

Collection of Patient Reported Outcome Measures Using Short Messaging Service

Experiences from the development process and a pilot study

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Abstract—Information and communication technology may improve clinical care and research. The advent of mobile technology offers many new possibilities. We present the development and pilot testing of a system that collects patient reported outcome measures using mobile phones in the field of rheumatological rehabilitation. Ensuring that the system was usable by the maximum number of patients resulted in choosing text messages for reporting from the patients over newer technology like mobile apps. The system was run in a successful pilot study where participants answered both with text messages and pen and paper. The text message reporting was more complete than the pen and paper method. A focus group and a survey showed that participants preferred using text messages to pen and paper. We detail our design decisions and why we feel that for our purposes within the domain of rheumatology, text messages provide the best suited overall solution given their simplicity, ubiquity in Norwegian society, and the fact that no new hardware or software is required for the respondent. The system is currently being used in a yearlong clinical study.

Keywords: Patient reported outcome measures, electronic capture, short messaging service, rheumatology, clinical research.

I. INTRODUCTION

Traditionally, outcomes measures used in clinical medical research are based on a biomedical model of health focusing on objective and scientifically accepted tests and measures. [1]. Today, it is recognized that the patients' subjective opinion is of importance, thus patient reported outcome measures (PROMs) reflecting the patients' perspective are increasingly emphasized in clinical trials [2, 3, 4]. PROMs address such constructs as health related quality of life, subjective health status and functional status [4]. Concrete examples of such information are pain or fatigue levels reported by patients.

In certain chronic health conditions, such as arthritis and diabetes, it may be appropriate to collect PROMs over time in so called health diaries [5]. Health diaries in this context mean one or more scientifically validated PROM questionnaires completed repeatedly over a period of time, for instance over weeks or months.

It is important that the diary data is of high quality, providing an accurate picture of the patient's subjective experience. The traditional diary collection method has been pen and paper (P&P). There are a number of inherent weaknesses with P&P collection, such as poor protocol compli-

ance, poor data quality and burdensome data management [6]. The problems may lead to the introduction of a variety of biases in the collected data. This may undermine the scientific value of the diary method.

Information and communication technology (ICT) may help combat the aforementioned biases when collecting diary data. With the advent of mobile handheld technology – notably personal digital assistants (PDAs), feature phones, smartphones, and tablet computers – data collection by means of electronic diaries (EDs) has become increasingly popular in clinical research [7, 8, 9]. Electronic capture of PROM data has a number of scientific and practical advantages over the P&P method [6, 8]. According to a systematic review, the ED diary method is superior to P&P collection in terms of feasibility, protocol compliance, data accuracy, and subject acceptability [8]. Additionally, it has been shown that the electronic PROM collection is equivalent to P&P PROM collection [10]. This is important to maintain scientific constructs such as validity and reliability to ensure that the psychometric properties of the questionnaires are carried over into the electronic versions.

With the superiority of the ED method established, one is faced with the questions: given that there are a number ED methods available, e.g., by means of PDAs, feature phones, smartphones, and tablet computers, which one do you choose? Currently, smartphones and applications (apps) are in vogue, but does an app installed on a smartphone always provide the optimal method when one wishes to collect PROMs? In another project, the Short Message Service (SMS) or text messages have been utilized successfully [11]. We need to ask whether this somewhat older and basic technology is obsolete, or is it still an option in ED collection?

This was the dilemma faced by the National Resource Centre for Rehabilitation in Rheumatology (NKRR) when they wanted to select an electronic collection method for a yearlong clinical study measuring the possible clinical effects of physical exercise in heated pools for persons with rheumatic disease. PROMs relating to subjective perceptions of pain, stiffness, fatigue, and how much the rheumatic disease affects the ability to engage in activities were to be collected twice weekly for a year.

Researchers at the Norwegian Computing Centre (NR) designed and implemented an electronic collection solution. As the paper will show, we opted for a solution using text messages. This paper detail the reasons for doing so, and in the process shed light on important issues and aspects that one has to reflect upon when wanting to choose an ED col-

lection method. We will do so by explaining and describing the technical set up, and the deliberation behind its construction. We will also detail our experiences from a pilot trial of the system that ran over a four-week period with 28 participants with rheumatic disease, as well as share and discuss the findings from a focus group and questionnaire survey conducted as part of the same pilot. Further, a brief conclusion and planned further work is provided.

