthcare are within Intensive Care Units. Clinical dashboards contribute to increasing efficiency, quality, safety, and clinician satisfaction in some situations [21]. In this paper we address the development of a clinical dashboard for iCBT.

2.5 Fast Healthcare Interoperability Resources

The HL7 FHIR standard [22] provides a common data format for health data. This is achieved by dividing data into logical resources where each resource represents a concept. The intention of the standard is to provide interoperability between health IT systems. For dashboards gathering data from various external sources, this is important. The clinical dashboard developed in this research makes extensive use of the FHIR Questionnaire, QuestionnaireResponse, and Observation resources.

3 METHOD AND DESIGN

In a Masters thesis by the first author, a design science approach was used to design and develop a clinical dashboard [23] as a web-app comprising two primary views: Master View and Detail View. The purpose of the dashboard is to display the overview and status of both a single patient (Detail View) and a group of patients (Master

View). The web-app uses FHIR to interface to the data source, and as such has the potential to support a wide range of iCBT treatments.

To our knowledge, and supported by extensive searches of the scientific literature databases Google Scholar and MEDLINE, this is the first implementation of a clinical dashboard within the domain of mental healthcare.

3.1 Master View

The Master View, see figure 1, is the landing page of the web-app. In this view, a therapist is presented with an overview of her group of patients. The view is designed to comply with Shneiderman's mantra [24], giving first an overview with possibilities to filter, and then details on demand. Status variables are presented to describe each patient. For particularly urgent patients, a warning string is presented. Each patient will have a progression string and numerical urgency score (if the data is present), with optional flags and warning strings.
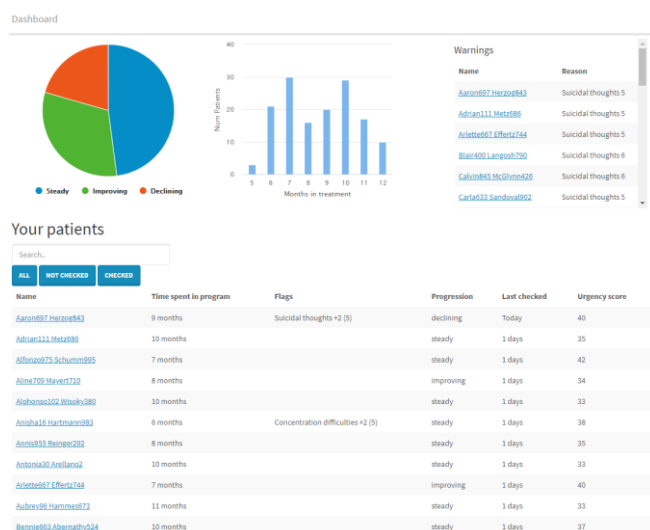
Figure 1 Master View

3.2 Detail View

The visualizations available in the Detail View, see figure 2, are dependent on the data available from the resource server. All QuestionnaireResponse and Observation resources for the patient are pulled from the FHIR server. QuestionnaireResponse resources are, by default, visualised as a line chart over the sum of its answers. The therapist can then select which of the available Observation resources should be shown. The Observation resources are visualised as regular line charts.
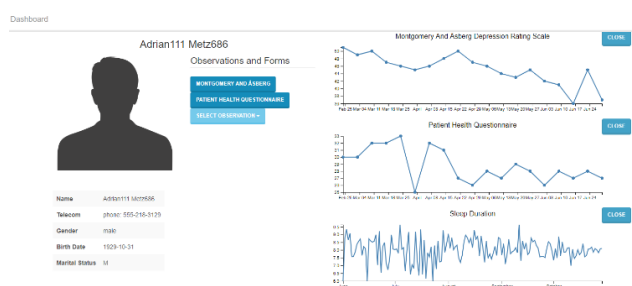

Figure 2 Detail View

Visualization of the QuestionnaireResponse resources requires a multidimensional approach. The method used in the artefact is an interactive combination of a spider chart and a line chart, as shown in figure 3.

3.3 Psychometric screening data as time series

There is a wide range of unique questionnaires suitable for iCBT. Based on the questionnaires used in eMeistring, we determined the following patterns applied to all questionnaires:

- Each question has a numerical answer, or an ordinal answer that can be converted to a numerical value.
- The number of answer choices is the same for all questions in the questionnaire.
- The set of answers can be aggregated to an overall result by, for example, summarizing all the answers in the questionnaire. This aggregated result can be compared to threshold values in order to determine a diagnosis.

By utilizing these patterns, series of questionnaires over time for a patient can be represented as an unevenly spaced multidimensional time series, as shown in table 1. We have not seen these patterns for psychometric screening questionnaires mentioned elsewhere. The basis for determining these patterns was the MADRS questionnaires used in eMeistring.

	t_0	t_1	t_2	t_3
1. Reported sadness	4	6	4	4
2. Inner tension	4	2	4	6
3. Reduced sleep	5	2	3	4
4. Reduced Appetite	4	2	2	0
5. Concentration difficulties	2	5	2	0
6. Lassitude	4	2	3	4
7. Inability to feel	1	2	4	2
8. Pessimistic thought	4	0	3	4
9. Suicidal thoughts	0	2	3	0

Table 1 Multidimensional time series example for the MADRS questionnaire

3.4 Visualizing multidimensional time series

With the goal of visualizing data from the format shown in table 1, we built a custom visualization, shown in figure 3. As a high degree of customizability was required, we chose the D3.js library for this task. A spider chart was chosen to represent a set of answers at one point in time. As the dimensionality of the intended data is mid-range, spider charts are a suitable option for visualizing the questionnaire data. For mid-range, we consider roughly between four and 20 dimensions. Three dimensions or less could be visualised in a line or bar chart. More than 20 dimensions requires more complex techniques.

The spider chart comprises two traces, one representing the most recent QuestionnaireResponse and the other representing an earlier QuestionnaireResponse selected by the user. Using the data representation in table 1, the blue trace represents column t_{n-1} where n is the number of data points. Similarly, the orange trace represents any column in t_0 to t_{n-2}. Two traces were chosen to easier display changes in patient state, where blue being lower than orange indicates improvement along an axis.
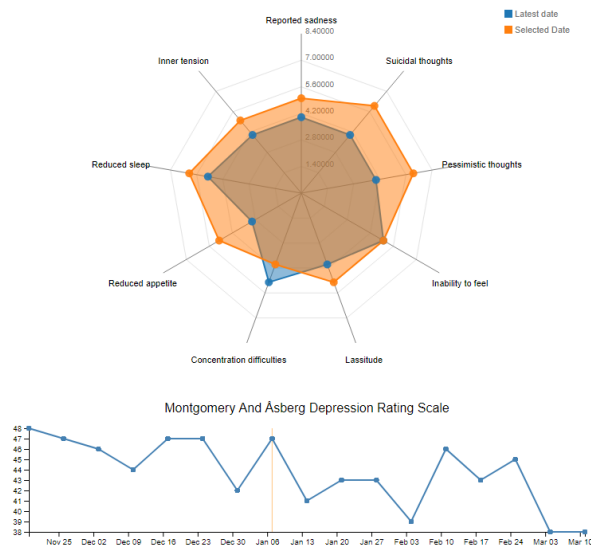
Figure 3 Interactive Spider Chart

When the therapist hovers over this line chart, the orange trace of the spider chart updates to the date closest to the cursor. The orange vertical line in figure 3 represents the selected date. This approach allows the therapist to quickly compare patient progress along each axis in the spider chart. Furthermore, each axis can be clicked on to display a line chart over the time series in the selected category (see under spider chart in figure 3), enabling the therapist to customize which visualizations to display for each patient. The visualization in figure 3 is designed for any series of QuestionnaireResponse resources, given the constraints previously described and at least two data points.

3.5 Calculating status variables

By using the FHIR format and the constraints described in section 3.3, we processed all QuestionnaireResponses for each patient in order to calculate their status variables. The status variables are displayed in the Master View. The algorithms used to process the resources (i.e., the QuestionnaireResponses) are isolated in the artefact through a strategy pattern and are subjected to simple interfaces. Due to this, it will be easy to replace/tune the logic for calculating the variables and tailor the artefact to any specific treatment.

4 IMPLEMENTATION

4.1 System Architecture

The architecture of the web-app is based on the Model View Controller (MVC) pattern [25]. The FHIR server, see figure 4, is an implementation of the HAPI JPA server [26]. This server is replaceable by any resource server implementation conforming to FHIR version DSTU3.
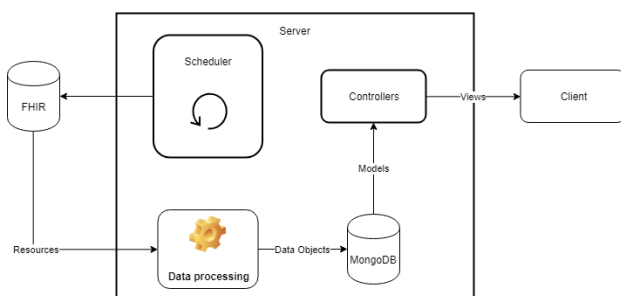
Figure 4 Architecture model

Due to the performance considerations discussed in section 4.2, interactions with the FHIR server run in a scheduled background process on the server. The scheduled update process runs independently of user interactions. When the client requests a view, the data is already available. This enables the artefact to scale well with respect to the amount of therapists using the application. A drawback with this approach can be that the data is not freshly updated when displayed.

4.2 Scalability

Throughout the development process, as more features were added, performance problems became more apparent. The main performance bottleneck was identified as the interaction with the FHIR server, where retrieving the resources for one patient could take multiple seconds. To mitigate this issue, we separated the logic for processing the bulk of the resources from the logic called on requests. The process handling the resources could then be scheduled to run at fixed intervals, resulting in pre-calculated data being available for the views.

5 EVALUATION

The evaluation of the web-app with dashboard is threefold. We performed a usability inspection and evaluated the dashboard against the clinical dashboard guidelines presented by Khairat et. al. [21]. Here we found our dashboard fulfilled eight of the ten guidelines. Then, we performed a user test of the dashboard and carried out semi-structured interviews with two experts in psychiatry and psychology. The psychiatrist was the same psychiatrist that participated in the initial phase of this project, and the psychologist is a colleague who is a CBT expert. Lastly, we measured empirical performance for the runtime of several of the procedures in the web-app.

5.1 User evaluation

The user test and interviews were structured as follows:

- A short presentation with a brief explanation of the dashboard features.
- A think aloud procedure was used while the expert tested dashboard (audio was transcribed and analysed).
- After testing the dashboard, the expert participated in a semi-structured interview (audio was transcribed and analysed).

Overall, the two experts expressed positive opinions about the dashboard functionality, and many of the implemented features (e.g. progression variables, warnings and spider charts) were found to be very useful, some of which they had never experienced before (e.g. interactive spider charts). In addition, the experts could see many new opportunities and suggested several new features (e.g. patient reported events and options for manipulating the line charts displayed for each patient). Furthermore, potential benefits of the displayed functionality were highlighted. These benefits are discussed in section 6.2.

5.2 Scalability measurements for evaluating system performance

In order to gain a detailed overview of how the web-app scales with respect to the number of data points, C# methods in the web-app were timed during the update. The empirical measurements show that interaction with the

resource server is responsible for most of the latency. The experiment was run twice with the same resources to observe the effect of resource server paging. For the experiment, the HAPI JPA reference implementation cloned in November 2018 was used. For the experiment, we used 147 generated patients with their corresponding data, giving in total approximately 22 thousand resources.

	μ time	σ time	μ RC	σ RC
Observations	0.90s	2.48s	95.4	163.3
Questionnaire Responses	0.34s	0.1s	52.4	23.9
Questionnaires	0.41s	0.04s	2.0	0.0
Total patient	3.05s	3.21s	149.8	166.7

Table 2 Single patient measurements, RC = resource count

The total runtime across all patients was 541 seconds, or about nine minutes. In the second experiment, with server paging of 10 resources enabled, we observed an increased runtime of about 56%. Table 2 shows measured time required to fetch a set of resources for one patient. There are multiple ways to mitigate this latency. We described one method for achieving this in section 4.2. As the scalability of HL7 FHIR was not the main concern of this paper, the results here only display that scalability problems can occur when using the HAPI JPA implementation. The reason for these problems and more robust solutions for handling large amounts of FHIR resources are topics for further research.

6 DISCUSSION AND FINDINGS

This research has followed a design science methodology [28]. Consequently, the findings are presented as contributions to the knowledge base of health informatics and to the domain of iCBT.

6.1 Contributions to the knowledge base

The main findings (see [23] for more detail):

- Psychometric screening questionnaires over time, can be represented as a multidimensional time series.
- The multidimensional time series from the questionnaires can be visualised through a novel interactive version of spider charts, for an arbitrary number of questionnaires per patient.
- Status variables can be calculated from a series of questionnaires to determine a patient's state and progression.
- The HAPI JPA reference server of HL7 FHIR STU3 does not scale well with respect to the number of requested resources.

6.2 Contributions to the domain

The development of the web-app and dashboard was motivated by a challenge to design and implement new functionality that can have the potential to make guided iCBT more cost-effective. Expert evaluation identified the novel functionality of the artefact as useful for both current iCBT, as well as potentially regular CBT. The main findings are:

- Status variables for a group of patients were identified to be useful for gaining an overview of a group of patients in iCBT.

- Visualizing quantitative measurements for patients enables therapists to faster gain an overview of their patients, their progress, and current status.
- Various additional tools for comparing patient sub-groups could be beneficial.

7 CONCLUSION

Through a design science methodology we designed, implemented, and evaluated a web-app and dashboard developed to address and improve relevant problems regarding a therapist's overview of patient data in iCBT [23]. Specifically, the web-app takes standardized mental health screening questionnaires and presents these as a numerical time series. We have introduced and proposed novel methods for providing therapists with overviews of both single patients and of groups of patients.

We identified patterns commonly occurring in psychometric screening questionnaires and used these to represent the data as time series, a novel approach we have not seen elsewhere. Similarly, the visual representation we built based on this representation, in the form of an interactive spider chart, is also a novel approach in iCBT. Both the representation of the data (described in 3.3) and the visualization (described in 3.4) are linked with the clinical domain. We visualize the most important information available for current clinical use in iCBT. The data representation also enables the use of other approaches of data analytics. Furthermore, we identified scalability problems with the HAPI JPA server reference implementation of the HL7 FHIR standard.

As this research was carried out in the scope of a Masters thesis, we were limited in both time and resources to do a more solid evaluation study that included more therapists We consider this to be a weakness of this study.

Research on iCBT is still in its infancy. iCBT has, however, already proven to be a game-changer within a field in desperate need of solutions to address the global epidemic of mental diseases. We believe that optimizing iCBT with respect to the quality and cost-effectiveness of the provided therapy will be among the future targets of the field – and that further research on the design and use of dashboards within guided iCBT will play an important role. Although we cannot yet make any strong empirical claims, this research represents some optimism.

7.1 Further work

The results from all components of our evaluation have provided valuable input towards a re-design and re-implementation of this artefact. Comments and suggestions made by the expert evaluators will be considered, and we will look at better ways to implement the HL7 FHIR standard with respect to performance and scalability. We feel that following established standards for health data interoperability is of uttermost importance to secure the development of sustainable eHealth applications.

The current version of the artefact uses simulated patient data. For the development of the next version, we will work on getting access to an anonymised set of real patient data, Furthermore, an expert evaluation of the algorithm that converts the questionnaires to multi-dimensional time series is needed.

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9 ACKNOWLEDGEMENTS

K-CUSUM: Cluster Detection Mechanism in EDMON

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Abstract

The main goal of the EDMON (Electronic Disease Monitoring Network) project is to detect the spread of contagious diseases at the earliest possible moment, and potentially before people know that they have been infected. The results shall be visualized on real-time maps as well as presented in digital communication. In this paper, a hybrid of K-nearness Neighbor (KNN) and cumulative sum (CUSUM), known as K-CUSUM, were explored and implemented with a prototype approach. The KNN algorithm, which was implemented in the K-CUSUM, recorded 99.52% accuracy when it was tested with simulated dataset containing geolocation coordinates among other features and SckitLearn KNN algorithm achieved an accuracy of 93.81% when it was tested with the same dataset. After injection of spikes of known outbreaks in the simulated data, the CUSUM module was totally specific and sensitive by correctly identifying all outbreaks and non-outbreak clusters. Suitable methods for obtaining a balance point of anonymizing geolocation attributes towards obscuring the privacy and confidentiality of diabetes subjects' trajectories while maintaining the data requirements for public good, in terms of disease surveillance, remains a challenge.

Keywords

Disease Surveillance, KNN, CUSUM, Clustering, Diabetes

1 INTRODUCTION

Electronic Disease Monitoring Network (EDMON) is an ongoing research project in symptoms surveillance at the University of Tromsø - The Arctic University of Norway. One of the main aims of the EDMON project is to detect infectious disease outbreak as early as the incubation stage of infection[1] through detecting infection incidences in people with type 1 diabetes and clustering them based on time and geographical region. The project uses self-recorded health related data from people with type-1 diabetes as input[1]. The project was initiated in response to recent challenges associated with existing disease surveillance systems.

The evolution of disease surveillance started with traditional disease surveillance systems which usually depend on laboratory confirmed results to detect disease outbreak [2]. This results in significant time lag between infection time and the time of detection of infection through laboratory confirmation [2]. The traditional surveillance system was hence improved to syndromic surveillance systems [2], which greatly relied on visible signs and synthons with data sources from emergency department records [3], school absenteeism, work absenteeism, disease reporting systems and over-the-counter medication sales[1, 4]. But delays have been observed between infection time and up to the visible sign and synthons stage[1, 4]. These types of disease surveillance systems do not detect the disease outbreak early enough and their data sources excludes the incubation phase of the infection[1, 4]. They mostly detect disease outbreak after the infected person is at the illness or after terminal stage, thereby increasing the disease burden such as infection rates (IR) and case fatality rates (CFR) [5, 6].

But through the electronic management of diabetes, big data is being generated as a "by-product" which can be processed to detect disease outbreak at an earlier stage in time. Diabetes Mellitus (DM) is related with the lack of insulin secretion (Type 1 Diabetes) or action (Type 2

Diabetes) [7, 8] but it can be treated and its effect mitigated through diet, physical activity, medication, regular screening and treatment for complications [7, 8]. People with diabetes often experience high Blood Glucose (BG) levels during disease infection incidents [7, 8]. EDMON is therefore exploring the idea of type-1 diabetes persons, exhibiting elevated BGs in the midst of other influential factors, for public good in terms of infectious disease surveillance. In EDMON framework, if infected individuals of Type-1 diabetes incidences are detected, which appropriate algorithms would be used in detecting aberrations for disease outbreak detections? What privacy, security and other requirement would be considered? The aim of this study was therefore to address these general questions through an exploratory and prototype implementations of cluster detection mechanism in EDMON. Specific objectives include developing a spatial classifier with a classification error margin of 1% and implementing a temporal method with 1% error margin of sensitivity, and specificity. The timeliness and methods to deal with privacy and location estimation challenges while generating visualization alarm and alert of outbreaks would also be explored.

2 LITERATURE REVIEW

In EDMON, if a person with Type-1 diabetes gets infected with a disease, the infected person is detected through the elevation of their BGs parameters at various points in time and geo-locations. Such infected incidences would be scattered across the surveillance area. Partitioning the surveillance area into manageable cells such as postcodes, and observing excesses of the infection incidences over time and space would reveal outbreak clusters [1, 4]. Clustering methods in disease outbreak detection helps in the identification of environmental factors and spreading patterns linked with certain diseases [9]. Furthermore, the spread of some viruses have been realized among clusters of people through hands resulting in person-to-person transmission [10]. In view of these, cluster detection

methods were explored to be used in the disease outbreak detection part of EDMON.

