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ORIGINAL ARTICLE

"HELL, YEAH!" A QUALITATIVE STUDY OF INPATIENT ATTITUDES TOWARDS HEALTHCARE PROFESSIONALS' USE OF MOBILE DEVICES

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Background: A 2017 study by Giles-Smith et al examining nurse use of and attitudes towards mobile devices at the bedside revealed nurses were reluctant to use mobile devices due to concerns patients would view such device use negatively.

Aims: To explore whether the concerns expressed in the 2017 study regarding mobile device use by healthcare professionals were valid, a qualitative study was conducted to determine patient attitudes towards healthcare professionals' use of mobile devices at the bedside.

Methods: Short interviews were conducted with 30 inpatients on medical and surgical units at a community hospital in Winnipeg, MB, Canada. Questions captured the inpatients' socio-demographic data, experiences with healthcare providers using mobile devices during their current stay, and opinions on the use of mobile devices by healthcare providers. The qualitative responses were analysed and coded to determine themes.

Results: Thirty (30) inpatients completed the interviews. Few inpatients reported observing mobile devices use during their current hospital stay. Participants were supportive of the idea of mobile device use in the hospital setting but felt use should be restricted to professional purposes. Results showed a high degree of confidence among patients in the professionalism of their healthcare professionals.

Conclusion: Patients expressed an acceptance of mobile device use in hospitals as a natural extension of the increasing prevalence of technology in modern society. As mobile device use in hospitals increases, healthcare policies that outline acceptable use and protect patient privacy will be necessary. Education will play an important role in improving patient understanding of how mobile devices are used at the bedside.

Keywords: Inpatients, attitude, qualitative research, surveys and questionnaires, mobile devices

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Introduction

The medical literature saw a new area of research open up in recent years with health professionals exploring new and potential uses of mobile technologies at the bedside. As researchers and clinicians consider the possibilities for handheld devices in the health sciences, the convenience is clear. Handheld devices are compact and can contain multiple mobile applications including reference books, organizational guidelines, and drug monographs[1–3.] The ability to provide enhanced communication, point of care tools, and electronic prescribing are just a few other features that allow mobile devices to contribute significantly to safer, more efficient, and higher quality patient care[4–7].

A study conducted at the Grace Hospital and Saint Boniface Hospital in Winnipeg, MB, Canada by Giles-Smith, et al [8], examined nurse use of and nurse attitudes towards mobile devices at the bedside. In this 2017 study, nurses reported rarely using mobile devices at the bedside and often expressed ambivalence towards using mobile devices in front of their patients for fear of disapproval and the appearance of unprofessional behaviour. In particular, participants felt elderly patients would not accept nurse use of mobile devices. These opinions, however, were not based on direct input from patients or family members themselves. Similarly, an earlier study by Stroud, Smith and Erkel[9] found that nurse practitioners in the United States felt patients would negatively view mobile device use in patient care. A 2020 scoping review by de Jong, Donelle, and Kerr on nurse use of mobile devices also pointed to nurse concerns about patient perception and potential patient complaints.[10]

There are many articles on mobile devices in healthcare that concentrate on healthcare professionals' use or assessment of mobile devices and applications in their work[8–17]. Those that focus on patients often examine the usage of mobile devices by patients as part of mHealth initiatives largely dealing with managing chronic conditions such as diabetes[18–22]. Other studies consider patient opinions regarding specific features of mobile technologies. For instance, Seth et al[23] discussed patient attitudes towards email communication with their healthcare providers in Southern Ontario. Hsieh et al[24] surveyed patients about their feelings regarding usage of mobile devices for photography and general use for reference and communication.

A small number of studies focus on the attitudes of patients towards their healthcare providers using mobile devices at the bedside. In a study of inpatient and caregiver attitudes towards mobile device use in Australia, Alexander et al reported that 73% of survey respondents accepted mobile device use if the doctors were using it for professional and not personal reasons. Patients were more favourable towards doctors using mobile devices than nurses. A major concern from Alexander's study was that mobile devices distracted both doctors and nurses. There were also participants who thought devices were being used by healthcare professionals for personal or social reasons such as texting and phone calls[25].

Blocker, Hayden and Bullock surveyed patients and staff on a trauma and orthopedics department in a teaching hospital in Wales. Of the 59 patients who completed their survey, most (78%) reported never seeing a doctor using a mobile device in the hospital. Those who did see a doctor use a mobile devices believed it to be for work-related communication or educational purposes. No patient thought it was being used for gaming or social media. However, despite the perceived use for professional reasons, most patients (57%) indicated their opinion of their doctor as a professional was negatively influenced by mobile device use. This study found no significant relationship between age of the patient and their opinion of doctors using mobile devices[26]. A Lebanese study of emergency department patients found 92.6% of study participants felt mobile devices improved healthcare delivery but many patients still did not like their use in the emergency department. Concerns included how it impacted their relationship with the healthcare provider, communication, and potential distraction[27].

Illiger et al investigated patients at Hanover Medical School in Germany regarding their acceptance of and use of mobile devices in medical settings. 213 patients were surveyed and most of these (51.6%) owned a mobile device. The majority of patients accepted their doctors using mobile devices but there were concerns about security with 22.3% replying they did not want their doctors to have their individual health-related data on a mobile device and 53.1% were concerned about data protection[28]. A 2019 study showed that ambulatory patients were more accepting of mobile device use when their physician explained why they were using it[29].

Given the juxtaposition of mobile devices as both a potential aid for healthcare professionals and also a potential source of patient disapproval, it is

interesting that a significant gap exists in the literature regarding patient perceptions of mobile devices at the bedside. Whether patients feel their healthcare providers are distracted or unprofessional is an important and under-addressed aspect of the discussion on the use of mobile devices in healthcare. While healthcare professionals may express these concerns on behalf of their patients, there are few studies that address whether these perceptions are correct.

The objective of this study is to describe Grace Hospital surgical and medical inpatients' attitudes and feelings towards healthcare professionals' use of mobile devices at the bedside. The Grace Hospital, at the time of the study, was a 251-bed community hospital located in Winnipeg, MB, Canada.

Methods

Patients were eligible for inclusion in the study if they were 18-years of age or older and had been an inpatient on a medical or surgical unit at the Grace Hospital for at least three days. Patients exhibiting active delirium or dementia and patients in isolation were excluded from the study. A nurse educator not involved in the research project approached eligible patients prior to the interviews. They were given information on the study and asked whether they would be willing to meet with the researchers to conduct a short interview. As an incentive, patients could enter a prize draw to win one of two $100 grocery gift cards.

The researchers conducted patient interviews from March until June 2016. Interviews were guided by a 20-item fixed and open-ended survey developed by the researchers to capture demographic data and attitudes of patients towards healthcare professionals' use of mobile devices (Appendix A). For the purposes of this study, healthcare professionals were considered to be any person the patient observed working in a professional capacity in the hospital. This included but was not limited to physicians, nurses, and allied health professionals such as pharmacists and occupational therapists. Consent forms were reviewed with the patients and signed at the time of the interviews. Copies of the consent forms as well as information about the project, including the researchers' contact information, were given to the patients.

Ethical approval for the study was obtained from the University of Manitoba Health Research Ethics Board (H2015:395 (HS19026)) and Research Access approval was obtained from Winnipeg West Integrated Health and Social Services. All participants gave informed consent prior to taking part in the study.

Results

Descriptive statistics were conducted including frequencies and means for inpatient demographics.

The researchers completed interviews with a convenience sample of 30 inpatients. Patients ranged in age from 25–89 years with the average age being 67 years. The majority of patients were retired. The most common length of hospital stay was 3–10 days. Fourteen (14) patients owned a mobile device and 16 did not. The group was evenly split between males and females.

Only ten (10) of the 30 patients interviewed recalled a healthcare professional using a mobile device in their presence during their current hospital stay. None of these patients had a negative response regarding this usage. When combined with those who were asked how they thought they would feel if they did see such mobile device use, the results were mostly split between those having a neutral reaction (n=15) and a positive reaction (n=12). A minority of participants expressed a negative reaction (n=3) (Figure 1).

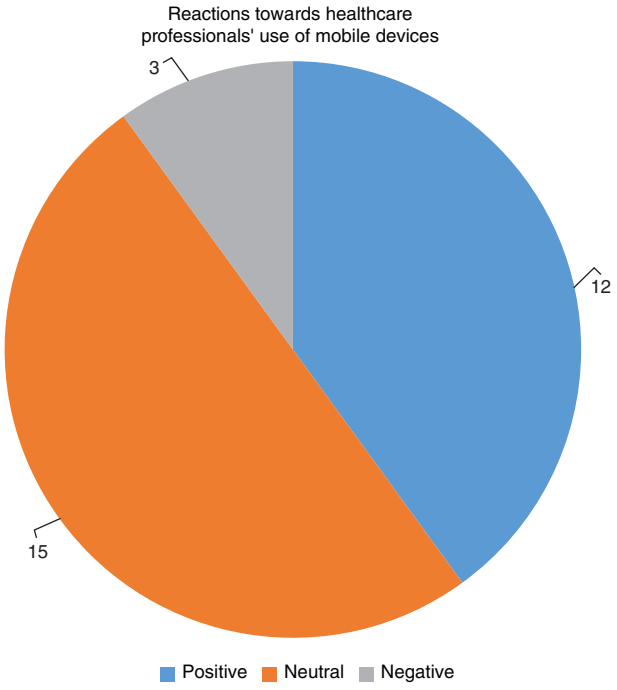

Figure 1: Reactions towards healthcare professionals' use of mobile devices.

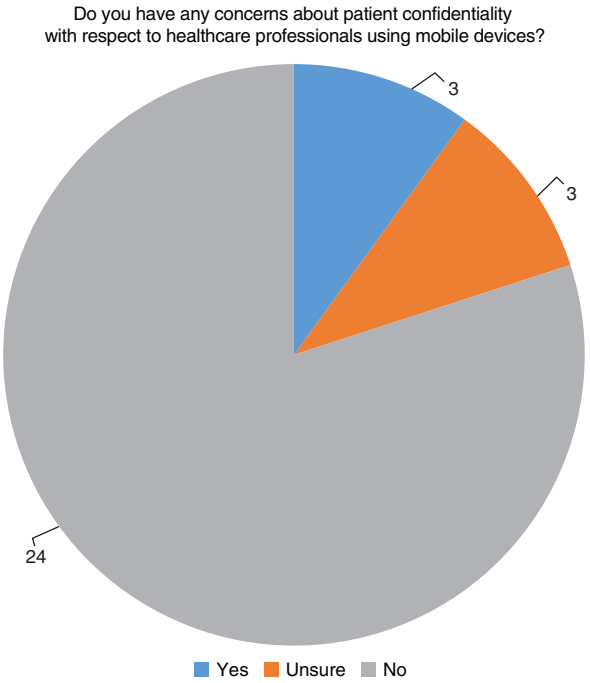

Figure 2: Do you have any concerns about patient confidentiality with respect to healthcare professionals using mobile devices?

When asked if they had any concerns regarding confidentiality with respect to healthcare professionals using mobile devices, the vast majority of participants said they were not concerned (n=24) while three (n=3) were concerned and three (n=3) were unsure (Figure 2).

Using methods described in the nursing literature[30–32], the researchers employed content analysis and constant comparison techniques to identify, code, and categorize the qualitative data collected in the inpatient interviews. The researchers developed a coding template and tested it for inter-rater reliability. When the authors disagreed on coding, discussion ensued until consensus was attained. The authors employed the coding template and analyses continued where similar codes were grouped into themes and subthemes.

Five main themes emerged from the qualitative data collected in the patient interviews;

1. **Modernization of healthcare: Mobile devices and applications as accepted technology in the modern healthcare environment.**

"Hell, yeah! It's about time . . . the world has stepped up and caught up instead of these misguided beliefs thinking that they should only be used in a closet or something like that. They're out there to educate, to make people smarter, and if you do not know you can find the answer. They're there to help. They're not there to hinder."

"Caught up with the times."

"If it was a doctor that had all my health information and my hospital stay, progress, and all that stuff for the health. Well, that's fine. That's what they're for. It's a new age."

Patients often expressed the idea that mobile devices are commonplace in modern society and expected this technology to be utilized in hospitals. Patients who embraced this technology themselves enthusiastically expressed their support for mobile devices. Other patients were less inclined to use mobile devices themselves but nonetheless recognized that advances in technology would impact healthcare. Some patients did not seem to understand how this technology worked or felt overwhelmed by the growing pace of mobile devices in society but they still accepted mobile device use as part of advancements in healthcare.

2. **Benefits of mobile devices in healthcare: Ideas on how healthcare professionals could use mobile devices in their work and ways in which mobile devices could have a positive impact on healthcare professionals' work.**

"It would reassure me that if they needed to confirm a diagnosis or a treatment or what I'd asked them they were giving me the proper answer."

"I think it's much easier than writing everything down and saves on paper."

"I mean it's a quick communication and if they need to connect with another area to ask a question about something."

"Ah, gives them an idea of what the condition of the client is. It allows them to, um, advise the client, ah, what the status is."

"I think they're smart . . . because we're human. We make mistakes."

Patients had many ideas regarding how healthcare professionals could use mobile devices at work including to communicate with colleagues, record data, and locate medical information. A reoccurring thought was that healthcare professionals would use it to verify information about the patient's condition, test results, and treatment. A few recalled

their experiences with healthcare professionals using mobile devices in their care including as a flashlight and to check for potential drug interactions. Patients cited conveniences such as saving time, ease of use, and reduction of paper. Many of the ideas patients articulated showed that they did not fully understand how mobile devices would be used in patient care. Answers were often vague as patients commented that their doctors would use them for "emergencies", "information", and "medications".

3. **Personal use: Thoughts and feelings regarding healthcare professionals using mobile devices for personal versus professional reasons.**

"I mean, I don't expect you people to ignore your families, you know."

"Ohhhhhh, if they are married they're checking on the kids! [laughs] I mean, that's natural!"

"Could be negative if they, say, if you are talking to them and they pull out their phone and start texting but I could see them not doing that. I don't think they would at least."

"I don't think they should use it for personal use while they are on the job."

Patients gave some surprising answers regarding healthcare professional's use of mobile devices at work for personal reasons. While most felt mobile devices should only be for professional purposes, some patients assumed healthcare professionals would use their mobile devices to check in with family and were comfortable with that type of usage. Other patients felt healthcare professionals could use mobile devices for personal reasons at work as long as it was not in front of their patients or when they were on a break. Most patients, however, firmly expressed that mobile device use for personal reasons had no place in the healthcare setting. Many stated they would be uncomfortable if mobile devices were used in front of them for personal reasons.

4. **Professionalism: Professional behaviour of healthcare professionals regarding mobile devices in the workplace.**

"I think they use it in good faith."

"Well, you would think if they be us-, be using them, they would be under the same rules and conditions that anything else they would be doing."

"I don't care what they do as long as they look after me."

Patients placed a high degree of trust in their healthcare professionals with respect to the use of mobile devices and did not expect healthcare professionals to misuse mobile devices. When patients expressed any misgivings about potential misuses of mobile devices they frequently followed it up by saying they never witnessed any inappropriate use or that they would not expect their healthcare professional to misuse them. Often patients said they would not question mobile device use by their healthcare professionals as they respected their judgment and felt confident that their healthcare professional was taking care of them.

5. **Confidentiality: Ideas on whether patient information was secure with mobile device usage.**

"Well, they should be accessible by passcode."

"Confidentiality . . . will not take place if they are using mobile phones or devices like that."

"Yeah, but that could be with anything. I mean with the records that they got there, how confidential is that? Or if they're talking there and someone goes by and they hear it. Like, what's confidentiality?"

"I work a little bit for government and I know all about FIPPA and PHIA and all that so I know that they would have to maintain the same confidentiality that they do already."

Most responses regarding confidentiality indicated patients wanted their information to be kept private but were not troubled by mobile device use as they expected security systems to be in place to ensure there were no breaches of privacy and data would not be lost. Respondents were often vague when commenting on how privacy would be protected, referring to "firewalls", "code numbers", and "passcodes". One patient pointed out that healthcare professionals were bound by the same privacy regulations if they used mobile devices as they would if they were not using them. No patient expressed concerns over their data being shared over social media or with non-healthcare professionals.

Discussion

In Giles-Smith's original study on nurse use of mobile devices, nurses expressed a fear that patients would perceive mobile device use unfavourably and view their nurses as disrespectful and unprofessional, especially if the patients felt the mobile devices were being used for personal or entertainment reasons[9]. The current study was conducted to

determine whether these concerns were valid and the results largely disproved these worries. While only one third of patients experienced a healthcare professional using a mobile device in their presence, overall attitudes towards the idea of healthcare providers using mobile devices was favourable. As Illiger et al similarly reported, patients expressed a high degree of confidence in the professionalism of their healthcare professionals[28]. This was, however, in contrast to research by Blocker, Hayden and Bullock who found that over half of patients viewed device use negatively even if it was being used for professional reasons[26].

Many of this study's findings reinforced results of previous literature on this topic. As in Alexander et al[25], patients thought their healthcare professionals would utilize mobile devices for communication and information though a small number also assumed the devices would be used for personal reasons. While some patients at the Grace Hospital felt healthcare providers should be able to use mobile devices for personal use, most did not find this appropriate. Personal use of mobile devices during work time is not acceptable practice for healthcare professionals at the Grace Hospital. Given the number of patients who thought their healthcare professionals would utilize them for personal reasons and the vague responses for why healthcare professionals would use them for professional reasons, education and communication will be crucial as hospitals look to implement policies regarding mobile device use among staff. Patients should understand why their healthcare provider is using a mobile device and be given enough information to feel comfortable when mobile devices are used in their presence. Clearly articulated policies need to be developed, communicated, and implemented that guide device use by healthcare professionals while at work to ensure the benefits of mobile devices are not undermined by negative effects such as distraction, noise, contamination, and breaches of confidentiality[30–32].

While recognized as an important issue, patients trusted their information would be kept private and felt security systems would be in place to protect their information. They were less concerned than Illiger's study group where 22.3% did not want their doctors to have their individual health related data on a mobile device and 53.1% were concerned about data protection[28]. In addition to how and why the device is being used, healthcare professionals should also advise patients that their confidentiality will not be compromised as a result of such device use. To alleviate any concerns patients do have about confidentiality, institution-provided mobile devices for patient care could be marked to alert patients and family members that the device is hospital sanctioned. This could remove concerns such as picture taking and confidential information being stored on a personal device. It would also reduce inappropriate use through the blocking of social media apps, inappropriate websites, personal email, and texting. To ensure proper use of mobile devices and security of information, healthcare professionals should be reminded of privacy legislation.

As there are limited studies on the subject of patient attitudes toward mobile device use among healthcare professionals, larger studies on this topic are necessary. It would be useful to determine whether there are correlations between age, gender, and ethnicity and attitudes towards mobile device use by healthcare providers. Future studies could explore how healthcare providers could involve patients and families when using mobile devices to promote acceptable use. As stated, one limitation of this study was that it was limited to inpatients on medical and surgical wards. Research involving patients in other hospital departments as well as outpatients would greatly improve our understanding of attitudes towards mobile devices in the healthcare setting. Technology such as mobile devices and applications is ever changing and, as evidenced in this study, patients are recognizing this. Research is required to plan and promote advances in healthcare that utilize this mobile technology for better patient care.

Conclusion

This study revealed the attitudes of medical and surgical inpatients towards their healthcare professionals' use of mobile devices in a community hospital in Winnipeg, MB. Though few patients experienced mobile device use by healthcare professionals during their hospital stay, results showed that these inpatients were very accepting of mobile device use and placed a significant amount of trust in their healthcare professionals with respect to their usage. Patient responses showed that while they would disapprove of using mobile devices for personal reasons, they trusted their healthcare providers to behave professionally. To ensure patients understand why mobile devices are being used in a hospital setting and to ensure appropriate mobile device use by healthcare professionals, policies and education need to be developed.

Declaration of competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: Giles-Smith and Spencer report grant money from Grace Hospital Foundation during the conduct of the study.