II. DESCRIPTION OF REQUIREMENTS, ENSUING SOLUTION AND PILOT STUDY

This section describes the requirements as expressed by NKRR, as well as detailing the solution that was developed and the pilot testing of the system.

A. System requirements and the solution developed

Below we detail the requirements a potential system had to meet. Further, we provide a description of the ensuing system developed.

1) System Requirements

For their clinical study outlined above, NKRR required an electronic collection system that would allow them to collect selected PROMs twice weekly for a year from persons with rheumatic disease across Norway. The participants were to take part in exercise classes in heated pools suited to the needs of people with joint disease. The PROMs would help indicate whether or not classes had any clinical effect.

The system had to allow flexible access for the researchers from multiple geographical locations. The project required a service that could contact participants, i.e., persons with rheumatism, and have them answer back during a 24 hour period. NKRR also wanted to check on the status of the responses, control the content of the messages, and specify when they were sent out. If a reply had not been received by a certain time, a reminder message was to be sent out.

It was also important that solution was secure and that the privacy of the participants was preserved. This meant that the relevant privacy laws in Norway were followed. Participants would be recruited from several different research and medical institutions, and a contact person at each institution would be in charge of recruiting and adding the participants.

The system would have to stay up during the entire year that the study would be running. The collected data was to be readily available both online and easily downloadable for analysis using statistical software. These requirements helped shape the final solution that was developed by NR in close cooperation with NKRR.

2) The solution developed

The final system is a web application with a front end that is run by a web interface written in Ruby on Rails. We only allow encrypted access (i.e., HTTPS) to the web application and only authenticated users are allowed further access.

The interface (see Figure 1) allows logged in users, e.g., researchers or other relevant staff members, to add participants to a study, schedule what days messages are sent out, write the message text, look at responses from the participants, and export the results for use in spread sheets or

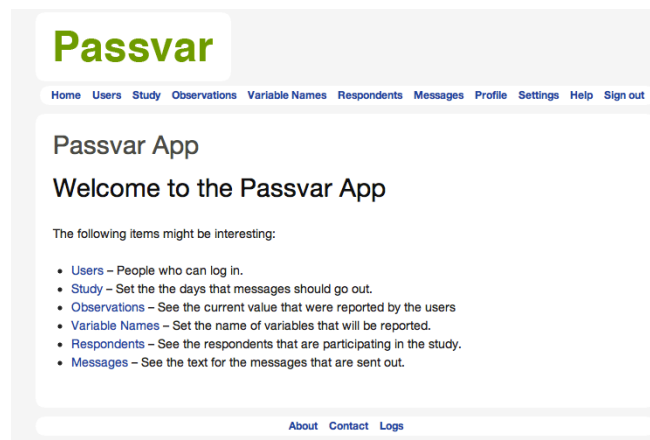


Figure 1. The user interface of the web application.

statistical programs. Special administration users are also able to create additional system users. This allows users to be added for each institution that decides to join in a particular study.

Participants are identified by an ID selected by the researchers. Participants' mobile phone numbers are entered into the database upon creation. For privacy reasons, users with no administration privileges are only able to see the phone numbers of the participants they have added. These users are able to see all incoming results, but they cannot see which result corresponds to which phone number.

As for sending and receiving messages to participants, we decided to use text messages for this. After some investigation, we found a Linux-based software solution called SMS Server Tools 3, and a modem that was well supported by it. We were then able to write some programs that would look at the information in the database, and send out reminder messages to those that had not sent a message yet. The program runs periodically using the cron service on the Linux system. The message that is sent out asks the participants to reply about the level of W, X, Y, Z (e.g. pain, stiffness, fatigue or any relevant PROM) and answer on a scale from zero to ten. The participant should send back the answer with each number separated by a period (e.g., 10.8.7.5). An overview of the whole system is provided in Figure 2.