A systematic review was conducted [11], to explore potential methods, evaluation techniques, visualization methods and other dimensions. The systematic review revealed various algorithms that could be used to achieve the spatiotemporal objective of EDMON [11]. Space Time Permutation Scan Statistics (STPSS), CUSUM, K Nearest Neighbor (KNN), K means clustering, WSARE, DBSCAN and Space Scan Statistics (SSS)[11] were some of the algorithms identified. STPSS and CUSUM were found to be the most used algorithms. From the review, STPSS could have been adopted in EDMON-Cluster since STPSS does not require population at risk data to draw the expected baseline value. STPSS dwells on the detected cases to determine the expected count [5]. This approach provides significant trend of baseline data while avoiding inclusion of historical data that is irrelevant to the current period. However, the STPSS algorithm is only efficient on outbreaks that start locally [5]. This suggests that STPSS is not suitable for detecting disease outbreaks which occur simultaneously in the entire surveillance area. STPSS is only efficient on disease outbreaks with higher rate of early symptoms [5]. According to Chen et al. [12],who studied into "Spatial and temporal aberration detection methods for disease outbreaks in syndromic surveillance systems"; spatial scan methods only detect clusters in simple regular shapes such as cylindrical, circular or spherical. The spatial scan algorithms do not also consider prior knowledge such as the impact of the infection rate or size or shape of the outbreak and it is computationally expensive as local cluster search require searching over a large geographical region. Khanita D. et al in their conclusion after evaluating their proposed study on "Symptom-based Data Pre-processing for the Detection of Disease Outbreak", with time series and K-KNN algorithm [13], indicated the potential for KNN algorithms as an efficient method for syndromic surveillance and suggested for further assessment of the algorithm. Nearest Neighbor and CUSUM were also statistically demonstrated to illustrate their feasibility of monitoring nearest neighbor statistics [14]. When there is an aberration in the surveillance area, the CUSUM can spot this with the mean distances of emerging diseases of various points in the surveillance area [14, 15]. Martin Kulldorff also support this opinion by emphasizing that "efficient disease surveillance will need the parallel use of different methods, each with their own strengths and weaknesses"[5]. Syndromic surveillance system is optimally effective when both spatial and temporal cluster detection methods work in unison to track emerging infectious diseases at an early stage over the surveillance area [12, 15]. Therefore, the combination of KNN and CUSUM was explored in this prototype study.

3 MATERIALS AND METHOD

The main task of this project was to develop an effective spatio-temporal cluster detection method in EDMON system. Synthetic data was simulated for about 12 months period containing 297 diabetes persons with normal period, non-outbreak period, and also certain known detected cases

of infections, outbreak period, both in spatial and temporal aspects. First, each individual person was classified into post code area using k-nearness neighbour algorithms. Then each classified clusters were further analyzed into temporal dimension using the cumulative summation (CUSUM) algorithm. The combination of the spatial algorithm (nearness neighbor) and temporal algorithm (CUSUM) formed the spatio-temporal method [16], hereinafter referred to as K-CUSUM. De-identification and one-way hashing technique were adopted for preserving privacy of the subjects involved in the study. A prototype and system development life cycle approach were adopted for the implementation of the system. The output was displayed on maps with indications of the level of aberrations from the baseline mean. Classifiication accuracy, sensitivity, specificity and timeliness of the algorithms were determined. Privacy preserving technique and other performances measures were also evaluated. Generally, the paper is organized as follows; section 3 presents materials and method, section 4 present results, and section 5 discusses principal findings.

3.1 Materials

Simulated dataset was used to test and evaluate the detection performance of the developed cluster detection algorithm. The simulated data was introduced by mimicking the spatial and temporal variables which could be associated with diabetes persons when they check and update their blood glucose dynamics with a mobile application system. The simulated dataset incorporates health status monitoring of 297 number of people with diabetes for a period of 12 months, with each having an average of 3 records of infection status of morning, afternoon and evening and totaling 968, geographical location information within 21 post code centroids for the region under surveillance. The dataset was split and 70% (660) of the data was used as a reference to classify the rest of the 30% (209) unclassified data. The centroid of the postal code was defined in terms of coordinate features of Latitude (Lat) and Longitude (Lon) in Decimal Degree (DD) units as shown in Table 1.

Each synthetic subject in the study was also simulated to contain the location coordinates, date stamp of where and when the infection incidences occurred in the form of Lat, Lon and their respective date and time. The simulated subject's data also had the infection status (1,0 or -1 as infected, not infected and suspicious respectively) and some personal identifiable features such as names and IDs. For each day, in every hour, the algorithm was to check for new dataset, classify and detect aberrations. What distinguished unclassified simulated dataset from the classified dataset was that the unclassified data set was not categorized into their various geolocations of postcode however, their actual classes were known for evaluation purpose. Each subject with a detection ID (DID), location features of Lat and Lon and temporal feature of time-stamp was classified into their respective response vectors of post codes (Code) area using the KNN algorithm. The classified dataset was also used as a training dataset for the KNN algorithm during classification of new observables in the unclassified dataset.

Lat (DD)	Lon (DD)	Code	CID
69.55799	19.33103	9027	1
69.57781	18.55499	9106	2
69.627957	18.915001	9006	3
69.63077	19.04736	9020	4
69.63702	17.981	9110	5
69.640574	18.927288	9007	6
69.64225	18.90889	9013	7
69.65079	18.95493	9008	8
69.251024	18.54714	9272	9

Table 1 Simulated Centroid of post codes of study area

The data was manually generated by first, creating estimated decimal degree coordinates (DDC) of centroids of postcode areas using google GPS coordinate lookup system[17]. The DDC were then varied randomly to create artificial locations for the fictitious data subjects. The random variation of the DDC could overlap to other post code areas which might introduce some errors. Therefore, carefulness was being taken not to introduce large degree of variations of the DDC.

3.2 System development tools used

The system implementation relied on various programming and messaging tools including Python 3.6, Leaflet.js 4.2, visual Studio Code 1.3.3 and Twilio SMS Python QuickStart. Python was used as a programming and data manipulation language. The leaflet.js was used to display the map for visualization alarm and alert of the surveillance system and the Twillio API was used to generate SMS alerts. Visual Studio Code was used as a source code editor for the python.

3.3 Methods

Partitioning the region of interest into different small equal cells[18] and assigning the diabetes subjects to the respective cells in which the diabetes status variables were captured could have been used in the study. Additionally, the diabetes persons could manually record the post code addresses during capturing of their diabetes statuses. However, patitioning the surveillance region is deemed expansive manually recording of the post code addresses would be an extra burdon and inconvinincing to the diabetes subjects[18].

The KNN was used as classification algorithm to classify infected persons into various postcodes areas. A dynamic odd value of the number of data points which are more close to the data point to be classified, (K), was determined after computing the Euclidean distances between the unclassified data point and the referenced or classified data point as shown in eqn (1) and eqn(2). CUSUM was also used in this study as a temporal algorithm to detect aberrations with baseline and observable occurrences using the z-score.

$$d_{x,y}^2 = (x_1 - y_1)^2 + (x_2 - y_2)^2 \quad .. \text{ eqn (1)}$$

$$d_{x,y} = \sqrt{(x_1 - y_1)^2 + (x_2 - y_2)^2} \quad .. \text{ eqn(2)}$$

The formula used to express CUSUM is as follows;

$$CuSum_t = \sum_1^t e_t \quad .. \text{ eqn(3)}$$

The e in eqn(3) represents the observed number of events minus the reference value (the baseline), while the t represents the time associated. Conventionally, the CUSUM value is initialized to zero[19]. A positive result indicates a change above expectation, zero outcome signifies a period when the observed number of events are the same as the expected number while a negative value of the result indicates that events have fallen below expected levels[19, 20]. Early Aberration Reporting Systems in CUSUM (EARS) are C1-MILD(C1), C2-MEDIUM(C2) and C3-ULTRA(C3) [20-21]. The C1 method depends on a conventional alarm level of Cl=2[22]. This means in the C1 algorithm, the current detected value is greater than the baseline means with an addition of three standard deviations (Z score) which has been calculated based on the past 7days of historical data [22]. The baseline of most syndromic surveillance systems depends on 3 to 5 years long historical data [20,23]. But developments in biological attacks in the United State and higher case fatality rates, consisted the need to develop efficient syndromic surveillance systems which are independent on baselines with long term historical data[20,23]. In a study which compared aberration detection methods with simulated data [23], the aberration detection algorithms with short term duration baseline data (C1, C2 and C3) were as effective as the methods requiring long term historical data in terms of specificity, sensitivity and timeliness [23]. C1, C2 and C3 algorithms have also been developed to accommodate daily and seasonal variations. Their mean and standard deviations were based on a week's (7 days) information which were computed in the same season [24]. To this end, the baseline in this study was chosen to be 7 days of past detected infections of diabetes persons in K-CUSUM.

The classification accuracy of the KNN was computed by determining the proportion of the correctly classified test sets. The performance of the developed CUSUM was evaluated using a confusion metric to asses the sensitivity (Se) and specificity (Sp) while the detection time was determined by considering average time used in the surveilance structure [24].

4 RESULTS

### 4.1 Framework and design considerations

The proposed framework for the detection of clusters based on a spatio-temporal detection algorithm is given in Figure 1. The framework was developed after a thorough assessment of the state-of-the art cluster detection system found in the literature [11]. Accordingly, the framework incorporates various units; Input data, Pre-processing, Clustering and Aberration detection, Visualization, Alarm and Alerts. The system accepts input data containing different features such as geocodes, infection status, date and time stamp. The input data then goes through cleaning and data conversion into the appropriate data format such as xml and comma separated values (csv). The suitable clustering algorithms are then applied yielding outputs such as alarms and alerts, maps and other visualization output as shown in figure 4.0.

The pictorial view of the clustering mechanism as shown in Figure 2 basically accept input from the unclassified data. KNN algorithm was then applied on the unclassified data to cluster it into the near centroid of postcodes.
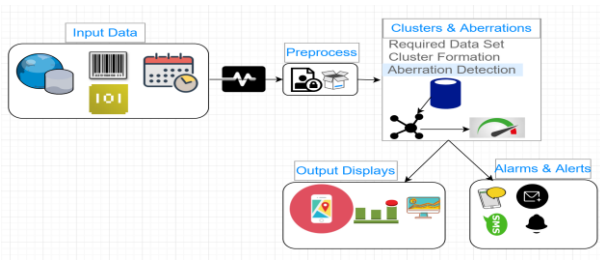
Figure 1 Layout of Framework

Eventually, the classified dataset was grouped and displayed on the map based on the centroid post code. Excess of observations per post code was then determined using the CUSUM algorithm.
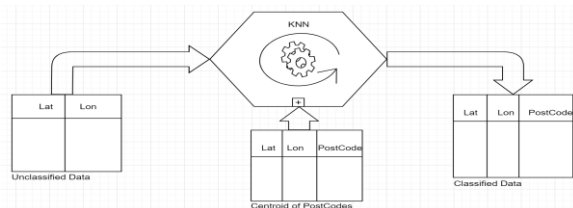
Figure 2 Clustering mechanism

4.2 Classification

Three modules were involved in the clustering of the infected individuals around the centroids of each postcode area. These include the K of KNN, computation of the Euclidian distance and the determination of the class based on the K factor. The K factor was determined by calculating the odd integer value of the square root of the total number of the classified data[25-26]. The Euclidean distance of each unclassified infected individuals was computed by using their respective geolocation coordinates (Lat, Lon), to each of the coordinates of the infected classified persons' location. The Euclidean distances were obtained, and these distances were sorted in ascending order as shown in Figure 3 and 4.. So, the first K number of the shorter distances were obtained as shown in figure 3 and 4. In an instance, K was determined to be 15, so the first 15 shorter distances were obtained as shown in Figure 4 and 5.


Figure 3 Sorted K Nearest Distances

Figure 4 Sorted IDs of K Nearest data points

After the selection of the K number of data points which were closer to various classified data points, the K data points further 'voted' or were categorized and tagged to various postcodes or classes based on their proximity to the centroid coordinates of the simulated postcodes as shown in Figures 5 and 6. The final counts of votes or tagged K number of data point distances to each postcode area, were declared and the post code with the higher number of K data points was declared as shown in figure 5 . In demonstrating with the synthetic data, 40% of the 15-total number of K were closer to the postcode, 9030 as shown in Figures 5 and

Figure 5 Voting results of infected individuals
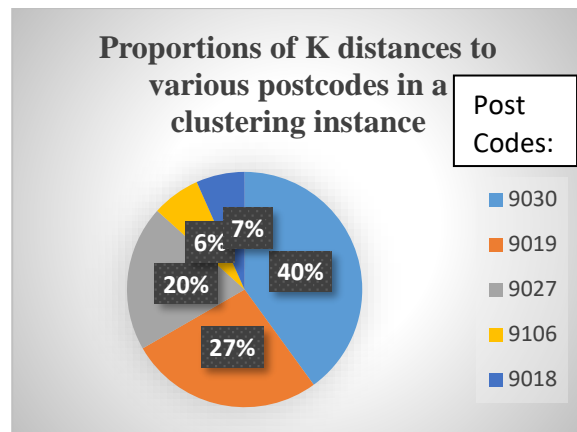
Figure 6 percentages of nearness of data point

4.3 CUSUM Aberration Detection

Having obtained infections data of 7 days baseline, 7 days observations, mean and standard deviation of the baseline per postcode area variables in the CUSUM calculation, a function was therefore developed as shown in Figure 7. From figure 7, if the observed count value was less than three times of the standard deviation plus the average cumulative value within the postcode area in the defined time frames, the cluster shows green to indicate no detections of aberrations as shown in figure 9. However, if the observed count value was more than three times of the standard deviation plus the baseline cumulative value within the postcode area in the defined time frames[22], the cluster showed red, to indicate detections of aberrations or outbreak of infected individuals as shown in figure 8 and 10. A cluster showed yellow if the observed count value was equal to three times of the standard deviation plus the baseline cumulative value within the postcode area in the defined time frames[22].

#function get color for aberrations

def Color_for_aberration_detection():

if observed_count < 3*(standDev)+(baseline_count):
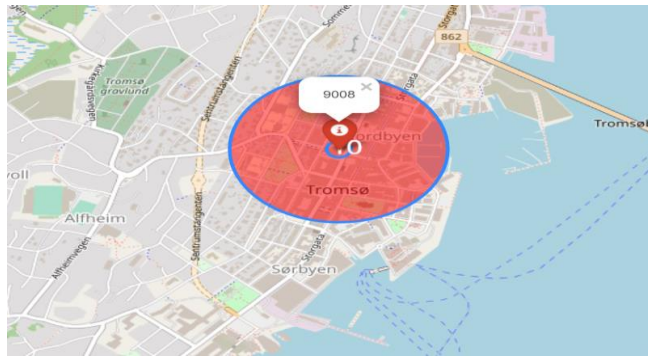
mycolor='green'

elif observed_count > 3*(standDev)+(baseline_count):

mycolor='red'
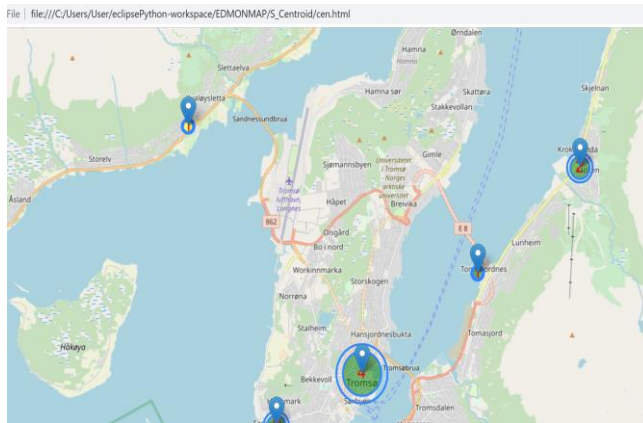
elif observed_count == 3*(standDev)+(baseline_count):

mycolor='yellow'

return mycolor

Figure 7 Aberration detection function

Figure 8 Outbreak cluster

Figure 9 Sample map presentation

Figure 10 Details of outbreak cluster

4.3 Assessment of KNN

The effectiveness of the KNN algorithm which was implemented in this study (K-KUSUM), was initially assessed with simulated infectious data containing location features with known targets or classes. The algorithm was trained with the entire dataset and was tested with the same dataset. All the features were correctly predicted to be the true classes. To overcome over fitting, under fitting and class imbalance issues, 660 training and 209 testing datasets of 70% : 30% were randomly simulated [28, 29] and evaluated with the algorithm. 99.52% of the test dataset was accurately classified. The same datasets were tested with Scikit Learn KNN algorithm which resulted in 93.81% classification accuracy.

4.4 Assessment of CUSUM

In the CUSUM evaluation in K-CUSUM, the baseline values of past one-week infections, were compared with the observed values of current one week while taking into consideration, the thresholding of the standard deviations of the baseline values

Figure 11: Observed and corresponding baseline

In the post code area of 9008 in figure 10, the observed count (counts_x)which was 10 infected individuals was indeed more than the average baseline value (counts_y) (1) in addition to three times the standard deviation (0) of the baseline. This indicates excess of infected individuals in the 9008-post code area which indicates a possible outbreak as shown in figure 4.3.3. Out of about 40 spikes of simulated infections which were injected, 13 of them which were spikes of outbreaks were all identified as outbreaks and the remaining 27 which were not outbreak were indeed determined by the CUSUM algorithm as either green or yellow clusters signifying no outbreaks.

5 DISCUSSION

A prototyping approach was used to explore, developed and assessed K-CUSUM with simulated synthetic data. The purpose was to determine the suitability of the hybrid of KNN and CUSUM algorithm towards empirical implementation of a cluster detection mechanism in electronic disease monitoring network (EDMON) project. The KNN was evaluated with 209 test datasets of which 208 records, representing 99.52% were correctly classified with simulated training set of 660. The CUSUM algorithm in this study was also able to accurately identify all spike injects of infected person's data as either outbreak clusters or non-outbreak clusters. The entire surveillance time was estimated to be 12.5 minutes with the input data.

The prototyping approach was highly useful in K-CUSUM since determining disease outbreak at the pre-symptomatic stage in EDMON is a novel area. As the certainty of the requirements for EDMON-Clustering at the unset was not clear, the iterative, try-and-error-approach of prototyping was ideal to systematically reveal the needed requirement out of the initial fuzzy and unclear visibility of the study.

The simulation of the synthetic data in K-CUSUM was quite useful since the algorithm needed to be tested and results evaluated with data to assess performance and robustness regarding erratic data requirements [29]. Apparently, actual data or semi-synthetic data could be used in the assessment however, there are regulatory hurdles and stringent privacy laws across the globe [30] protecting the sensitive healthcare data which cannot be toyed with. To succeed in implementing this prototype despite these challenges, synthetic data was an obvious choice since it served as a playground or surveillance range which can be manipulated in different ways to test the scalability and robustness of new algorithms without transgressing on privacy laws [31].

The KNN algorithm in the K-CUSUM demonstrated high accuracy by correctly classifying 99.52% of the tested dataset with error margin of 0.48%. A further test with another KNN algorithm in Scikit Learn with the same training and test dataset showed that the KNN in K-

CUSUM performed better as the Scikit-Learn KNN had 93.81% classification accuracy with higher margin of error of 6.19%. Disease surveillance systems which relies on geographical location of each detection point with the aim of aggregating the detections in smaller spatial units such as the zip codes for aberration detection, can easily rely on KNN with distance measures. In EDMON, the infection persons (unclassified or unknown classes) are geographically located on their respective latitude and longitude coordinates. If other detections of infectious persons have reference of post code in their geolocations, the Euclidean distances between the unclassified infected person and the referenced subjects with labeled post codes can be computed with their geocodes. What remains a hurdle is to locate a balance point of using geocodes of the surveillance subjects for detecting disease outbreak to safeguard the health of the entire community while maintaining privacy of the subjects. Much as one-way hashing and deleting anonymization techniques used from the recommended techniques of GDPR was effective in shielding sensitive data of the subjects, suitable methods for effective anonymization of location data remains a challenge since the geocodes in this experiment are required for computation of the Euclidean distances.

The CUSUM was also evaluated in this prototype by injecting spikes of simulated synthetic data. A total of 13 outbreak spikes of data which were injected were accurately identified by the CUSUM algorithms as outbreak with example shown in figure 4.3.3 and about 27 spikes which were injected as non-outbreak were all detected by the algorithm as either green or yellow non-outbreak clusters with an instance shown in figure 6.0.1. CUSUM is generally known to be very sensitive in the disease surveillance system. The current prototype results have further confirmed the effectiveness of CUSUM for aberration detection if adopted in EDMON. Therefore, the great performance of the hybrid of KNN and CUSUM is deemed ready for further assessment with empirical data for real implementation in EDMON.

