Craven, Michael P. and Selvarajah, Kirusnapillai and Miles, Robert and Schnädelbach, Holger and Massey, Adam and Vedhara, Kavita and Raine-Fenning, Nick and Crowe, John (2013) User requirements for the development of smartphone self-reporting applications in healthcare. In: HCI International 2013: 15th International Conference, 21-26 July 2015, Las Vegas, NV, USA.

User requirements for the development of Smartphone self-reporting applications in healthcare

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Abstract. Two case studies of the development of Smartphone self-reporting mHealth applications are described: a wellness diary for asthma management combined with Bluetooth pulse oximeter and manual peak flow measurements; and a questionnaire for ecological assessment of distress during fertility treatment. Results are presented of user experiences with the self-reporting application and the capture of physiological measurements in the case of the asthma diary project and the findings from a phone audit at an early stage of design in the case of the in vitro fertilisation (IVF) study. Issues raised by ethics committees are also discussed. It is concluded that the optimal adoption of Smartphone self-reporting applications will require a good appreciation of user and ethics panel requirements at an early stage in their development, so that the correct design choices can be made.

Keywords: mHealth, Self-monitoring, Adherence, User experience, Consumer and User, Ecological interfaces, Evaluation methods and techniques, Human Centered Design and User Centered Design, Human Factors Engineering Approach, Meaningfulness and Satisfaction, New Technology and its Usefulness

1 Background

Mobile health (mHealth) applications based on cellular phones, Smartphones and tablet computers are a rapidly growing trend in healthcare. The World Health Organization recently surveyed fourteen categories of mHealth services: health call

centres, emergency toll-free telephone services, managing emergencies and disasters, mobile telemedicine, appointment reminders, community mobilization and health promotion, treatment compliance, mobile patient records, information access, patient monitoring, health surveys and data collection, surveillance, health awareness raising, and decision support systems [1].

In the area of patient monitoring, the recording or self-reporting of patient health state or well-being has the potential to become ubiquitous through the use of Smartphone Apps. Furthermore, connection of Smartphones to sensors capable of physiological measurement (carried or wearable on/in the body or clothes, or present in the near environment) and storing or transmitting the data, promises to expand the established uses of medical 'remote' and 'ambulatory' monitoring based on conventional medical devices. These innovations should enable individuals to better monitor their own health, keep carers informed, or aid healthcare professionals in giving advice or informing treatments. Examples of applications in existence include self-reporting of physical health states or mood, behaviours (such as alcohol use) and those recording regular or continuous readings from devices (e.g. weight, level of exercise, blood glucose levels), entered either manually or through wireless connections. Another example of self-reporting that could transfer well to Smartphone technology is ecological momentary assessment, a methodology which highlights the benefits of repeated sampling in real time in subjects' natural environments [2].

With Smartphone technologies the distinction between health service remote monitoring and patient self-monitoring is becoming blurred. For instance the involvement of clinicians in presenting or interpreting results for the patient may be reduced with users either expected to, or wishing to, do more for themselves.

Whilst the usability of Apps and mobile devices is a natural area of study for HCI researchers [3] and context of use has been studied for medical devices from a human factors systems perspective, including adherence to self-monitoring [4], the contextual user requirements of mHealth have been little explored. McCurdie et al. have noted that mHealth interventions are often designed from the healthcare system perspective rather than with a user-centred approach [5]. Whilst Smartphones (and tablets) are becoming ubiquitous, potential users of mHealth applications will also have different existent practices for communication and receiving reminders, e.g. text messages on non-internet mobile phones, and different prior experiences in their use of the Internet, e.g. on a Desktop or Laptop PC, or none at all.