Another program is run whenever we receive a text message. This program checks the phone number that sent the message and imports the message if it matches any numbers of the participants in the database. It will also parse out the numbers in the message and match them up to the values that are asked for in the study. As a precaution, we also store the raw message in the database as well. This ensures that if a message is incorrectly interpreted, we can look at the original message and see if there was a problem. Administration users also have access to the logs of every message that has been sent out and received, so it is possible to know if the system is working.

The system is designed such that on certain days at a certain time, participants will get a message where they answer with some numerical values. If a response has not been received in 24 hours, a reminder text message is sent out. If participants have not answered the question after that 24-

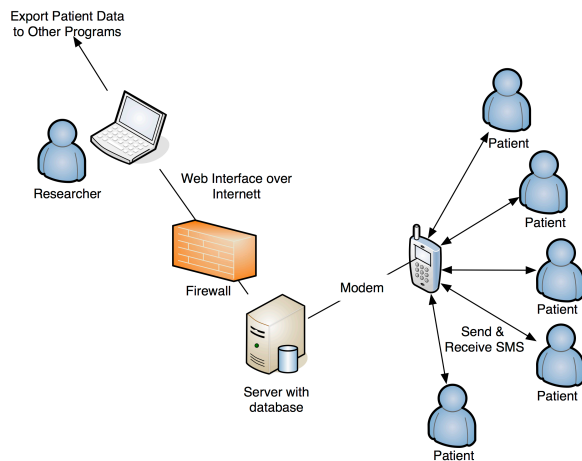


Figure 2. An overview of the system. The patients respond to text messages generated by the system. Their answers are store in a database. The collected data can be viewed in a web interface, or exported for analysis.

hour period, the response for that period is dropped and will be counted as non-compliance in the study protocol. The system interprets the incoming message, and if this is ambiguous or cannot easily be interpreted according to built-in logic, it is discarded. Since the days that the message is sent out is the same for each week, we used a simple interface where we could set up the actions for each day of the week (either send a message, send a reminder, or do nothing) and then specified how many weeks this action should repeat.

The system is running continuously on a virtual machine, and is backed up regularly. There are monitoring scripts checking for and alerting us if there is any malfunction.

B. Pilot study

A pilot study was conducted to test the system in real world conditions, as well as to compare the compliance rate and to examine validity and reliability issues between P&P questionnaires and their text message equivalents. 28 adults with a rheumatic disease were recruited to take part. They were asked to answer the following text message every other day for four weeks: “Degree of pain, fatigue, stiffness and how the disease affects your ability to conduct daily activities? 0=none, 10=worst possible. Remember a full stop separating the numbers. Thank you!”¹ The message consisted of abbreviated questions used in rheumatological research, e.g.: “Please, state how much pain you are experiencing! 0 = no pain, 10 = worst pain possible, 0 2 3...9 10”. The questions were also provided in full text to the participants on small laminated cards that they could carry with them.

Every other day they were asked to report the same PROMs using P&P. The responses for both modalities were a value between 0 and 10 for each PROM. A text message with the correct syntax could look like this: “1.2.3.4”. All the P&P responses were to be mailed to the study coordinator.

¹ Text messages have a 160-character limit per message. This message is 160 characters in Norwegian.

Detailed written instructions were provided for each participant. Since the pilot study format alternated days with texts and P&P, we did not use the text message reminder functionality if a response was missing.

In total, the participants would respond with 14 text messages and 14 P&P forms to be compliant with the protocol. The data from the incoming texts was imported into SPSS statistical software for analysis. The P&P data was manually typed in to the same software. To obtain the participants’ perspective, we conducted a focus group after the pilot was completed to discuss the experiences with five of the participants. In addition we mailed out a questionnaire survey to the participants asking 14 questions related to their participation and ED collection.

III. RESULTS

Below follows a brief summary of the experience from the pilot divided into data collection issues and participants’ feedback provided in the focus groups and questionnaires.

A. Data Collection Issues

The system worked satisfactorily for the duration of the pilot with no downtime. Only brief comments about the integrity and quality of the incoming data will be provided here, as such results will be reported more comprehensively in a future publication. Overall, the text message data sets were more complete than the P&P data sets; that is, there was fewer missing data in the text message records when compared to the P&P records.