The main output of the framework includes timely alerts through alarms and visualizations of detected aberrations. From the studies, various visualization tools for output displays such as bar charts, pie charts, graphs and maps have been realized. Guided with the results of the systematic review [11], ArcGIS, Leaflet-Open Source or Google Map tool was used to implement the visualization module such as what was used in Google flu trend visualization and Flu near you [32]. This visual display would mainly be mapped with other displays such as time series and graph. The maps would indicate where and when clustering and aberrations occur. Leaflet map was chosen for the prototype due to it being open source, less expensive and does not require license to use [33]. The short messaging service (SMS) was created with a trial version of an application development interface (API) known as Twilio [34]. The Twilio API was selected based on cost, ease and flexibility of use.

6 CONCLUSION AND FUTURE WORKS

K-CUSUM was explored in EDMON with prototyping method to cover the gap created by existing infectious disease surveillance system. This was a combination of KNN and CUSUM algorithm to form a spatiotemporal method. Each algorithm was assessed with simulated data.
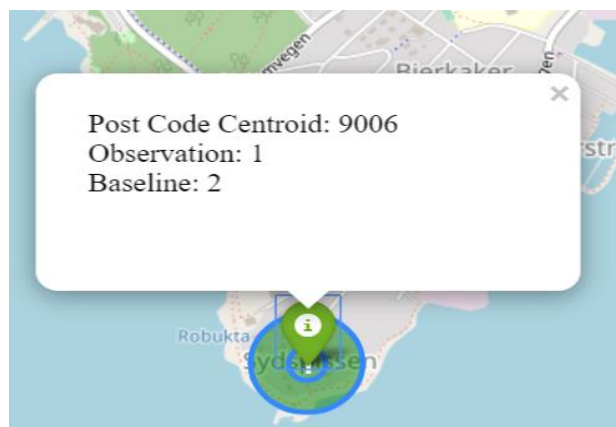
Figure 12 Non-Outbreak Cluster

The KNN registered 99.52% classification accuracy with less than 1% margin of error. The CUSUM algorithm was also able to correctly identify all outbreak and non-outbreak spikes of infection injects. Base on the results, the K-CUSUM can further be assessed with empirical data for adoption in EDMON as effective cluster detection mechanism. Suitable methods for obtaining a balance point of anonymizing geolocation attributes towards obscuring the privacy and confidentiality of diabetes subjects' trajectories while maintaining the data requirements for public good in terms of disease surveillance, remains a challenge. In future consideration, unsupervised learning methods can be explored for cluster detection in EDMON since gathering adequate training data can be challenging.

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Application of Patient Journey Methodology to Explore Needs for Digital Support
A Multiple Sclerosis Case Study

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Abstract

Multiple sclerosis (MS) is a chronic disease with a highly variable course, and patients face a large number of health professionals during treatment and follow-up. We introduce a methodology for detailed analysis and visualisation of patient journeys. The purpose was to gain insight into MS-patients' needs, experiences, and desires. A case study with three patients over a period of 4-6 weeks revealed how they interact with health professionals in managing their disease. We have identified several areas where digital tools may improve the patients' quality of life, and support health professionals in their follow-up and treatment of MS.

Keywords

Patient journey methodology, multiple sclerosis, patient needs, digital support.

1 INTRODUCTION

Many chronic disease patients experience highly variable disease courses where recurring symptoms or complications can severely affect function level, quality of life and/or relations with their loved ones. Still, they need to manage these day-to-day challenges largely on their own with only intermittent contacts with health professionals.

Multiple sclerosis (MS) is an example of a chronic disease with a very variable disease course. People with diagnosed, stable MS typically consult a neurologist on a yearly basis. These consultations focus primarily on the pathological changes and disease progression, and less on other symptoms and their practical implications. Thus, the patients must handle much of the smaller and larger everyday burdens of the disease on their own.

Digital support tools can be a valuable help for patients who need to navigate a complex and variable disease progression. These tools include eHealth (electronic/web-based health), mHealth (mobile/app-based solutions), and various electronic devices, which can all be active ingredients in order to reduce disease burden, promote self-management, and improve quality of life. However, for such solutions to be helpful, they must be designed based on the patients' needs and experiences and how this varies over time.

The current study therefore aimed to take the patients' perspective and gain insight into their situation and experiences, and how MS affects their lives. A method for mapping of actual patient journeys has been applied to three MS patients over a period of 4-6 weeks. The study also encompasses the health services and the health professionals' needs. Finally, we have identified areas where digital tools may support management, follow-up and treatment of MS patients, and discussed these from the perspective of both patients and health professionals.

2 BACKGROUND

2.1 MS and health service system

Multiple sclerosis is the most common non-traumatic neurological disorder affecting young adults and with high costs for the society [1]. The prevalence of the disease in Norway is 203/100.000 and among the highest world-wide [2]. Disease onset is mainly between 20 and 40 years of age, and women are more often affected than men. In MS the immune system is causing inflammation in the brain and spinal cord leading to lesions and secondary neurodegeneration. Inflammatory episodes are experienced by the patients as episodes of physical or cognitive disability with variable remission. The disease course is highly variable with large inter- and intra-individual variations. The cause of the disease is a combination of a genetic predisposition and most probably environmental factors such as infections, smoking, and lack of vitamin D among other unknown factors [3]. Typical symptoms include gait problems, other motor- and sensory problems, bladder- and bowel problems, fatigue, visual problems, and cognitive issues including reduced attention and memory. Thus, the majority may receive a disability pension of some degree, and many will be in need for practical assistance and different assistive devices. In recent years, several immune modulating treatments have become available aiming at reducing the risk of disease progression, but these treatments are usually most effective early in the disease course, and the long-term efficacy remains to be proven.

Patients with MS will be followed both by the family doctor, specialists in neurology and MS nurses (usually hospital based in Norway). Other specialists needed as well may be physiotherapists, occupational therapists, social workers, psychologists, neuropsychologists, nutritionists, and speech therapists. Many patients will also need short-term stays in rehabilitations units for help with more

complex problems, but most of the time they must manage their life with the disease on their own. As about half of the patients may experience some degree of cognitive problems, the coordination of the support may be a great challenge.

2.2 Existing practices and tools for patient self-management

The use of eHealth and mHealth solutions by persons with MS has been surveyed in a North American cohort in 2017. From 6423 participant responses, it was found that use of IT tools was common in the MS population in order to facilitate health related information, and several (46.2%) also used one or more MS-related apps [4]. A literature review from 2018 reveals an increased availability of new eHealth/mHealth solutions targeted for the MS population [5], and another review gives an account of mHealth apps suitable to support persons with MS [6]. Although the latter study included 30 unique apps, it was found that the apps in general failed to meet patient needs and demands. Still, a literature review revealed that tools for self-management improved quality of life in six out of seven studies, also with some evidence of improvement of depression and anxiety though more robust and further evaluation is needed [7]. In Norway, a self-help program called SPIRIT [8] is offered to support MS patients in managing their disease and the challenges they face. The first experiences in Norway seem positive, but it should be used in a larger extent and then be evaluated.

2.3 Patient pathways and patient journeys

Patient pathways (or clinical pathways, care pathways) have become a key concept when addressing challenges in providing coherent and sustainable healthcare services [9]. Although primarily associated with the clinical dimension, pathways transcend many dimensions like logistics, administration, patient rights, technology, and economy. In this paper we focus on the experience of individuals. For simplicity we use the term *patient journey* to distinguish the actual, individual patient encounters from the planned, normative pathway offered by the healthcare service system.

3 METHOD

3.1 Meetings and observations

We have had several meetings with health service representatives to a) establish an overview of actors and roles involved in diagnosing and follow-up of MS patients, b) reveal challenges and the potential for digital support in a subset of work processes, but also for patient self-management. We have participated in a full-day introductory course for patients at a specialized rehabilitation centre for people with MS, enabling observations and informal conversations with MS patients.

3.2 Mapping of patient pathways and journeys

Service design is an interdisciplinary and practice-based method which originates from the field of service marketing [10] and user-centred development [11]. Service design has a problem-solving approach and originated in the private and public service sector. Lately it has been adopted also in the health sector.

SINTEF has developed a modelling language for service processes and user journeys. The Customer Journey Modelling Language (CJML) can be used both for documentation and analysis purposes and is well suited for describing health service processes and patient journeys [12]. This approach makes a conceptual distinction between the planned, hypothetical journey and the actual journey experienced by a patient. Human experiences are only assigned to real patient journeys, supporting the ISO standard for user experience [13]. A web resource page about CJML and guidelines for use is available at www.sintef.no/cjml.

We conducted an in-depth study of three persons with MS over a period of 4-6 weeks using the method Customer Journey Analysis [14]. First, the target group and the service context are specified. Inclusion criteria were 1) persons who have lived with MS for more than five years and experience challenges, and 2) persons being full time or part time employed.

Patients were recruited through Oslo university hospital. A brief telephone interview was conducted to invite subjects to participate in the study and a physical interview. During the subsequent interview we made inquiries about family situation, work, digital habits, challenges related to MS, need for health services and actors involved, type of treatment and their experiences, and finally needs and suggestions concerning digital tools and support in managing their disease. The three informants were then given a structured diary to fill in. They were instructed to report on every event (contact points, suggestions, thoughts, experiences) relating to MS during the study. After the documentation period, a debriefing interview finalized the data collection with a detailed review of the diary and follow-up questions.

3.3 Ethical perspectives

A description of the planned study and handling of personal data was submitted to the Norwegian Centre for Research Data (NCR) for assessment. The study was found to satisfy the requirements of data protection legislation and was approved by NCR. Participation in the study was voluntary and based on written informed consent. To ensure full anonymity fictitious names have been used throughout, and one or more of the following variables have been manipulated: age, gender, occupation, and family situation. The informants' subjective experiences, however, are reproduced verbatim and authentically, i.e. in their own words.

4 RESULTS

Based on data collection from meetings with key actors in the MS health service we have identified and mapped typical patient pathways for diagnostics and treatment of MS. Next, we have analysed and modelled the actual patient journey of three persons with MS. Finally, we have gained insight in patient needs and derived the potential for digital support. Due to space limitations we only present one patient story and patient journey in section 4.1 to demonstrate the CJA method and the nature of the results. However, data from all the informants are included in the patient's point of view (section 4.2) and the subsequent sections.

4.1 Patient stories and patient journeys

Here we present Sara's situation and her experience with the MS health service. A full description of all the patient journeys can be found in [15].

Sara is 42 years old, married and has three children. She works full time as a medical doctor in a hospital. Sara was diagnosed with MS 15 years ago after experiencing numbness and paralysis in her legs. She sought medical help immediately, and the diagnosis was established in less than a week. It was a tough message to receive as a 27-year-old. Sara was breastfeeding a baby at the time and did not start treatment immediately. The paralysis in the legs gradually subsided by itself, and the disease was calm. After a few years she started with medical treatment in the form of infusions every 4th week at the outpatient clinic. This keeps her mostly free from relapses.

Sara has no visible signs of physical impairment and seems to be very little affected by the disease. Most of her work colleagues and acquaintances do not know she suffers from MS. However, Sara is often completely exhausted after work and experiences periods with fatigue regularly. She is very grateful that her husband takes care of the children's activities after school and during weekends. A few times a year Sara suffers from severe fatigue, making her unable to work for 2-4 weeks. She characterizes herself as a sedate person who enjoys relaxing on the couch with a good book. She thinks that it would have been much more difficult to cope with MS if she had been an active outdoors person.

Digital habits: Sara uses a smartphone, but she is not active in social media. She also uses PC at work and at home. The following health actors are involved in Sara's treatment: the general practitioner (GP, sporadically), the MS outpatient clinic (treatment every 4th week), the neurologist (yearly appointment including MR scans), a physiotherapist (sporadic for guidance with physical exercise). Sara's patient journey is shown in Figure 1, and we follow her through one immunotherapy infusion and the arrangement of the next one. She does not consult neither her GP nor neurologist during the study, thus their corresponding 'swim lanes' are empty.

4.2 From a patient's point of view

The patient journeys analysed were limited in time, but still reveals that the patients are in contact with several health service actors including the GP, a neurologist, a physiotherapist, the pharmacy, labour and welfare services, and human resources department at their employer. One of the informants says: "*You have to be strong to be sick! You must fix everything yourself. Nothing comes automatically.*" From the patient's point of view, a single point of contact or a personal contact who can assist with coordination of services would be helpful especially during periods when the disease is demanding. Digital tools enabling users to get an overview of the various appointments could improve the patient's experience of fragmented services.

Fatigue is common for persons with MS [16-17]. Sara struggles with fatigue regularly. In her opinion, fatigue always comes abruptly without any warning. However, she says: "*My husband complains that I respond too late on early signals of fatigue. But I am not sure these signals exist!*" More knowledge of what causes and possibly reduces the experience of fatigue would be important for MS patients to handle work and everyday life. Furthermore, identification of early signs of an upcoming period of fatigue would be important. If such knowledge exits, simple tools could be developed to help predict periods of fatigue, and thus possibly reduce the effects of fatigue or at least prepare for it. This would be helpful as 40% of persons with MS experience fatigue as the major problem of the disease [16].

Another patient mentions the challenge of handling depressions and periods of discouragement. She says, "*You do not call your neurologist when having a depression!*" She would like to have a low-threshold service enabling her to ask for help in coping with the mental side of the disease. "*I do not participate in courses about MS – it becomes too much focus on wheelchairs and hospital*" says another patient. They point out that they miss courses for persons who are mildly affected by MS. The neurologists point out the existing possibilities for mildly affected patients: there are different courses available and also relevant rehabilitation options. The national MS society facilitates networks and arrangements for various patient groups. These are important arenas for information and guidance, in addition to establishing informal groups and relations between persons sharing the same challenges. The health care professionals further point out that the patients are not necessarily aware of the options available in MS care, such as the actual content in courses for newly diagnosed or updated rehabilitation courses for mildly affected patients. Nevertheless, these mentioned possibilities are scarce and most often with waiting lists.

Another area mentioned is physical activity and exercise, which the patients in the study experience to be positive for their disease but must be adapted in periods with relapses and/or fatigue. Knowledge is growing on how exercise and activity affect quality of life in general, and how it affects symptoms and fatigue in particular. Some patients mention that they do not want exercise groups targeting persons with MS, although they would like to get in touch with peers facing the same challenges.

These experiences address MS patients' wish to manage their everyday and professional life and to reduce the burden of their disease.
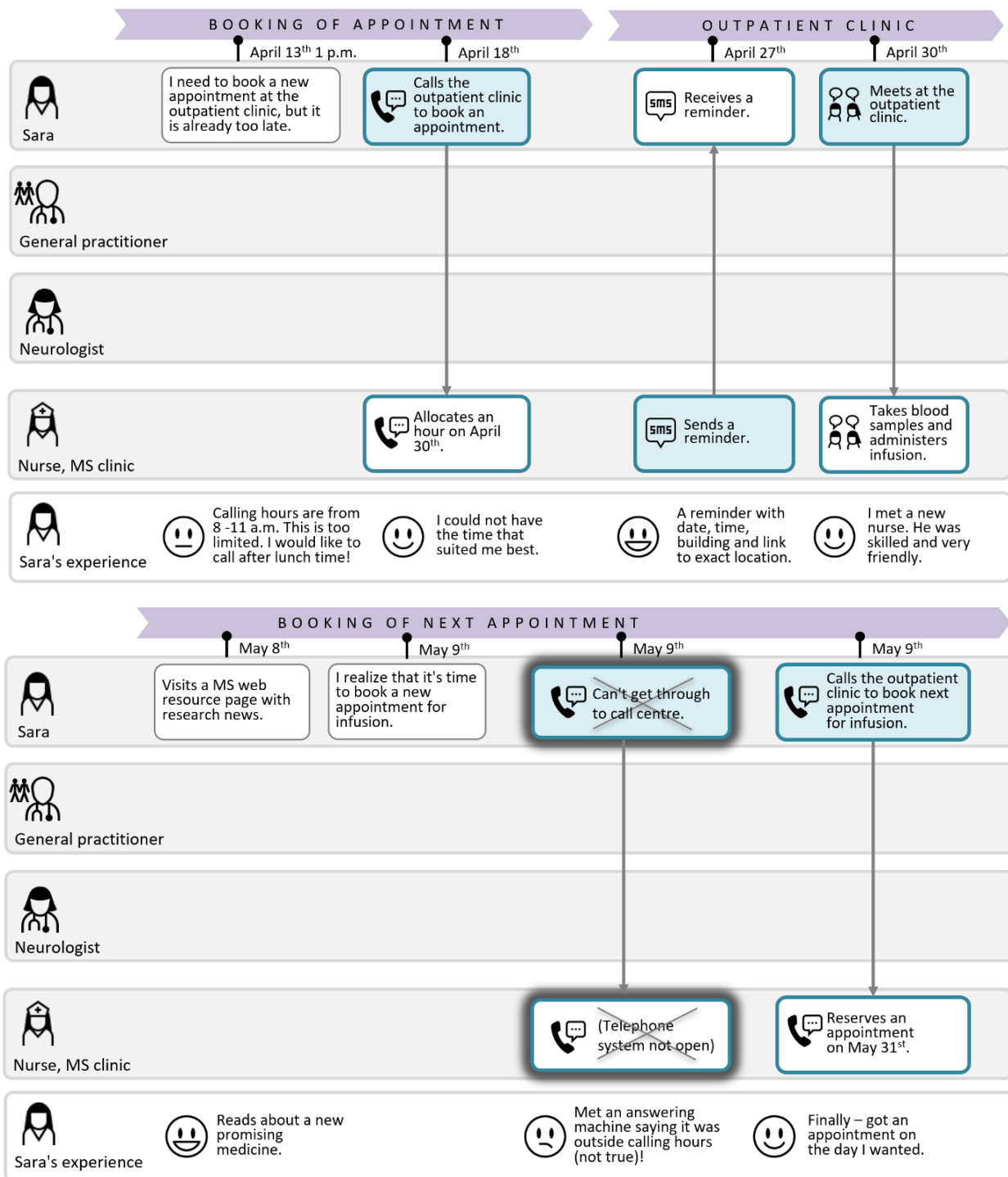
Figure 1 Sara's patient journey.

4.3 The health service and digital support

The study has mainly focused on the patients, their journeys and related experiences. Through the patient journey methodology, we have established insight into their needs and the potential for digital support. Further insight is achieved through meetings with health professionals and observations at a MS rehabilitation centre.

In the following areas, digital solutions can be developed and utilised to support MS patients and the healthcare professionals:

- Communication, interaction and cooperation between various health service actors and patients.

- Patient diaries for documenting treatment and patient experiences throughout their (fragmented) journey, for their own interest and to share with their therapists.
- Documentation of a) planned journeys to support a common understanding across various health service actors, and b) communicating examples of actual journeys experienced by patients.
- Facilitate the start and the end of a rehabilitation period – and related evaluation.
- Follow-up in collaboration with the patient and other prime stakeholders relevant in the patient journey.

Next, digital solutions can be utilised to get further insight in the following areas:

- Monitoring and follow-up of patients with symptom registration, to study impact of exercise and activity.
- Impact assessment of different follow-up and treatment schemes, including rehabilitation periods. Motivate and engage patients to follow up interventions and activity in a tailored manner.

5 DISCUSSION

While patients often find the medical treatment satisfactory, several studies indicate that the coordination among health actors are poor [18,19,20]. For MS patients, the family doctor does not know what the neurologist has done until the report is available and the opposite. There is no (or scarce) formal communication between the doctors and the other therapists, and the patient will often have the role as "the messenger" and "the service integrator" [21]. Thus, the patients wish for real-time communication systems between the different health care providers, and for the ability to themselves follow the communication and be updated. In addition, easy access to the different health care providers through a secure digital solution is a wish from the patients.

Digital support for the follow-up of medications, mental and physical training, and other rehabilitation interventions, may also be useful for the patients. Digital solutions for self-management for persons having MS may be helpful and improve quality of life. The study identifies a need for digital solutions to promote exercise, activity or other behavioural changes over time and to evaluate the effect/impact of exercise, activity, and other interventions. This can also be used to support their mental health. Next, the patients addressed the need for a diary to keep notes related to their treatments and their own experiences through their journey. Such a diary can also provide therapists with more information on the development of the disease and symptoms. The opportunity of digital support for appointments to remind the user and potentially for cooperation between various actors and to follow-up medication, was also highlighted.