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Appendix A: Survey

Patient Attitudes Towards Mobile Communication Device Use by Health Care Professionals

Grace Hospital, Winnipeg, MB

Definitions for purpose of this survey:

Mobile Device: A portable computing device such as a smart phone or tablet that you can use to access the internet

Mobile Application: Software application designed for mobile devices

ABOUT YOUR MOST RECENT STAY AT THE GRACE HOSPITAL

1. When were you admitted to the hospital?

2. During your stay, did any health care provider use a mobile device in your presence? (If the answer is yes, proceed to question 3. If the answer is no, proceed to question 10)

3. When health care providers used a mobile device in front of you, did they ask your permission to do so?

4. When health care providers used a mobile device in front of you, did they explain why they were using it?

5. When health care providers used a mobile device in front of you, did you feel you understood why they were using it?

6. During your stay, did a health care provider use a smart phone or tablet to answer a question you asked?

7. During your stay, did a health care provider show you their mobile device when explaining something?

8. If a health care provider used a mobile device in front of you, how did you feel?

9. If a health care provider used a mobile device in front of you, do you think it effected how you communicated with them?

10. What do you think when you see a health care professional using a mobile device?

11. Do you have any concerns about patient confidentiality with respect to health care providers using mobile devices?

12. Is there anything else you would like to share about health care providers using mobile devices?

ABOUT YOU

1. What gender do you identify with?

____ Male

____ Female

____ Other

2. What is the highest level of education you have completed?

____ no high school

____ some high school but did not graduate

____ high school or high school equivalency certificate

____ some postsecondary

____ trade, vocational or technical diploma

____ undergraduate degree

____ postgraduate or professional degree

____ prefer not to answer

3. What year were you born?

19____

4. What is your annual household income? _____ $0 – 24,999

_____ $25,000 – 49,000

_____ $50,000 – 74,000

_____ $75,000 - $99,000

_____ Over $100,000

5. Employment status. Are you;

____ Employed

____ Retired

____ Currently unemployed

____ Homemaker

____ Student

____ Unable to work

____ Self employed

____ Prefer not to answer

Other _____

6. Do you identify with any particular cultural or ethnic group?

7. Do you own a mobile device (e.g., smartphone, tablet)?

8. If you own a mobile device, how important is its use in your daily life?

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ORIGINAL ARTICLE

MIND THE GAP – A STUDY ON MHEALTH BASED TREATMENT PROCESS OPTIMIZATION IN ADDICTION MEDICINE

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Background: In rural areas, a considerable lack of therapy and self-help facilities has been described with regard to drug dependence treatment. Mobile technologies are supposed to bridge geographical distances and improve access to healthcare.

Aim: The paper therefore aims to compare conventional vs. mHealth supported delivery processes in drug dependence treatment.

Methods: We use BPMN process modelling to compare usual vs. mHealth assisted treatment pathways for drug addiction. The details of mHealth support (mHealth configuration, monitoring, interventions, information processing) are also demonstrated.

Results: The paper shows (1) that the medical treatment gap mainly occurs at the interface between inpatient and outpatient care and (2) that mHealth support eliminates this interface problem. mHealth effectively supports drug dependence treatment in rural areas.

Conclusion: The paper demonstrates an mHealth based optimization of a complex treatment process. Our approach is also expected to improve theoretical and practical knowledge in mHealth service engineering.

Keywords: patient-therapist collaboration, mHealth, clinical pathway, drug addiction, BPMN, interface

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Introduction

IT for healthcare professionals

Performance and service quality of healthcare crucially depend on the availability of information[1]. The high complexity of medical processes also meets IT based support at the point-of-care[2]. Therefore, modern mobile IT applications have the potential to assist with improving healthcare outcomes and adapting the treatment as appropriate for the current situation. In this regard, particular attention has been paid to the healthcare perspective: hospital staff, practitioners and therapists, community nursing and paramedic staff or rescue workers have been addressed as target groups[3,4,5,1].

The patient perspective

Improved use of information fosters not only professional orientation for providers but also their patient relationship[6,7]. Therefore, some working groups[8,9] have already dealt with provider-client-interaction, i.e. (tele-)consultations. On the consumer or patient side, this could also be facilitated by long-established mobile IT usage, particularly of smartphones and corresponding applications[10,11,12].

This contribution uses a broad perspective including affected patients, professional healthcare providers, from the field of psychiatry and psychotherapy, and necessary treatment pathways. On the one hand, as described in detail in Chapter 4, the conventional addiction treatment process contains serious gaps[13,14], in particular due to the physical distance of drug- dependent outpatients from specialized healthcare providers. On the other hand, Tryon et al.[15] emphasize patient–therapist collaboration to enhance psychotherapeutic outcomes. Following Oates[16] (pp. 296–298) for a critical research perspective, this contribution challenges the status quo but could also help with fundamentals for empowering patients. This results not only in maintaining a more seamless care but may also leads to improved shared decision making, patient-centricity and better autonomy and independence from health service providers. It might also assist with patient collaboration in terms of electronic availability of self-help groups. This also corresponds to Probert's[17] (pp. 137, 151) call for linking social aspects, such as relationships, of stakeholders with meeting organizational or economic pressures (e.g. costs) while providing users more control over the IT applications.

Motivation and introduction to the research problem

One author of the present study is a senior physician in a counselling centre specializing in addiction diseases treatment. In his more than 10 years' experience, drug-dependency disorders are chronic diseases with patterns of complex mental, physical and socio economic damage. In contrast to 'purely' alcohol-dependent patients, the abstinence rate of drug-dependent individuals is much lower, partially attributable to a considerable lack of drug-specific therapy and self-help facilities, especially in rural areas[13,14,18].

To bridge this gap, the German Centre for Addiction Issues (german: Deutsche Hauptstelle für Suchtfragen / DHS) demands the development of digital solutions to complement and optimize the existing analogue therapy processes[14]. It has already been proven that mobile technologies in particular are suitable to compensate for the greater geographical distances and the resulting inefficiency and supply deficits in rural areas[19,1]. A recent study with participation of key stakeholders created the research hypothesis that "a mobile technology-based system could (a) be successfully implemented for patients recovering from drug dependence and (b) improve the outcome for these patients"[18].

This resulted in the motivation to systematically examine the treatment process for drug dependent diseases with regard to the optimization potential through mHealth systems. In the present study, this could be achieved by close cooperation between healthcare providers and two academic IS research institutions (Information Management & Information Systems, Osnabrueck University, Germany; Faculty of Informatics, Wilhelm Büchner Hochschule – Mobile University of Technology, Germany).

Research objective

The study aims to evaluate the scientific hypothesis that an mHealth application might be suitable for process optimization in the area of drug dependence treatment. Our Business Process Model and Notation (BPMN) based approach of comparing (conventional vs. mHealth supported) delivery processes is also expected to provide theoretical and practical knowledge that might be useful with regard to mHealth service engineering.

Method

In contrast to natural sciences (aiming to map the status quo as precisely as possible), problem solving and further development of complex systems require

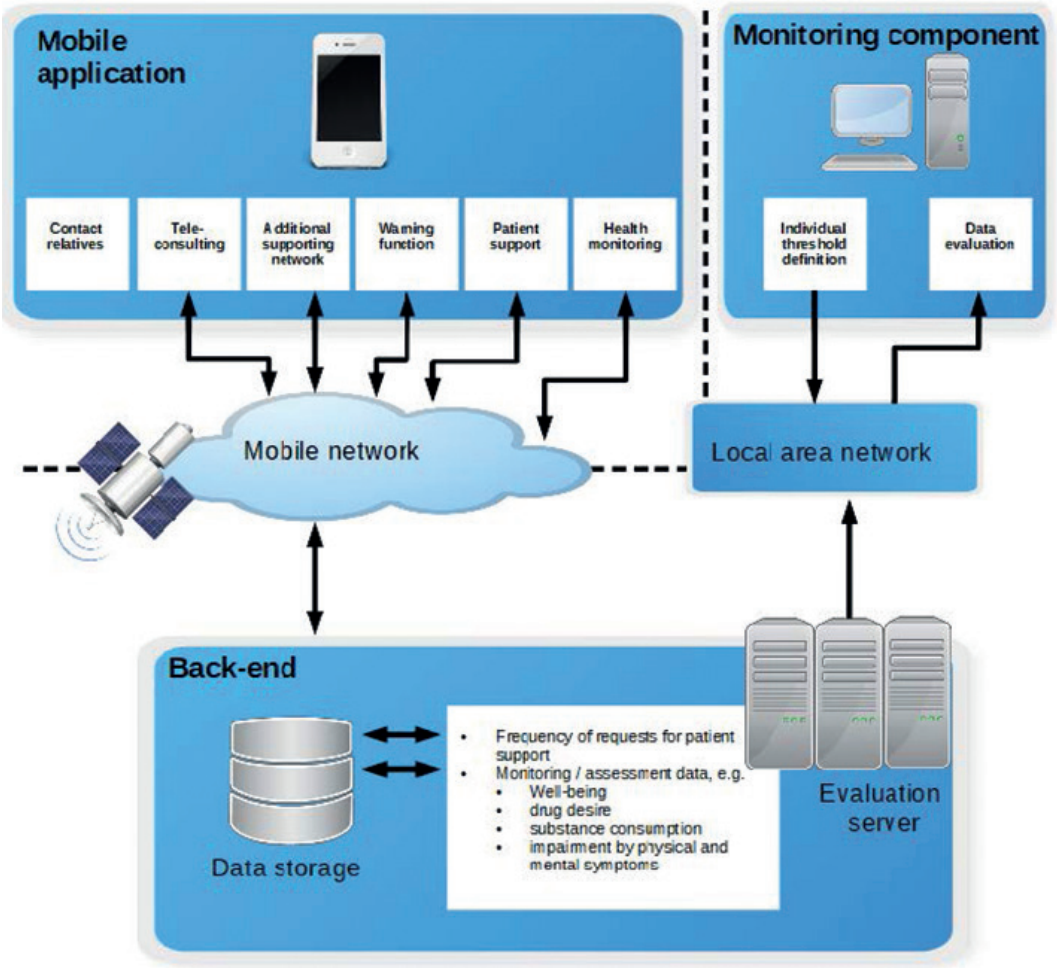

Figure 1: Architecture of the solution from[51], refined and updated

the detection and evaluation of novel, i.e. not yet existing approaches. In this context, typically more than one single solution can be regarded as effective or "correct". The number of possible solutions may also increase over time, so that additional solutions may come possible due to changed theoretical frameworks or due to new technological or social conditions. These solutions are called "***artefact***" if they "have, or can be transformed into, a material existence as an artificially made object (e.g., model, instantiation) or process (e.g., method, software)"[20]. For innovative (socio-)technological objectives, such as the one described above, design-oriented approaches are proposed for healthcare: for modelling[21] and for the use of healthcare IT[22].

In the initial phase of Design Science (DS), purely intuitive procedures dominated the handling of artefacts. In order to convert this randomized "hacking"[23] into a verifiable, targeted scientific process, an appropriate research methodology is essential.

From 2004 to date, based on the seminal works by Simon[24], Hevner[25,20,26] and Peffers[27,28,] essential milestones of ***DS Research Methodology (DSRM)*** including 6 consecutive research "activities" have been developed and published. The basic DSRM reference work by Peffers[28] already pointed out "there is no expectation that researchers would always proceed in sequential order from activity 1 through activity 6. In reality, they may actually start at any step and move outward".

As the present research project arises from a "problem centred initiation"[28] (p. 54, figure 1), it starts with DSRM activity 1 (problem identification & motivation) and extends to activity 2 (definition of the objectives for a solution) in the following[28] (pp. 52–56). According to the "DSR knowledge contribution framework", our main scientific contribution is an "improvement", as the solution maturity is low (i.e. a new solution is studied) while the application domain maturity is high (i.e. a known problem is studied).

DSRM Activity	Activity elements	Chapter of present paper
Problem identification & motivation	Definition of specific research problem	1,2
	Atomizing the problem conceptually	4
	Resources: knowledge of the state of the problemand the importance of the solution	4,5,6b
	Motivation	1
Definition of the objectives for a solution	Rationally infer objectives for a solution from Activity 1 - results	6c,7
	Explain in which aspects a desirable solutionwould be better than the current one	8
	Resources: knowledge of problem and currentsolutions	4,5,6b

Table 1: DSRM activities of the present research paper (in accordance with Peffers[28] pp. 52–56)

For best-possible orientation within the present paper, Table 1 correlates the DSRM activities components to the corresponding chapters.

We are convinced that the understanding and mHealth based optimization of a complex treatment process can be strongly supported by suitable visualization and representation in models; such reference representations may also increase process and outcome quality[29].

Another advantage of this approach could be an increased healthcare transparency for patients and their relatives[30]. Standardized health care processes are also considered essential for patient safety[31]. For psychiatry, it has previously been undertaken to model care pathways[32] (for definition of clinical pathways see Table 2).

The ***BPMN standard*** is well-established in clinical IS development[33]. The corresponding methodology has been developed by the Business Process Management Initiative (BPMI, later merged with the Object Management Group OMG) to ensure comprehensible presentation, monitoring and control of complex processes. through the years[34], BPMN has become "the de facto and ISO (International Standards Organization, Geneva) standard for process modelling, providing support for modelling control flow, data flow and resource allocation". It also allows for explicit modelling of the collaboration between various stakeholders by use of so-called swimlanes (cp. Fig. A4, for instance). BPMN has been proven to be easily understood by stakeholders, to represent the real organizational processes and to facilitate a translation of business models into business process execution language[35]. Pryss et al.[2,36] successfully used BPMN for process conceptualization and realization on mobile devices (2011) and surveyed its usage for clinical process visualization as helpful (2015).

The paper at hand therefore uses BPMN process modelling to investigate to what extent a drug-specific mHealth application offers potential for reducing barriers in the processes of drug addiction treatment and aftercare with the main intention to close the shortage of care in sparsely populated regions.

Introduction to the medical challenge

In Germany, about 1.7 million people suffer from alcohol addiction, and worldwide 3.3 million deaths result from alcohol related disease every year[37]. Dependency disorders lead to poverty and numerous secondary diseases such as liver cirrhosis, polyneuropathy, psychosis, seizure, persistent personality changes and chronic infectious diseases. In the US, recently a national emergency was declared due to the increased deaths associated with opiate dependence[38].

As alcohol is the main addictive substance, the corresponding German medical care structures for alcohol dependence are developed to a very high standard. These include addiction counselling centres, where patients receive low-threshold counselling, motivational therapy and – and after gaining sufficient intrinsic motivation – referral to the medical treatment. In Germany, the gold standard is considered to be an inpatient withdrawal treatment, ideally following a detoxification treatment to eliminate the addictive substance from the body under medical

control of the risks (eg seizures or a potentially life-threatening delirium)[39]. Unfortunately, a definitive cure for an addictive disorder is not possible, so that a "maintenance therapy" is required after the weaning treatment. This includes an outpatient follow-up treatment of about 6–12 months carried out by addiction therapists and physicians in outpatient institutions or, again, in the addiction counselling centres. Lifelong participation in self-help groups has proven to be prophylactic against relapse[40,41].

At first glance, these medical care structures are available for drug dependent patients as well as for alcoholics. However, the treatment structures for drug users show a clear geographic heterogeneity in contrast to a nationwide sufficient treatment for alcohol dependence. While there are sufficient drug-specific offers of follow-up care and self-help work in larger cities and agglomerations, there are neither enough addiction specialists in the sparsely populated German regions nor appropriate drug-specific addiction self-help groups. Only 2.5 % of drug dependent patients have access to adequate groups, so that the German Centre for Addiction Issues (DHS) names drug dependent persons as a "target group (that has) not (been) reached"[13]. Consequently, there is a gap in the drug addiction treatment process with regard to drug-specific therapy and self-help which probably contributes to the high relapse rate of about 90% within a year of discharge after inpatient detoxification treatment[42].

Clinical pathways are used as "an effective and efficient approach in standardising the progression of treatment, to support patient care and facilitate clinical decision making" [43] as shown in Table 2.

Structured multidisciplinary plan of care	Criterion must be met
	AND
Translation of guidelines or evidence into local structures	3 of 4 criteria must be met
Detailed steps (plan, pathway, algorithm, guideline etc.)	
Time-frames or criteria based progression	
Aim to standardise care	

Table 2: Definition of clinical pathways in accordance to Aspland[43] and Kinsman[44]

Numerous healthcare process modeling publications focus on standardized clinical treatment pathways with rather selective, technical focus, e.g. optimization of operating theatre activities[45] or radiation therapy treatment planning[46].

However, the lack of resources in medicine makes it particularly necessary to focus also those complex chronic diseases causing relatively high resource consumption by repeatedly passing through different medical sectors and supply levels. It is obvious that the identification of possible ways out of this vicious circle is not only economically necessary, but can especially offer a significant quality of life improvement for those patients concerned.

Towards a solution/Introduction to mHealth

mHealth offers the possibility of providing information and medical services even in sparsely populated regions by using a sophisticated IT infrastructure. In a country with many remote areas, for example, an information platform has been established[47] for midwives who would otherwise have had no access to up-to-date specialist information. Another typical example is an application supporting rural medical services[48,49].

Considering telepsychiatric settings, there is evidence for sufficient efficacy "for psychiatric assessment and treatment in the adult, child, and geriatric populations"[50]. However, as yet there is no marketable mHealth product for the most affected group of drug dependent patients .On the other hand, concrete elements / requirements of such an application have been described in detail involving experts on the patient and therapist side[18]. Its basic feasibility has been shown[51] meaning that it could "be transformed into a material existence as an artificially made process (e.g., software)" and therefore – strictly speaking – represents an "artefact" in the sense of DS[20].

In accordance to[51], we propose a possible architecture of the mHealth system:

Results[i]

Classical treatment pathway for alcoholism (Fig. A1)

After the admission procedure in the addiction clinic with specialist diagnosis and therapy plan preparation, the inpatient therapy process, i.e. the actual addiction therapy, begins. The core of this sub-process is a daily group (max. 12 patients) psychotherapy and accompanying individual

[i]All BPMN diagrams can be found in the Appendix.

therapy performed by inpatient addiction therapists. In addition, there is a broad spectrum of individualized therapy modules depending on the physical and emotional comorbidities of the patient. This can range from multimodal pain therapy to trauma-specific therapy offers and also concepts for professional reintegration. As one result of such a multi- faceted and profound inpatient treatment lasting on average 15 weeks, the inpatient addiction therapist usually obtains a very comprehensive picture of those patient- and context-related factors contributing to the development of the addiction disorder. In a second step, individual coping strategies can be developed. This comprehensive and differentiated addiction therapeutic information package will be further updated in the context of a cross-professional final conference and a final medical examination and then forwarded as standard by the inpatient addiction therapist to alcohol-specific aftercare providers.

To ensure a sufficient information flow, the hospital discharge report is preceded by a telephone conference. This ensures that (similar to e.g. an electrocardiogram [ECG] or magnetic resonance imaging [MRI] finding in internal medicine) at the interface between inpatient addiction treatment and aftercare, the information obtained during inpatient stay will be available seamlessly in the alcohol-specific follow-up treatment. As a result, the generally available outpatient therapists (specialized in the treatment of alcoholism) can directly refer to the existing individual disorder models, coping strategies and crisis intervention techniques.

Classical treatment pathway for drug addiction (Fig. A2)

The inpatient drug addiction treatment course from the admission procedure to the inpatient therapy process to the final case conference and final examination is comparable to that already described for alcoholism treatment. It generates as much post-stage essential information regarding individual disorder models, coping strategies and crisis intervention techniques. Of course, a seamless further therapeutic use of this differentiated support package would be highly desirable and useful especially for the young and socioeconomically as well as medically severely impaired drug dependent persons.

Unfortunately, there is often neither a drug-specific follow-up treatment with appropriately qualified outpatient addiction therapists available. This also concerns drug-specific self-help groups for the large number of drug dependent patients living in the sparsely populated regions outside the major cities and metropolitan areas.

A comparison of the illustrated drug addiction specific treatment pathway with that for alcohol dependency clarifies the termination of both the process flow and the flow of information at the interface between the inpatient drug addiction treatment and the outpatient follow-up treatment. Exactly this phenomenon is also felt by the patients concerned[18]: they are cut off from further drug-specific treatment or self-help. That means that the solutions developed in the intensive inpatient treatment cannot be used efficiently, but "sand down" due to a lack of drug-specific outpatient support.

The likelihood of re-developing a desire to consume drugs due to post-hospital personal and occupational stressors, and then to relapse due to the loss of those coping strategies developed during inpatient therapy, is obvious.

The resulting extreme high relapse rates threaten the individual patient's health, but also represent a huge economic burden: e.g., as increased costs of crimes by drug-using persons, as lower social security contributions or as growing numbers of high-frequency acute hospital treatments (e.g., acute detoxification, treatment of expensive addictive consequential damages).

mHealth assisted treatment pathway for drug addiction (Fig. A3)

Compared to the above-mentioned classical treatment pathway for drug addiction, the inpatient addiction therapists provide training for the patients with regard to the future implementation of a mHealth application during the actual inpatient therapy. The developed individual disorder models, coping strategies and crisis intervention techniques are then used for the individualized configuration of a mHealth application in parallel to the inpatient therapy process.