2 Case studies

2.1 First case study: Mild asthma self-reporting with and without physiological measurement

The first case study concerns persons with mild asthma. This condition presents a measurable lowering of blood oxygenation levels both leading into and during an exacerbation, such that sufferers are often given oxygen following an attack [6]. Furthermore asthma can be directly or indirectly related to psychological states such as

anxiety, panic or depression [7] which may be manifest in other physiological measurements, e.g. heart rate. Severity of asthma can also be measured by lung function, one measure of which is Peak Expiratory Flow (PEF). This project was a pilot study of self-reporting by means of a daily Smartphone questionnaire with or without regular additional physiological measurements, to study user requirements and interactions between self-reporting and measurement tasks. Eleven volunteers self-reported their wellness once a day for two weeks using a Smartphone web App, with physiological measurements taken in the second week only. Participants were males of age 18+ who reported having mild asthma, recruited by emails to university mailing lists and poster advertising. Ethical approval was obtained from the University of Nottingham Computer Science ethics committee and participants received a cash inconvenience allowance of £25 each week of the two week study. Volunteers were scheduled to visit the university to begin their participation, where they were provided with a Participant Information Sheet and given an opportunity to ask questions and ensure that they fully understood the information before signing a consent form.

The ethics committee initially expressed a concern for data security which was fulfilled by using an HTTPS connection with password protection. For analysis, the data was downloaded over a secure connection to university computers, with the usual safeguards restricting access to named personnel. Smartphones were lent to the users by the project researchers and no user identification was collected or stored on the phone. In addition, participants were able to set a passcode to lock the phone, preventing unauthorised access.

Each participant first completed a questionnaire devised by Juniper et al. [8] which involves choosing up to five activities in which the individual feels limited by their asthma and answering a series of questions about their health over the last two weeks. The questions included the extent to which the person was limited in their activities, the frequency of specific symptoms and emotions (e.g., breathlessness, interference with sleep, fear of not having medication available) and degree of discomfort or distress experienced (e.g., from coughing). The responses were then used to pre-populate an electronic version of the questionnaire (Fig. 1) that was closely based on Juniper et al. but modified in our study to ask only about the current day and prefaced with an additional yes/no question, 'Have you had a severe exacerbation of your asthma today?'. The daily questionnaire was hosted as an online form, to be accessed through the Smartphone web browser.

For the additional physiological measurements (collected in the second week only) the study used off-the-shelf technologies (Fig. 2): an Android phone running the SimpleEye Live Pulse Oximeter App [10] in association with a Nonin 9560 Onyx II Bluetooth-enabled fingertip pulse oximeter which is able to record heart rate and blood oxygen saturation (SpO_2) data with a one second sampling period. In addition, peak expiratory flow was measured using a Mini-Wright Standard Range peak flow meter, using the EU scale in accordance with ISO 23747.

The details of the self-monitoring task were as follows:

- **First week**
  - Each weekday evening
    - Complete the questionnaire on the Smartphone.

– **Second week**

- Each weekday morning
  - Take 3 peak expiratory flow measurements and enter on the Smartphone.
  - Record 5 minutes of pulse oximeter data using the App.
- Each weekday evening
  - Take 3 peak expiratory flow measurements and enter on the Smartphone.
  - Record 5 minutes of pulse oximeter data using the App.
  - Complete the questionnaire, as done in the first week.