This paper demonstrates a methodology to elicit insight into patients' challenges and a visual format for patient journeys using a modelling language. Comparing the three patients included in this study showed several shared challenges. The neurologists, as representatives of specialized health care professionals, found it particularly useful to gain insight in the patients' detailed experiences with the health service, which are typically not elicited through the regular, medical consultations.

The study has been conducted with a limited number of informants and for a restricted period of time, and the results are thus not representative neither for the health services in general, nor for MS patients in general. MS is a disease with highly variable disease course, thus a greater number of informants is needed to cover all aspects of the disease. However, the study has described a methodology that was suitable to reveal detailed patient journeys, and how individuals manage and experience a chronic disease, their needs and desires.

6 FUTURE WORK

Our premise is that digital tools may support persons with MS and the health actors involved in their treatment and follow-up. We suggest further investigations into the following areas:

- Establishment of a larger set of actual patient journeys across age groups and health regions to achieve more conclusive data on needs and preferences.
- Further development of the methodology to incorporate experiences from other informants, e.g. next-of-kin, supplementing the actual journeys with highly relevant and valuable perspectives.
- Digital support for structured diaries that incorporates perspectives and experiences from involved health professionals.
- Knowledge on how symptoms, for example fatigue, be measured, managed and possibly reduced.
- Digital support for increased physical exercise with inclusion of a "digital coach", and how it may affect fatigue and quality of life.
- Digital support for managing, and possibly prevention of, psychological challenges.
- Digital solutions to integrate and structure the scattered communication among all the health professionals and healthcare organizations involved in treatment of MS.

7 ACKNOWLEDGEMENT

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Developing a Digital Platform for Telerehabilitation of Patients Treated with External Fixation Device after Complex Tibia Fractures

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Abstract

In Denmark, more than 500 patients are treated yearly with external fixation device after complex tibia fracture and this affects the lives of patients and relatives physically, mentally and socially. The aim of this study was to develop a digital platform prototype for telerehabilitation of patients treated with external fixation device at Aalborg University Hospital based upon participatory design. In order to identify challenges for the patients and develop a prototype, an iterative process took place in collaboration with patients (n=8), relatives (n= 4) and healthcare professionals (n=6). The following data collection techniques were used: cultural probes, observation in patients' homes, qualitative interviews (n= 18) and workshops (n=3). The prototype was evaluated with focus on design, content and relevance. The users found that the prototype was easily manageable, and the content supported their needs in the rehabilitation context. The prototype has to be tested on a larger scale.

Keywords

Complex tibial fracture, external fixation device, participatory design, telerehabilitation, qualitative evaluation.

1 INTRODUCTION

The treatment of complex tibia fractures is challenging and requires specialized orthopedic surgery [1,2]. In Denmark 503 treatments with external fixation device (EFD) were registered in 2018 (Figure 1) [3]. Regardless of the treatment method, the complication rate is high [1,4], and the long-term outcome is often associated with a risk of knee pain, malalignment and persistent articular damage with an increased risk of post-traumatic osteoarthritis [1,2,5]. Operative treatment with EFD has significant benefits, including the fact that patients can put stress on the leg during the treatment period [1,4,6–8]. At the same time, it is possible to restore misalignment both during and after surgery, and gain easy access to observation of the skin, which may be necessary for larger skin lesions following trauma [4,6].
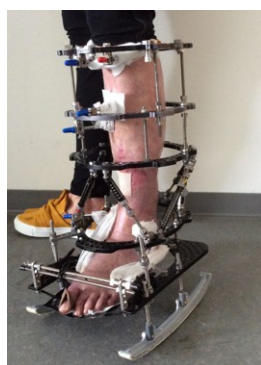
Figure 1 shows an image of EFD attached to the lower leg of one of the users in the study.

However, the treatment with EFD is long-lasting (8-87 weeks), complex and burdens both the healthcare system, patients and relatives [1,4,6–8]. In Denmark patients are continuously monitored at the outpatient clinic at the nearest hospital specializing in treatment with EFD.

A minimum of once a week the nurses in the municipality will have to do pin site care, and up to three times a week, the patients will go to specialized rehabilitation at the hospital [9]. In addition, the patients must also handle the activities that belong to sick leave, insurance, etc. Treatment with EFD is based on a highly specialized and evidence-based approach, and due to the long treatment period, the process must be coordinated across sectors. The patients account for a smaller group of the orthopedic surgical patients, which means that healthcare professionals (HP) outside the hospital specializing in EFD do not get much experience with patient care.

The most frequent complication of EFD treatment is superficial pin site infection. Studies report that up to 70% of patients will experience some degree of infection during treatment [10,11]. Several studies indicate that patients also experience a high level of mental and social stress, including anxiety, depression, and reduced quality of life, both during treatment and after removal of EFD [2,4,6–8,10,12,13]. Therefore, treatment requires a high degree of mental strength and ability to self-care in patients [1,7,12]. There is a need to systematize counseling and knowledge sharing across sectors to achieve quality, continuity and patient safety. This is why we want to develop a digital platform for telerehabilitation.

The aim of this study was to:

1. Identify challenges in a rehabilitation context for patients treated with EFD
2. To design a digital platform prototype for telerehabilitation of patients treated with EFD
3. To test and evaluate the digital platform prototype for telerehabilitation of patients treated with EFD

2 METHODS

The study was inspired by participatory design (PD), in which user are involved in the development and design of technological solutions in order to ensure usability and inclusion of relevant functionalities [14,18].

2.1 Setting and sample

The study was conducted in collaboration with the Department of Orthopedic Surgery, Aalborg University Hospital, specializing in EFD, and Home Nursing, Aalborg Municipality. HPs, patients and relatives were involved in the process and recruited through the Orthopedic Surgical Ambulatory and Orthopedic Surgical Ward, Department of Orthopedic Surgery, Aalborg UH.

2.2 Ethical considerations

We contacted the local Ethics Committee and the study did not have to be reported. An agreement on handling personal data was obtained. The study followed the Helsinki Declaration and all participants signed an informed consent.

2.3 Theoretical frame of reference

To develop the concept, we were inspired by Aaron Antonovsky's theory, Sense Of Coherence [15], because it can contribute perspectives on mental health and coping, which is an area where the patients are challenged [5,7,12,16]. In addition, theory of inter-organizational networks helped to provide perspectives on the organizational challenges that arise in patient care, where many parties are involved and tasks cross sectors, as is the case with EFD [17].

2.4 Phases in the study

The study was divided into three iterative phases:

1. Identifying needs
2. Idea generation
3. Design, test and evaluation

Phase 1: Identifying needs

The aim of this phase was to identify the user's needs. We conducted interviews with patients (n=8), relatives (n=4) and HPs (n=6) (Table 1), did observations in the home of the patients and used cultural probes. Criteria for selection of patients and relatives were: 1. Patients treated with EFD after complex tibia fracture in North Jutland, Denmark, 2. Patients must have EFD or had EFD removed maximum four weeks ago, 3. Patients have given consent that contact can be made by telephone in order to participate in the study. Criteria for the HPs were in-depth knowledge of the treatment with EFD. The interviews were conducted as respectively individual interviews and group interviews (e.g. patient and relative).

Baseline data for patients
P1 (M), age 36, Butcher
P2 (F), age 37, Flex job
P3 (F), age 56, Account assistant
P4 (F), age 38, Work at a farm
P5 (F), age 60, Early retirement
P6 (M), age 65, State pension
P7 (M), age 42, Biblical archaeologist
P8 (M), age 48, Window cleaner

Baseline data for relatives
R1 (M), Parent of P4
R2 (F), Parent of P4
R3 (F), Parent of P2
R4 (F), Wife of P8

Baseline data for HP
HP1 (M), Orthopaedic chief doctor, clinical lecturer
HP2 (M), Physiotherapist and PhD
HP3 (F), Nurse, Orthopaedic Ambulatory
HP4 (F), Nurse, Orthopaedic Surgical Ward
HP5 (F), Home Care Nurse specialized in wounds
HP6 (F), Home Care Nurse specialized in wounds

Baseline data for researchers
Researcher1 (F), KVT student, Nurse
Researcher2 (F), KVT student, Physiotherapist

Table 1 shows baseline data for the users and researchers.

An interview guide was developed based upon the following themes: context, challenges and collaboration across sectors. All interviews were recorded, transcribed and analyzed following the process described by Kvale [19] and using NVivo [20] in the following steps: coded into central themes, condensed into descriptive statements and in the end interpreted. In order to achieve inter subjectivity in data processing and analysis, we coded the interviews that we did not perform ourselves. During the coding, we noted definitions and thoughts on the codes used along the way to create transparency and to increase the reliability of data [19].

Phase 2: Idea generation

The aim of this phase was to gain mutual understanding and collaborate to create, reflect, and evaluate ideas for a digital solution that can meet these needs through workshops. Three workshops were held with the users and took place at Aalborg UH. The workshops lasted on average 2-3 hours, and tools like cards of inspiration, graphical scenario and future workshop were used for generating ideas [21].

Phase 3: Design, test and evaluation

The aim of this phase was to design and evaluate the digital platform prototype. The prototype was developed based on identification of needs and idea generation in Phase 1-2 and designed using interactive mockups in the prototype tool Justinmind Prototypes (25). The prototype was the first iteration of the platform and served primarily to contextualize the capabilities that a digital platform can provide. The platform was tested on five users in three steps, providing a first view of the prototype's functionality (content) and ease of use (design and structure). The approach was inspired by Jakob Nielsen's perspectives on development and design [22]. The three steps of evaluation were: 1. Orientation in platform, 2. Questionnaire designed as Likert scale and 3. Open questions.

3 FINDINGS

Physical, mental and social challenges and challenges related to collaboration and knowledge sharing across sectors were found and led to the development of a digital platform prototype, which was tested and evaluated.

3.1 Challenges in a rehabilitation context

The users in this study describes challenges related to physical, mental and social aspects in treatment with EFD and how these challenges affect each other (Table 2).

Physical challenges	P	HP
Limited in daily activities	X	X
Infection	X	X
Edema	X	X
Pain	X	X
Bad sleep	X	
Psychological challenges		
Stress	X	X
Depression and mood swings	X	X
Concern of complications	X	
Impotence	X	
Insecure and lack of control	X	
A lot of information/lack of overview	X	X
A lot of appointments and transport	X	X
Social challenges		
Social Isolation	X	X
Lack of community	X	X
Dependency on relative	X	X

Table 2 shows challenges described by users. P: Patients, HP: Health professionals. X indicates if the challenge was described by the patient (P) or HP.

Patients are temporarily physically limited and largely dependent on their relatives. In addition, there are mental challenges, where mood swings, feelings of impotence, lack of control over one's own life and concern about complications are periodically dominant. As a result of the physical and mental challenges, patients' social activities are affected with mental deficit and an experience of social isolation.

'There have also been days when I could barely manage it - especially remembering all the things I have to do'

The users also describe challenges regarding collaboration and knowledge sharing across sectors and HPs as listed in Table 3.

Challenges of collaboration and knowledge sharing across sectors	P	HP
Knowledge of treatment	X	X
Knowledge of training	X	
Knowledge of painkillers	X	
Knowledge of help supplies and clothes	X	X
Knowledge/experience in pin site care	X	
Sick leave/activities in the municipality	X	X
General knowledge sharing	X	

Table 3 shows challenges described by users.

Patients and relatives experience a lack of overview, knowledge and milestones in the process, which result in a feeling of lack of control over their own lives. All users point out that the knowledge that exists at Aalborg UH is not sufficient in the patients' local areas, including local hospitals, Home Nursing and the municipality, because the HPs in the municipalities do not continuously gain experience with patients with EFD.

'They [the Home Care nurses] seem insecure, and it [pin site care] seems to be a bigger task than they are used to'

3.2 The digital platform

The platform had two parts: one for the patient and relative, and one for the HPs that could provide various services for each part.

The overall features for the patients' user interface were:
- Overview of appointments
- Rehabilitation
- Pin site care
- Information
- Social forum
- Information for relatives

The overall features for the HPs user interface were:
- Pin site care
- Rehabilitation
- Information
- Access to the Electronic Health Record (EHR)

We integrated the possibility of video communication between the two parts in order to target the challenges of knowledge sharing across sectors and e.g. to support patients who do pin site care themselves. The platform is based on individualized treatments, so the HPs were able to set up the system according to the patients' individual needs by a management function.

Pin site care
We selected one focus area from the list of features to base the design upon and to serve as an example of the platform's function and design: Pin site care. The following features were designed to meet the needs of patients and HP's in relation to pin site care:

- Individual set-up of the patient (management function) regarding who, where and when pin site care is performed. This results in individual information being made available to the patient.
- Assessment of the pin sites and action instructions for the Home Care nurses (Figure 2) to share knowledge and ensure quality and patient safety in relation to pin site care.
- An overview for the patient with milestones (Figure 3) gives the patient and relatives opportunity to follow the development, e.g. in relation to the progress of pin site infections.
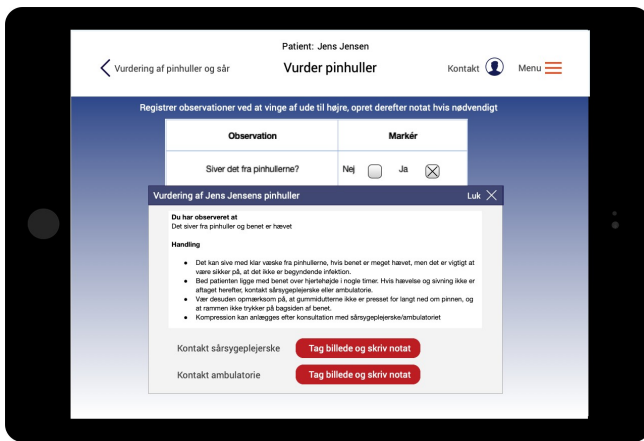
Figure 2 shows the feature "Pin site assessment", which is an action guide for the Home Care nurse (user interface for HPs).

Figure 3 shows "Pictures and notes" regarding progress in infection in a fictitious patient, which is used to display milestones for the patient (user interface for patients).

3.3 Test and evaluation
Figure 4 shows an overview of how the users evaluated the prototype.
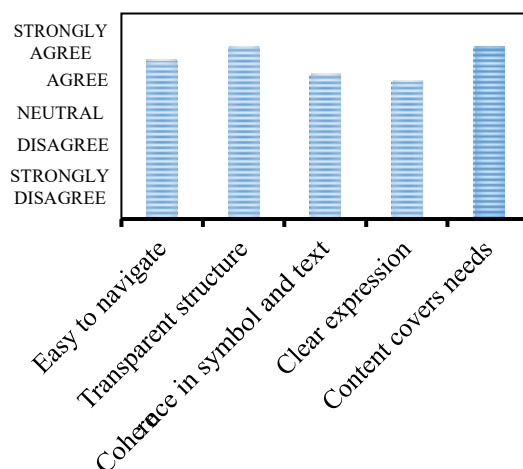
Figure 4 shows the average of user responses in the questions using Likert scale in evaluation of the platform.

The patients' evaluation was predominantly positive. As one of the patients stated:

'These are just the things we needed access to.'

At the same time, the HPs highlighted an immature prototype that will require many changes and tests by several users before a final version of the platform can be designed. Some of the improvements that were pointed out by the HPs were 1) The platform would require extra workflows for them 2) Risk of double documentation.

4   DISCUSSION
In this study, the challenges in a rehabilitation context for patients treated with EFD have been identified through a PD process: physical, mental and social challenges as well as challenges related to cross-sectoral collaboration. We designed, tested and evaluated a digital platform prototype for telerehabilitation. The users evaluated the platform in an overall positive way, but several adjustments remain necessary.

4.1 Challenges
The users in this study report on both physical, mental and social challenges, which affect each other and put a massive strain on periods of the treatment (Section 3.1, Table 2). Previous studies have shown that the patients experience a high level of mental and social stress [4,5,7,10,12,13] in which changes and unpredictability, together with reduced control of their own lives, dominate, and this has been found to contribute to symptoms of anxiety and depression [10]. Concern of complications, including pin site infection, is described by patients in this study. This is supported by Krappinger et al. (2013), who points out that fear of complications is mentally stressful for both patients and their relatives [7]. As the complication rate for fracture types where EFD is used as treatment is relatively high this fear is well-founded. Pin site infection is the most frequent complication in relation to treatment with EFD, in most cases, however, it will be a local problem and irrelevant to the clinical outcome [7,11]. To address the fear this information is important to communicate to both patients and relatives [11]. Modin et al. (2009) also report a degree of physical and mental impact 2 and 4 weeks postoperatively but conclude that physical limitations are minimized over time [12]. Bashera et al. (2014) finds that patients 10 years after surgery with EFD are satisfied with the treatment and that they would undergo the same treatment again if needed [4].

Modin et al. (2009) points out that some of the challenges experienced by patients and some of the causes associated with impaired patient compliance could be related to inadequate information and understanding of the treatment [12]. Findings in this study support this, and further adds that it is complicated by the fact that the knowledge at Aalborg UH does not find its way across sectors. Santy et al. (2009) emphasize that there is a need for the knowledge provided to be structured and located where it can be found when the need is there, while the information is accurate and easy to understand [23]. In addition, Modin et al. (2009) and Limb

et al. (2006), points out that psychological adjustment to treatment i.a. can be supported by setting milestones for the patients along the way, as this helps them to cope with the situation [5,12]. A need for clear milestones is also described by the patients in this study and integrated in the design of the digital platform prototype.

4.2 Design

Telerehabilitation has proven promising in achieving improvements in some of the areas where the patients with EFD are challenged: quality of life, anxiety and depression [24,25]. Personalization of Health Care is described as a key element in the development of new tele health solutions [26]. In this study, patients also express the need for individualized milestones, and a key feature of the platform was the HPs' management function, so that information for the patient appears tailored to the individual, e.g. regarding pin site care, training, etc.

We have not identified other studies in which telerehabilitation has been developed for patients with EFD, but similar telerehabilitation programs including digital platforms have been developed for patients after knee [27] and hip surgery [28]. Naeemabadi et al. (2019) designed and developed a sensor-based telerehabilitation program for knee patients as an alternative solution for conventional rehabilitation [27]. Jensen et al. (2018) investigated whether a telehealth solution (app) can assist hip patients in their recovery and found that patient information and education could be supported by the app [28]. Our prototype differs from the above-mentioned solutions because of a personalized holistic-oriented solution where both information, rehabilitation and pin site care for patient, relatives and HPs across sectors are a part of a shared digital platform.

4.3 Test and evaluation

The test and evaluation of the prototype showed a general satisfaction with the selected functionalities and the simple design. The patients and relatives were particularly pleased, but the evaluation also showed that the HPs expressed concerns about extra workflows and risk of double documentation. In developing and implementing technologies, it is essential that HPs see benefits before restrictions [26]. It is well known that technological developments are taking place at a faster pace than development of clinical workflows and their concern is important to take seriously as the technology in the end is only as good as its use in practice.

In conclusion, the digital platform prototype developed in this study has to be tested in several clinical test. If results from clinical tests show promising results, the system can be further developed and implemented. It will be important that the system is able to integrate with other IT systems in healthcare that the HPs are using in their daily work with patients.

5 LIMITATIONS

This study has several limitations. The study included a total of 18 users, eight of whom are patients, four are relatives and six are HPs. The number is not enough to generalize but can indicate whether there is a potential for change. Key elements of the findings are also supported by other studies

[1,2,12,23], but future research is required. The digital platform prototype has only been tested by five users and already after the first design iteration. The prototype needs to be further developed, tested and evaluated in more clinical trials.

6 ACKNOWLEDGEMENT

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Experts Perception of Patient-Reported Outcomes (PROs) in a Danish Context

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Abstract

This paper elucidates the understanding of Patient-Reported Outcomes (PROs) among experts in a Danish context. PROs are currently implemented on a regional and national level in Denmark (DK); even though, their purpose and functionality seem unclear.

Methodologically the study is based on seven semi-structured interviews with core PRO-experts.

PRO was identified as: data on an individual/population level; an active/passive functionality; contextual dependent; quality improvements; Value-Based Healthcare; patient-centred care; part of clinical practice; technology and as an economic tool.