The mHealth application also offers the possibility to store the detailed information about the inpatient therapy together with resulting therapy recommendations and coping strategies in password-protected form (see section 7c: mHealth information processing). This is because a direct transfer of information between inpatient addiction therapists and (because

non-existent) drug-treatment-specialized follow-up therapists is not possible. At discharge, a multi-dimensional mHealth support can begin.

The mHealth application regularly monitors important mental parameters such as depressivity, drug desire and drug relapse. The results are processed via a server and viewed by an inpatient addiction therapist who in turn has various intervention options (see section 7b: health monitoring and mHealth interventions).

In addition, the mHealth application itself offers several options to counteract adverse events such as an impending relapse: A low-threshold opportunity to contact with important caregivers, a chance to meet with other stakeholders in the sense of a spontaneously formed self-help group and the possibility of direct patient support through the mHealth application. The corresponding key caregivers and successful strategies for mHealth-based patient support (e.g., use of relaxation procedures, memory of important therapeutic goals, physical exercise, etc.) have been previously been set up as part of the inpatient app configuration. Furthermore, the mHealth application offers the possibility to activate a location-based warning function using the smartphone's GPS system, i.e. alerting the drug-addicted user if approaching one of his former typical drug-buying and consuming places. The corresponding location information has already been implemented in parallel to the inpatient therapy process.

Two special features should be emphasized: first, there is an input option for the addiction therapists so that – in the absence of well-informed outpatient follow-up therapists – the general and individual expertise of drug-specialized addiction therapists in inpatient settings will be used.

Second, the mHealth application may provide the appropriate physicians and therapists with the high-detail discharge report package if the patient is to receive further medical and / or therapeutic treatment in the future. This includes individual crisis intervention and coping strategies generated during inpatient addiction treatment, thus significantly increasing outpatient treatment efficiency. In order to protect these particularly sensitive data from unauthorized access, they are encrypted on the one hand and not stored on the patient's end device on the other hand (see section 6f: mHealth information processing).

Individualized configuration (Fig. A4)

During the inpatient stay, training of the future app users is conducted by a trained inpatient addiction therapist ("trainer") in parallel to the therapy process. As part of this structured training course, the trainer first provides information on the installation and activation of the mHealth application. After successful activation, the trainer educates the future users in relation to the functions contained in the application. At the same time, the application carries out a self-configuration and guides the user through a structured information recording. Contents are the user profile, important caregivers as well as motivational aids developed in the inpatient therapeutic course of treatment (including individual disorder models, coping strategies and crisis intervention techniques).

The more complex alerting function is part of the training. Those users willing to set up this function are guided by the app through a suitable implementation module. Past purchase and consumption locations are individually maintained and the alerting function is set up correspondingly. At the end of the app setup and customization process, the app functionality is tested (for technical implementation see section 6g: synergism of IT and therapists in mHealth individualization).

Health monitoring & mHealth interventions (Fig. A5)

The monitoring is initially based on a structured exchange of information between the user and the mHealth application. As a result, the monitoring / assessment data such as e.g. well- being, drug desire, substance consumption and subjectively perceived impairment by physical and mental symptoms are transferred to the evaluation server under strict observation of data security regulations. On the basis of predefined scores, the evaluation server is able to prioritize the raw data from monitoring and, in the event of impending decompensation ("high risk"), sends a corresponding alert message to the inpatient addiction therapist responsible for intervention decisions. Thus the latter is well informed about the corresponding intervention priority.

After reviewing the patient profiles, the inpatient addiction therapist has the option either to contact the patient directly and to give individual assistance or, if available, to include a non-specialized follow-up caregiver (for example family doctor or psychotherapist) after reviewing the patient profiles.

However, he or she may also propose an intervention selectable from a portfolio of suitable measures formerly prepared during the inpatient app customization.

mHealth-based information processing (Fig. A6)

The highly informative mHealth package of discharge report plus individual crisis intervention and coping strategies generated during inpatient withdrawal treatment may be very helpful for sufficient outpatient treatment, but it also contains highly sensitive data. Therefore, a process-oriented presentation of the mHealth application should also include information about the mHealth information sharing process.

If both the inpatient addiction institution and non-specialized aftercare providers use the same information (e.g. from *EPA-S* medical record via a hospital information system such as *PATFAK,* a domain specific HIS) reliably evaluated with regard to security, the mHealth-based information processing is relatively easy given the corresponding consent of the patient. However, if the data transfer is to take place outside of such a protected system, it must be ensured that the patient remains "master of his data". For this purpose, in the illustrated mHealth process BPMN model we propose that an encrypted file is created and sent to the non-specialized aftercare practitioner upon request by the patient via the mHealth app.

The password required to open and decrypt the files is submitted exclusively to the patient who then has complete control over the processing of his data. If he or she wants to make the information available to a caregiver, he or she can forward the password either by phone or alternatively through personal contact.

Synergism of IT and therapists in mHealth individualization (Fig. A7)

The therapeutically moderated individual customization of the mHealth application as described must also be technically represented. As with other IT solutions in healthcare, this is done by the application specialists in the IT department of the respective inpatient addiction clinic.

After hospitalization of a patient with substance use disorder, these application specialists can create a link between the newly created patient profile and the account of the responsible reference therapist in the hospital information system. The therapist who is automatically informed of this action has the opportunity to prepare information from the therapeutic progress report and the discharge report. She or he can also organize the results of the case conference at the end of inpatient treatment in such a way that they can be deposited in compliance with data protection regulations.

The information can be made available to other caregivers at a later stage, but only if the patient has consented (see Section 6f: mHealth information processing). In addition, a patient- individual adjustment of the application is performed by the responsible therapist during the inpatient stay. The inpatient therapist also checks to what extent the configuration steps controlled by the application itself have been successfully completed (e.g., the registration of supporting persons).

In addition, support measures already set by the patient (e.g., with regard to individual disorder models or coping strategies, e.g. stress management, deflection, relaxation techniques) may be modified by the reference therapist. In practical implementation, this would presumably mean that the reference therapist and the patient jointly work on these mHealth individualization aspects particularly important for the success of the treatment – or at least intensively discuss these aspects. In order to enable monitoring and targeted / controlled intervention options after discharge from inpatient treatment, the reference therapist also sets individual threshold scores. These relate to important addiction-related medical parameters such as well-being, drug desire, substance consumption and individually perceived impairment of physical and emotional symptoms.

Evaluation & Discussion

In general, any mHealth initiative requires rigorous evaluation[52] which is in line with the chosen design science approach. Inherent to design science, however, a thorough evaluation *before* implementation should be considered as debatable since their effects cannot, from a logical perspective, already be part of the development. An evaluation also depends on the ultimate individual benefit in practice. This can therefore be analysed satisfactorily – if at all (e.g. Schryen[53] doubts whether the added value of information systems in organizations can be rigorously demonstrated) – only ex post. That analysis requires real-life experiences with applications and the resources required for design science projects[54].

Critical research also denies the possibility of such objective knowledge[55] as often suggested by DS evaluations. Therefore, at this point we primarily evaluate in a descriptive manner as legitimized by relevant scholars[25]. Initial patient interview results advocated moving forward from the status quo[18], based on the evidence for sustainable mHealth engineering[56] and mHealth technology[57]. As a result, the concept and base architecture as updated in Figure 1 and the overall approach[51] have been welcomed by scholars at a German information systems conference.

So far, reviews on the topic of digitalization in healthcare have focused mainly on the inpatient area[58]. But patient satisfaction after hospital treatment closely depends on interface communication (between the inpatient and outpatient sector)[59]. First, prior contributions let expect lowered barriers in relationships to the providers due to mHealth, and secondly positive outcomes on telepsychiatry in general[60] as well as for addiction scenarios in particular[61].

As added value, the facilitated healthcare delivery should be highlighted since it benefits patients, service providers, and other stakeholders in this context. It is also considered a paradigmatic goal of IT support for the domain[62]. The use of IT leads to more confidence, empowerment, increasing knowledge and inproved health status, while neither a lack of face- to-face meetings nor a lack of privacy appeared problematic to stakeholders. Partly, they evaluated it better than face-to-face settings, to be more private, intimate or comfortable[6,8]. Amongst consumers, there is openness to accept mHealth support[63,49], and not only patients but also professionals confirm the quality of joint therapeutic alliance in telepsychiatry as to be adequate to face-to-face[64].

A recent literature review[65] supports the use of BPMN as "an effective methodology to optimize clinical processes" and pointed out that it "has proven to be a feasible and useful methodology to design and optimize clinical processes, as well as to automate tasks". Weber[34] showed that BPMN can also be used to identify conflicts between clinical care guidelines. The OMG Healthcare Domain Taskforce denotes BPMN as "our choice for workflows" in clinical pathway modeling[66].

The comparison between the classical treatment pathways shows a striking difference between the supply processes of alcohol dependency versus drug addiction outside metropolitan areas. This medical treatment gap does not manifest during inpatient addiction treatment, but rather at the interface between inpatient and outpatient care. The presentation of an mHealth-supported treatment pathway shows that an mHealth application is suitable for alleviating or eliminating precisely this interface problem. This results in an effective support for these often young and medically and socioeconomically severely affected patients.

Our approach has not been necessarily targeted to minimize or reduce treatment steps, but to fill today's gaps of care. Comparative modelling of current and mHealth treatment pathways shows that the latter meets the requirements for bridging such supply gaps as recently identified by an approach including structured expert interviews[18,51]:

> ***Control:*** on the one hand, the mHealth application regularly collects treatment-related parameters such as well-being, drug desire, substance consumption and subjectively perceived impairment by physical and mental symptoms. Due to cut-off values defined during the inpatient stay, the data collected can be automatically prioritized and, in urgent cases, rapid assistance can be offered. On the other hand, the application also warns patients against geographical proximity to places where they preferred to consume drugs before their inpatient therapy or where they have bought their addictive substances. This is empowering patients and particularly significant from the critical research background.
>
> ***Relationship:*** the establishment of a stable relationship can be achieved regardless of the medium, with Internet-based forms of therapy being assessed by both patients and therapists comparable to conventional face-to-face therapies[64]. The mHealth application contains a contact feature that allows a patient to contact her or his important caregivers at any time for teleconsultation as advocated by Åkesson[6], but especially in critical situations. Important collaborators may include both private (e.g., parents, siblings, spouse) and professional (e.g., family doctor, legal guardian, physicians, and therapists) supporters. Those important caregivers are individually identified during the inpatient treatment in close cooperation with the inpatient´s reference therapist. In addition, the application contains another function, which is to enable the formation of an additional supporting network. This function had been proposed by the patients themselves as a result of participative requirement engineering[18]. It uses the smartphone GPS system for identification of geographically nearby like-minded people and the opportunity to establish a kind of "spontaneous self-help group" and to stabilize each other.

Therapeutically oriented patient support: in addition to the monitoring and contact- enabling components, the application also contains therapeutic functions in the narrow sense. This is achieved through the targeted, individualized use of the individual disorder models, coping strategies and crisis intervention techniques developed during inpatient therapy and also by the application-based use of standardized therapeutic relaxation methods. In addition, if the evaluation server has identified impending decompensation ("high risk"), the responsible inpatient addiction therapist may in turn propose a supportive intervention to the patient.

Storage and disseminating of therapy-relevant information: an important therapeutic issue is to document the psychotherapy progress and to pass on important therapeutic findings to the following outpatient specialist as promptly and seamlessly as possible. This interface between inpatient addiction therapy and outpatient treatment follow-up is precisely where the supply gap has persisted. For this reason, and as previously pointed out, at the time of transition between the inpatient and outpatient sectors it is often unclear whether further drug-specific follow-up treatment will be possible at all and who will carry out this treatment.

Thus, the mHealth application contains a special function for the backup and data protection-safe transfer of therapy-relevant information. Together with the hospital discharge report and the result of the cross-professional final case discussion, the individually developed disease models and intervention options are stored in a password-protected document. This document can only be reopened with patient consent.

If the patient moves to an area with adequate follow-up treatment or undergoes a new inpatient weaning treatment, the suggested mHealth solution allows the drug-specialized addiction therapists to adopt and continue where inpatient therapy had ended. However, it can also be used for further caregivers even if non-drug- specifically trained, e.g. general practitioners, psychotherapists, acute hospitals or addiction counselling centres specialized in alcohol addiction treatment. For both specialized and non-specialized caregivers, the application is an extremely valuable source and is provided in a patient-centric way.

Restrictions: the individualized mHealth application can basically only work if the appropriate individualization parameters are identified and implemented into the application during inpatient addiction treatment.

In addition, the best-possible functioning of the application depends on appropriate staff resources being available in the inpatient clinics for the individualization of the application, for the evaluation of the data transmitted by the application and for therapeutic interventions.

Conclusion & Outlook

The paper at hand offers evidence that BPMN represents the standard for process modelling not only in economic contexts[34,35], but also to optimize clinical processes[65,34]. Furthermore, in comparison to the classical treatment pathway, individualized mHealth-support eliminates the interface problem from occurring between the various treatment providers and thereby bridges the existing supply gap[18].

A challenge could be to refine a viable business model of the mHealth application that can roughly be describe as based on the Business Model Canvas approach[67] and its nine dimensions: *value proposition*; supply side with *key partners, activities* and *resources*; customer side with *channels*, *customer segments* and *relationships*; financial side with *cost* and *revenue structure*. As a *value proposition*, the mHealth app will be able to close the treatment gap occurring at the interfaces between inpatient and outpatient segments of drug addiction treatment. Besides therapy-relevant information storage, on a patient-to-patient basis in virtual self-help groups, the main mHealth related service improvements in addiction treatment refer to patient support, better control of the treatment process, an enhanced relationship between patient and caregivers or more barrier- free collaboration.

Before refining supply, customer and finally financial aspects of the business model canvas, five mHealth domain-specifics – *ethical* and *sociocultural* aspects, *data protection*, *technology* and *location-independence* – should be further considered[68].

As discussed against the background of John Rawls' theories[69], from an *ethics perspective*, any patient or healthcare delivery support has to be welcomed, as long as fair and equal access can be granted counteracting the digital divide. Following proposed guidance such as the European Code of Practice for Telehealth Services[70] or the codes listed by ZUR Institute[71] should ensure ethical compliance. The *sociocultural* conception must address cost-sensitivity of healthcare systems[72], in particular organizations responsible for reimbursement (such as in Germany's health system), its professional providers[73] and – again for counteracting the digital divide – consumers (cp. also *financial* side at the end of this

section). Also, adoption issues[74] require measures such as an action plan for successful and continued usage (as for any organizational application). This includes educational resources, updates and, as scholars suggest for organizations integrating telemedicine or consultation support[75,76]. The advantages of teleconsultation such as fewer medical errors[77] or better access could generate rising acceptance by consumers thus contributing to their usage motivation. The *Shamrock* model provides further critical success factors for service deployment[75].

In regard to *data protection*, and supporting Peddle's requirements[73,] national (in Germany, state and for confessional hospitals also church laws can apply) and European Regulation (especially GDPR) have to be followed: this also fostering trust, another sociocultural aspect. It can be realized by encryption technology, safe user accounts and the client's confirmation or self- definition of privacy preferences. However, a completely anonymized service would not work between therapist and client. *Technology*-wise, platform and hardware independence of clients' devices must be guaranteed. Use of wide-spread syntactic standards in the domain – such as HL7 and its derivate Fast Healthcare Interoperability Resources (FHIR) for communication with mobile devices – is recommended. As specified earlier, the application should run *location*-independently: especially outside of clinics.

Referring back to the Business Model Canvas, *customers* in terms of main beneficiaries in our understanding will represent patients with a drug addiction (e.g., ICD-10 code: F19.2) without any social, demographic or geographic restriction. The main distribution *channel* may be a recommendation from the treating addiction clinic staff; in addition, also distribution via social networks or word-of-mouth is possible. On the one hand, keeping and growing *customer relationships* could be achieved directly within the app and on the other hand by contacting the client electronically.

Key resources in development will be of financial (e.g. insurance companies, public grants, software companies) and intellectual kind (medical knowledge, software engineering, programming) as well as physical resources (servers, mobile devices). *Key partners* of such a project may be insurance companies, public sponsors, software companies, research facilities and drug addiction healthcare providers. *Key activities*, after successfully implementing the mHealth app in the market, will be updating the therapeutic monitoring and intervention aiming at closing the treatment gap and improving the outcome in drug dependency. Main mHealth related improvements in addiction treatment refer to control of the treatment process, relationship between patient and caregivers, patient support, and therapy-relevant information storage.

If the app is approved as a medical device or accepted in terms of options abiding to recent DiGAV-act[78], the *revenue* model can be based on health insurance benefits in Germany. This seems to be necessary, as from experience a large portion of the clients are economically not capable to independently fund *costs* (on provider side: staff, software, hardware). At this point, a cost calculation from a provider perspective has not yet been fully completed. We do estimate that the mHealth app development and implementation represent rather minor costs compared to the main share stemming from long-term therapeutic mHealth care.

Future work in this field will have to focus on transforming our artefact into "material existence"[20], i.e., a marketable mHealth app with the aim of clinical efficacy studies and finally official approval. An alternative model could only be realized for a customer group both willing and able to self-pay. Since cost-effectiveness of telemedical solutions has been proven[79], expected benefits or outcomes should outweigh any costs easily when the solution is thoroughly implemented.