Further, as we were able to monitor the incoming text message data, respondents could be contacted if there were repeated violations of the protocol, e.g. systematic syntax error in the responses, or numerous missing data. The project coordinator contacted two of the participants once to guide them on how to respond correctly after detecting incomplete incoming data.

Based on the experiences gained in the pilot, we made adjustments to the system and added features. This included new logical rules of how the incoming messages were to be interpreted, and the possibility to access a log of all outgoing and incoming text messages.

B. Focus groups and questionnaire survey

We used a focus group and a questionnaire survey to obtain feedback on how the participants experienced taking part in the pilot.

1) Focus group

The purpose of the focus group was to get input from the respondents on how they experienced taking part in the pilot. This input was used in the development process to further improve the solution. Five participants – two male, three female – took part. The focus group session lasted 90 minutes and was audio recorded. An interview guide was used to structure the session.

In the pilot, all five focus group participants had used smartphones that they carried with them at all times. They stated that they had responded to all messages, except one who had forgotten to answer on a couple of occasions. It was pointed out that it sometimes was socially inappropriate to

answer, and this meant that they responded at a later time. One of the participants said that it could be somewhat socially awkward to receive a message in the presence of others, as others may see the message content of the message. This was especially sensitive if the participant did not want others to know that the participant had a rheumatic disease.

In the pilot the text message was sent out to all respondents at 3 P.M. Three informants preferred this time, while two preferred to receive a message between 5 and 7 P.M. If they were to receive a reminder, all agreed that this should be sent out the same day as the original text message.

Few practical problems were raised. One informant reported problems sending a response on a couple of occasions, but was unsure if this was because of problems with the mobile phone or with the network. Another person thought she had used a wrong syntax in a reply once, but assumed that the message went through. Despite this uncertainty, none of the group members wanted to receive a receipt acknowledging that their answer had been received and was a valid response.

One of the informants had been abroad during parts of the pilot, but had not experienced any practical problems receiving and sending texts using foreign mobile networks. Anecdotal evidence of occasional delays in receiving texts sent between international mobile networks are known.

The whole group preferred text messages to P&P, and they thought it was easy to respond using the mobile phone. There was some interest in using a smartphone app as a response medium. It was highlighted that this would enable them to answer more in-depth on suitable questions instead of the 160-character restriction on text messages. As they all had smartphones, this limit of 160 characters per text message poses no practical and usability limitation as the phone will automatically combine and present two or more both outgoing or incoming messages into one message on their screen. Some older phone, however, split messages longer than 160 characters into multiple messages that must be opened separately. This could be a usability issue.

Several of the participants stated that it was very helpful to have the laminated card with the questions written out in full. As for the text used in the text message, it was suggested to include an example of a correct response, e.g. "3.5.6.9".

There were also a number of suggestions and views concerning the principal idea of collecting PROMs. Some of the issues raised were the problem with quantifying subjective experiences such as pain and fatigue. It was also suggested that they would also like to be able to add additional information like stress levels, mood, and other factors that will possibly influence the PROMs.

TABLE I. CHARACTERISTICS OF THE SURVEY RESPONDENTS.

Number of responses (N):	12
Gender:	10 women; 2 men
Age range (years):	27 to 62 (mean 50 and sd 12.2; median 55)
Type of phone:	Touch UI 8 Standard keyboard 3 Touch UI & physical keyboard 1

2) Questionnaire survey

The purpose of the questionnaire survey was to gain insight into how the respondents had experienced taking part in the pilot. It was mailed out to 20 of the pilot participants as we lacked the addresses for the remainder. The characteristics of the respondents are given in TABLE I.

All but two stated that they had a 100% data completion record using the mobile phone. One had simply forgotten to reply on one or more occasions, and another was busy and could not respond on one or more occasions. Two-thirds agreed that 3 P.M. was a suitable time to receive a text message to respond to, while the rest suggested a different time window. Suggested times ranged from 5 P.M. to 8 P.M.

Nine out of 12 would like to have a text message reminding them to answer if they have not done so, whereas two did not, and one did not know. Of those that wanted a reminder, five would like this the same day as the original message while four suggested the next day.

No one reported any technical problems that affected their performance, and one-third of those answering had been abroad during periods of the month long pilot. 10 preferred text message to P&P, one did not have a preference, and one answer was discarded as several mutually exclusive choices had been selected.