An analysis of the discrepancies among PRO-experts reveals that their perceptions are associated with their experiences and/or organizational positions.

Keywords

Patient-reported outcome, PRO, PROM, HRQoL, PRO-experts.

1 INTRODUCTION

In 2015, PRO was for the first time part of the annual economic agreement between the Ministry of Finance, The Local Government Denmark and Danish Regions (1). Thus, this document marks the introduction of Patient-Reported Outcomes (PROs) on a national level within the Danish healthcare sector. Formerly, PROs have been developed on a regional level and as bottom-up projects, initiated by enthusiastic healthcare professionals. Therefore, PROs background and integration into the Danish healthcare system is influenced and shaped by different stakeholders. Hence, it is interesting to elicit how PRO is perceived among experts who have worked with PRO in different ways and on different organisational levels. Especially, considering that the current perception of PRO among these experts likely indicate the direction of the future PRO-development may take within the Danish healthcare sector.

A common understanding of PRO originates from the American Food and Drug Administrations (FDA) coining (2009): 'Any report of the status of patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' (2). A broad interpretation as 'any report' allows several different interpretations and applications of PRO. However, the Danish expert group who authored 'Program PRO' (2016), agreed on a more specific definition of PRO: 'Data concerning the patient's health condition such as physical and mental health, symptoms, health-related quality of life and functional ability reported directly by the patients themselves' (3). Thus, PRO was no longer merely 'any report', but a specific type of data. A focal point in the majority of PRO-definitions is that the answers come directly from the patient, as this feature is what makes PRO-data so valuable in current healthcare.

Since PRO in Denmark has evolved bottom-up as well as top-down, potential conceptual discrepancies are

important to elicit; potentially, ensuring correct and meaningful application of PROs in the future. Therefore, the following research question is examined in this study:

RQ: What perspectives on PRO can be identified among Danish PRO-experts, located at a regional and national level?

Moreover, the results presented in this paper is an initial step regarding the creation of a theoretical PRO-framework, which is done, firstly, to develop a more accurate nomenclature and a common PRO-language in a Danish context and, secondly, to contribute to current research and literature concerning PROs theoretical foundation. An endeavour inspired by Joanna Greenhalgh's encouragement to apply a theory-driven approach when applying PRO in clinical practice (4). Hence, a stronger theoretical understanding of PRO in a Danish context might improve the application, implementation and evaluation of PRO in practice.

2 METHOD

The unit of analysis for this study comprises of seven semi-structured interviews with core Danish PRO-experts. Data was collected, by the first author, between the 23rd of October 2018 and the 30th of January 2019.

The informants have been included due to their engagement in and influence on PRO activities in Denmark. Thus, the informants operate on a national or a regional level; have clinical and/or political experience with PRO and work as either developer, implementer, coordinator and/or theoretical contributor. Hence, they arguably have a thorough practical understanding of PRO.

The identification and sampling of experts are based on two sources. Firstly, a broader PRO-engagement in a Danish

context is quite recent meaning that the amount of relevant PRO-literature produced in DK is limited. Thus, reading of the most pertinent reports and articles regarding PRO in DK and identification of experts was relatively manageable. Secondly, through fieldwork, e.g. participation in national workshops concerning the development of new PRO-questionnaires and as part of regular meetings among implementers on a regional level, further knowledge regarding PRO-stakeholders and experts was acquired. Hence, the fieldwork enabled informal meetings with several of the experts, which may have paved the way for the interviews included in this article. Therefore, inclusion and identification of informants were based on knowledge stemming from literature and fieldwork pertaining to PRO.

Work experience	Informant						
	A	B	C	D	E	F	G
National level	x	x				x	
Regional level			x	x	X		x
Clinical experience		x		x	X		
Political level	x	x	x			x	
Developer	x			x			
Implementer				x	x		X
Coordinator	x		x		x		X
Theoretical input		x		x		x	

Table 1 Main characteristics and experiences of the informants.

All informants have given informed consent and allowed citation by name. However, due to ethical considerations aligned with recommendations made by Kvale and Brinkmann (2015)(5), the informants' identities are kept anonymous. This is done as PRO is embedded in a political context, where they are key actors, which means that their statements might have personal consequences.

Interviews conducted were qualitative and semi-structured, which allowed for a nuanced understanding of each informant's perception of PRO. An approach which was chosen, since it provides room for flexibility, openness and exploration during an interview (6). Moreover, as the informants were considered experts and it was their perspective on PRO, which was the subject field, the interview design had to be flexible to ensure that the initial interview guide did not exclude valuable understandings and reflections regarding PRO.

All interviews have been transcribed and thematically analysed based on acknowledged guidelines and recommendations made by Braun and Clarke (2006)(7). Hence, interview data were analysed through an inductive thematic analysis, meaning that informants understanding of PRO in this article is based on patterns elicited in the empirical data. However, since knowledge obtained during an interview is socially constructed, and as findings in the interview data are based on interpretations, the social context and the preunderstanding of the main author are important factors. Factors, which were taking into consideration during the interviews through the application of a flexible interview design; subsequently, ensuring that the informants', and not the interviewers, perceptions were prioritized during the conversations.

All the interviews were conducted in Danish, and quotes have been translated. In this process, interpretations prioritize the original meaning of a statement above exact verbatim reproduction.

3 RESULTS

3.1 Population PRO and Individual PRO

When explaining what PRO is and how it is used, some of the informants refers to individual PROs and population PROs. Used on a population level PROs are accumulated data designed for scientific purposes, while applied on an individual level, PROs are targeted clinical practice and patient-provider consultations (informant C and D). A dichotomy explained by informant C: '…PRO as part of the individual process, where one, e.g. selects or complete some questionnaires, which then are used in collaboration with the physician, e.g. during a consultation to figure out, how is it going? What works for you? What does not work for you? Which kind of experiences you had lately regarding effects or side-effects etc., used as a dialogue tool and on the other side of the continuum is where one collects and accumulate PRO-data as part of quality development' (informant C). Hence, the functionality and purpose of individual PROs and population PROs are different. Furthermore, informant D points out that individual PROs integration into clinical practice obliges healthcare professionals to use them. An accentuation he makes as PRO in clinical practice stands in contrast to how aggregated PRO-data and similar data, obtained through questionnaires, formerly has been used, or rather, not used by clinicians (informant D).

3.2 Active PRO and Passive PRO

The group of 29 experts who authored 'Program PRO' (3), also looked into the PRO-terminology. As a result, the conceptions 'active PRO' and 'passive PRO' emerged (informant B). Informant B explains that passive PRO has been part of the Danish healthcare sector for several years; however, primarily as a post-treatment instrument to assess patients health status, as a means to collect data for the clinical quality databases used for research purposes. A functionality, which explains the rigorous scientific requirements traditionally attached to PRO-measures (informant B).

Thus, the new 'active use of PRO' is different (informant B): '…'Active PRO' means that one applies it in a way, where the patient is asked to report [data] regarding his/her health status physically, mentally, etc. by the use of a PRO tool; hence, a questionnaire one completes, which then forms the starting point of the consultation with a healthcare professional…' (informant B). Since 'active' PROs has a different purpose than 'passive' PRO, informant B underscores that methodological requirements ought to be less restrictive (informant B): '...I actually believe that PRO should be seen as much as a communication tool as a measurement, but it is true that there is a dimension of PRO, where PRO-data is used for research purposes, which is fine, then you can optimize your tool, which allows you to measure…' (informant B). Hence, PRO instruments should be shaped according to their specific purpose; consequently, the PROs used for research need to be validated tools (informant B).

3.3   PROs contextual dependency

Informant G explains that PROs utility depends on the particular disease area: '…diabetes is a bit more complex in relation to PRO, exactly due to all the measurements, there are quite some examinations and so on, which needs to be conducted; thus, PRO-data can not to the same extent, stand-alone, as the case is for epilepsy..' (informant G). Hence, in the area of diabetes, PRO-data acts as a supplement, whereas in the case of epilepsy, it is acknowledged as a primary data source in clinical practice (informant G). As a result, informant G foresees that PRO-data probably has a greater clinical effect in areas where clinical decision-making is less reliant on other types of data sources (informant G). Furthermore, informant G explains how PROs used as a tool for visitation support have no effect in relation to chemotherapy; whereas, patients ability to register symptoms and side-effects has a huge effect as it enables physicians to adjust treatment accordingly (informant G). Hence, the use of PRO in clinical practice ought to be considered in relation to its contextual purpose (informant A, G).

3.4   PRO as quality improvement

PRO as a tool to enhance quality within healthcare was one of the perceptions shared by a majority of the informants. Both by one of the authors behind 'Program PRO', which is the white paper, that lay down the tracks for PROs dissemination on a national level in DK: '…as we started [the 'Program PRO'-initiative], is this something one can use? Is it a type of patient data that one can use to improve quality?' (informant F). And by informant C, who is positioned on a regional level, where PROs are supposed to be part of clinical quality databases (informant C): '…PRO-data is being accumulated to make us smarter when patients report data concerning their quality of life or self-perceived health, etc. it might indicate that some treatments should be changed, classical quality improvements…' (informant C). Similarly, PRO is also perceived as supplemental data in relation to benchmarking and knowledge-sharing across healthcare departments; however, a functionality which does require standardized PRO tools (informant F). Thus, this use of PRO-data enables measurement of quality seen from a patient perspective; subsequently,   complementing traditional experience and satisfaction data (informant C).

3.5   PRO as Value-Based Healthcare

Three of the informants mentions how PRO might be used as part of Value-Based Healthcare. Informant C explains how departments and hospitals used to be evaluated in relation to their respective effectiveness, productivity and activity. Hence, an increase in the number of surgical operations within a department resulted in more funding. However, it was a problematic system as too many of the patients ended up having side-effects, eventually making it a less effective system (Informant C). Thus, Value-Based Healthcare is currently a new and attractive approach: '…if we somehow can identify what brings value to the patient, this is value, and then divide it with its costs…' (informant C). An approach which is inspired by Michael E. Porter, who according to informant C, invented the original Value-Based Healthcare model (informant C). Informant C explains how this approach is currently worked on, which

stands in contrast to Informant B and F who acknowledge it as a future possibility but consider it a secondary application of PRO-data (informant B, F): '…at some point people talked about Value-Based Healthcare; however, the system is not ready to attach economy, to economically punish some actors, we perceive it [PROs functionality] through a quality and learning perspective…' (informant F).

3.6   PRO as patient-centred care

Another understanding of PRO that surfaced was as patient-centred care, where PRO is used as a tool to facilitate patient involvement, patient empowerment and improved self-management. According to informant E the use of PRO resembles patient-centred care, since the patient perspective functions as a baseline for the patient-clinician consultations (informant E). '…you need to elicit the individual patient and the individual patient pathway since you need to meet the patient where he is…' (informant E). Therefore,   PRO-data   potentially   enables   patient involvement during the patient-clinician consultations, as PRO-data systematically ensures that the patient perspective becomes an integrated part of the conversation (informant F). A focal feature since patient participation is a central purpose when applying PROs in clinical practice (Informant B), and as informant E points out: '…to me, it is really important what the patients think, but the patient can't have an [informed] opinion without proper knowledge…'(informant E). Moreover, as patients are able to show up informatively prepared for consultations, they potentially feel more empowered and able to engage in conversations with a healthcare professional (informant A). Another perspective accentuated by informant A concerns PROs ability to affect patient's self-management: '…there are definitely some patients who say that it [PRO] provides them with an opportunity to manage their own disease, actually quite a lot of them mention this…' (informant A) This self-management manifests when patients use PRO as a learning tool. Thus, PRO-data might increase patients knowledge   regarding   their   respective   condition; potentially, enhancing their self-management (informant A, E).

3.7   PRO in clinical practice

Three other descriptions of PRO are linked to its use in clinical practice, as a tool for enhanced treatment, improved decision-making and as a means to strengthen the patient-clinician dialogue: '…well, PRO is a way for the patients to completely subjectively communicate with the clinician about how they actually are doing…' (informant G). Hence, patients' subjective assessment of their current health status is, via PRO-data, given a central position during consultations (informant B). Consequently, it provides the patient with an opportunity to articulate and confront the healthcare professional with subjects, which otherwise might be skipped (informant A). The physicians might also benefit from PRO as part of the patient-clinician dialogue since it enables physicians to construct more systematic anamneses (informant B). Moreover, the use of individual PRO-data might provide clinicians with valuable information, potentially used to improve decision-making and treatment (informant G). Especially, within surgery, the use of aggregated PRO-data, where a patient's profile pre-operation is compared to data stemming from a similar

population; PRO might facilitate patient-tailored solutions and shared decision-making (informant A, C).

3.8 PRO as Technology

PRO is also perceived as a tool for visitation support, increased productivity and monitoring, which are functionalities emanating from PROs digitalization.

A very common understanding of PRO, mentioned by almost all the informants, pertains to its functionality as part of a visitation system. Basically, it is a triage system where patients, based on their PRO-answers, are categorized as either 'green', 'yellow' or red', a sorting which is handled by preprogrammed algorithms. Thus, patients are automatically divided into two groups, based on their present health status: a) those who need to show up for consultation at the outpatient clinic and b) those who are allowed to skip consultation, as it is assessed to be unnecessary (8). According to informant D, the visitation system is required within the Danish healthcare sector since patients are hospitalized for a shorter duration of time, while the number of outpatient consultations simultaneously have arisen (informant D). Moreover, it is an application of PRO, which apparently is acceptable to patients (informant D, E): '…and a lot of consultations, when the patient comes in, then it turns out, that right now the patient does actually not have any problems..you ask those 2-3 questions until you figure out that this is completely irrelevant, and the patient also finds it irrelevant..' (informant D) Furthermore, the visitation support system allows patients to skip their travel back and forth to the hospital; hence, it is particularly useful in settings where the physical distance between hospital and patients are an issue (Informant D, G). A functionality, which is attractive for and therefore demanded at the management level: '…there have been a huge demand from the top management, there has been a demand from hospital management and department management…but particular, the demand from top management has been related to the reduction of [patient] appearances…' (informant G).

Hence, PROs has an ability to increase the productivity and efficiency of the outpatient clinics (informant D). Thus, by using epilepsy as a case, informant D explains how patients now are able to get timely appointments at the outpatient clinic, which after the implementation of the triage system has resulted in increased productivity. However, as he points out, this change does not reflect that the number of patients consulted by a healthcare professional has risen. The increase in productivity actually indicates that some patients, due to the visitation system, are allowed to skip outpatient consultations; subsequently, creating extra timeslots for more critical patient cases (informant D).

Another dimension relating to PROs technological and digital mediation materialize when PRO-data is utilized as a monitoring tool (informant A, C), thus: '…when PRO is used by chronic patients, it becomes [a tool for] continuous real-time monitoring…' (informant C). Subsequently, enabling preventive care as symptoms over time are continuously monitored, assessed and managed (informant A, B). Additionally a feature which provides the patients with an option to self-monitor; hence, an opportunity to follow and manage their own disease progression assisted through the use of PRO-data (informant B).

Furthermore, the digitalization of PRO enables the data to be used as a coordination tool; potentially, resulting in improved patient pathways (information F): '…patient pathways are actually one of the things we have considered, whether it [PRO] could be used as a mutual tool applied across sectors somehow…'(informant F). A functionality, which might bring great benefits to the entire healthcare system, but as informant F underscores, successful coordination facilitated by PROs requires an improved technological infrastructure and a more homogeneous culture within the healthcare sector (informant F).

3.9 PRO as economic efficiency

Besides an increase in productivity, the management level, also perceived PRO as a tool, with economic efficiency potential: '…the top-level management did not expect that it would actually cost more resources, there was definitely an expectation that the implementation of PRO would lead to efficiency improvements, that is for sure…' (informant G). Hence, there seems to be a discrepancy between the expected economic gains and the actual result in practice (informant G). However, according to informant A and D, the implementation of PRO is not meant to be a money-saving exercise (informant A, D): '…first and foremost, this is not a money-saving exercise, and this did not start as a money-saving exercise…' (informant D). Therefore, a more accurate description of PROs economic characteristics is as a tool used for reallocation of resources (informant D). Thus, in practice PRO is a redistribution tool used to allocate resources more effectively, ensuring that the neediest patients have the highest priority regarding access to consultations with healthcare professionals (informant A).

4 DISCUSSION

To sum up, several different understandings of PRO rife in a Danish context. Thus, perceptions regarding PRO on an individual versus population level; active versus passive PRO; PROs contextual dependency; PRO as quality improvements; PRO as Value-Based Healthcare; PRO as patient-centred care; PRO in clinical practice; PRO as technology and PRO as economic efficiency, were among the themes informants elaborated upon.

When scrutinizing how informants perceive PRO compared to their respective organizational position, functionality and experience with PRO, a few noteworthy patterns appear. What primarily distinguish the informants acting on a regional level compared to those on a national level, is their heavy emphasize on PRO as a visitation tool, whereas, informants on a national level accentuate the potential advantage pertaining to patient-centred care and PROs benefits in clinical practice.

The informants understanding of PROs functionality on a population level aligns with the UK tradition exemplified here by researchers like, e.g. Appleby et al. (2015)(9) and Greenhalgh (2009)(10). Thus, Appleby et al. analyse and discuss how PRO, among other things, functions as a tool for qualitative improvements on both a clinical and management level, and how PRO might be used to increase productivity and measure cost-effectiveness (9). Themes also mentioned by the experts mirroring their impact on Danish healthcare. Value-Based Healthcare, which is

related to the perceptions qualitative improvements were also mentioned; however, this approach was by the informant directly linked to the American economy professor Michael E. Porter's thoughts on this subject, presented in the article 'What is Value in Healthcare?'(11), where he emphasizes the inclusion of patients values in healthcare, which resembles some of the informants' reflections regarding this subject.

Greenhalgh's description of the difference between 'Group PRO data' and 'Individual PRO' is quite similar to how the informants divide PRO-data into an individual level used in clinical practice and a population level where accumulated data is used for research and preventive healthcare (10).

Some of the perceptions also stem from conceptualizations of PRO inherent in a Danish context. For example, Active' versus 'passive' PRO was coined in 'Program PRO'(3), the white-paper, which contained guidelines regarding the development and implementation of PRO.

A third division, which is related to the others, was PROs aimed for research versus PROs targeted clinical practice. Thus, these dichotomies descriptions of PRO all bring relevant insights to the table, making them essential parts of a future theoretical PRO-framework. Understandings of PRO pertaining to the clinical level and patient-centred care are closely linked to how PROs functionality is presented by the national PRO-secretariat, where PRO is presented as a patient-oriented tool (12).

Despite divergent interpretations of PROs, it seems quite clear that PROs digitalization is pivotal regarding its current functionality. Hence, both the visitation system and PROs patient-centred aspects are dependent on proper technological infrastructures.

As this study is as a first step in constructing a theoretical framework, some reflections concerning general patterns in data are appropriate. There seem to be at least five different dichotomies in play: PRO on an individual level versus PRO on a population level; active PRO versus passive PRO; PRO used for research and preventive healthcare versus PRO used in clinical practice; Standardized PROs versus contextual adapted PROs; PROs increasing economic efficiency/productivity and patient-oriented PROs improving patients healthcare. However, the identified dichotomies are arguably intertwined; thus, through analytical scrutinization of PROs perceived functionality, two main categories emerge. One focusing on the 'system-level', where PROs functionality revolves around improvements of the healthcare system, economically and qualitatively and another category, pertaining to the 'patient-level', where the patient's health situation is focal; thus, PRO-data can support patients both during consultations and in managing their disease from at home.

Since the results in this article are based on seven interviews, findings are not statistically representative. However, the informants interviewed possess in-depth knowledge regarding PRO, and they are key actors regarding the development, implementation and application of PROs in a Danish context. Hence, the experts' understandings contain a unique qualitative value at this stage as PROs functionality and distribution is increasing in DK. Nonetheless, additional perceptions and experiences concerning PRO among different stakeholders, e.g. among managers, politicians and patients and on other levels like, e.g., in municipalities and in General Practice. Furthermore, perceptions of PRO as part of surveys might also be of value in the future as the common Dane becomes increasingly familiar with PROs.