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Appendix

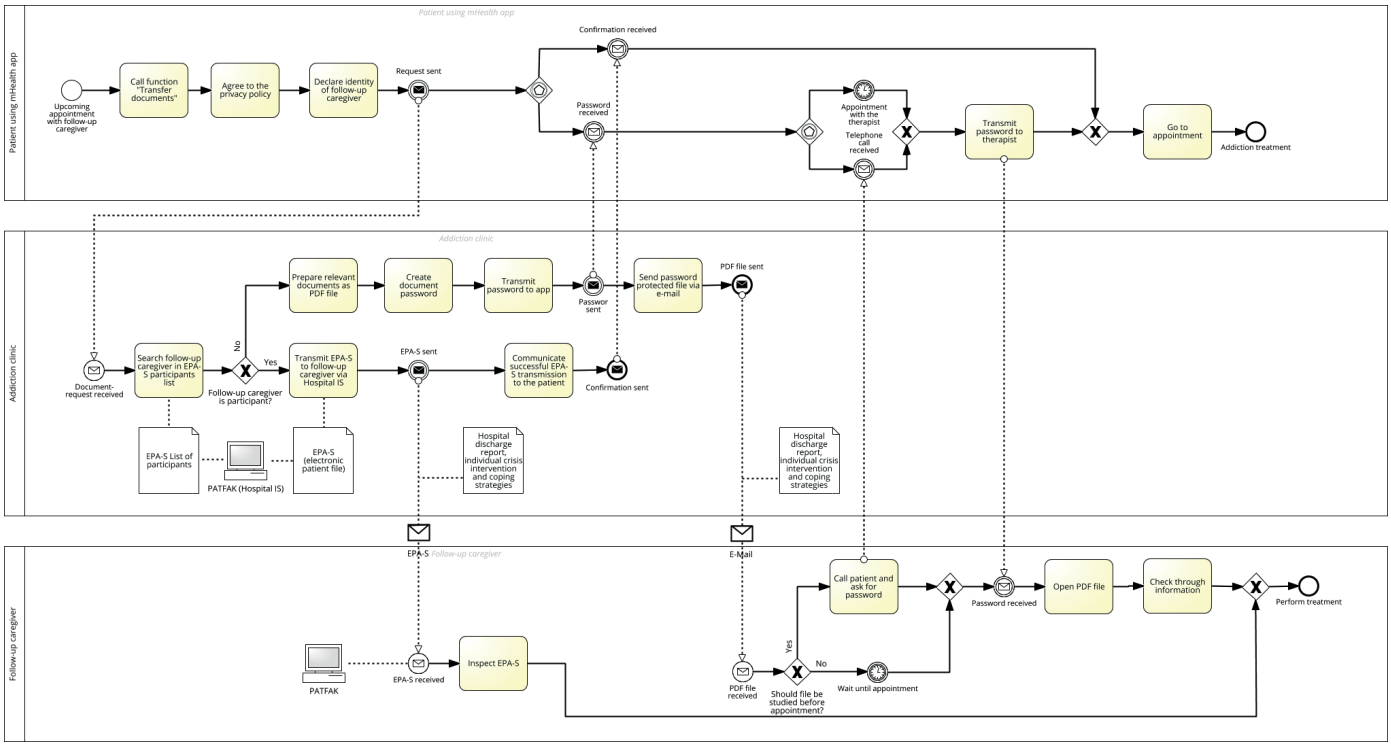

Figure A1: Usual treatment pathway for alcoholism in Germany

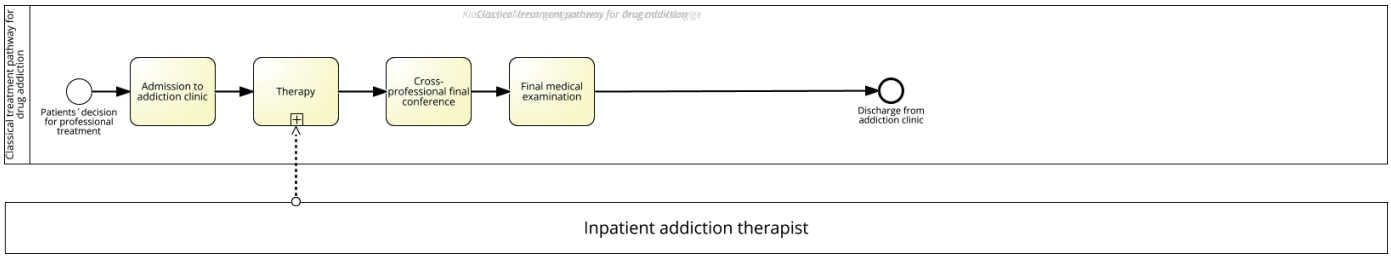

Figure A2: Usual treatment pathway for drug addiction in Germany

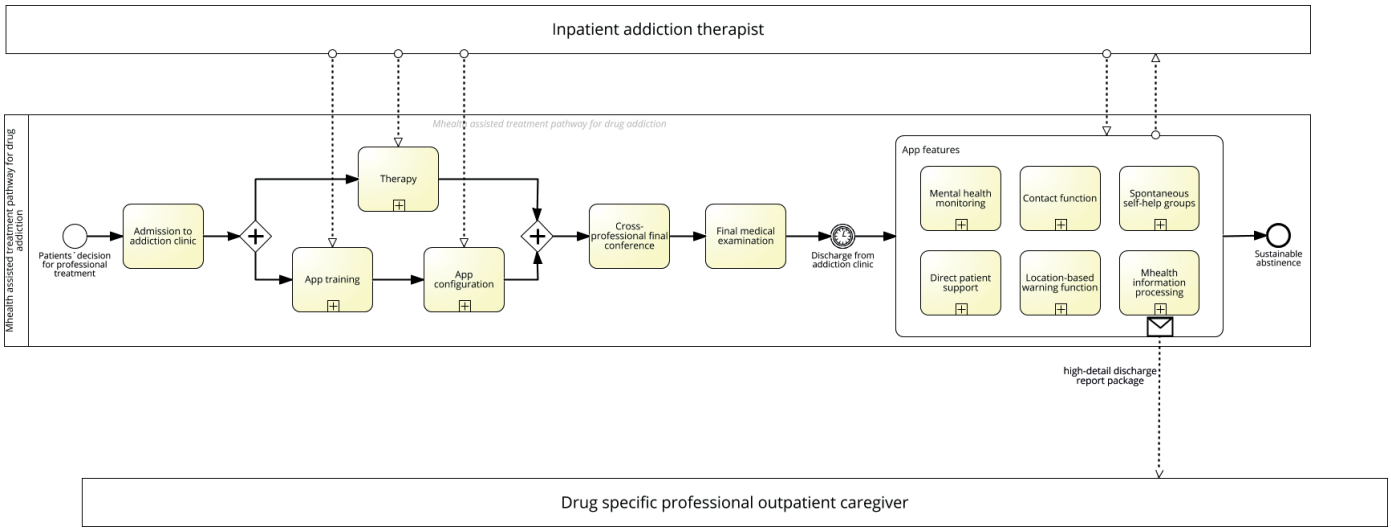

Figure A3: mHealth assisted treatment pathway for drug addiction

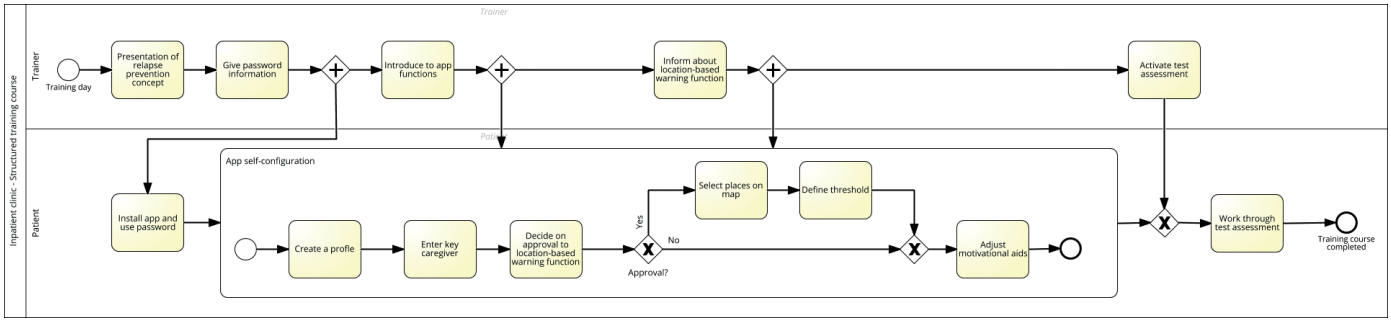

Figure A4: Individualized mHealth training & configuration advice

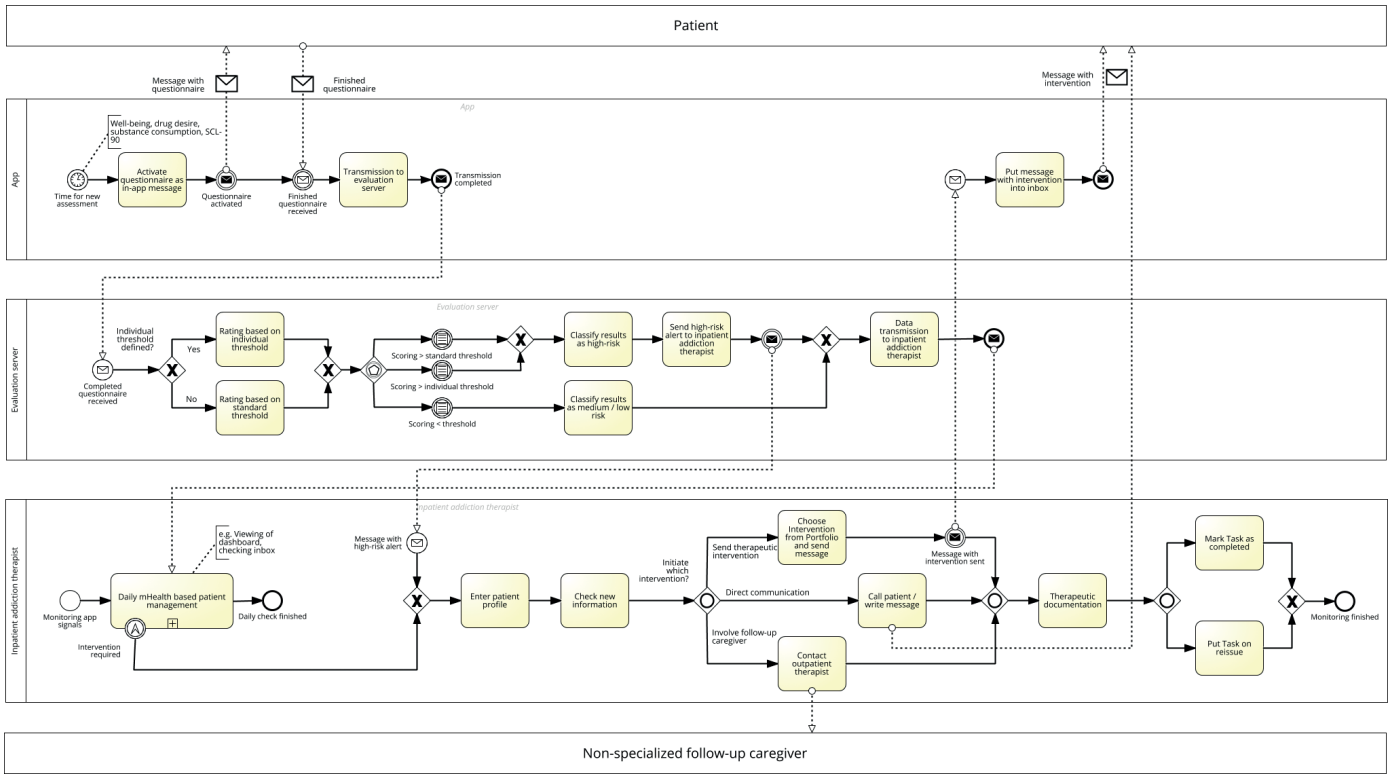

Figure A5: Health monitoring and mHealth interventions

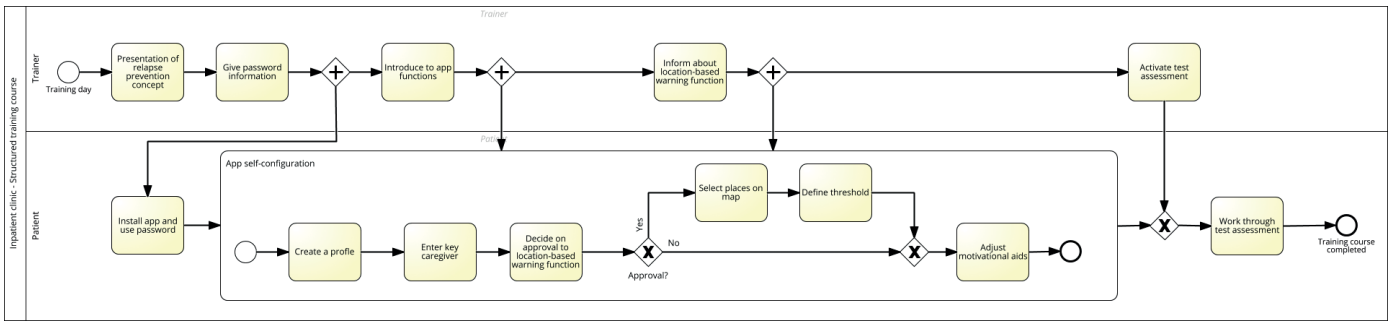

Figure A6: mHealth-based information processing

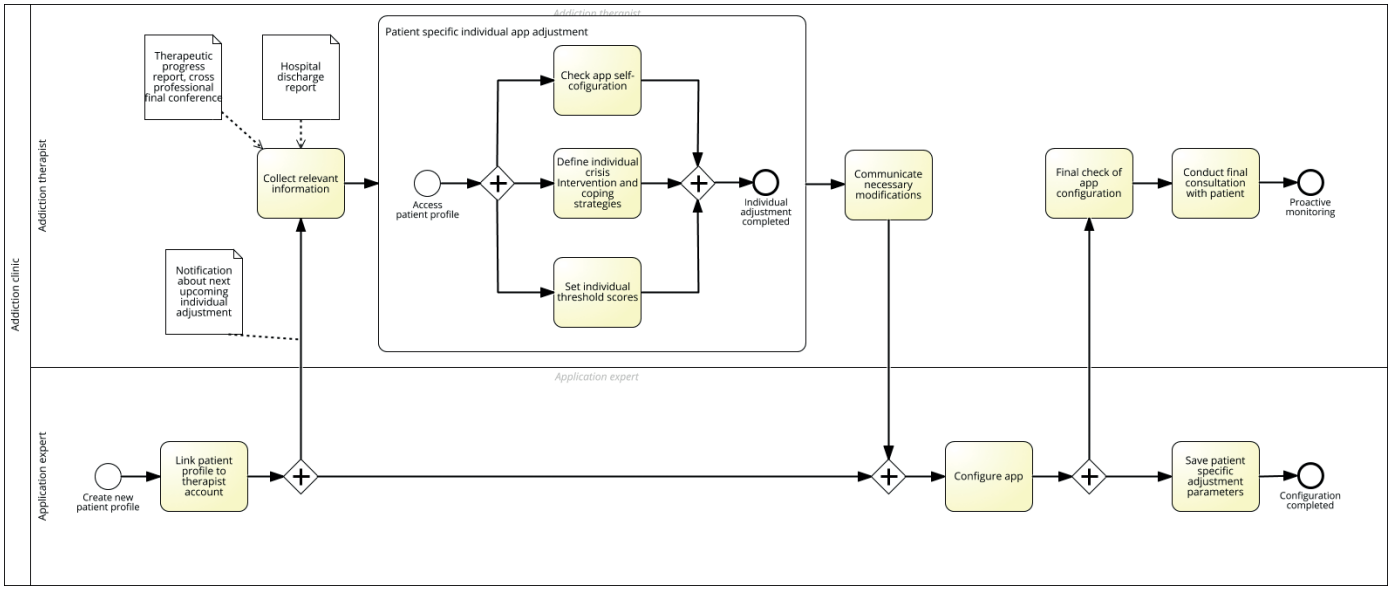

Figure A7: Synergism between IT and therapists in mHealth individualization

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ORIGINAL ARTICLE

A Pilot Study of Using a Personalised Video Message Delivered by Text Message to Increase Maternal Influenza Vaccine Uptake

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Background: Despite influenza vaccination being recommended, widely accessible and available free of charge for all pregnant women in Australia, vaccine coverage remains low. Novel strategies to increase uptake of influenza vaccine by pregnant women need to be explored.

Aims: This report aims to describe the implementation of a customised educational video about maternal influenza vaccination sent by text message, and its impact on maternal influenza vaccine uptake.

Methods: We trialled a customised video message as a strategy to improve maternal influenza vaccination coverage. Two hospitals in regional Victoria produced videos featuring senior local maternity care providers conveying information on the seriousness of maternal influenza infection and the benefits of maternal influenza vaccine. A link to the video was sent via text message to all pregnant women registered to give birth at that health service. Women were subsequently asked to complete a questionnaire about access to and relevance of the video.

Results: In May and August 2019 respectively, 842 and 742 text messages were sent. 233 pregnant women completed the questionnaire. 72 (31%) recalled receiving a text message. 26/72 (36%) of respondents watched the video, and 35% were motivated to receive influenza vaccine by the video. More than 70% of those who viewed the video confirmed that it was relevant and easy to understand.

Conclusion: Sending health information using a personalised video delivered via text message is a novel and acceptable method to provide maternal vaccine recommendation to pregnant women. This intervention could be considered along with other strategies to improve maternal vaccine uptake.

Keywords: maternal immunisation, text message video link, health promotion, influenza vaccine, pregnancy

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Introduction

Influenza disease causes significant morbidity and mortality for pregnant women and may lead to adverse fetal and neonatal outcomes.[1,2] Influenza vaccine has been demonstrated to protect pregnant women from severe influenza infection.[3,4] The protective effect of vaccinating pregnant women (maternal immunisation) extends to their infants and has been demonstrated to reduce the incidence of influenza infection in the first six months of life.[5] Despite the evidence of benefit of maternal influenza vaccination, access to the vaccines free of charge, and national recommendation for pregnant women to receive influenza vaccine in Australia, vaccine uptake remains low, with reported uptake ranging from 25 to 61%.[6-9]

Healthcare provider recommendation of a vaccine during pregnancy is one of the most important factors associated with a woman's decision to be vaccinated.[10,11] While traditionally healthcare provider recommendation has been delivered from provider to patient during a consultation, new technologies such as text messages, links to credible websites etc. can be utilised to augment health promotion messaging. In terms of maternal immunisation, automated text messages with information about maternal influenza vaccine have been trialled in two randomised controlled trials.[12,13] One study included information about influenza vaccine along with routine text message appointment reminders. This study reported a 30% increase in vaccine uptake compared to those who only received appointment reminders.[12] Another study compared use of text messages conveying general health information related to pregnancy with and without influenza vaccine information. No difference in vaccine uptake was noted between the two groups.[13] Two randomised controlled trials have examined using videos with recommendations on maternal vaccines as a strategy to improve uptake.[14,15] Pregnant women allocated to the video intervention arm were given time at their antenatal clinic appointment to watch the video on a handheld device provided by the investigators. Neither of these studies reported a significant impact on maternal vaccine uptake, and neither of these studies examined sending the video directly to the pregnant woman's personal device.[14,15]

A systematic review identified 28 studies that used mobile phone technology as an intervention to improve a variety of maternal-fetal health outcomes, in areas such as smoking cessation and weight management.[16] While the outcomes were mixed in this review, it concluded that using mobile phone technology such as text messaging could be utilised to deliver health messages to pregnant women.

In this study, we assess an innovative approach of delivering a customised video featuring local maternity care providers, directly to the woman's mobile phone via text message. If acceptable to pregnant women, and demonstrated to be effective, this could be utilised to improve maternal immunisation coverage.

Methods

The researchers identified two hospitals interested in trialing customised video messaging in their antenatal clinics through a larger project aimed at improving uptake of maternal influenza vaccination. Hospital A is approximately 250km from Melbourne with more than 600 births per year and Hospital B is approximately 150km from Melbourne with approximately 1400 births per year.

Senior obstetric and nursing/midwifery staff at the respective health services partnered with the researchers, and a consumer representative to develop the content of the video. These local clinicians also featured in the video. The video contained information related to the potential harms of influenza infection for pregnant women and their infants, the safety and efficacy of influenza vaccine and where pregnant women could receive influenza vaccine in their hospital/ community.

Nebula Health is an Australian digital communications team, led by doctors, that have made over 450 medical patient education videos and delivered those videos directly to patients via different software systems. Nebula Health collaborated on this project to provide technical advice on the script, shoot the videos onsite at the health services, edit the video and send the text message with video link utilising customised third party software.

A text message containing a link to the health service-specific video was sent to all pregnant women booked to give birth at each service. Clicking on the link directed the text recipient to a webpage where they could click 'play' to watch the video. The first round of text messages was sent in May 2019. Due to low initial engagement with the first round of text messages, the process was subsequently modified. The modifications included: changing the phone number that the text message came from so that the hospital and doctors were clearly identified within

the text message. In addition, to make it easier for women to view the video, the link was modified to connect directly to the video, which then played automatically. The second round of text messages were sent in smaller batches in August 2019 (sent to 50 individuals at a time), to allow view rate to be monitored more frequently and further modification of text messages to be made if required.

A convenience sample of women attending antenatal care at these hospitals was invited to complete a questionnaire to assess the acceptability and impact of the video message intervention. The principal investigator approached women while they were in the waiting room of the antenatal clinics in August and September 2019 and asked whether they had received an influenza vaccine during pregnancy. If so, they were offered the questionnaire.

This project was approved by the Human Research and Ethics Committee at both hospitals.

Results

The first round of text messages was sent to 241 women at Hospital A, and 601 women at Hospital B. Analysis after sending this first round of text messages revealed that very few women viewed the video; two viewers (2/241, 0.8%) at Hospital A, and nine viewers (9/601, 1.5%) at Hospital B. The second round of text messages was sent in August 2019 to 266 women at Hospital A, and 476 women at Hospital B. The number of views at each site increased to 127 views by 60 viewers (60/266, 23%) at Hospital A and 201 views by 121 viewers (121/476, 25%) at Hospital B (Figure 1).

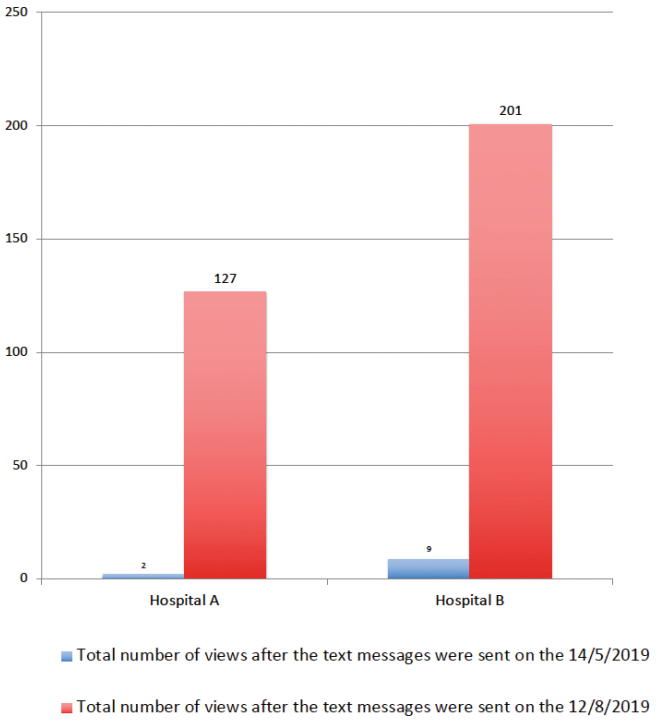

Figure 1: Number of video views.