Seven would consider using the mobile phone to register health related information such as pain, fatigue and stiffness on a regular basis, two did not, and three were not sure. A comment from one of the respondents was that such information should not be collected more frequently than monthly. In terms of other types of information that they would consider to register on their mobiles was information relating to exercise (50%); dietary information (50%), and intake of medication (25%).

IV. DISCUSSION AND IMPLEMENTATION ISSUES

Below follows a discussion of the collection method chosen, as well as an elaboration on several implementation issues.

A. Discussion

There are a number of electronic capture methods. How wise was the decision to opt for text messages as a collection method in this project? While creating mobile apps or web apps at present is a favourite topic in the business world, we had no guarantee that potential respondents would own phones able to run such apps. To run apps, the participants would need a smartphone that would run Android, Blackberry, iOS, Windows Phone, or similar. Since there are a number of different platforms, it would mean either choosing only one platform or creating versions of the app for all platforms. This would have been very resource demanding for this small project.

Since the prevalence of rheumatism increases with age and it is a chronic disease [12], many of the potential respondents would be older. As smartphone ownership amongst the elderly is still low, we decided that this would preclude many potential participants from entering the study. This would have had the potential to cause bias in the results. One could for instance expect that a majority of participants

would be younger if one opted to go for a mobile app or a web app given this groups higher smartphone ownership.

An option would be to lend participants smartphones for the duration of the project. This measure would be both costly and would require a great deal of training and support. Research has also shown that seniors would like to have basic phones, and that complex phones can be confusing [13]. Making them use a new smartphone seemed to be an option that could end up being both costly and fraught with support problems.

Further, we were sure that there would be a wide variety in the functionality of the mobile phones amongst potential participants. Text messages were the only method we could be sure that everyone had access to. Text messages are also so ubiquitous in Norwegian society that we could be sure that participants could answer a text message without any training. They would be able to use their own phone that they are familiar with.

Another reason for using text messages was that they are cheaper than data costs when participants are abroad. A mobile app or web app would require some sort of data connection, either over Wi-Fi or using mobile data. Many Norwegians with rheumatic disease travel to countries in Southern Europe for the winter as a therapeutic measure, and roaming data is currently much more expensive than a roaming text message. Text messages only require GSM coverage, and this available across the populated world. The use of text messages also allows for two-way communication: allowing us to do things like send out encouragement messages to keep up motivation.

Although, text messages have many advantages in the context of this particular project, there are a number of shortcomings one needs to keep in mind. One limitation is the 160-character limit per message. This limits the number of questions one can pose, as well as the amount of information the responses can contain. In our case, we were able to ask for four PROMs in each message based on abbreviated P&P questions. Using an app we could have been much more flexible in terms of mimicking the original P&P questions used, and thereby presenting the respondent with one question at the time in full. The respondent could then answer a particular question before moving on to the next.

We could have worked around this by sending multiple text messages for the participants to answer one at a time. This has been done in prior projects [11]. We considered this too inconvenient and intrusive for the respondents, so we opted to go for one message per communication.

Another problem using text messages is that the participants need to structure their response in a manner that is easily interpreted by the system, e.g., “value1.value2.value3.value4”. This is because there is no inherent structure in the text message itself. When we are parsing, we look for any numbers that are separated by any non-number character, not just a period. We chose to be liberal in what we accept since participants may forget the exact format of the answer. Although we have flexibility in the system, the possibility of the respondent making an error is always there. This may result in missing or corrupted data, and subsequent incomplete data sets.

This problem can easily be addressed when one uses apps as a response medium as each question is linked to a response, and there are measures one can make to ensure respondent answers are well formatted. One can even use text messages as the medium for sending well-formatted responses from an app and avoiding expensive data charges as well. Yet, this may add another level of complexity if there are problems with the text messages. It also does not give a great experience for informing the participants: first, they get a text message informing them they need to answer, and then they need to start up the app to respond.

Another issue with text messages is that there is no guarantee that they will be received and no indication for successful delivery. You can only know that a message was sent. Messages are also either sent with weak encryption or no encryption depending on the service provider that is sending the message. These issues need to be considered to determine the reliability, security, and privacy you wish to have. All of these issues can be addressed in an app.