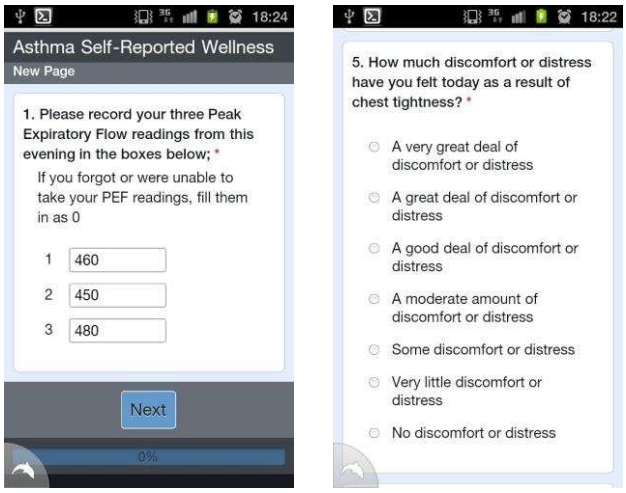

Fig. 1. Screenshots from the Asthma Self-Reporting Wellness mHealth web App

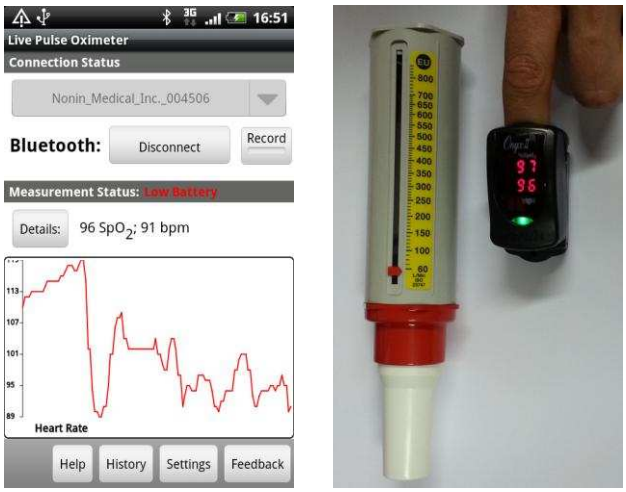

Fig. 2. SimpleEye Live Pulse Oximeter App, pulse oximeter and peak expiratory flow meter (screenshot and photograph by authors)

Table 1. Adherence in the asthma pilot study: Diary data

Participant	Days with diary entries, week 1 (of 5)	Days with diary entries, week 2 (of 5)	Days with diary entries, total (of 10)	Days with full diary data (of 10)
1	5	3	8	6
2	3	0	3	3
3	1	1	2	2
4	2	2	4	3
5	4	5	9	8
6	1	5	6	4
7	4	1	5	4
8	2	0	2	2
9	3	3	6	4
10	4	4	8	4
11	2	1	3	3
Average (%)	**56**	**45**	**51**	**39**

Table 2. Adherence in the asthma pilot study: Physiological data

Participant	Mornings with oximeter data (of 5)	Afternoons with oxi-meter data (of 5)	Mornings with peak flow data (of 5)	Afternoons with peak flow data (of 5)	Days with some phys. data (of 5)	Days with full phys. data (of 5)
1	4	4	3	3	5	1
2	0	0	0	0	0	0
3	2	2	5	5	5	2
4	3	4	1	2	4	1
5	4	5	4	5	5	4
6	3	4	4	5	5	3
7	4	3	2	2	5	0
8	2	2	1	0	2	0
9	3	3	3	3	4	1
10	1	1	4	4	5	0
11	3	3	3	1	4	1
Average (%)	**53**	**56**	**55**	**55**	**80**	**24**

The time of each data collection episode was recorded in order to analyse user adherence to the self-monitoring. A short semi-structured interview was conducted at the end of the two week session to ask participants questions about: ‘Using the technology’; ‘Effect on Lifestyle’; ‘Effect on Condition’; ‘Thinking about Condition’; ‘Difference between the two weeks’. Statistical analysis of the data in SPSS using the

Wilcoxon Signed Ranks Test was also performed to compare the questionnaire answers between the two weeks (although no significant correlations were subsequently found, which may be due there being no difference or because of the small sample size).

It can be seen from Table 1 that, on average, participants completed the diary on around half of the intended number of days, with a maximum of 5 days in both weeks and a minimum of 1 day in week one and 0 days in week two. On average, the second week with the additional physiological readings resulted in a smaller number of diary days being completed (although this difference was not statistically significant in a Wilcoxon Signed Ranks Test). No participant fully completed the diary every day for the full ten days. Users fully answered the questionnaire on an average of four out of the ten days (with at least one answer omitted on the other days). In the second week adherence to (or ability to perform) physiological data collection was a little over half of the maximum number of days with little difference between morning and afternoon, however the proportion of days with full physiological data was only one quarter overall (Table 2).

From summarising the post-study interview transcripts it was found that:

- 5/11 participants said they found the technology 'nice' or easy to use. Two found it 'interesting'. Six experienced some (mostly minor) technical problem either with internet/Wi-Fi, Bluetooth or battery. One was not confident about data upload having succeeded. One said it was 'sometimes a bit of a hassle … overkill for mild asthma'.
- 5/11 participants said that taking part had had little to no effect on their lifestyle or that they had 'got used to it'. One said he had been more cautious about remembering his inhaler. One reported the need to plan when going out. One reported interference with daily activities. Two reported difficulty or annoyance scheduling the recordings correctly. One mentioned the inconvenience of having to sit down to take measurements.
- 11/11 participants said that taking part in the study had no effect on their condition itself, although one had experienced a worsening during the study.
- 7/11 participants said that they were thinking more about, or were more aware of, their condition whilst taking part. Two qualified this by saying it was a 'good thing'. One expressed the opinion that 'thinking about a cough exacerbates it'.
- 8/11 commented on differences between the two weeks. Two commented on the quantitative nature of the recordings and its relation to how they were feeling. Three said the second week with the physiological recording was 'less convenient' or 'took a bit more time'. One said it was 'a lot more difficult'. One reported 'no inconvenience'.