The questionnaire assessing women's acceptability of this intervention was completed by 233 pregnant women across both maternity services. Nearly one third (72/233, 31%) recalled receiving the text message, and three quarters of these women (55/72, 76%) reported no problem using the link to the video. Of the 72 women who recalled receiving a text message, 26 (36%) watched the video, and nine of these 26 women (35%) reported being motivated to receive influenza vaccine by the video. Of the remaining 17 participants who reported that the video did not encourage them to have the vaccine, five participants volunteered that they had already received the vaccine. We are unable to clarify the rationale for the remaining 12 participants about why they were not motivated. However, all but one of these participants had already received influenza vaccine at the time of completing the questionnaire.

Of the women who watched the video, the majority agreed that the video was relevant and easy to understand. The majority of them also believed that receiving a personalised video message from the antenatal staff of their maternity service made the health message more relevant to them and agreed that it was convenient to receive health information via text message (Figure 2).

Discussion

Our study reports on an innovative way to deliver influenza vaccine recommendation to pregnant women. It demonstrates that providing pregnancy-related health information via text message directly to pregnant women is acceptable, relevant, easy to understand and informs their decision making.

Healthcare provider recommendation is a key driver of influenza vaccine uptake amongst pregnant women.[10,11] However, external factors may influence whether influenza vaccination recommendation occurs in a busy clinic environment amongst the multiple other competing priorities of antenatal care. There is a need to develop new methods to facilitate healthcare provider recommendation. Strategies to increase healthcare provider recommendation via automated platforms such as sending text messages have been previously trialled with mixed results.[12,13]

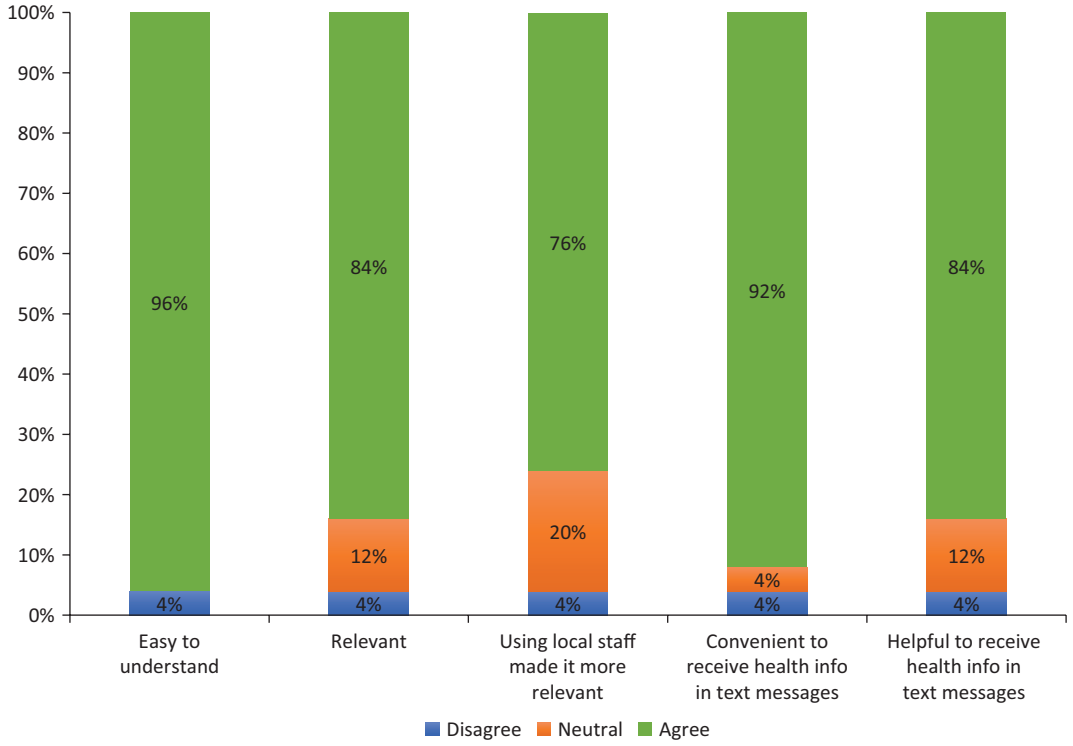

Figure 2: Consumer attitudes toward the video.

To the best of our knowledge, our study is the first to use a video developed by local stakeholders to promote maternal influenza vaccine uptake delivered directly to the woman's mobile phone. The video contributed to women's decision to be vaccinated in more than a third. Our study differed from the two previous studies in the way in which pregnant women received and viewed the video message. This difference has several advantages. Women in our study received the video via a text message sent to their personal device, so they were able to watch the video at their convenience. This method of delivery also meant that they were able to save the link and view the video again in the future. Another key difference in our study was that we produced and implemented the video message with active involvement from local maternity providers, which was not reported in either of the previous studies.[14,15] Personalising the video increased the relevance of the messaging for women and may have contributed to the health impact of this intervention.

Receiving text messages with a link to a video is also less likely to impact the workflow of the antenatal clinic. Whilst incorporating healthcare provider recommendation into routine consultation is essential in promoting vaccine uptake, it may be challenging for some providers to achieve given the busy clinic environment.[17] Many pregnant women have competing obstetric, medical, or psychosocial priorities during a consultation. A literature review on the barriers and predictors of maternal vaccine uptake found that some maternity service providers did not have time during their consultation to promote and administer maternal vaccines.[18]

There were several learning points worthy of note for maternity services who may want to adopt a similar intervention. Firstly, the timing of sending the video is important given the seasonal nature of influenza. Our video was sent in May and August 2019, several months after the seasonal vaccine became available (typically in early April in Australia). Five of the women surveyed indicated that they had already received an influenza vaccine and, therefore, the video did not change their intention to be vaccinated. While we did not specifically ask why women who recalled watching the video were not motivated to be vaccinated, it is possible that they may have already received the vaccine by the time they received the text message. With this in mind, consideration should be given to the optimal timing to deliver this intervention for it to have the most significant impact. Perhaps this strategy could

focus on women who have "not yet" been vaccinated during pregnancy despite the vaccines being available. A challenge with this approach is to identify women not yet vaccinated in real-time.

Another key lesson learned from this study is the importance of clearly identifying the hospital and the intention of the text message to avoid the text message being treated as 'spam'. The text message sent in the first round did not identify the name of the sender, nor an explanation that the link was to a video. A Cochrane review looking at recipients' perception and experiences of receiving health messages via mobile devices, found that the recipients' perception of the senders' identity can influence the trust and perception of the credibility of the text message.[19] This review noted that the sender's phone number should be identifiable and recognisable as being from known health professionals or an official source.[20]

The importance of this introductory text was demonstrated in the increase in view rate in the second round of text messages in our study. To increase recognition of the text message as being for them and from the hospital, healthcare providers could inform women during their antenatal consultations that they will be sent health information via text message and video during their pregnancy. Furthermore, the same instruction could be added to the patient information package provided to all pregnant women at their initial consultation.

A limitation of our study is that the video was only available in English and may not be suitable for maternity services where there is a high proportion of pregnant women from culturally and linguistically diverse backgrounds. We also did not have a control group to assess the efficacy of this intervention in comparison to other methods to encourage vaccine uptake in pregnant women. The proportion of women who recalled receiving a text message was 31%. Some women who completed the questionnaire may have received the text message several months prior and may have forgotten. Furthermore, the fact the text message was not clearly identifiable as coming from their maternity service in the initial round of messaging may also have contributed to poorer recall. Approximately a third of those who recalled receiving the message reported watching the video. Again while this seems like a low response rate this is comparable to the average open rate (21%) of marketing emails sent to consumers in other industries.[20] Similarly, the proportion of women who watched the video is also higher (26/233: 11%) than the 'click rate' of marketing emails sent to consumers in other industries (the percentage of users who are sent an email and click on the link attached to email), which is on average 2.6%.[20]

Conclusion

Healthcare provider recommendation has consistently been demonstrated to be one of the most important factors in improving maternal vaccine uptake. There is a need for novel strategies to facilitate the delivery of this recommendation. Our study demonstrates that delivering a customised vaccine-related health message via video to a large number of pregnant women by means of a text message is an acceptable and potentially persuasive strategy. In the current environment, with an urgent need to ensure maximal coverage of COVID-19 vaccines among the adult population, (particularly pregnant women) it may be timely to leverage the lessons learnt from this project to trial a text message linked video for pregnant women related to the recommendations and safety of COVID vaccines in pregnancy.

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The investigators wish to thank the maternity staff members at these two health services who were featured in this video.

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ORIGINAL ARTICLE

COMPARISON OF MID-STERNUM AND CENTER OF MASS ACCELEROMETRY TO FORCE PLATE MEASURES FOR THE ASSESSMENT OF STANDING BALANCE

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Background: Accelerometric assessment of balance is typically conducted from lower back locations approximating the center of mass (COM).

Aims: Because placement of accelerometers at the approximate COM may not always be practical, the purpose of this study was to determine if significant differences exist between acceleration measures recorded from the mid-sternum, COM, and center of pressure (COP).

Methods: Data were collected from 25 subjects (13 male; 22.4 ± 3.3 years) as they performed 30 sec trials of bipedal standing and single leg standing. Accelerations were simultaneously recorded via tri-axial accelerometers attached at the mid-sternum and approximate COM (i.e., over L3), and by force plate. Signals were tilt corrected and root mean squared (RMS) values of the accelerations were calculated. Repeated measures ANOVA were performed to determine if differences exist between accelerometer measurement locations as a function of stance and accelerometer location.

Results: No significant differences in mean RMS acceleration between the accelerometer locations were observed during bipedal standing in the anterior-posterior ($p = 0.140$), medial-lateral ($p = 0.170$), or vertical directions ($p = 0.270$). For the single leg stance, significant differences were observed between measurement locations in the anterior-posterior ($p < 0.001$), medial-lateral ($p = 0.002$), and vertical directions ($p < 0.001$).

Conclusion: Trunk accelerations recorded from above the center of mass may provide useful measures for identifying those with reduced postural control.

Keywords: balance, accelerometers, force plate, center of mass, postural control

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Introduction

Human balance is a complex and multi-dimensional process that allows for the maintenance of a specific posture, or postures, while executing any number of different tasks. These tasks can vary from simple activities of daily living such as sitting upright or static standing, to more complex skilled activities executed while performing work duties or recreational activities. Our ability to perform this wide range of activities is dependent upon our capacity to coordinate and control various components of multiple intrinsic systems which contribute to the process of maintaining balance.[1] These include biomechanical, motor, and sensory components which are further influenced by task demands, environmental constraints, and individual capabilities.[1–5]

The quantitative assessment of standing balance has traditionally been accomplished with the use of a single force plate. Here, the amplitude and velocity of center of pressure (COP) excursions are measured in the anterior-posterior and medial-lateral directions. An increase in these values is then generally interpreted as the individual demonstrating poor balance.[6] Force plates have been reported to be valid and reliable for the assessment of standing balance.[7] However, the use of COP excursion measures has been questioned by some as it may indicate a change in postural control strategy as opposed to poor postural control.[8–10] An alternative method for quantitatively measuring balance is with the use of accelerometers.

For the measurement of balance, accelerometers are typically placed along the lumbar spine at the approximate location of the whole body center of mass (COM). When attached here, accelerometers have demonstrated fair to excellent correlation to force plate balance assessments.[6,11–13] A number of authors further report that, during both bipedal and single leg balance assessments, acceleration patterns recorded from the estimated COM behave similarly to COP acceleration patterns measured via a force plate.[6,12,14] It has additionally been argued that, for the assessment of balance, the accelerations recorded from the COM may provide a better indicator of postural control than do COP measures.[8]

Another potential site of sensor attachment for balance assessment is the sternum. In an investigation of gait and balance in those with Huntington's disease, Dalton and colleagues[15] attached a single tri-axial accelerometer to the sternum just inferior to the suprasternal notch. Balance was assessed utilizing four Rhomberg balance tests including feet together with eyes open and closed, and feet apart, eyes open and closed. Results indicated that acceleration data recorded from the sternum could differentiate between pre-symptomatic and symptomatic Huntington's disease patients. Janssen and colleagues[16] additionally attached accelerometers to the sternum to assess balance during sit-to-stand movements. Subjects performed sit-to-stand movements on a force plate with an accelerometer placed over the sternum. These investigators reported a correlation coefficient of 0.77 between force plate and acceleration data. However, the authors stated that the purpose of the study was to quantify trunk movements during the sit-to-stand test, and not to use the attachment site data as a corollary to balance as assessed by center of mass variables.[16] Recent investigations have investigated the use of a tri-axial accelerometer built into a mobile consumer electronics device for the purpose of providing a quantitative clinical balance assessment.[17,18] The device is held at the level of the mid-sternum for ease of placement, and measures trunk accelerations that result from the balance control strategy employed by the subject. However, it is currently unknown how trunk kinematics recorded at the mid-sternum level for the purpose of assessing balance compares to those recorded from the more accepted measurement locations, such as the estimated COM or from a force plate.

Given the previous research, a question arises as to whether similarities or correlations exist between accelerations measured at the mid-sternum and other measurement locations such as the estimated center of mass and at a force plate. An answer to this question could provide insight into understanding various instrumented balance assessment methods and clarify whether findings from one study can be compared to those of another using different accelerometer placement. Therefore, the objective of this study was to determine if differences exist in balance measures (i.e., accelerations) recorded with tri-axial accelerometers attached at the mid-sternum level and that measured at other commonly used sites, including the approximate COM, and measured with a force plate. It is hypothesized that accelerations measured from the mid-sternum location will be significantly different than accelerations measured from the COM and COP.

Methods

A total of 25 subjects (13 male, 12 female; aged 22.4 ± 3.3 years) volunteered to participate in this study (Table 1). All participants were university graduate and undergraduate students free from any

Variable	Mean ± SD
Age (yrs)	22.4 ± 3.3
Weight (kg)	81.3 ± 22.5
Height (cm)	171.6 ± 9.2
Body Mass Index (kg/m^2)	27.5 ± 6.5
Suprasternal Notch (cm)	139.1 ± 8.0
Xiphoid Process (cm)	120.2 ± 7.2
Sternal Midpoint (cm)	129.7 ± 7.7
Posterior Superior Iliac Spine (cm)	104.5 ± 5.7

Table 1: Subject Demographic and Anthropometric Data.

condition or injury that may have limited their standing balance. All methods and procedures were approved by the Wichita State University Institutional Review Board for Human Subjects. An Informed Consent form describing the nature of the testing to be completed, as well as exclusion criteria, was provided to all participants upon arrival to the testing facility. Testing procedures were then explained to all participants and exclusion criteria confirmed verbally. Participants were excluded if they reported any current or pre-existing neurological, musculoskeletal, visual, vestibular, or other conditions that may have altered their ability to balance normally. Upon receiving approved informed consent, demographic and anthropometric measures were recorded.

Anthropometric measures were collected using a GPM calibrated anthropometer (Siber-Hegner, Switzerland). Anthropometric measures recorded included standing height, height from the floor of the suprasternal notch, height from the floor of the xiphoid process, and height from the floor of the third lumbar vertebrae as determined by palpation.[19] Height from the floor of the suprasternal notch and xiphoid process were averaged to determine the sternal mid-point. Standing height and weight were used to calculate each subject's body mass index (BMI). For all measures, subjects did not wear shoes.

Acceleration measures were recorded utilizing two Zephyr BioHarness 3 (BH3) devices (Zephyr Technology Corp., Annapolis, MD, USA). The BH3 device is a compact monitoring system that is designed for mobile physiological monitoring. The device includes a MEMS tri-axial accelerometer capable of measuring accelerations of ±16g,[20] an inclinometer to measure tilt in the X-Z plane, and an elastic strap to secure the device to the user. The first BH3 device was placed on the chest at the calculated height of the sternal midpoint, and measured accelerations of the upper trunk. The second BH3 device was placed on the lumbar spine at the level of the third lumbar vertebrae (L3), determined by palpation, as the approximate whole body COM. COP movements were recorded using a multi-axis force plate (AMTI BP600600) (Advanced Mechanical Technology, Inc., Watertown, MA, USA) (Figures 1 and 2).

After recording all demographic and anthropometric information, the BH3 devices were placed at the sternal midpoint and L3 locations with an elastic strap fit with a custom receptacle to secure and orient the device (Figure 1 and 2). The mid-sternum BH3 device was oriented in a manner that accelerations in the positive X-direction corresponded with anterior movement, and accelerations in the positive Y-direction corresponded with lateral movement to the right. The L3 BH3 device was oriented such that accelerations in the positive X-direction corresponded with posterior movement, and accelerations in the positive Y-direction corresponded with lateral movement to the left. The elastic strap for each BH3 device was positioned around the subject's torso so that the accelerometer Y-direction was as closely aligned with the transverse plane as possible. After the BH3 devices were attached, subjects were instructed to stand on the force plate.

Accelerometer and force plate ground reaction force data normalized to body mass (i.e., center of pressure standard deviations)[21,22] were collected simultaneously while subjects performed one trial each of two Romberg stances, which included bipedal standing with feet together and eyes closed, followed by dominant leg single leg stance with eyes open. Each stance was performed without shoes for a period of 30 seconds, and subjects rested for a period of no less than two minutes between stance conditions. For each test, subjects were instructed to stand quietly as accelerometer and force plate signals were measured at 50Hz and 1000Hz, respectively. Accelerometer data was transmitted wirelessly via Bluetooth to an external computer for storage. Force plate signals were time synchronized to match the 50Hz accelerometer data. Subjects performed a familiarization trial prior to performing each stance. The middle 15-second window of each trial was used in the RMS calculations.[21]

All acceleration data was post-processed in a custom MATLAB program (The MathWorks, Inc., Natick, MA, USA). Accelerations from the L3 BH3 device were transformed so that the positive and negative

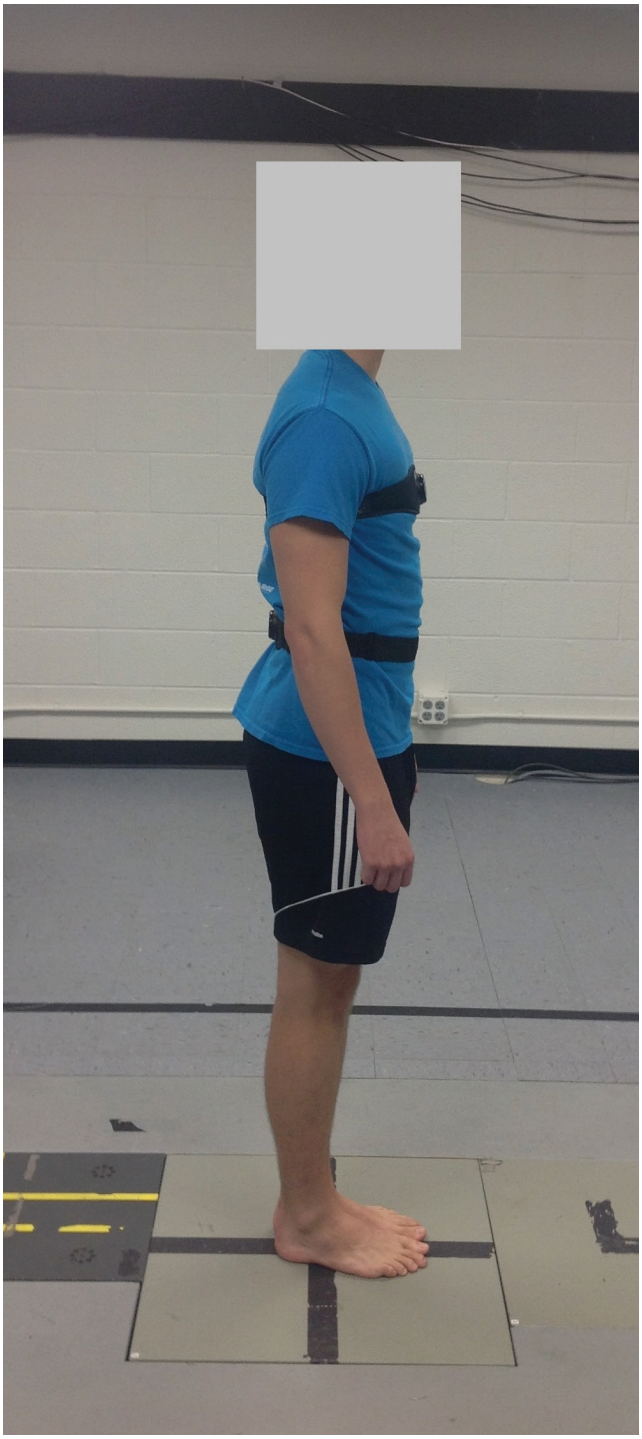

Figure 1: Bipedal stance condition with subject standing on force plate and tri-axial accelerometers attached at the mid-sternum and L3.