5 CONCLUSION

This study shows how perceptions of PRO among experts in a Danish context are numerous and varying. Thus, PRO is understood as: data on an individual and population level; a tool used actively and passively; a contextual dependent tool; a tool to improve quality in healthcare; measurement of Value-Based Healthcare; patient-centred care; a tool in clinical practice to enhance dialog, treatment and decision-making; a technology, where particular the visitation system was emphasized and as an economic tool. Viewpoints and perceptions of PRO were associated with the informants' PRO experience and their organizational position. Hence, regional actors heavily emphasized PROs visitation functionality, whereas national actors focused mainly on PRO as a patient-centred tool. Furthermore, some understandings of PRO can be associated with PROs application in the UK. e.g. PRO as a tool used for quality improvements, as individual/population data and a way to increase productivity and economic efficiency. While the experts accentuating PROs capabilities in clinical practice and in relation to patient-centre care aligns closely with the official understanding of PRO in a Danish context.

This study was a first step in the development of a theoretical PRO-framework, intended to improve the understanding and conceptualization of PRO. Next step is an analysis of the perception of PRO within the academic literature. Therefore, findings in this article and results from an ongoing systematic search and review are the pillars the future theoretical framework are build upon. As a result, conceptual and theoretical insights might enable improved and appropriate application, implementation and evaluation of PRO in the future.

Nevertheless, changes are already occurring within healthcare, as, it seems evident that the traditional one-size-fits-all approach slowly is being replaced by functionalities inherent in PRO, partly enabled by PROs digitalization.

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Using Physical Activity Monitor to Check a Patient´s Rest before Blood Pressure Measurement During Home Blood Pressure Telemonitoring

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Abstract

Home blood pressure telemonitoring (HBPTM) with automatic data capturing and its transfer enables us to effectively monitor a patient´s blood pressure measurements at home environment, to eliminate transcription errors and, in combination with physical activity monitoring, to check a patient´s taking the recommended time 5 min to rest before BP measurements.

The data of 35 patients with essential hypertension using Diani telemonitoring system were used to evaluate the suitability of using activity trackers to monitor patients´ step counts before and during the BP measurements. Two datasets (scheduled measurements and daytime profile ones) were processed separately and compared. The majority (83.6%) of data were indicating zero steps before BP measurements with no significant difference either between scheduled measurements and daytime profile ones or between men and women. Standards for the limit of acceptable step counts in a defined time window before each BP measurement could be set when larger datasets are available.

Keywords

Blood pressure, home blood pressure telemonitoring, home blood pressure monitoring, activity tracker, telemedicine, self-monitoring.

1   INTRODUCTION

Hypertension is one of the most common chronic diseases requiring a long-term care. The overall prevalence of hypertension in adults is around 30-45%, increasing progressively with advancing age. [1].

Self-monitoring of blood pressure by patients at home (home blood pressure monitoring – HBPM) is being spread in many countries and is well accepted by patients [2].

HBPM should be performed by trained subjects/patients, always under the supervision of their doctor [2]. There is also evidence that patient´s self-monitoring may have a beneficial effect on medication adherence and BP control [3,4].

Home BP is described in ESC/ESH Guidelines as follows: *"Home BP is the average of all BP readings performed with a semiautomatic, validated BP monitor, for at least 3 days and preferably for 6–7 consecutive days before each clinic visit, with readings in the morning and the evening, taken in a quiet room after 5 min of rest, with the patient seated with their back and arm supported. Two measurements should be taken at each measurement session, performed 1–2 min apart."* [5]

However, BP values reported by the patient may not always be reliable due to transcription errors. Some patients even select the more optimistic lower BP values from multiple measurements. Mistakes can altogether reach up to 30 % of all reported BP values. [8]

To eliminate these errors, mobile and web applications may be used to store and review BP data in a digital diary and transmit them automatically from connected devices [5-8].

Another source of invalid measurements can be when optimal time of rest before BP measurement is not respected. [9]

Moreover, thanks to the motion sensors we are able to track patients´ physical activity throughout a day, and also, just before and during the measurement. Such a tool can reduce the difficulty to check whether the patient takes a rest sitting relaxed before BP measurements as recommended. With this information we may better assess the reliability of a given BP value measured at home.

To our knowledge, no study in which the patient´s movement would be tracked during the blood pressure measurement have been done yet. Therefore, there are no existing standards that would evaluate reliability of

such a tracking method and define the limit of steps the effect of which on blood pressure can be considered as negligible.

In this study, we aim to demonstrate the feasibility of using activity trackers as a part of our HBPTM system to check and monitor patients´ 5 min rest before BP measurements.

2   METHODS

2.1   Home blood pressure telemonitoring

Diani telemonitoring system enables us to track blood pressure measured in home environment. There are two ways of data transfer: a) using a miniPC or Raspberry Pi connected to a FORA P30+ BP measuring device (monitor) and activity tracker Xiaomi MiBand 2, both supporting Bluetooth communication, or b) using a smartphone connected to the FORA P30+ BP monitor and activity tracker Xiaomi MiBand 2. These two different measuring sets enable the patients with different technical skills and their home environment facilities to use the system. The data transfer is fully automatic, without any patient´s interaction.

The data visualization and online sharing with clinicians is provided via a web application.

The web application visualizes parameters recorded by connected devices, i.e. systolic and diastolic blood pressure, heart rate from both the BP monitor and the activity tracker, and also arrhythmia occurrence, if detected by the BP monitor, and the intensity of physical activity represented with number of steps per time and recorded via a connected wristband activity tracker.

To ensure compliance with the recommendations of inactivity before and during the BP measurement, the patient´s movement is tracked by the activity tracker and evaluated in a 5-minute window prior to the measurement performance.

Any steps taken by a patient before or during BP measurements can be controlled through data displayed in a table that summarizes 1) results from the BP monitoring,

2) the intensity of movement as an average number from the 5-minute interval before the first BP measurement was made, 3) the number of steps 5 minutes before the measurement, and 4) the total number of minutes from the past 15-minute interval before the measurement in which no steps were made.

2.2   Recruitment of study participants

Adults pharmacologically treated with essential hypertension, who have sufficient abilities to self-measure blood pressure at home (i.e. have no physical obstacle to operate the monitor, understand the measuring process and are able to perform the measurement based on the obtained instructions) are included in the study. Patients were recruited by their preventive cardiologists and general practitioners

according to the mentioned criteria. Acceptance rate was by 80%. Exclusion criteria are pregnancy, diagnosis of atrial fibrillation, or inability to handle the operation of any device included in the device set.

2.3   Study sample

Thirty-five patients (24 men and 11 women) with essential hypertension, with an average age of 59±13 years and average weight 91.6±19.1 kg. The weight was measured in the study office just before starting the study. The patients were using HBPTM system in which activity tracking was included, were recruited for the study analysis.

2.4   Collected data

The data collected via connected devices include systolic and diastolic blood pressure values, heart rate, and number of steps in 1-minute intervals.

2.5   Instructions for patients

Each patient performs a cycle of BP measurements at the beginning of each month of the period of three months. For seven consecutive days the patient measures his BP twice a day - in the morning and in the evening, 3 measurements per occasion, 1–2 min apart (this is a scheduled week cycle). Sometimes, substantial differences were found between the two BP values taken at one HBPM session in the hypertension clinic. Therefore the number of measurements was increased to 3 measurements at each session. This modification of HBPM Guidelines was agreed by G.S. Stergiou, one of the authors of HBPM Guidelines [2].

During the first week of the study, the patient can select one day of that week to perform a daytime profile. It means the patient is required to measure BP every hour from the morning till the evening, starting immediately before the first morning medication intake to demonstrate possible hypotension during the peak effect of drugs (it had been additionally introduced for the hypertension clinic earlier). In remaining weeks, the patient can select one day in each week to check his/her BP either in the morning or in the evening.

The patients are also instructed to wear the activity tracker during the days in which BP is measured for the whole period of the 3 months. The instructions include requirement to place the wristband on the wrist of the arm which was not used for the BP measurement. Patients were informed that their rest before BP measurement would be checked via connected activity tracker.

2.6   Data analysis

From all the data of 35 patients we have selected those containing information about step counts and at least one nonzero heart rate record 15 minutes before or during the measurement. With this condition we can ensure the patient was wearing the activity tracker on his/her wrist.

Two datasets are processed separately and compared,

i.e. *daytime profile measurements* and *scheduled measurements* containing week cycle measurements and selected days with one occasional measurement in other weeks.

We have used the Wilcoxon signed rank test to test the null hypothesis of equal medians of relative frequency (%) of 0 step counts before the measurements in scheduled regimen vs. daytime profile days, and Wilcoxon rank sum test to test the null hypothesis of equal medians of men and women in each of these two regimens.

3 RESULTS

The data of 34 patients (24 men and 10 women) of the 35 patients we analysed contain scheduled measurements and the data of 27 of these 35 patients (18 men and 9 women) contain daytime profile data.

From all the measurements used for the analysis, 83.6% of the measurements (5768 records, the average number of records per patient is 193±116) signalized no steps during the 5-minute period before the measurement. The percentage of correct measurements in individual patients varied from 43.3% to 100% in case of scheduled measurements and from 23.1% to 100% in case of daytime profile measurements. The results are summarized in Table 1.

Figure 1 shows the frequency of measurements in each category of number of steps that appeared 5 minutes before the BP measurement.

There is no significant difference either between the scheduled measurements and daytime profile measurements (p=0.7423, see Figure 2) or between men and women in scheduled measurements (p=0.6134, see Figure 3) and in daytime profile measurements (p=0.9793, see Figure 4).

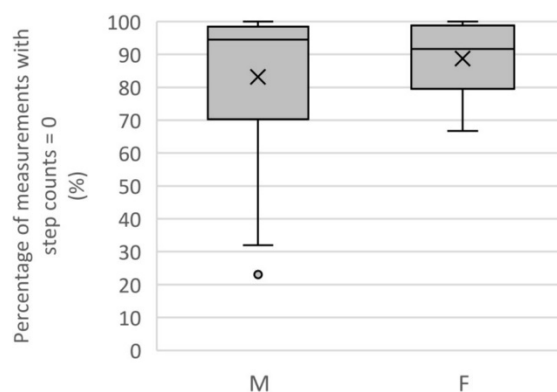|	All data	Daytime profile	Scheduled measurements
Number of patients included	35	27	34
Total number of records	6899	977	5922
Number of records with step counts = 0	5768	852	4916
% of records with step counts = 0	83.6	87.2	83.0

Table 1 An overview of the number of records in each measurement category and the percentage of correct measurements.
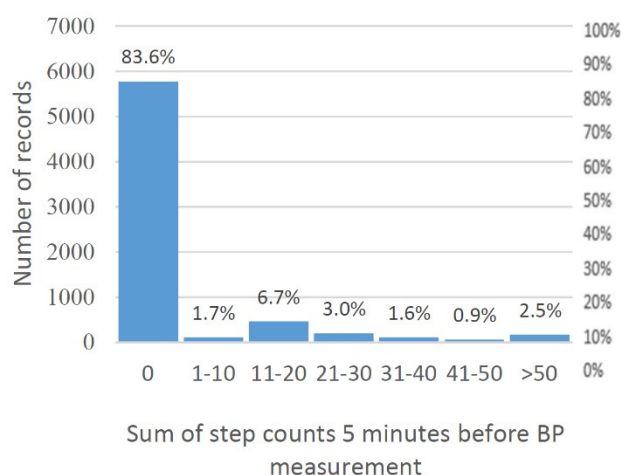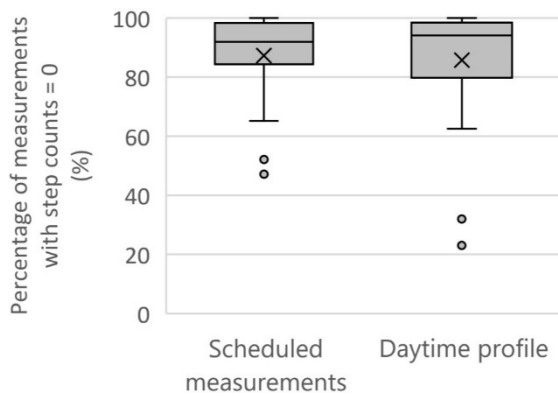

Figure 1 Frequency of BP records in each category of number of steps that appeared 5 minutes prior to each BP measurement.
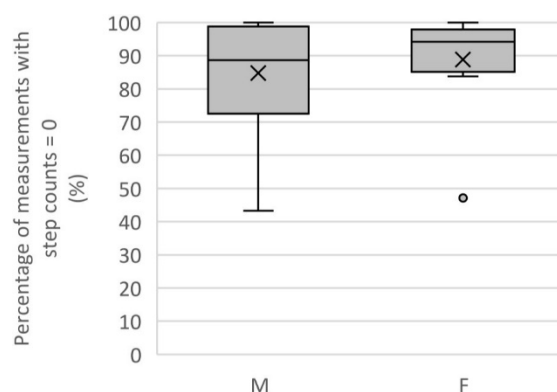
Figure 2 Comparison of scheduled measurements with step counts = 0 for group of men (M, n=24) vs. group of women (F, n=10).

Figure 3 Comparison of measurements from daytime profiles with step counts = 0 for group of men (M, n=18) vs. group of women (F, n=9).

Figure 4 Comparison of patients´ scheduled measurements with step counts = 0 vs daytime profile measurements of these patients (n=26 for each group). Included are patients whose data contain both daytime profile and scheduled measurements.

4   DISCUSSION

BP telemonitoring together with physical activity monitoring could improve the reliability of HBPM, which is important in the time of recommended wider use of out- of-office BP measurement, especially HBPM. However, so far there have been no standards saying what the limits for the number of steps before the measurement for given time window are, and which limit should be considered as accepted for the relevance of measured value and which should not. Based on the results from our datasets visualized in Figure 1, we suggest to keep the limit for accepted measurement of 0 step counts in 5-minute window before each BP measurement, as a clear evidence of keeping the condition given by the current 2018 ESC/ESH Guidelines [5]. Due to the fact we have used each separated blood pressure measurement record, most of the measurements containing any step records higher than zero that comes from the first of the three separated measurements of each measuring session.

To ensure we process only those segments in which the patients were wearing the activity tracker on their wrist, we had to exclude all the data in which no measurement of heart rate 15 minutes before the measurement occurred, even though some step counts could be present at that time.

To ensure the heart rate is being measured correctly, it is also required to wear the wristband tight on one´s wrist.

Thus, proper education of each patient with respect to the wearing of the wristband should be included prior to the implementation of this method of control.

There was no significant difference either between types of measurements or between men and women, despite our expectation of at least gender differences.

Data from more patients need to be analysed to increase study power.

5   CONCLUSION

In this study we have presented the possibility of using a physical activity tracker in patients on HBPTM system to assess compliance with the resting regimen before BP measurement.

With proper instructions patients are able to keep rest before measurements. From the results we can conclude there was majority (83.6%) of data indicating zero steps before BP measurements with no significant difference either between scheduled measurements and daytime profiles or between men and women. Standards for the limit of acceptable step counts in a defined time window before each BP measurement could be set when larger datasets are available.

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7   ACKNOWLEDGEMENT

Using Patient-Reported Outcomes in Real-Time Shared Decision-Making
How to Activate Data in Value-Based Healthcare

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Abstract
This paper examines how data can be activated in the care cycle to support the strategic transition toward value-based healthcare. We used the value-based healthcare framework and applied the cross-industry standard process for data mining methodology to create a data infrastructure showing how real-time, shared decision-making, and clinical support systems can be built and applied in real-time to patients referred to a hip or knee replacement. The results demonstrated that using outcomes in real-time combined with archive data like risk factors enhances the implementation of outcome measurement and, thus, a shift toward VBHC.

Keywords
Value-based healthcare, Prediction models, Shared Decision-Making, CRISP-DM

1 INTRODUCTION

Most western countries, including Denmark, face significant challenges with rising healthcare cost due to a large elderly population, new and expensive treatments, and higher expectations for healthcare delivery from both patients and politicians [1]. As a result, in 2006, Porter and Teisberg [2] introduced the value-based healthcare (VBHC) framework based on the assumption that the above-mentioned challenges can be solved by shifting focus from volume to value. VBHC is often described as a concept or agenda consisting of several components: 1) integrating practice units; 2) measuring outcomes and costs for the entire care cycle; 3) bundling payments; 4) integrating care delivery across separate facilities; 5) expanding excellent services across geography; and 6) building and enabling the information technology platform [3]. One of the most central points of the concept is its explicit focus on value creation during the entire care cycle, measuring outcomes and costs for each patient as well as the integration of relevant information between IT systems and sectors [3]. Several hospitals have accepted the VBHC framework and implemented some of the components, however most of them have focused on collecting and using patient-reported outcomes (PRO) [4-7], new reimbursement systems based on pay for performance or bundled payments [8-11], and the implementation of integrated practice units [12]. All of the above-mentioned studies have described the current data infrastructure as a challenge, specifically the availability of already collected data, flexibility, and the ability to share the collected data across facilities and sectors [3,13-16].

Denmark, like most Scandinavian countries, has a long history of collecting and digitalising healthcare data, which has generated a significant amount of data, driven by the demand for record-keeping, compliance, regulatory requirements, and patient care [17]. Healthcare data can consist of historical data like previous diagnoses and resource consumption, as well as real-time or close-to-real-time data like patient-reported outcomes collected prior to examination [18-19]. Most of the historical data is stored in the business intelligence (BI) unit, with some of the data being subjected to a comprehensive quality control process using error lists in order to establish its accuracy; however, this can cause an inevitable delay in the availability and flexibility of data usage [17]. In contrast to historical data, real-time data is available and can be used by the clinic to, for example, inform patients of their health status, or clinical support systems like Ambuflex, which relies on PRO-data for visitation purposes [20]. When using real-time data, especially real-time patient-generated data, quality control systems cannot be applied to the same extent as with historical data stored in the BI unit, which ultimately can be a risk factor when creating decision systems based on data [21]. Moreover, some patient-generated data is transferred to local BI units and stored as historical data, but. primarily, the data is either non-retractable or stored in business systems outside the hospital/region. In Denmark, this is true for most PRO-data. The fact that data is stored in different systems that cause different delays and collected for various purposes, like patient treatment, research, or statistics, creates significant barriers regarding the availability and flexibility of data [13] in supporting VBHC. This article describes the ways in which a hospital in Denmark has tested how data can be activated in the care cycle, using both historical data from the patient administrative system (PAS) and the laboratory system (LABKA) as well as real-time generated PRO-data to support the transition toward VBHC through the creation of both clinical support systems and shared-decision making systems [4, 22-23].

2 METHOD

The present case builds upon Aalborg University Hospital's experiences applying the VBHC framework to patients receiving hip or knee replacements (THA and TKA). This case is a part of the national VBHC project, examining the

development of outcomes by using recommended tools from VBHC, like the process map. Furthermore, the cross-industry standard process for data mining (CRISP-DM) methodology [24] was employed to investigate the ways in which data can be activated during the care cycle to create more value.

The CRISP-DM methodology consists of six generic phases; business understanding, data understanding, data preparation, modelling, evaluation, and deployment [24]. The translation of each generic phase to the healthcare sector was made with the sole purpose of using known terminology when interacting with healthcare professionals. Phase one, business understanding, was translated into the understanding of the entire care cycle, which can be obtained using a process map [25]. Phase two, data understanding, involved measuring outcomes and defining risk factors for subgroup analysis, which can be obtained using a Delphi Process [26]. Phase three, data preparation, consisted of extracting relevant patient data containing information on both outcome and risk factors, establishing the data quality, and conducting statistical analysis with the purpose of developing algorithms to identify the prediction and visitation thresholds for shared decision-making. Phase four, modelling, was translated into the development of a data infrastructure within the local BI environment, containing extraction of patient data on relevant risk factors, the developed algorithms and the results of the algorithms visualized as scales and color-coding figures launched into the electronic health record (EHR) used by physicians. Phase five, evaluation, consisted of evaluation of the data infrastructure in terms of correct data extraction, correct prediction, and availability of the result in the EHR. Phase six, deployment, was translated into the implementation of the prediction model as well as the visitation threshold for follow-up visits.

2.1 Understanding the care cycle

Understanding of the care cycle was conducted using a process map developed at a national level and facilitated by Quorum consulting. The purpose was to outline all activities, from general practice referral to rehabilitation, occurring in the municipality. A national expert group, consisting of physicians, an employee from the national patient association for arthrosis, and health economists, participated in the process. The expert group further defined challenges in healthcare delivery during this process.