It seems like text messages are useful when there are few and brief questions requiring short responses, whereas apps allow for many questions as well as opens up for open-ended questions and different types of responses such as multiple choice and Likert scales. We have summarized some of the pros and cons for text messages and apps in TABLE II.

In our project, we believe that the advantages with text messages outweigh their disadvantages. The use of an app would have excluded too many people from taking part. Alternatively, were we to have supplied smartphones to all participants, the added expense and resources for training, support, and follow-up would have been prohibitive.

In addition, an app requires the selection of an implementation platform. This would further have shut out potential participants. A possibility in the future when all phones are smartphones would be to use a web app that would run in a

TABLE II. PROS AND CONS FOR USING SMS OR APP ON SMARTPHONE.

SMS		App on smartphone	
Pros	Cons	Pros	Cons
<ul style="list-style-type: none"> • Universal technology. • Highly adopted in elderly age group. • Works on all phones. • Only requires mobile coverage. • Can use respondents own phone. 	<ul style="list-style-type: none"> • Maximum of 160 characters. • May have to receive/respond with several messages. • Need to interpret incoming message. • No guarantee of delivery. • No guarantee of privacy. 	<ul style="list-style-type: none"> • Very flexible in terms of design and user interface. • Can design layout of questions very similar to P&P originals. • Can control input through design. • Easier to automatically insert data into database. 	<ul style="list-style-type: none"> • Need expensive smartphone. • Many different platforms to design for. • Few elderly have smartphones. • High threshold for use. • Roaming data fees may incur. • May need training. • May have to provide phone for respondent.

web browser. This would also be able to run on PCs and tablets, providing a solution for the collection of PROMs on multiple platforms.

B. Implementation Issues

We saw two possible solutions for sending and receiving text messages. One solution was to use a commercial text messaging service. These are services that have infrastructure for sending and receiving many text messages and can be controlled through a web service. These are typically used for large surveys. The second solution was to create our own system by getting a subscription for only text messages and either controlling a mobile phone or installing a GSM modem. Regardless of which solution we would choose, we would have to write some custom software to send the text messages and store the responses. Ultimately, we decided to go with our own custom solution instead of using a text message service. The main reason being that adding a text message service meant adding another data processor into the mix; this meant extra cost and paperwork and eventually an extra contract that needed to be signed. Further, we were concerned about the implications of doing this in terms of security and privacy. We also felt that developing our own solution would be good experience in seeing how text message services worked.

We only allow encrypted access through HTTPS to the web application for the researchers and other admin personnel, and only authenticated users are allowed further access. This solution was chosen as it provides adequate safety, while at the same time allowing access in institutions such as hospitals and research facilities that may have strict security policies when it comes to Internet access that would prevent other types of communication.

An advantage to using a web app is that the website can be accessed by researchers and admin personnel from any location with Internet access instead of having to be on a certain network, e.g. a certain hospital or research institution.

V. CONCLUSION AND FUTURE WORK

In this paper we have detailed the development and implementation of a system that collects PROMs by way of text messages, as well as shared our deliberations in the development process. Further, we have detailed our findings and experiences from a pilot run of the system, which included a focus group and a questionnaire survey.

A major issue for us was the decision to use the more traditional medium of text messages for communication as opposed to an app installed on a smartphone. We feel that for our purpose and within the domain of rheumatology, text messages provide the best overall solution. We further expect that text messages will be suitable to use in the foreseeable future.

The context for use is within clinical research, but we also believe that text messages can be an appropriate medium also in clinical practice when PROMs are to be collected over time to be used in patient follow up and care. Its strengths lie in its simplicity, ubiquitousness in Norwegian society and the fact that no new hardware or software is required for the respondent. We are, however, convinced that

in future, we will all carry smartphones, and that an app or perhaps a web app will be the preferred medium for carrying out PROM collection. Meanwhile, as our experiences have showed - text messages are more than adequate.

The system is currently being used in the aforementioned heated pool clinical research project that will last for approximately one year. We have a number of concrete features and improvements we would like to include in future implementations of the system. A more flexible and individual text message schedule, and a smartphone version giving patients the option to choose response modes are among the possible improvements.

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