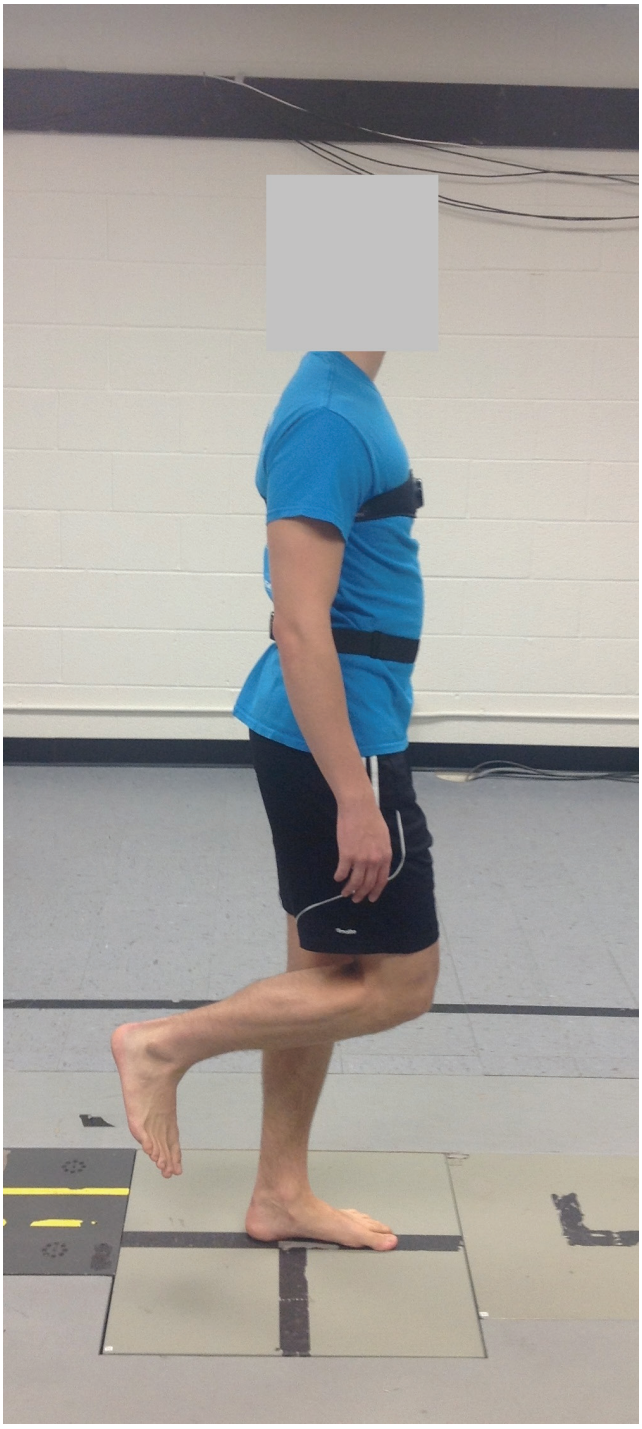

Figure 2: Single leg stance condition with subject standing on force plate and tri-axial accelerometers attached at the mid-sternum and L3.

anterior-posterior, medial-lateral, and vertical directions corresponded to the mid-sternum BH3 device and the force plate. Anterior-posterior acceleration data from both BH3 devices were corrected for tilt in the X-Z plane using the respective BH3 anterior inclinometer measures. Subsequently, medial-lateral acceleration data were corrected for tilt in the Y-Z plane.[9,23] After processing, the acceleration root mean square (RMS) in the anterior-posterior, medial-lateral, and vertical directions were calculated for each measurement location.

The statistical analysis consisted of a two-way repeated measures Analysis of Variance (ANOVA),

performed separately for each of the three directions (i.e., anterior-posterior, medial-lateral, vertical). For each ANOVA, the independent variables consisted of the location of acceleration measurement (mid-sternum, L3, force plate) and the stance (bipedal, single leg), and the dependent variable was the RMS of the acceleration. Significant main effects were assessed by the Tukey Honest Significant Difference post-hoc test. Significant interactions were assessed by the least significant difference post-hoc test, with a Bonferroni adjustment for the number of comparisons, where comparisons of interest included the mid-sternum to the L3 and force plate locations. Significance was indicated using α=0.05. All statistical analyses were performed with the use of SAS Version 9.1 (Cary, NC).

Results

The mean RMS acceleration values measured at L3 were higher than those for the mid-sternum and force plate in the anterior-posterior (0.700 vs. 0.462 and 0.064m/s^2, respectively) and medial-lateral (0.703 vs. 0.352 and 0.069m/s^2, respectively) directions for single leg stance and in the medial-lateral direction for bipedal stance (0.794 vs. 0.236 and 0.058m/s^2, respectively). The mean RMS acceleration values measured in the anterior–posterior and medial–lateral directions at the force plate for both bipedal and single leg stance were lower than those measured at both the mid-sternum and L3. In the vertical direction, the force plate mean RMS acceleration values were highest for both bipedal and single leg stance. The resulting mean and standard deviation of the RMS accelerations as a function of direction (anterior-posterior, medial-lateral, vertical), stance (bipedal, single leg) and measurement location (mid-sternum, L3, force plate) are shown in Table 2.

Plane - Direction	Bipedal Stance Mean ± SD	Single Leg Stance Mean ± SD
Anterior – Posterior		
Mid-sternum	0.384 ± 0.356	0.462 ± 0.515
L3	0.204 ± 0.056	0.700 ± 0.641
Force Plate	0.044 ± 0.025	0.064 ± 0.038
Medial – Lateral		
Mid-sternum	0.236 ± 0.043	0.352 ± 0.302
L3	0.794 ± 0.937	0.703 ± 0.793
Force Plate	0.058 ± 0.024	0.069 ± 0.022
Vertical		
Mid-sternum	9.737 ± 0.056	9.702 ± 0.066
L3	9.700 ± 0.164	9.661 ± 0.175
Force Plate	9.828 ± 0.019	9.830 ± 0.030

Table 2: Mean (SD) RMS of acceleration measured at the mid-sternum, L3, and mean RMS of center of pressure acceleration measured at the force plate, as a function of the anterior-posterior, medial-lateral vertical planes, for the bipedal stance (feet side by side) and dominant leg single leg stance.

Statistical analyses showed the RMS accelerations were different as a function of stance and location, depending on the direction of the acceleration. In the anterior-posterior direction, there were significant main effects of measurement location ($p < 0.001$), stance ($p = 0.002$) and a significant location×stance interaction ($p < 0.001$). Post-hoc analysis of the significant interaction indicated that for the single leg stance, the mean RMS acceleration measured at the mid-sternum was significantly different than that measured at L3 ($p = 0.006$) and the force plate ($p < 0.001$). For the bipedal stance, the mean RMS acceleration at the mid-sternum was significantly different than that measured at the force plate ($p = 0.002$), but not significantly different from the L3 measurements ($p = 0.034$) (see Figure 3). In the medial-lateral direction, the RMS acceleration varied significantly as a function of measurement location ($p < 0.001$), but not by stance ($p = 0.851$), nor was there a significant interaction ($p = 0.260$). The post-hoc test on the significant location effect found that the RMS acceleration at the mid-sternum was significantly different from that measured at L3 and the force plate (see Figure 4). In the vertical direction, the RMS acceleration varied significantly as a function of measurement location ($p < 0.001$), but

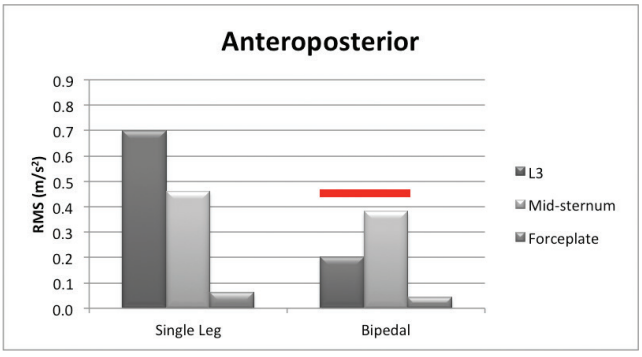

Figure 3: Mean RMS acceleration in the anterior-posterior plane as a function of measurement location and stance. Solid horizontal line indicates conditions that were not significantly different from each other.

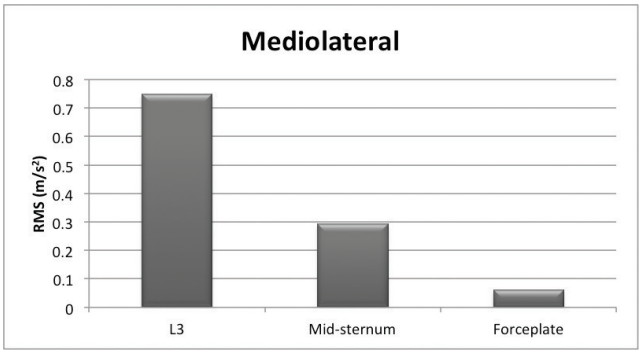

Figure 4: Mean RMS acceleration in the medial-lateral plane as a function of measurement location. Solid horizontal line indicates conditions that were not significantly different from each other.

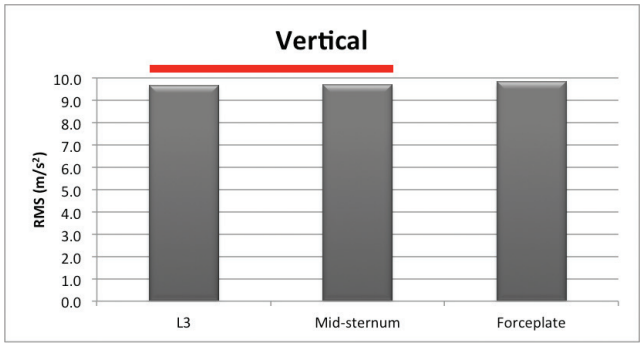

Figure 5: Mean RMS acceleration in the vertical direction as a function of measurement location. Solid horizontal line indicates conditions that were not significantly different from each other.

not as a function of stance ($p = 0.155$), nor was there a significant interaction ($p = 0.422$). The follow-up post-hoc test indicated that the RMS acceleration measured at the mid-sternum was significantly different than the RMS acceleration measured at the force plate, but not at the L3 level (see Figure 5).

Discussion

Because accelerometer placement on the body in balance studies varies and because the correlation between balance measures from the chest and other body locations has not been widely reported, the objective of this study was to investigate the balance measures of tri-axial accelerometers attached at the mid-sternum and the estimated COM. The second objective was to examine the balance measures recorded at the mid-sternum and a force plate. One finding from this study was that the balance measures from the two tri-axial accelerometers exhibited differences for both bipedal and single leg stance conditions. Another finding was that balance measures from the mid-sternum accelerometer differed from the force plate for both the bipedal and the single leg stance conditions. The interpretation and importance of these findings are discussed below.

The results for bipedal stance identified statistical differences in mean RMS accelerations in the medial-lateral direction but not the anterior-posterior direction. In a similar study, Mancini and colleagues reported that accelerometer signals recorded from the estimated COM behaved similarly to signals obtained from an accelerometer placed at the C7 vertebra during quiet bipedal stance in both the anterior-posterior and medial-lateral directions.[12] The difference in the medial-lateral acceleration results between our study and that of Mancini and colleagues may be due to the bipedal stance width; subjects in our study stood with their feet together. This foot arrangement yields a narrow base of support in the medial-lateral direction, which has been shown to increase medial-lateral movements.[24] Additionally, bipedal corrections of medial-lateral sway involve shifting weight between the feet to compensate for COM motion.[8] COM motion in the frontal plane will require a concomitant motion by the torso, and therefore mid-sternum, in the opposite direction to maintain the COM over the base of support.

The significant differences in mean accelerations observed in the anterior-posterior and medial-lateral directions between measurement sites during single-leg standing were likely the result of subjects utilizing a combined ankle and hip strategy for maintaining balance. Traditionally the ankle strategy is considered as the primary strategy, particularly with younger subjects.[25] In the ankle strategy, the center of mass is manipulated through torques applied primarily at the ankle joint, requiring that the upper and lower body move in unison, similar to an inverted pendulum, as the center of mass is manipulated. Under this scenario, linear accelerations would increase in proportion to the distance from the axis of rotation, the ankle. However, our results indicate larger magnitude accelerations at L3 relative to the mid-sternum in both the anterior-posterior and medial-lateral directions, implying the hip strategy may have been used. With the hip strategy, the center of mass is manipulated through torques applied primarily at the hip joints, causing the upper and lower body to move in opposite directions as the center of mass is manipulated. Additionally, the

ankle strategy is generally limited in the medial-lateral direction due to torque generation limitations of the ankle invertors and evertors.[8]

Comparisons between the acceleration measures at the mid sternum and the force plate indicated differences for both bipedal and single leg stance conditions in the anterior-posterior, medial-lateral, and vertical directions. In the anterior-posterior and the medial-lateral directions, the significant differences in mean accelerations may have been the result of flexion and extension at the hip which coordinated the movement of the trunk relative to the COM.[5] The force plate did not record the larger accelerations as the hip strategy creates a compensatory horizontal shear force exerted against the support surface which acts to decelerate the center of mass to control balance.[5,26–28] In the vertical direction, significant differences were observed between the mid-sternum and force plate locations. This is likely the result of the hip strategy and the height of the accelerometers above the force plate. As compensatory anterior-posterior and medial-lateral movements of the upper and lower body are made in an effort to control balance, the vertical positions of the accelerometers will change to a greater extent than the whole body center of mass, which is reflected by the force plate acceleration measurement.

A discussion of the study methods is warranted to provide context to the results. The sample population consisted of students recruited from the WSU. These students were also free of injuries or other conditions that could have adversely affected their standing balance and increased the magnitude of the measured accelerations. As a result, the findings may not be generalizable to the larger population. The bipedal stance condition had subjects stand with feet together. The close proximity of the feet resulted in a narrow base of support that could have yielded different acceleration measures than had the feet been placed further apart. Also, this study was conducted in a laboratory setting with few visual and auditory distractions, which may limit the generalizability of these findings with regards to less controlled environments.

Conclusion

Overall, the results of this study indicate that, for those with normal balance, the choice between mid-sternum and L3 measurement locations may be of little consequence. However, as indicated by the differences between the mid-sternum and force plate measurement locations, bipedal and single leg balance measurements recorded at the mid-sternum may provide valuable information with regard to the amount of trunk movement required for a subject to maintain balance. This is further supported by the overall increased anterior-posterior and medial-lateral mean acceleration at the mid-sternum when compared to the force plate. Additionally, the mid-sternum location was able to identify a change in vertical position with trunk movement. The vertical component could potentially be an indication of increased postural instability. This information could prove useful when considering the potential use of MEMS tri-axial accelerometers built into many consumer electronics devices. These devices could be positioned against the mid-sternum location, allowing for the accelerator to capture larger variations in postural sway.

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Conflict of Interest

There are no potential conflicts of interests, including financial arrangements, organizational affiliations, or other relationships that may constitute a conflict of interest regarding the submitted work.

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ORIGINAL ARTICLE

TELEULTRASOUND IN REMOTE AND AUSTERE ENVIRONMENTS

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Health services in remote and austere settings are challenged by limited resources and geographic distance. Lack of investigative tools or local specialist care may impede timely diagnoses or focused treatment. Teleultrasound is an effective tool to overcome these obstacles, permitting trained experts to provide guidance to isolated environments. This paper reports on the many applications of teleultrasound and recent developments in the field.

Keywords: teleultrasound, remote, austere, mobile

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Background

The provision of global health is impeded by limited resources and geographic barriers in remote and austere environments. Despite global advances in connectivity, these populations experience higher rates of morbidity, mortality and poorer access to health services in comparison to metropolitan areas.[1] Telemedicine, defined as 'healing at a distance' aims to bridge this disparity by utilising mobile telecommunication technologies to provide health care services across geographic, social and cultural barriers.[2] Whilst the incongruence between urban and remote locations is multifactorial, the burden of inequality is greatly alleviated by access to diagnostic tools, to assist clinical decision making, counselling, intervention and triaging need for patient transfer.

Teleultrasound

Ultrasonography is an ideal solution. The World Health Organization has determined ultrasound to be an essential technology for developing countries, with access to ultrasonography designated a minimum global standard.[3] Non-invasive and without ionizing radiation, ultrasonography is highly portable, cheaper and more accessible than other diagnostic modalities.[4] Indeed, ultrasonography may be considered an extension of the physical examination, much like the stethoscope.[5] The applications for ultrasonography are myriad and their portability has seen them used in many non-hospital settings such as military deployments, onboard aircraft, and at natural disasters.[1] In most metropolitan healthcare systems, ultrasonography is performed by trained technicians with images interpreted by experts. Thus, even if ultrasonography equipment is available, in untrained hands or in the absence of professionals to interpret images, care for remote populations is still ultimately lacking.

This conundrum led to the development of 'teleultrasound', the transmittance of ultrasonographic images to experts at remote sites. In early stages, sonographic images were transmitted along telephone line internet connections.[1] Studies may be transmitted asynchronously or synchronously.[6] Asynchronous studies are characterised by obtaining ultrasonographic images, saving them onto storage and transmittance later for interpretation.[6] Proponents of asynchronous transmission suggest this modality to be superior, as resolution is lost during live transmission.[7] Limitations of asynchronous transmission are due to lack of direct interaction between the operator performing the ultrasound

and the remote expert, preventing immediate supervision, with the potential loss of valuable contextual information.

Technology later expanded toward utilising wireless internet and satellite connections. As technology evolved to become more compact and portable, ultrasounds with smart phone or tablet compatibility emerged, allowing seamless integration of video conferencing, internet connectivity and scanning in a single handheld device.[8] Here, images are transmitted synchronously, or in 'real-time', with adjunctive video-conferencing software. This allows live assessment of ultrasound images, also permitting a remote expert to supervise an untrained provider in achieving the appropriate sonographic planes or implementing a procedure.[1] With synchronous transmission, real-time teleultrasound can be expanded to any remote or austere setting where there is internet or satellite connectivity for both clinical guidance and educational purposes.

Applications

Ultrasonography is a vital tool with both diagnostic and procedural capabilities and can be applied in almost any setting to all organ systems. In obstetric care, ultrasound is the diagnostic tool of choice for both metropolitan and remote settings. The lack of ionizing radiation is safe to foetuses, and suitable for evaluating intrauterine growth, pregnancy complications or developmental abnormalities.[9] Studies have demonstrated close correlation between local and remote diagnosis in obstetric examinations. Unfortunately, many pregnant women are not near specialist foetal ultrasound services. Rabie et al. evaluated teleultrasound in the diagnosis of foetal structural abnormalities, finding similar sensitivity and specificity to on-site ultrasound.[10] In Queensland Australia, Chan et al. established a foetal tele-ultrasound service, linking patients in Townsville to subspecialists in the capital city Brisbane, located 1500 kilometers away. In their series of 90 teleultrasound scans, local providers diagnosed all anomalies and significant diagnoses, and reported that one third of patients avoided costly transfer for further care, due to teleultrasound.[9]

Trauma in remote areas results in morbidity and mortality two to threefold.[1] Rapid diagnosis is imperative for dictating the treatment algorithm. Ultrasound can be used to quickly assess patients for peritoneal, pleural or pericardial effusion or tamponade using a Focused Assessment with Sonography for Trauma (FAST) scan.[11] Similarly, ultrasound can be extended to assess pneumothorax, pneumonia, intraperitoneal free gas, maxillofacial fractures or even raised intracranial pressures via optic sheath examination.[4] Results have significant logistic and cost ramifications in remote or austere environments; a positive scan might pre-empt a laparotomy or urgent transfer to tertiary service, whereas a negative scan provides reassurance and can prevent a costly unnecessary transfer. In Calgary, Canada, Dyer et al. created a tele-link between a remote health care service and a tertiary trauma centre. Using synchronous ultrasound and video livestreaming, FAST scans were observed or supervised, facilitating algorithmic treatment as well as providing clear educational benefits.[12]

Education

Teleultrasound demonstrates clear educational utility in its supervisory capacity for nontrained remote providers. Remote mentoring has been demonstrated to be effective for non-expert physicians but also non-physician professionals such as paramedics and even astronauts. In one study, naive ultrasound paramedics assisted remotely by emergency physicians were able to achieve adequate FAST views in less than five minutes.[13] Similarly, a study of 21 non-medical undergraduate students supervised by a remote expert were able to obtain sonographic planes to assess for pneumothorax, cardiac function and abdominal free fluid, with blinded and non-blinded interpreters achieving 100% agreement on views.[14]

The potential for teleultrasound are apparent in its various applications by the National Aeronautics and Space Administration (NASA) in space, the ultimate austere environment. On the International Space Station (ISS), nonphysician astronauts have been able to complete comprehensive ocular examinations using ultrasonography under remote supervision, obtaining excellent anatomic detail and fidelity.[15] Similarly, aboard the ISS, teleultrasound has been used to perform genitourinary scans, FAST scans in trauma, and even to visualize nitrogen bubbles to evaluate decompression sickness.[4,16,17] Whilst teleultrasound has clear utility in the evaluation of real-time clinical problems, it is evident that it is also an excellent educational tool to provide training to providers, distant from traditional training facilities. Various suggestions regarding optimum duration have been proposed; however, it is likely that almost anyone can perform teleultrasound with minimal training provided they are motivated and attentive.[1]

Furthermore, with smartphone or tablet 'app-based' ultrasound and integrated internet connectivity, collaboration with other health professionals is enhanced. Ultrasound results can be transmitted via email, shared to a network for dissemination, or saved to the device for later review.