2.2. Outcomes and risk factors

The national expert group conducted the definition of outcomes and risk factors. The expert group defined the relevant outcomes of the care cycle based on the process map and in accordance with the VBHC framework [25]. Furthermore, they defined all the relevant risk factors that could affect the outcomes of a THA and TKA treatment. To define these relevant risk factors, the project group used the Delphi Process, a commonly used process to obtain knowledge from a group of experts [26]. The project group provided the expert group with a list of relevant risk factors obtained through a literature search, and the national expert group then added new risk factors to the list based on their

medical expertise. Following this, the project group initiated the Delphi-process, which consisted of two rounds. During the first round, the national expert group scored each risk factor on a numeric scale from one to ten, for which one equalled not relevant and ten equalled highly relevant. Based on the scores, each risk factor was placed in one of three groups: 1) relevant; 2) potentially relevant; and 3) not relevant. If more than 70% of the expert group ranked a risk factor as a seven or above, the risk factor was defined as "relevant", and similarly, if more than 70% of the expert group ranked a risk factor with a three or below, the risk factor was defined as "not relevant". Otherwise, the risk factor was defined as "potentially relevant". During the second round of the Delphi Process, the expert group received a new list with only the risk factors marked as relevant or potentially relevant. They were once asked to judge all the risk factors in the "potentially relevant". If the expert group believed the potential risk factor was relevant, they were asked to note a "yes" and, if not, a "no". If more than 50% of the expert group marked a risk factor with a yes, the risk factor was included into the project for further analysis.

2.3 Data Preparation

Data definitions were based on the literature and definitions from regional quality databases when possible (RKKP). If none data definitions existed, medical expertise were used. Furthermore, the project group identified legal barriers like e.g. was the data collected allowed to be reused in patient treatment, and availability barriers by analysing registration validity and updating the frequency for each identified data source. Based on the legal and availability barriers, the project group adjusted some of the data definitions to include only data from registries approved for patient treatment. When adjusting a risk factor and thereby deviating from a best practice definition, the project group consulted a medical expert within the area. After completion of the data definitions, the project group extracted data on all patients who had delivered both a baseline patient-reported questionnaire and a one-year post-operative follow-up questionnaire between November 2015 and December 2017. The project group excluded one of the observations if the patient had received the same type of operation in both left and right knees and the hip. Furthermore, the project group excluded observations containing missing information in baseline data regarding type of operation, operation site, and patient-reported outcomes on function and quality of life. The identification of risk factors was achieved for each observation, and every risk factor was subjected to statistical analysis estimating its impact on functional outcome and the risks associated with an operation. A group of physicians at hospital was presented with the relevant material, and, based on the unadjusted results, they chose the relevant risk factors for the prediction model and threshold values. Algorithms for prediction were based on linear and logistic regressions, while threshold values for one-year post-operative follow-ups were based on information from previous literature and the medical knowledge of the expert group.

2.4 Data infrastructure

The creation of the data infrastructure, consisted of developing a platform in the local BI unit, in which the risk factors of newly referred patients could be extracted, calculation based on the developed algorithms could be performed, and the results could be visualized upon preliminary examination. Patients referred to the hospital under relevant diagnoses was included in the database table. From this, the system searched for relevant risk factor information based on specific risk factor data definitions and personal identification IDs. This specifically embodies all previously completed PRO questionnaires, diagnose-related group (DRG) database information, PAS data containing information on comorbidity, procedures, and referrals for both outpatient and inpatient contacts, LABKA containing laboratory information, and the pharmaceutical reimbursement database. The data platform transformed and filtered the raw data by date to represent the correct data definition of a risk factor and then saves the information as background data. Before the first consultation, the patient filled in the first PRO questionnaire on-site. After submission of this form, the PRO data is stored in a database table. The platform then automatically extracted the information and merged it with the background data in a data table on the platform where calculations was made based on pre-trained algorithms. Numeric estimates from the algorithms as well as explanatory factors was saved in a persistent database. Batch jobs and web services performed all communication between databases and algorithms. The estimates was presented in a web interface linked to the hospital's sign-in. This so-called front-end was developed and tailored specifically to this field with the possibility of visualizing specific estimates or performing a standardized walk-through of all available information. A business intelligence module of overall patient flow and individual patient look-up is was available for the chief physician. One year after surgery, the patient answered a new PRO-questionnaire, and the data was stored in the same database table as the first PRO data, which enabled the possibility of calculating the value creation for each patient to determine the need for one-year post-operative follow-up.

2.5 Evaluation

Evaluation consisted of evaluating the data infrastructure. The project group produced a test document, physicians tested the time from entering ID to the graphic appearance

of the expected result. Both the Physicians and the project performed the test of correct data extraction and calculation. In beginning of 2018 the project group extracted data on a random patient group (20 THA patient and 20 TKA) referred to treatment after 01.01.2017 and thereby not included in the original data for analysis. The patients had answered both a baseline PRO questionnaire and a one-year follow-up questionnaire. For every observation, the physicians examined the EHR, and noted relevant risk factors. Subsequently, a staff member in the economy department crosschecked the notes made by the physicians with the data extracted on the patient from the data infrastructure. Lastly, the predicted result for every ID was crosschecked with the actual score one year after surgery.

2.6 Implementation

The data infrastructure was implemented with the prediction model for THA and TKA on the 1st of April 2018. The project group initiated the implementation process through a futuristic workshop with all the physicians. A futuristic workshop is a concept for investigating new areas in which no previous experience is available like e.g. how to implement PRO data in the clinic. The theme of the futuristic workshop was "PRO in the cycle of care for hip and knee surgery." At the beginning of the workshop, the chief surgeon presented the prediction model, the visitation threshold and the results from evaluation. The physicians then discussed the possibilities and challenges of using data, PRO, and prediction models. Furthermore, the physicians discussed the visitation threshold for one-year follow-up.

3 RESULTS

The national process map resulted in an in-depth description of the major activities in the care cycle, from referral to the hospital to rehabilitation, as illustrated in Figure 1. The challenges identified in the care cycle included patient satisfaction resulting in patient complaints due to different reasons:

1. Poor alignment between patient expectations and clinical expectations regarding the result of an operation.
2. Some patients would benefit from physiotherapy before or instead of an operation.

**HOW TO USE OUTCOME DATA IN THE CARE CYCLE FOR HIP AND KNEE REPLACEMENTS**
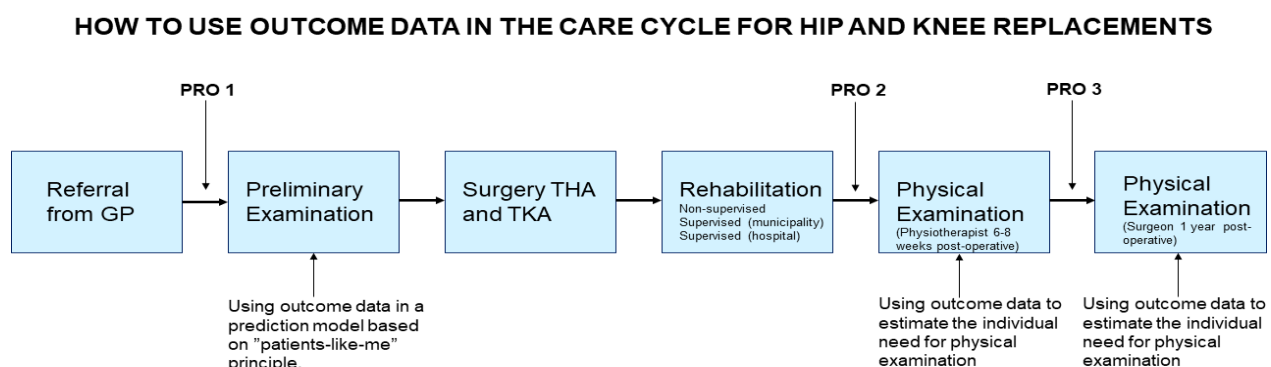
Figure 1 The major activities of hip and knee replacement (THA / TKA) identified in the national process map and the possibilities of patient-reported outcome (PRO) measurement data in the care cycle for value creation.

Furthermore, the group identified difficulties in differentiating the need for post-operative follow-up one year after surgery prior to actual physical examination, with one of the major reasons being missing information on effect (defined as difference between pre-operative and post-operative scores).

Based on the care cycle, six relevant outcomes were defined: function, quality of life, satisfaction with the result of the operation, complications within 30 days, re-operation, and the ability to return to work. Four of the identified outcomes were available in the regional databases as well as a local PRO database at the hospital. Furthermore, the expert group identified 48 relevant risk factors, of which 20 were available in the aforementioned databases, mainly risk factors concerning patient characteristics and chronic diseases.

The data analysis was based on a dataset consisting of a total of 243 THA and 208 TKA, which fulfilled the inclusion criteria. Based on the unadjusted estimates on the outcome of each risk factor, the physicians at the hospital chose four relevant risk factors for the local prediction model: age, BMI, pre-function, and number of chronic conditions. To create a prediction model available in real-time upon preliminary examination, the physicians explicitly demanded there be no extra registration tasks for the healthcare professionals. Furthermore, the data infrastructure had to be capable of searching for relevant risk factors in the different systems and merge them with the information available from the PROM-questionnaire answered minutes prior to the examination, thus making it possible to visualize the expected results for the patients upon preliminary examination.
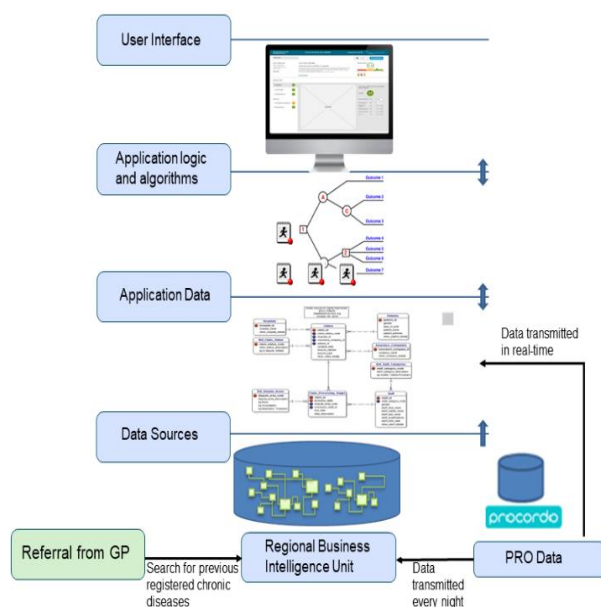
Figure 2 Data pathway from business intelligence units to algorithms used to predict the expected effect of surgery. PRO = patient reported outcome.

As illustrated in Figure 2, the data pathway begins with the referral from the general practitioner, which initiates the search for risk factors in the regional databases. When the task is completed, the data is stored in a separate location in the business intelligence environment. Before the preliminary examination, the patient answers the first PRO questionnaire. Then, when the patient enters the preliminary examination, the physician enters the unique patient ID into the EHR and from there accesses the prediction model. The prediction model aligns all risk factors in the database table, and, when a PRO-questionnaire is answered, the PRO data is merged with the risk factors in real time, and the algorithms are applied. The results of the algorithms, which were presented to the physician and patient at the preliminary examination, are illustrated in Figure 3.
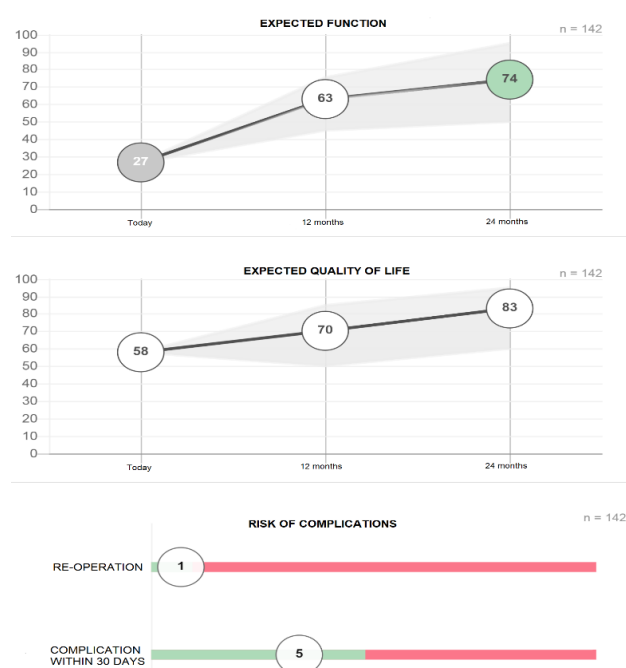
Figure 3 The transformation of the algorithms into graphs. The graphs were made available to the physician and patient as a shared decision-making system in the EHR.

All data was stored in the model; when the patient answered a new PRO-questionnaire one year after surgery, the PRO-data was merged with the stored data. Based on the information, the department then could evaluate the need for physical follow-up based on an actual increase in function. If a patient did not exhibit an increase of more than 14 percentage points in function score, he was contacted by telephone by a nurse. Approximately 10% of the patients were contacted by telephone in this study.

The stored data in the data infrastructure was saved, making it possible for the chief physician to oversee all patient records and create status report for each physician. Thereby, the saved data in the data platform also serves as registry available for the chief physician and used for quality, research and benchmarking purposes.

Evaluation studies of the data infrastructure indicate that the data was extracted correctly, while challenges with data information on mental disorders like depression and anxiety were present, as many patients were treated by their general practitioner without ever being diagnosed at the hospital. The time span from entering the patient ID into the EHR to making the prediction was determined to be between two and three minutes. Early studies indicate that the predicted results of the model vary between ± 20%.

However, the evaluation also illustrated that a prediction indicating an improvement did, in fact, result in an improvement. Furthermore, early studies indicate that the visitation threshold seems to be at a proper level in order to differentiate between the patient's need for physical follow-up one year after surgery. Based on the result, the clinic accepted both models in the futuristic workshop by demanding new modelling in the future to ensure the most accurate prediction. The physicians also demanded an investigation of potential challenges relate to higher resource consumption among secretaries and nurses when creating new workflows using PRO.

The chief physician, the physician responsible for research and the project group, developed a learning programme, emphasizing that the prediction model should be used together with a normal physical examination and compared to patient expectations to create shared decision-making. To secure the correct use of the prediction model, the chief physician had overseen preliminary examinations for each physician to support questions from both the patients and physician on how to interpret the results. The project group then implemented a control system, with the purpose of providing an overview of the physicians using the system. A newly extracted statement illustrated seven out of ten doctors are currently using the system.

4 DISCUSSION AND CONLCUDING REMARKS

Previous literature has mainly described how measuring outcomes can improve value by, for example, benchmarking through clinical registries and the GLOBE program [5,7,14], or using outcomes in new reimbursement models [8-11]. Although the value created through using outcomes for quality improvements has been documented, several studies have emphasized that the future of outcome measurement and VBHC involves using outcomes and other collected data in shared decision-making in real-time in the clinic [4-5, 22-23]. However, many previous studies have also reported challenges with the existing data infrastructure, which supports the transition from using data and measured outcomes as historical data to using data in real-time. This paper demonstrated the feasibility of combining the VBHC framework with the CRISP-DM model, which can be used to activate data in the care cycle in real-time by developing a shared decision-making system usable in preliminary examination as well as a clinical support system for identifying the patient needs for physical follow-up one year after surgery. The CRISP-DM methodology fit well in the VBHC framework, as the method has an explicit focus on creating business-value, business understanding (defined in healthcare as the care cycle), data understanding, and data preparation. All of these concepts are important in determining how data activation can improve value creation in healthcare, as defined in component six of the VBHC framework.

The CRISP-DM methodology has previously been criticized for its lack of definition and details [27]; however, its explicit focus on the care cycle, outcomes, and risk factors in the VBHC framework provides a guiding principle for the methodology. Resultantly, the critique of CRISP-DM methodology can, in this case, be viewed as a strength as the methodology, enabling DM projects within different patient groups to be tailored to disease-specific areas (e.g., in terms of how and when to measure outcomes and the possibilities of transforming data into clinical, actionable knowledge).

This study identified a general method and guideline through which to integrate both historical and real-time data from different systems into clinical support systems and shared decision-making systems. The present case also illustrated that an important component of data activation involves understanding the care cycle and identifying the data usable for value creation as well as building a data infrastructure that enables the merging of both historical and real-time data. The data infrastructure establishes the access necessary for transforming the data into usable information in real-time without burdening healthcare professionals with extra registration tasks. The ability to transform historical and real-time data into real-time shared decision-making creates new possibilities to not only use patient-reported outcomes for evaluation and quality improvement but also for acting upon these collected outcomes, improving the results for each specific patient. Establishing a usable data infrastructure has enforced the clinical implementation of outcome measures and patient involvement in terms of shared decision-making, which is fully aligned with the VBHC framework [22].

This case illustrated how data can be activated, but the project did not fully investigate the entire value creation of both the prediction model and visitation threshold for one-year post-operative follow-up. Furthermore, the value creation based on the data models should be evaluated in accordance with the entire VBHC framework [28]. This includes not only the evaluation of the feasibility of the models but also whether the organizational set-up, reimbursement models, and health care delivery facilities support new decisions and quality improvement based on the models (e.g., decreased number of operations or referrals to supervised rehabilitation).

Future models based on the data infrastructure could expand to include, among others, the prediction of treatment for both operative and non-operative patients, prediction of subgroups benefitting from supervised rehabilitation compared to non-supervised rehabilitation, and clinical decision-making systems for individual patients needing postoperative physical follow-up based on baseline data compared to post-operative data. When scaling this case to other medical specialties, the data infrastructure can be reused but the other phases of CRISP-DM model combined with the VBHC framework should be repeated. Further, the infrastructure is capable of extracting data for risk stratification; however, the risk profile is based on the data available in the regions and at the hospitals and may not have sufficient data to provide a proper data definition. In this case, this was illustrated by some of the mental disorder definitions, like depression, which were difficult to identify since most of the patients were diagnosed and treated by their general practitioner. Furthermore, the data infrastructure can only be used when extracting data from registries owned by the region or hospital and where data are where the legal purposes for the collected data is patient treatment or quality development.

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A Key Factor for Improved Use of Health and Welfare Technology-Objective Scientific Evaluations: The Somnox and ErgoNova Example

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Introduction

Social care and health care organisations in the Nordic countries all request objective evidence of value, use and effects of health and welfare technology (HWT). Today, procurements of HWTs are primarily based on the business' subjective, often small and "light", own produced evaluations. This provides decision makers, managers and buyers with insufficient data for high quality decision-making processes. Here academia has the important task of providing objective scientific evaluation studies of different HWTs. Additionally, cost benefit analyses are also desirable. At Mälardalen University we are building a national centre with the aim to provide such evidence. An initial task is to gather experiences in conducting such studies. This far we have experiences from evaluating some HWTs: JustoCat, Music Doll, ErgoNova, ATEA VR and Somnox. These products have different target groups such as persons with dementia, adults with profound intellectual disabilities and adults suffering from sleeping problems, with or without autism diagnosis. This paper provides examples from the completed ErgoNova study and the planned Somnox study.

Materials and Methods

The ErgoNova chair offers rocking chair therapy, the chair is programmed with a choice of rocking programs, flexible in positions and includes relaxing music in combination with massage. The Somnox sleep robot is a bean-shaped pillow that has been designed to relieve the mind and body of stress, which is provided by three elements: breathing, sound and affection. Both studies have a single case study design (Kazdin, 2011), in an A-B-A structure with a mixed data collection. The single case methodology needs several base line data, to ensure a stabile base line (A), the intervention (B) means the time when using the HWT, the second A phase, means a time when the HWT the intervention is removed. The ErgoNova study included persons with dementia (n=7) using QUALID (QoL) and NPI (BPSD) scales, and semi-structured interviews with professional caregivers (n=7). The persons with dementia used the rocking chair in an average of five times per week, during an eight-week period. The planned Somnox study has a similar single-case design including persons having sleeping problems (n=5), two of them having autism diagnosis. Data collection will be conducted by using Beurer SE80 for sleep registration and a sleeping diary in combination with qualitative interviews exploring the users' experiences. Both studies are following Swedish law (2003:460) concerning research ethics. The ErgoNova study had ethical approval from the regional committee of research ethics (Dnr. 2018/301). The Somnox study will follow a similar procedure.