Smart phone and tablet handheld ultrasound devices

The merging of mobile technology and ultrasonography resulted in the production of third generation handheld ultrasound devices. These are characterised by smartphone and tablet-based platforms utilising 'apps' (mobile applications). These ultrasound units consist only of the ultrasound probe connected to a smart phone or tablet via a cable, with images appearing on the smart device's native display. Here, maximum portability is achieved, the ultrasound easily transportable in a bag or clothes pocket. These ultrasound devices offer integrated synchronous transmittance, including inbuilt video livestreaming, using the native smart device's camera. Gain, depth, power and colour can all be customized by touching the screen of the mobile or tablet. Furthermore, probes can be interchanged to perform any ultrasound application such as lung, abdomen, obstetrics/ gynaecology, FAST, soft tissue or vascular examinations.[8]

Several third-generation handheld devices exist currently. The Phillips Lumify permits colour Doppler, M-Mode, advanced XRES and multivariate harmonic imaging and SonoCT. Its 'Reacts' integrated videoconferencing technology permits multiple simultaneous audio-visual inputs: the ultrasonographic images, video from the smart device's camera so the observer can guide probe placement, and also video from the observer transmitted to the local provider.[18] Another recent addition to the market is the Butterfly IQ ultrasound. This features 'Butterfly Cloud' an online sharing system and is affordable, priced under $2000 USD, whereas most standard portable ultrasound machines are in excess of $10000 USD.[19, 20]

Successful clinical application of the Phillips Lumify ultrasound has been reported as an acceptable alternative to traditional high-end ultrasound devices. In a study of 56 plastics surgery patients, Miller et al. used the Phillips Lumify ultrasound to successfully locate dominant perforator vessels for perforator flap reconstruction, facilitate transversus abdominis plane anaesthetic blocks in patients undergoing abdominal reconstruction, and to identify the superficial fascial system in body contouring patients.[21] In another study, twenty radiology trainees used a Phillips Lumify ultrasound attached to a Samsung Galaxy S2 tablet to evaluate 10 wrist structures and completed a Likert scale-based, pre- and post-test survey, with 3 days of independent practice in between. Value as a learning tool was evident by greatly improved pre-test and post-test mean scores (2.5 ± 2.16 vs 9.85 ± 0.37, $p<0.001$). Trainees reported that these devices could enhance their ability to perform musculoskeletal ultrasound and ultrasound-guided interventional skills.

An inevitable limitation of portability is battery life, particularly in austere environments. However, the experience of Nolting et al. who charged a Lumify ultrasound exclusively with a solar panel, whilst visiting communities trekking through the Himalayas, demonstrates that smart handheld ultrasound devices are effective and feasible for even the most austere environments.[22] Given their affordability, portability and inherent advantages with internet connectivity and videoconferencing, smart phone compatible ultrasound devices represent an essential tool in minimising healthcare disparities.

Robotic Teleultrasound

Robotic guided ultrasonography has emerged as an alternative to remote supervised sonography. A remote expert manipulates a master system whose movements are reproduced by a robotic arm equipped with an ultrasound probe. Haptic technologies are also integrated to provide tactile feedback.[23]. NASA's Extreme Environment Mission Operations has used robotic systems in underwater habitat 3000 kilometers away to perform simulations such as ultrasound guided needle puncture.[24] Although expensive and used predominantly in research settings, this technology represents a novel diagnostic and treatment method for the future.

Conclusion

Teleultrasound is a quintessential adjunct in the provision of healthcare to remote and austere environments. As communities become more connected, teleultrasound embodies a vehicle for sharing knowledge and expertise to communities with limited resources or specialist providers. Synchronous transmission of sonographic images expands the scope of care. In the absence of providers trained in sonographic interpretation, images can be transmitted in real time for immediate assessment and clinical

supervision by remote experts. Similarly, in austere locations where medical care is provided by nonphysicians, studies demonstrate that via teleultrasound, standards of treatment comparable to urban healthcare systems can be provided. In cases of trauma when rapid diagnosis is necessary, teleultrasound embodies an invaluable adjunct in clinical assessment or determining need for patient transfer.

Just as provision of timely care is quintessential to acceptable healthcare, the education and training of remote and austere health services is vital to closing global inequalities. Teleultrasound represents a suitable educational modality, in which local providers can receive remote supervision and teaching from expert providers. Global healthcare is tasked with disseminating appropriate resources to the furthest corners of the world. Novel technologies continue to cultivate this evolving field. Recent development of mobile portable ultrasound devices with synchronous transmission capabilities, represent the ultimate platform for providing this technology to remote and austere environments.

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ORIGINAL ARTICLE

PILOT STUDY: REAL-TIME MONITORING AND MEDICATION REMINDERS IN GLAUCOMA PATIENTS

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Background: Medication Event Monitoring System (MEMS) technology in glaucoma medication adherence has not yet addressed reminder fatigue, in which patients become desensitized to reminders after repeated exposure.

Aims: To study how the prototype of a novel device, which couples real-time monitoring with custom SMS text reminders, can affect medication adherence.

Methods: We piloted a randomised prospective clinical trial, recruiting patients between June 2017 to February 2018 from the Stanford Byers Eye Institute who had been prescribed daily latanoprost for open-angle glaucoma. We monitored each participant's usage for 13 weeks, randomising each participant into one of three arms: Arm 1 controls were monitored, Arm 2 subjects were also notified via SMS texts for missed doses, and Arm 3 subjects were monitored, notified via SMS texts for missed doses, and called monthly and/or if adherence fell below 75% to collect qualitative data on reasons for lack of adherence.

Results: Of 78 subjects who were consented, 50 subjects participated. By week 7, Arm 1 subjects had a decline in adherence compared to Arm 2, which had maintained its adherence at 78.57 ± 5.13% ($p = 0.01$). Arm 3 subjects maintained a steady adherence for the first 5 weeks; however, at week 6 their adherence peaked at 90.48 ± 4.12%, compared to Group 1 which had fallen to 46.43 ± 15.68% ($p = 0.01$).

Conclusions: Real-time custom reminders can improve glaucoma medication adherence. This pilot can aid future clinical trial design in assessing real-time electronic monitoring and custom reminders in glaucoma medication adherence.

Keywords: Adherence, Glaucoma, Reminder, Real-time, Monitoring

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Introduction

Background

Medication nonadherence has become an epidemic. As of 2013, nonadherence was responsible for wasting between $100 and $300 billion in avoidable health care costs in the US annually.[1] According to the WHO, approximately 50% of patients do not take their medications as prescribed.[2] The detrimental ramifications of poor adherence have been studied extensively in the

treatment of chronic conditions such as hypertension and glaucoma.[3,4]

Glaucoma is a leading cause of irreversible blindness, affecting three million Americans in 2000 with increasing prevalence every year.[5] It is a chronic, largely asymptomatic, and progressive optic neuropathy leading to irreversible blindness, so early diagnosis and treatment are crucial in delaying progression of the disease[6,7]. There is currently no cure for glaucoma and newer methods such as neuroregeneration are still being investigated.[8,9] The most common form of glaucoma treatment is reducing intraocular pressure, which has been demonstrated to be the main modifiable risk factor in slowing disease progression.[9] Glaucoma patients who do not routinely take eye drop medication may greatly increase their risk of disease progression. However, data from prior studies demonstrates that glaucoma eye drop adherence rates are 70% or less for prescribed treatment.[10] As such, inadequate intraocular pressure control due to poor medication adherence is thought to be a significant cause of worsening clinical outcomes in glaucoma care and escalation of therapy.

To assess reasons for poor glaucoma medication adherence, previous studies have used Medication Event Monitoring System (MEMS) technology to compare self-reported versus monitored adherence. MEMS technology was originally developed out of growing concerns over poor medication adherence and works by electronically detecting, time-stamping, and storing data on usage of the associated medication delivery system[11]. In this way, MEMS differs from standard messaging-based reminder services in that it tracks medication adherence by clearly distinguishing initiation, implementation, and discontinuation of usage[11]. Multiple studies have found discrepancies between self-reported versus measured adherence, suggesting that electronic methods of measuring medication adherence can be more objective than inherently-biased self-reported adherence.[12–16] For instance, one study found that self-reported adherence was 94% compared to 79% according to the MEMS. Further, in the same study, the independent predictors of adherence included self-efficacy, motivation, intention, cues to action, race/ethnicity, and dose frequency.[17] In this sense, reasons for medication nonadherence are manifold and have been shown to include forgetfulness, low self-efficacy, difficulty with drop administration, and difficulty with medication scheduling in complicated regimens.[18–23] In light of these factors, studies on glaucoma adherence have attempted to identify innovative interventions to help patients improve adherence.

Prior studies have attempted to improve glaucoma medication adherence by designing interventions based on data collected by monitoring devices.[24,25] For instance, Okeke et al. found that using weekly phone call reminders and/or audible and visible reminders on their electronic sensors resulted in improved adherence for patients with baseline poor medication adherence.[13] However, this study's device could not provide real-time reminders because its data had to be synced in clinic at the end of the study period. Consequently, the reminders were employed without real-time knowledge of medication adherence, and thus did not specifically target patients who were missing doses. This is important because reminder fatigue, in which a repeated exposure to the same alert over time desensitizes a subject to the reminder[26], has been studied and reported to be both excessive and detrimental in various healthcare settings.[27,28] Manifestations of harm from reminder fatigue include erroneous medication prescriptions and inappropriate dosing in computerized physician order entry systems.[27,28]

To our knowledge, no study using MEMS has yet designed an intervention that addresses reminder fatigue. Kali Drop (Kali Care, Santa Clara, CA) is a novel MEMS device that can monitor medication usage in real-time, as an electronic sensor sleeve that fits over an eye drop bottle.[29] The version used in this study was a prototype that fit round bottles such as generic latanoprost, as opposed to cylindrical or rectangular bottles. As a prototype, the device was also novel in that it contained a cellular connection in the base unit charger and required neither Wi-Fi setup nor an app. To respect patient privacy, this prototype did not collect personal data including GPS location tracking.

We hypothesised that an intervention which reminded the patient only when a medication dose was missed could improve adherence by reducing overall reminder fatigue. The different variables tested were real-time measurements of eye drop usage without any intervention vs. real-time measurements with a smart automated reminder. In addition, to better understand the key obstacles to medication adherence when using customised phone reminders, we collected qualitative feedback by phone counseling with a third arm of study subjects who were also receiving the intervention. This phone counseling was done on a monthly basis and/or if these

subjects consistently demonstrated poor adherence of less than 75%.

Methods

Trial design

We designed a pilot randomised controlled trial (RCT) consisting of three arms (see the Consolidated Standards for the Reporting of Trials [CONSORT] diagram in Figure 1). Arm 1 subjects were the control group and used the MEMS device for adherence monitoring only. Arm 2 subjects, in addition to using the device for adherence monitoring, received a standardised SMS text notification to their personal mobile phone following a missed dose. Arm 3 subjects received the same intervention as Arm 2 but also received phone counseling monthly or if adherence fell below 75% of expected doses. Arm 3 subjects also gave qualitative feedback on the device during the monthly phone calls. To perform the randomisation procedure, we used a computerised, randomly-generated list of 1, 2, or 3 to represent the three study arms. These numbers were placed in consecutively marked, sealed envelopes that were opened when we received written informed consent from a participant. Subjects were informed of all three possible study arms during the consent process and were not blinded to their assignment.

For the entrance survey, each participant reported a "medication time", defined as the average time of day when they regularly took their medication. During the week-long baseline, subjects did not receive any notifications regardless of which study arm they had been randomised to. After the week-long baseline data collection, subjects were able to receive notifications according to their randomised study arm assignment. Subjects otherwise continued with routine follow-up and treatment for their glaucoma as a part of the standard of care and did not undergo additional testing or interventions. There was no placebo arm as all subjects received the monitoring device.

The notification schedule is outlined in Figure 2. We set the "medication window" to be at two hours before and after the medication time. For example, given a medication time of 8PM, we counted a drop as taken if it was taken two hours before the medication time or one-third of the two-hour window after the medication time (i.e. between 6PM and 8:40PM). To avoid reminder fatigue, we sent the reminder

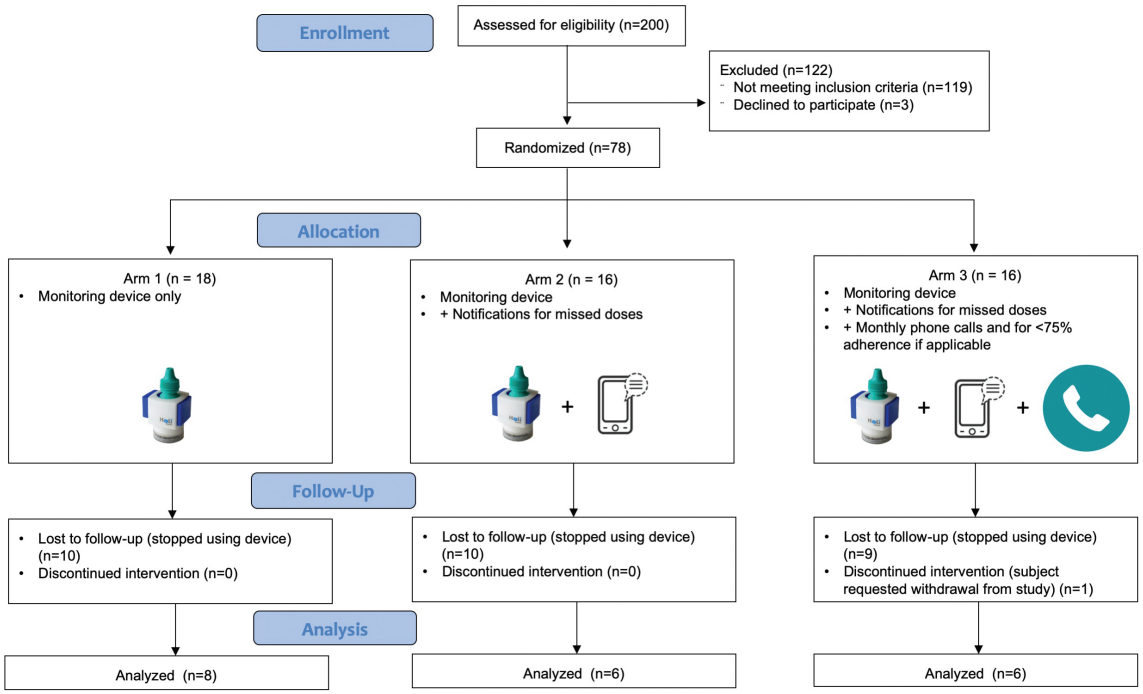

Figure 1: CONSORT Flow Diagram. Reasons subjects were lost to follow-up included: subjects were travelling and decided not to take the device with them, subjects were not accustomed to the device so stopped using it, or subjects stopped using the device (despite consistent signal from the device confirming the issue was not lack of signal connectivity). One subject in Arm 3 requested early discontinuation of the study due to a change in residence.

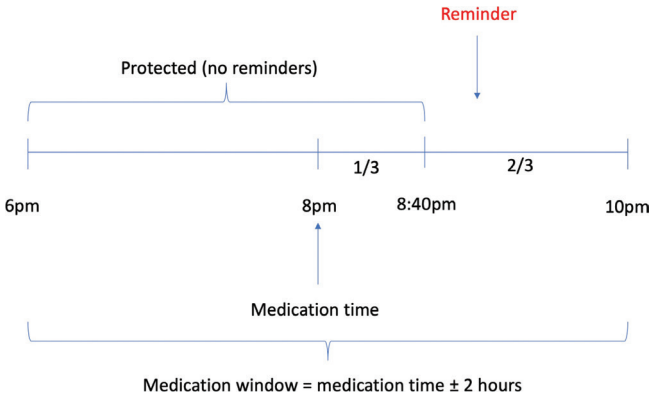

Figure 2: Reminder Configuration. In the example shown here, the subject usually expects to use their eye drops at 8PM. We used a medication window of two hours, meaning the subject was registered as adherent that day if they used their drops sometime two hours before 8PM or one-third of the two hour medication window after 8PM (i.e. between 6PM and 8:40PM). Subjects not in the control arm who missed this window received a SMS text reminder at a random time in the remaining two-thirds of the two hour medication window (i.e. in the 80 minutes between 8:40PM and 10PM).

SMS text at a random time within the remaining two-thirds of the medication window after the initial third protected time. For instance, a subject with a medication time of 8PM would not receive a notification within the first third of the medication window of 2 hours (i.e. in the forty minutes between 8PM and 8:40PM), but would receive a notification at a random time in the remaining two-thirds of the medication window (i.e. in the 80 minutes between 8:40PM and 10PM). This way, subjects who regularly missed their medication time could not anticipate receiving a reminder at a set time.

Subjects who missed their drop and received a reminder had the chance to have their drop counted any time before midnight that day. For subjects who were travelling across time zones during the study, we asked them to notify the research team of their travel dates. This allowed the device to maintain the time of day and reminder window for which the corresponding subject was regularly expected to take their medication.

For Arm 3 subjects who received a phone call when their weekly adherence dropped below 75%, qualitative data was collected to assess reasons why subjects had decreased adherence. This included feedback on device convenience, design, and timing of reminders. The 75% threshold was chosen to recapitulate a previous study that had also defined adherence at this level.[13,30]

Notifications in this study were in the form of a standardised, pre-written SMS text message to the subject's personal mobile phone. The rationale for a text message as opposed to a phone call or other means of communication was based on previous research demonstrating the ability of text messages to improve medication adherence for multiple conditions including asthma medication adherence and diabetes management.[31,32] Further, studies on the effect of text messages on memory have suggested text messages can motivate behavioural change by affecting elements of cognition such as working memory.[33] Subjects were also aware that any SMS text message charges would be associated with their cellular plan.

Participants

Patients were recruited from the Stanford University Department of Ophthalmology at the Byers Eye Institute. To be eligible, patients had to be receiving glaucoma care at the Byers Eye Institute, have a diagnosis of glaucoma, be at least 18 years of age, own a personal mobile phone, be able and willing to receive SMS text notifications, and have been prescribed generic latanoprost at a dosage of one drop in each eye daily for at least four months without adverse effects. The reason for generic latanoprost as opposed to other medications was to standardise for how well the device fit the bottle. We excluded patients if they were not reliable enough to operate, maintain, or keep a mobile phone, were unable to administer the eye drop due to physical limitations, had a history of eye surgery for glaucoma, had a history of very poor adherence who did not return for visits, or were concurrently enrolled in another clinical research study.

A member of the research team introduced the study to eligible consecutive patients from the clinic population during their regularly scheduled visit. Upon obtaining written informed consent, all study subjects completed an entrance survey assessing for perceived adherence, time of day they usually took their medication, and barriers to access such as cost. Collected demographic characteristics included sex, age, self-reported race, household income, and education.

Ethics Statement

The Institutional Review Board at Stanford University approved this study before its initiation.

We deidentified all data according to HIPAA guidelines and adhered to all principles outlined in the Declaration of Helsinki. As all participants were already receiving the standard of care treatment, we did not need to define any stopping rules.

Device

Prior to this study, the device had already been studied for technical feasibility, had previously been studied at another institution, and at the time of this study was concurrently being used in other clinical trials commercially outside the US.[29] The device is a prototype of an add-on electronic sensor that monitors eye drop bottle usage. It attaches over an existing eye drop bottle, in which the bottom of the sleeve carries the electronic hardware and the side of the sleeve facilitates the subject's ability to squeeze the eye drop bottle. Further, the sleeve is customised to fit the shape of the particular eye drop bottle.

When trigged by bottle movement, the device sends anonymous usage data to an external cloud server. An algorithm determines usage pattern to track both the pressure on the sides of the bottle and the orientation of the bottle itself, so that the device is able to measure the number of drops squeezed out of the bottle according to how accurately both the pressure and orientation of the bottle match the preset algorithm. If the algorithm is not matched, the device interprets this as the subject not having used one drop in each eye that day. In this case, an automated reminder system is triggered for subjects to receive a standardised, pre-written text message notification on their mobile phone ("Reminder: take glaucoma medication").

Outcomes

The primary end point was adherence to eye drop medication use, defined by the proportion of prescribed doses that had been taken each day over the total number of days of study participation. Each day was a binary data point; either two eye drops (presumably one per each eye) had been taken or not. Finally, this was within a window of 2 hours before or after each subject's set medication time (see *Trial Design* above). For instance, within a week, adherence was calculated as the number of days medication had been registered as taken over 7 days. We analysed quantitative data collected by the device by comparing the average medication adherence (%) of the baseline first week vs the final 13th week. To gain a visual sense of adherence trends, we also analysed the average adherence per week. In total, we collected data points for the following timestamps: the subject's medication time, the time at which the subject actually took the medication, the time at which the subject missed the medication, the time at which the subject was sent a reminder notification, and the time at which the subject took the medication after having received a notification.

Arm 3 subjects who received phone calls were interviewed to assess reasons for nonadherence and to receive feedback on the device. This was adapted from the Glaucoma Treatment and Compliance Assessment Tool GTCAT and a previous pilot study on health coaching in glaucoma medication adherence.[34,35] Key elements of the interview were as follows: (1) we told subjects their adherence data to assess if informing them of their adherence was in itself an intervention that could change behaviour, (2) counseled them regarding questions on device usage and timing of their reminders, and (3) answered any other questions they had about their glaucoma medication regimen.

Statistical Analysis

We reported adherence as a continuous variable with comparison of means by Student's t-test and compared variances by Fisher's-test. To achieve 80% statistical power, our calculated target sample size was 16 subjects per arm assuming a mean adherence of 75% before intervention, improvement in adherence of 20% after intervention, and a Type 1 error of 5%. No correction was made for multiplicity.

Results

Recruitment and demographics

Demographic data is outlined in Table 1. A total of 50 out of 78 consented subjects (64%) participated in the study. Quantitative data was collected from the prototype for all subjects who participated in the study and qualitative reasons for drop out were collected and communicated to Kali. The first subject was enrolled in June 2017 and the last subject was enrolled in November 2017 with subsequent follow-up until February 2018. The subjects who finished the study (63.6 ± 12.33) were on average 8 years younger than the 28 subjects who did not begin the study (71.07 ± 13.27; p = 0.03).

Efficacy of the device on adherence

The primary objective of this pilot RCT was to determine if real-time monitoring coupled with custom notification reminders could improve adherence,

Baseline Characteristics	N (%)
Age	
< 50	7 (8.97)
50–59	11 (14.10)
60–69	19 (24.36)
70–79	29 (37.18)
≥ 80	12 (15.38)
Mean ± SD	68.14 ± 12.53
Gender	
Female	35 (44.87)
Male	43 (55.13)
Race	
Black or African American	3 (3.85)
White	36 (46.15)
Asian/Pacific Islander	29 (37.18)
Hispanic or Latino	6 (7.69)
Other	2 (2.56)
Declined to answer	2 (2.56)
Household income	
Less than $10,000	11 (14.10)
$10,000 to $149,999	36 (46.16)
$150,000 or more	25 (32.05)
Declined to answer	6 (7.69)
Education	
No college degree	14 (17.94)
Bachelor's or trade/technical/ associate degree	28 (35.90)
Master's degree	22 (28.21)
Doctorate degree	14 (17.95)

Table 1: Demographics of Baseline Characteristics (n=78)

namely by comparing the baseline versus final adherence between Arm 1 and Arm 2. We defined the baseline adherence as the average adherence of the first 7 days (week 0) while the final adherence was defined as the average adherence of the last 7 days (week 13). The Arm 1 baseline adherence was 75.89 ± 7.11% versus the final adherence was 54.76 ± 14.95%, representing a 28% decrease from baseline. By comparison, the Arm 2 baseline adherence was 78.57 ± 6.76% versus the final adherence was 60.71 ± 13.70%, representing a 23% decrease from baseline. Finally, the Arm 3 baseline adherence was 72.32 ± 8.60% versus the final adherence was 66.67 ± 7.06% adherence, representing only an 8% decrease from baseline. Nevertheless, none of the changes between baseline and final adherence were different between Arms 1 and 2 (p = 0.12) or Arms 1 and 3 (p = 0.34).

To gain a visual understanding of adherence as subjects progressed through the study, we outlined weekly adherence trends (Figure 3). Arm 1 subjects had an initial decline in adherence, reaching its lowest adherence of 42.86 ± 14.03% at 7 weeks, down from its baseline adherence of 75.89 ± 7.11%. This marked a statistically significant difference from Arm 2, which at the 7th week had maintained its adherence at 78.57 ± 5.13% (p = 0.01). Further, the difference in variance among all weekly adherence values between Arms 1 and 2 was significant, with 102.21 for Arm 1 versus 32.92 for Arm 2 (F-test, p = 0.05). After the 7 week mark, Arm 1 adherence appeared to increase to the same adherence as Arm 2 subjects throughout the remainder of the study. However, the apparent increase in adherence for Arm 1 between weeks 7 and 12 was confirmed to be due to selection for subjects who remained in the study and were consistently adherent anyway.

Similarly, a comparison between Arms 1 and 3 showed significant differences at weeks 6 and 7 (Figure 4). Specifically, Arm 3 adherence peaked at 90.48 ± 4.12% compared to Group 1 at 46.43 ± 15.68% (p = 0.01). The following week, this difference maintained statistical significance with Arm 3 adherence at 82.14 ± 6.47% versus Arm 1 adherence at 42.86 ± 14.03% (p = 0.02). To determine if the additional phone calls for group 3 accounted for this difference, we compared adherence between Arm 2 and Arm 3 and found no statistical difference over all weeks of the study (lowest p = 0.15; Supplementary Figure 1).

Impact of the device on participants with full completion of the study

A comparison between Arm 1 and 2 subjects who did not drop out at any point during the study demonstrated no significant difference in adherence across all thirteen weeks of the study (lowest p = 0.08; Supplementary Figure 2). Nor was there a significant difference in the variance between groups 1 and 2; the variance of group 1 was 171.22 while the variance of group 2 was 72.19 (p = 0.13).

Discussion

This study assessed if real-time custom notifications provided an intervention that could improve medication adherence. In accordance, we found that subjects receiving real-time custom notifications (Arm 2) were able to maintain their baseline adherence over a longer time span in the thirteen-week

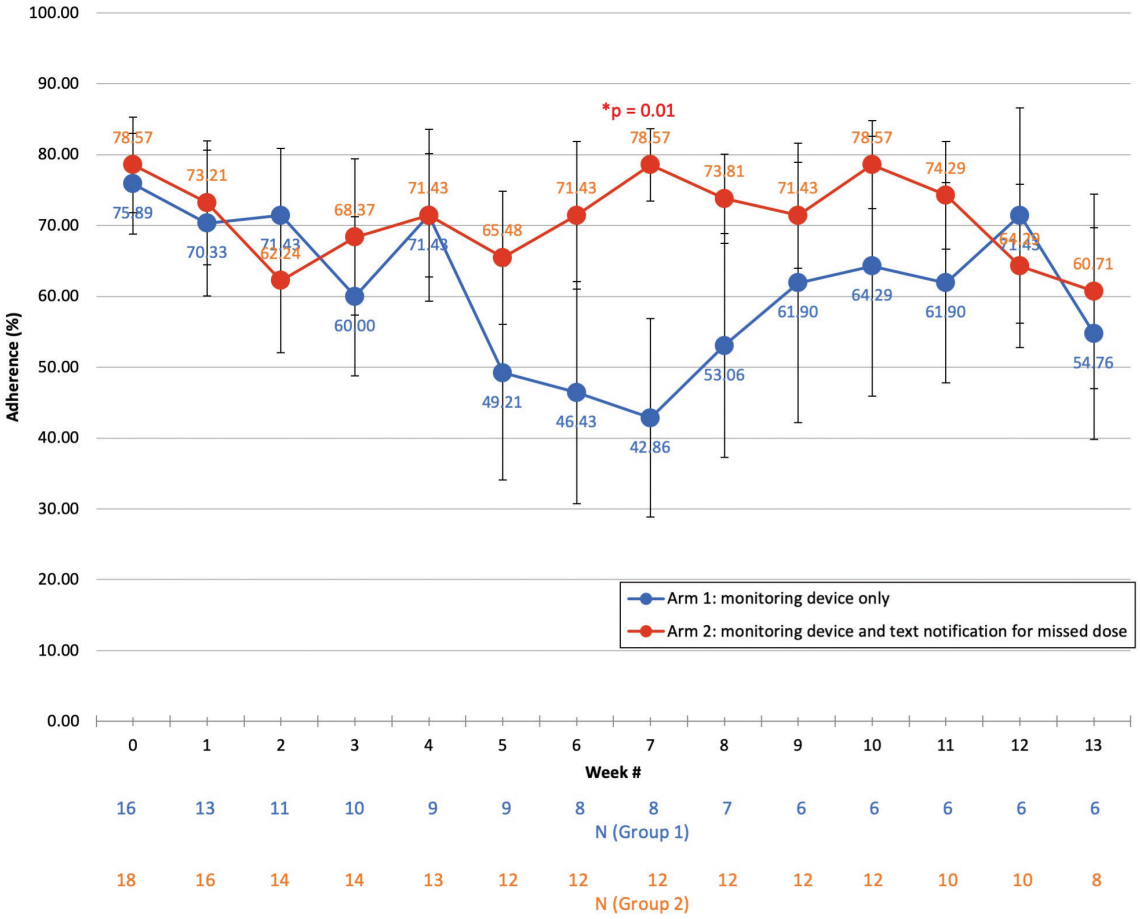

Figure 3: Weekly Adherence Trends Between Arms 1 and 2. Arm 1 subjects had an initial decline in adherence, reaching its lowest adherence of 42.86% at 7 weeks, which increased to roughly the same adherence as Arm 2 subjects during weeks 7 to 13. Meanwhile, Arm 2 subjects maintained a relatively steady adherence. The difference in variances between the arms was significant, with 102.21 for Arm 1 versus 32.92 for Arm 2 (F-test, p = 0.05). Week 7 also had a significant difference in mean adherence, with Arm 1 at 42.86 compared to Arm 2 at 78.57 (Student's t-test, p = 0.01). To account for weekly drop off, the remaining number of subjects in each arm is shown per week along the x-axis.

study compared to the control group (Arm 1). Although comparing baseline versus final week adherence demonstrated no statistically significant difference between Arms 1 and 2, this approach may not have been sensitive enough to discern a significant difference. We reasoned this could have been due to attrition bias, as the subjects who were likely to drop out early were also likely to have worse adherence and that further, this phenomenon may not have occurred equally among the three arms. In retrospect, the effects of attrition bias could have been minimized with factors such as a larger sample size and a standardized protocol for home setup.

In line with a previous study that analysed adherence via visual representation of adherence data and identified four easily-defined patterns of adherence (good adherence, discontinued usage, frequent drug holidays, and frequent missed doses with low adherence rates), we graphed weekly adherence to assess how usage trends differed among our three study arms.[14] Indeed, by week 7 the intervention had led to a significant difference in adherence between Arms 1 and 2, with Arm 1's graphical representation most closely resembling increasingly frequent missed doses with each week while Arm 2's graphical representation most closely represented good adherence. This was supported by a similar finding when the control arm (Arm 1) was compared to the group that, in addition to receiving texts for missed doses, also received monthly phone calls and/or if adherence fell below 75% (Arm 3). This difference was likely driven primarily by the custom text notifications instead of phone calls, as there was no difference in adherence across all weeks of the study between Arms 2 and 3 (lowest p = 0.15).

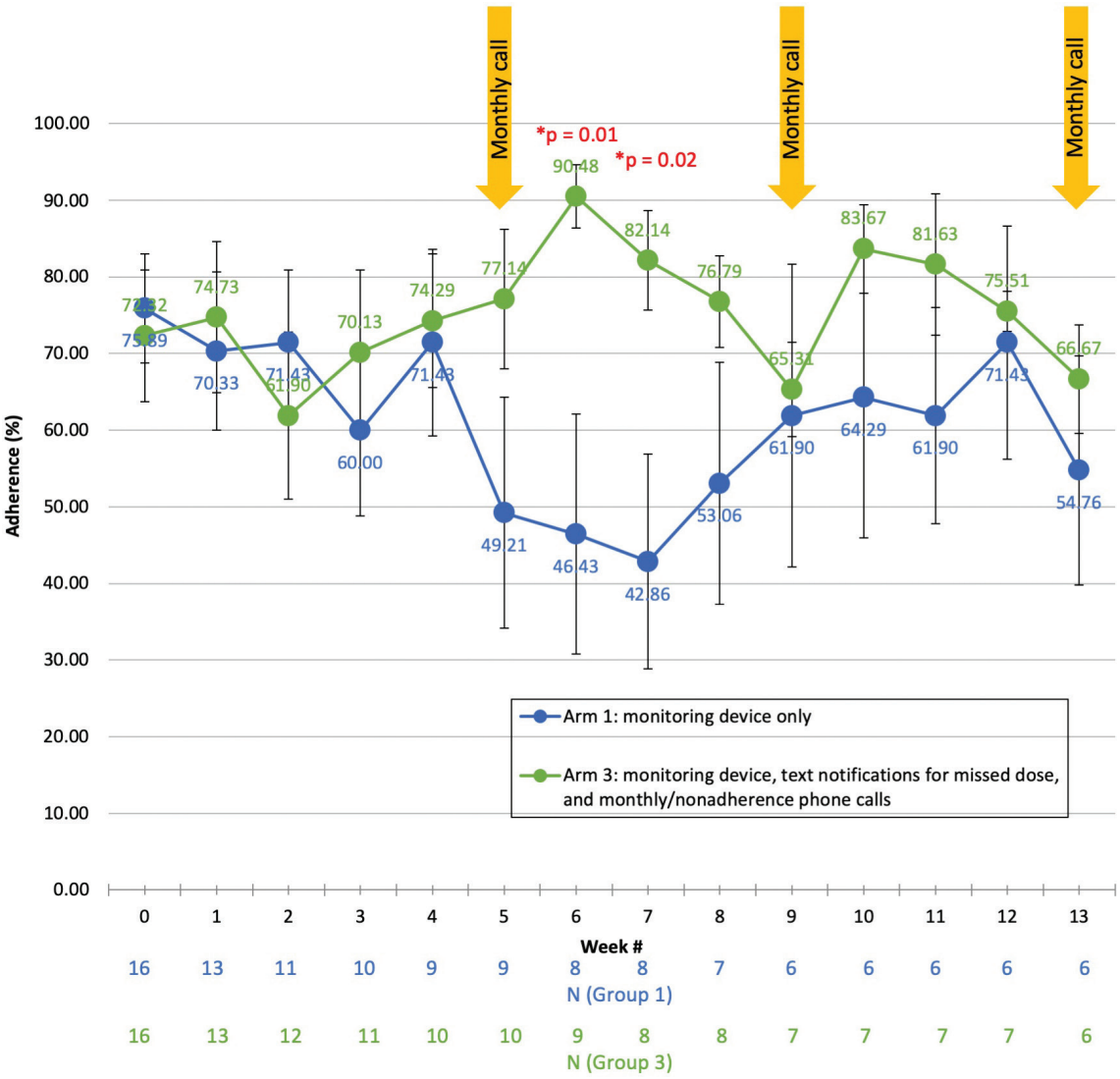

Figure 4: Weekly adherence trends between Arms 1 and 3. There was a significant difference in Arm 1 versus Arm 3 adherence at two different weeks in the middle of the study. First, at week 6 when Arm 1 adherence was 46.43 versus Arm 3 adherence was 90.48 (Student's t-test, p = 0.01) and second, at week 7 when Arm 1 adherence was 42.86 versus Arm 3 adherence was 82.14 (Student's t-test, p = 0.02). There was no significant difference in the variance between Arms 1 and 3; variance of Arm 1 was 102.21 while variance of Arm 3 was 55.98 (F test, p = 0.29). Yellow arrows indicate timing of when monthly phone calls were made for Arm 3 subjects. To account for weekly drop off, the remaining number of subjects in each arm is shown per week along the x-axis.

Further, when we analysed the average adherence of the subjects who completed the full thirteen-week study, we found no significant difference in adherence between Arms 1 and 2 (p = 0.08, Supplementary Figure 2). This suggests that the subjects who had the perseverance to use the device throughout the study period were going to maintain their adherence regardless of whether they received reminders or not. This suggests this subgroup of study-compliant individuals were able to maintain their adherence through behavioural mechanisms that do not necessarily require reminders but rather interventions such as education and environmental restructuring.[36] For instance, several compliant subjects qualitatively reported not believing that they relied on the device's notifications because their eye drops were left next to their toothbrush or glasses, i.e. associated with an object they used every day. Furthermore, home setups of the devices were not standardized which may have contributed to a reporting error or measurement error in the data.

Demographically, the subjects who finished the study were on average 63.6 years old, which was

approximately 8 years younger than the subjects who consented to but did not begin the study ($p = 0.03$; Table 1). Possible reasons include that older patients were less willing to participate in a study and/or were less able to use the device due to ongoing conditions such as arthritis or dementia. Although this is consistent with prior work that did not find adequate evidence showing that elderly patients have poorer adherence than younger patients,[37] in a previous study conducted by Kali Care with their monitoring device, adherence did tend to increase with age ($r = 0.673$, $p < 0.001$).[29] Further investigation of glaucoma medication adherence in elderly patients may require clarifying differences between elderly patients who manage their own care versus those who rely on younger caretakers or family members.

Limitations of this study included the small sample size which may have precluded the achievement of statistical significance in baseline versus final week adherence among the study arms. Another limitation was the prototype was designed to only fit bottles of generic latanoprost, which limited the number of eligible subjects for the study and could have led our study to select for subjects of a given socioeconomic status. Further, the prototype's inability to automatically update the system to account for a change in time zone if a subject traveled; for this study we could only update time zones manually for patients who told us of their travel plans. A possible solution could be installing GPS tracking in future versions to automatically maintain customised reminders across time zones, although this innovation would need to be balanced with each subject's permission for tracking their location. In addition, while the Hawthorne effect on medication usage is a consideration in any electronic monitoring of medication usage, it was of less concern for this study because both our control and intervention subjects were aware of being monitored.[38] A previous study of medication usage in glaucoma patients supports this point, as they compared open versus masked monitoring and found no significant difference.[39]

Future work includes running a clinical trial with a larger sample size to further validate the findings of this pilot study. Additional features of this study should include broadening the medication window from two hours to a more forgiving time window and introducing personalised health coaching at the start of the study, which has been shown to improve medication adherence not only for glaucoma[13] but also for other chronic conditions including Type 2 diabetes mellitus[40] and chronic obstructive pulmonary disease.[41] Finally, a more focused way to prevent reminder fatigue could involve incorporating artificial intelligence (AI) technology for writing unique SMS texts that never repeat the same message and are personalized to each subject.

Conclusions

This randomised clinical trial piloted an innovative prototype that provided real-time monitoring coupled with custom notifications and found that subjects receiving these notifications were able to maintain their baseline adherence over a longer time span than the control group. Future studies may aim to include a randomized clinical trial with a larger sample size and varied reminders with more customized or dynamic parameters.

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Declaration of Competing Interests

All authors have completed the Unified Competing Interest form. RTC is an advisor to Kali Care which supplied the devices for this research; all authors declare no other conflicts of interest including no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

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