Results

After four weeks, there were strong tendencies that the rocking chair therapy reduced agitation, irritability, motor restlessness, depression and sleep disturbances for some of the persons with dementia. Reduction of symptoms co-varied with increased QoL. The implementation of the rocking chair therapy was easy for the professional caregivers who also considered rocking chair therapy as an adequate and sustainable tool to reduce the persons' BPSD and increase their QoL. Since the Somnox study is in its planning stage no findings can be presented. However, results are expected to produce sleep registrations, sleeping behaviour, any changes during the intervention period and show possible residual effects in the second phase A. The interview data will explore the users' subjective experiences of sleeping with Somnox.

Discussion

A trustworthy design to guarantee the consumers; purchaser, mangers and procures objective evidence of value, use and benefits of different HWT is crucial. The HWT business can advantageously be involved in the pre-phases of the studies, although, not in data collections and analyses, where they would be biased. Another aspect is the funding, who should pay for these evaluations? A best-case scenario would be if the HWT business would be funders however, this is not the case since HWT companies often are small, and lack financial resources for research funding. To be a national centre for scientific evaluations of HWT, we need experiences in designing and conducting such research, especially in collaboration with HWT business. Collaboration with business is sparsely in the field of social care and nursing research. Many researchers in these fields are inexperienced and, sometimes suspicious to be engaged in these kinds of research collaboration. This far, our experiences are good, and factors for success include retained research integrity, competencies in research design and clear and straight collaboration and communications with the HWT business.

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Let's Co-design a Tool to Assess Overweight and Obesity Health Apps.

EVALAPPS project

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Introduction

Health apps are fast, versatile, manageable tools and empower patients. There are more than 320,000 accessible health apps, the most downloaded being those that aim to encourage the practice of physical exercise and weight control. There are several initiatives to validate apps in health, but all of them address only partial aspects of the evaluation.

The EVALAPPS project aims to develop an app assessment tool in the field of overweight and obesity management, based on the evaluation of efficacy, effectiveness and safety.

Materials and Methods

First, a systematic review of the existing evidence through searches in PUBMED, PsycINFO, Scopus and Cochrane until April 2019 was undertaken. Dimensions and criteria have been identified, both in relation to the process variables (usability, acceptability, satisfaction), as well as to the result variables (weight loss, number of steps). Secondly, a Delphi study was carried out to sight agreement on the tool content: the identified criteria were sent out to 31profesisonals to validate, select and optimize criteria. Finally, a co-creation discussion session allowed the definition of the items that should be included and the format (look and feel) of the assessment tool. The EVALAPPS assessment tool is now under development and being tested.

Results

From 233 potentially relevant publications, only 28 studies were included. The studies were classified as low (15), high (7) and moderate (6) quality according to Scottish Intercollegiate Guidelines Network criteria. In 11 studies the apps were used as stand-alone interventions, the others were multicomponent studies that included other tools for support such as sensors or web sites. The main management tool included in the apps was feedback messaging (24), followed by goal-setting mechanisms (20) and self-monitoring (19). The majority of studies took weight/body mass index loss as the main outcome (22) followed by changes in physical activity (14) and diet (12). Regarding outputs, Usability/Adherence/Engagement (17) were the most reported, followed by Satisfaction (7) and Acceptability (4).

After de systematic review 114 criteria were listed and on the first round, 105 criteria were agreed through the Delphi technique. On the second round, 2 were also agreed, showing a total agreement of 94% (107 of 114). Half of criteria agreed were from final outcomes and mainly belonged to Security-Privacy and Usability dimensions, followed by user's physical state and activity information and Clinical effectiveness. Look and feel, design, data collection and storage and log-in process were defined through the co-creation process and are being implemented in the first versions of the assessment tools that is being tested.

Discussion and Conclusions

The potential for apps to positively help users manage their obesity or overweight has yet to be attained. There is a remarkable heterogeneity among studies that try to validate health apps, which main aim is to manage overweight and/or obesity, and the majority of them have methodological limitations that leave considerable room for improvement. Relevant criteria to evaluate the effectiveness of mHealth interventions in the management of overweight and obesity have been identified and agreed. Also main features of the assessment tool have been defined. Once the tool is developed it will be piloted on users of overweight and obesity management apps.

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Digital Health Information in Iringa, Tanzania: Development, Provision and Testing the Effect of Digital Health Messages to Rural Communities

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Introduction

The expansion of digital technologies and global interconnect-edness have a significant potential to accelerate progress to-wards achieving the health-related Sustainable Development Goal 3 at a global level, which includes access to free health information and education. The Non-discriminating access for Digital Inclusion (DigI) project aims to establish hotspots for the *InternetLite* access in selected villages in Tanzania, includ-ing free digital health messages for rural communities. The aim of this study is to prevent the spread of HIV/AIDS, tuberculosis (TB) and *Taenia solium* cysticercosis/taeniosis (TSCT) by in-creasing health knowledge on these diseases.

By providing free digital health messages to the population of Izazi and Migoli villages in rural Iringa, Tanzania, the project intends to promote early health care seeking behaviour and access of health care services, in addition to the adoption of preventive strategies.

Materials and Methods

The hotspot, a place where a digital platform is installed, is providing the communities with free access to digital health messages and *InternetLite*. The clients can use their own smart mobile phones or devices available in the hotspots. These hotspots are currently being installed. The digital health mes-sages addressing prevalence, transmission, symptoms, treat-ment and prevention for HIV/AIDS, TB and TSCT have been finalized. In parallel, a two-armed controlled study with 600 participants is ongoing to measure the uptake and retention of health knowledge on HIV/AIDS, TB and TSCT, pre and post the digital health intervention.

Results

The participants in the intervention group have been exposed to the digital health messages once. Baseline knowledge scores (in both intervention and control villages) and immediate after exposure knowledge scores (in the intervention group) are cur-rently being analysed. The 3-month post exposure assessment is currently ongoing and will be finalized in September 2019. The hotspots will be rolled-out in the communities immediately after this follow-up. Through this design we will investigate the effect of the single-time exposure to digital health messages, whether the effect will remain over time, and the effect of free access to the digital health messages via the hotspots in the communities.

Discussion

We anticipate that providing health messages in a digital format will increase health related knowledge, which ultimately will lead to an adaptation of health seeking behaviour. The digitiza-tion of health information toward clients may contribute to the strengthening of health systems, especially in low-income economy settings.

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Clinical Transfer of Distance Therapy From Institution to Home Environment Patient's Education Protocol

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Introduction

The aim of this study was to verify usability of mobile biofeedback therapeutic system Homebalance (HB) in group-based therapy as a substitution for individual therapy and for home use, to evaluate therapeutic effect of this type of group-based intervention, evaluate whether manpower requirements will be affected. HB is an interactive system for treatment of balance disorders. It consists of tablet, Wii balance board (WBB) and diagnostic and therapeutic software providing game-like therapy. WBB is a valid tool for the quantification of postural stability

Materials and Methods

The study included 319 patients with vertebral algic syndrome (VAS) in the subacute and chronic phase, who were hospitalized in Rehabilitation centre Kladruby, with ability to maintain standing position for at least 20 minutes and ability to perform required exercises.
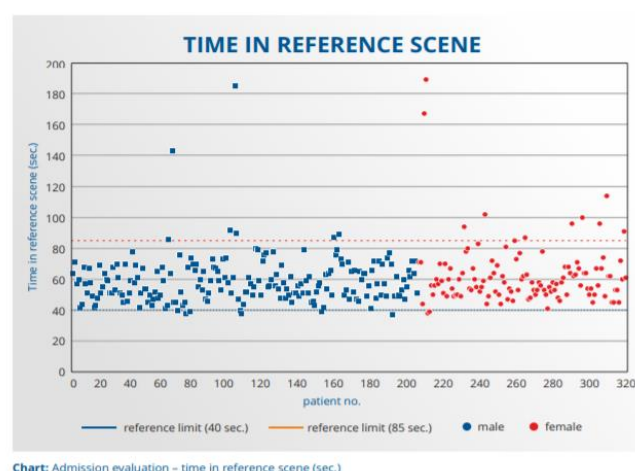
The exclusion criteria included blurred vision, pregnancy, psychiatric disorders or severe cognitive impairment, epilepsy and overweight ($\leq$ 150 kg, maximum weight allowed by the developers of Wii Board Balance).

All patients received conventional individual physiotherapy (1:1 ratio) four times per week and group balance therapy with Homebalance under a physiotherapist's supervision (1:7 ratio) once a week. The patient stands on the force platform and controls the game scene displayed on the tablet display by changing the position of their centre of gravity during training. The whole program lasted for 3-6 weeks. The group "individual balance therapy" consisted of testing and reference exercises using HB, therapy with HB and independent exercise.

Results

The study demonstrated cost effectiveness on simulation of distance therapy in home environment with use of HB system. Patients who used HB system could exercise five times per week for 20 minutes (manufacturer recommendation) at home and thus they can increase therapeutic time in home environment up to 33,3% compared outpatients setting.

During admission evaluation we found that 7 females and 10 men with VAS (from n = 319) had higher time of reference scene in comparison to value for healthy population according to the manufacturer's recommendations (see Chart below). Those 17 patients had postural stability disorder as well.

Chart: Admission evaluation – time in reference scene (sec.)

Conclusion

This study demonstrated that the system can be used by patients independently without any undesirable side effects and therefore it can be included in home-based distance therapy. The average use of therapeutic time in group individual therapy was 1:7 at the clinic. With the utilization of 1 therapist in 3 x 20 minutes training units, a total of 21 therapies, the number of therapists needed for regular individual therapy was decreased by 18 therapists, thus by 86%. We found out that this application of HB system in group – based therapy can serve as a training and patient's education tool for further use HB in the home environment (distance therapy) as well.

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Design of the CAPABLE Prototype:
Preliminary Results of Citizen Expectations

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Introduction

Having access to and opportunity to an overview of all personal health-related information is important to citizen health empowerment. Today, citizens can access subsets of their health information through dedicated, secure portals, manually enter information into specific apps of their choice or keep paper logs. The result is a mix of paper documents and digital snippets of exchanges and data in incompatible formats. This may be supplemented with ad-hoc strategies for interpretation and management. There is currently no simple way to collect, complement and control health information from multiple sources, institutions, services and systems, and thus no way to get a good overview and understanding of its implications. CAPABLE aims to create a tool that enable citizens to actively utilize their clinical and personal health information to manage medication, improve nutrition, and facilitate health services coordination.

Materials and Methods

The CAPABLE prototype development is based on user-centred design (UCD). In the first phase to understand user needs, values and context, 57 citizens have participated in two focus groups (n=13), five personas workshops (n=15), a design workshop with five groups (n=24), a pluralistic usability walkthrough (n=4), and a paper prototype user testing (n=1). Among the project partners are health advocacy groups (NGOs) and municipalities, which are recruiting participants. They ranged from adolescence to elderly, with and without disabilities, had a variety of health problems, different digital health literacy and different roles: pupils, workers, next of kin and retirees. Thematic analysis of detailed field notes from the activities has been performed.

Preliminary Results

The results show how citizens have a wide range of expectations toward the CAPABLE tool – both affirming and contradictory to each other, ranging in level of detail and developmental implications. However, the overall expectation from all citizens is for the CAPABLE tool to be easy to use, requiring only small amounts of work or efforts for a citizen to utilize it. They expect that everything that can be automatic to be automatic. This overriding theme has three main expressions:

a) Citizens expect to utilize existing personal health information in digital form in the CAPABLE tool.

Providing citizens with a registration tool for health information has very limited value for users. They expect to be able to collect information that already exists in various digital platforms.

b) Citizens expect to have access to checklists and resources where they can personalize content.

Citizens want a structured way to record and store questions and experiences before health appointments and to note what they have learned from health personnel, but they do not want to write everything down in full text. Providing information, checklists and templates they can personalize to their specific needs seems to be a usable and useful way to complement health information.

c) Citizens expect to guard their health information from the community and choose to share parts of their information from trusted parties in the CAPABLE tool.

Citizens are conscious of how health data needs to be protected and guarded, and the threats of not doing so. At the same time, they would like functionality to share their health information with people of their own choice, select what to share, to decide for how long the shared information is accessible for others.

Discussion

Results from the user-centred activities provides some fundamental design implications for the CAPABLE tool. They are:

a) A successful prototype has opportunities to gather and use personal health information in digital form, and interoperability with existing health information systems are crucial.

b) Citizens propose checklists as a way to prepare for health encounters. Unstructured note-sections are expected to be laborious and limiting use. Checklists provide an important starting point to personalize and annotate, as one size does not fit all.

c) "Privacy by design" is important from a legal perspective, and paramount for citizens' maintained trust. The tool needs to provide easy and flexible ways to control and share personal information, and avoid unintended or unforeseen incidents.

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Development of an ICT Solution to Obtain Annual, National, Representative Health Indicator Data for Non-Communicable Diseases – A Pilot Study

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Introduction

The World Health Assembly adopted in 2012 a target to reduce premature deaths of non-communicable diseases by 25% by 2025. Later, the goal was changed to a 30% mortality reduction by 2030, which Norway consented to. The World Health Organization has defined non-communicable diseases as cardiovascular disease, cancer, chronic obstructive pulmonary disease (COPD) and diabetes. The common underlying risk factors (health indicators) are the use of tobacco, unhealthy diet, physical inactivity and harmful alcohol use. The purpose of this pilot study is to develop an Information and Communications Technology (ICT) solution to obtain annual, national health indicator data for non-communicable diseases.

Materials and Methods

The Population Registry in Norway will provide a random national sample of 11000 men and women aged 16-69 years, registered with a mobile phone number and geographic location. Altogether, 1000 individuals from each of the 11 counties as of January 1st, 2020 will receive a SMS from Healthcom AS inviting them to participate.

There will be a link A, to the survey. Then a more detailed invitation will be displayed if participants press the link. A link B will appear with more information about the survey. Link B will lead to a special website named "*My E-health*" explaining the rational for the survey, who is responsible, funding and the long-term goals.

The survey comprises 29 questions, estimated time to complete the survey is 5 minutes. The questionnaire elicits information on weight and height, dietary intake, alcohol consumption, physical activity and tobacco use, using standardized questionnaires. Demographic variables such as age, education, marital status and selected diseases are included as background variables.

Healtcom AS will collect the data and transfer them to the data management tool RedCap. The data will be stored with an identification number, but otherwise they will be de-identified from the personal information number received from the Population Registry. The linkage key will be stored on a secure server provided by the University Hospital of North Norway. The results will be displayed on the My E-health website as a heat map over Norway. We will use the 11 counties or the five health regions depending on participation proportion.

Results

We expect a participation of 30-40% after 1-2 reminders. We will examine responders according to demographic factors and geographical area. Preliminary results as well as the developed website, technical solution and heat map will be presented.

Discussion

Our overall objective is to provide residents in Norway, health authorities and politicians with a picture of the change of health indicators for non-communicable diseases year by year. These changes will tell us how we are doing on important health indicators, towards reaching the goal of a 30% reduction in premature deaths of non-communicable diseases by 2030. If the ICT solution is successful, the next step will be to write a proposal to Horizon 2020, with the goal of expanding the study in Norway as well as conduction of a similar study in two additional countries. The results, technical challenges, strengths and limitations of the pilot study will be discussed. Furthermore, possibilities for applying to the upcoming calls of the Horizon 2020 Work Programme in the field of Information & Communication Technologies, Future and Emerging Technologies (FET), and Societal Challenges.

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The Relationship Between Anxiety/Depression, Electronic Health, and Doctor Visiting Decisions Among People with Diabetes

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Background

Despite the increasing prevalence of diabetes, the increasing prevalence of anxiety/depression and the increasing use of electronic health (eHealth), little is known about the associations between these increasing trends. Our objective was to study whether the use of eHealth and self-reported anxiety/depression might change patients' doctor-visiting decisions, and in particular regarding the Use of Out-of-hours (OOH) Services.

Methods

We used e-mail survey data collected in 2018 from members of The Norwegian Diabetes Association (18 to 89 years). Using logistic regressions, we studied patients' internet-triggered changes in decisions regarding doctor visits, and whether these were associated with self-reported anxiety/depression. In particular, we studied associations between anxiety/depression, the use of eHealth, and the use of OOH services. Analyses were adjusted for gender, age, education, and self-rated health.

Results

We used two samples, one consisting of 523 people diagnosed with type 1 diabetes (T1D), and one consisting of 895 people diagnosed with T1D or type 2 diabetes (T2D). In the sample of 523 people with T1D, 26.7% had visited OOH services once or more during the previous year. The use of OOH services was positively associated with self-reported anxiety/depression (odds ratio [OR] 4.53, CI 1.43-14.32) and with the use of apps (OR 1.73, CI 1.05-2.85). Those who had felt anxious based on information from the internet, more likely visited OOH services compared with those who had not felt anxious (OR 2.38, CI 1.50-3.78). In the sample of 895 people with T1D or T2D, 75.4% had never made an internet-triggered change of decision in any direction regarding visiting a doctor, whereas 16.4% had decided to visit and 17.3% had decided not to visit. The probability of changing decisions decreased with higher age and increased with the severity of self-reported anxiety/depression. Those with severe anxiety/depression were 3 times more likely to make an internet-triggered change of doctor-visiting decision, compared to those with no anxiety/depression.

Conclusions

Our findings suggest that using eHealth has a significant impact on doctor visiting decisions among people with diabetes, especially among young people and people with anxiety/depression. The use of OOH services was positively associated with the use of apps and with self-reported anxiety/depression. Our findings suggest that ensuring high quality of apps and internet information is important, and that information should be tailored to a wide variety of users, in particular regarding age and mental health. More research is needed to further explore the relations between anxiety/depression, the use of eHealth, and the use of provider-based health care services.

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The 3P-project: Evaluation of Telemedicine Solutions in Patient-centered Care Teams

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Abstract

The research project "3P- Patients and Professionals in Productive Teams" aims to study different patient-centered teamwork models for patients with chronic conditions and multi-morbidities. This paper presents the outcomes from a qualitative study on the information flow and technology use in patient-centered care teams utilizing telemedicine, located in three health regions of Norway and Denmark. The aim was to identity barriers for collaborative work and propose models for the e-solutions of the future.

Keywords:
Technology Assessment, Patient-centered Care, Telemedicine.

Introduction

Due to demographic changes, health services face challenges in providing individualized treatment to a population prone to long-term conditions and multi-morbidities. In many countries, reforms, strategies and national projects have urged a re-organization of health service models with an increased use of technology-assisted interventions. For instance, telemedicine are remote electronic clinical consultations using technology for the delivery of health care and exchange of medical information across distance. In this context, the research project *3P- Patients and Professionals in Productive Teams* (2015-2019) aims to study health services models that are run with an inter-disciplinary patient-centered teamwork approach [1]. This paper presents a study on the information flow and use of technology in patient-centered health care teams utilizing telemedicine for follow-up of chronic pulmonary obstructive disease (COPD), located in different health regions of Denmark and Norway. The aim was to identify barriers for collaborative work across organizational bordes and propose e-solution models for the future. The research question stated was: *What are the benefits and constraints of telemedicine technology in a patient-centered care perspective*?

Methods

Qualitative methods were used for data collection, including observations and interviews. The interviews were both individual and in groups, targeting the technology, information flow and barriers for collaboration. The Norwegian Centre for Research Data approved the study with project number 53771.

Results

The study showed that the organizations used three different telemedicine systems for remote follow-up. The technologies were all tailored for telemedicine and described as well-functioning by the users, but the systems were run beside the electronic health record and administrative systems of the organizations. The telemedicine installations were proprietary solutions and a standalone system, not integrated with the main information system of the organizations, meaning that the operator needed to log in separately to use the service and the information was available only for users of the telemedicine systems. Two of the organizations had digital communication with other health care providers such as general practitioner and municipal health care services, where standardized massages could be exchanged. For the patients, there was no access to own health information stored in the telemedicine solutions, except for self-recorded data.

Conclusions

The study concluded that telemedicine technologies need to be implemented as sustainable solutions, fully integrated with the information system of the organization, to support person-centered telemedicine follow-up of COPD patients and complex team work collaboration. There is a need for information flow that includes all health care services, as patients might be receivers of multiple types of services.

Acknowledgements

References

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