2.2 Second case study: IVF treatment stress diary

The second project concerned women undergoing in-vitro fertilisation (IVF) treatment. It is known that IVF is a 'multidimensional stressor' and the treatment itself is most likely to evoke anxiety [10]. Ecological momentary assessment during IVF

treatment may shed light on the dynamics of distress, using a technique that is already considered to be highly promising for mood disorder research, see [11] for example. 76 women attending a fertility clinic completed a questionnaire about mobile phone usage in order to inform the App design in a forthcoming study to examine distress during IVF treatment. The new App would be run on patients' own phones, allowing them to complete entries in a stress diary in a secure manner [12]. First, information was obtained regarding phone usage and preferred modes of communication amongst the user group (since this was an audit it did not require ethical approval). Audit questions were posed as follows:

1. What type/model of mobile phone do you have?
2. Is your mobile phone a smart phone?
3. Which air time provider are you with?
4. Is the phone on pay as you go or on contract?
5. Do you use email or internet access on your phone?
6. Is internet coverage included in your contract?
7. Do you use an alarm clock function?
8. Are you familiar with the use of 'Apps' on your phone?
9. How regularly do you use an 'App' on your phone?
10. If you were to be asked to report your distress levels throughout your treatment which of the following methods would you prefer?

Table 3. Results of phone audit (a) Phones & functions (b) Frequency of App use (c) Communication preference

(a) Phones & functions	**Yes %**
Is your mobile phone a smart phone?	75
Do you use email or internet access on your phone?	80
Is internet coverage included in your contract?	82
Do you use an alarm clock function?	92
Are you familiar with the use of 'Apps' on your phone?	80

(b) Frequency of App use	**%**
Not at all	26
Everyday	53
Weekly	17
Monthly	4

(c) Communication preference	**%**
App	58
Text Message	30
Telephone conversation	8
Questionnaire	1
Other	3

From the survey, in which all participants had access to some kind of mobile device, it was found that 75% of users owned what they considered to be a Smartphone. The majority (74% of all phone users) had either Apple iPhones or ones that were Android based. Minority phones included Blackberry devices or Nokia handsets (mostly without internet access). App use was found to be prevalent amongst 74% of all phone users (and almost all Smartphone owners). In addition, 90% of all phone users were

on a contract with the rest on Pay-As-You-Go (across a wide variety of networks). Communication preferences are given in Table 3 that also contains details of responses to the other audit questions. These results show a majority preference for an App but also include preferences for other modes of communication (SMS text, voice, paper questionnaire). Email was mentioned in the 'Other' category. Furthermore, there was a high usage of an alarm clock function.

The subsequent ethics committee submission to an NHS panel raised some interesting points. In particular, the panel thought that text messaging could potentially compromise confidentiality and security of the data if the phone was lost. In contrast an advantage of using an App would be that data would be recorded on a secure server with password protection. Also for this particular project, the potential use of telephone conversations as a method of prompting/signalling users to carry out the ecological assessment was considered to be an unacceptable burden because this would entail ringing the patients every two days; it would also have been a burden to the researcher.

The panel did not specifically comment on the use of email as a means of communication, although there are similar issues to that of texting with respect to confidentiality. However, the main issue with email from a study point of view is that signalling the patient and their response by email would be subject to delays, dependent upon how their inbox is updated. A benefit of developing an App with immediate prompting is that the signal to the patient and their response are expected to be as close in time as possible, which is fundamental to the method of ecological momentary assessment.

3 Conclusions

The results of the two case studies highlight some important user considerations when using Smartphones for patient self-reporting of wellness. In a patient population, even one where all users have experience with some kind of mobile device, there will be a spectrum of phone capabilities and different existent preferences for modes of communication. This is a shifting landscape which will continue to change as newer mobile devices become more prevalent (e.g., iPads/tablets) and older ones become obsolete. Furthermore, some communication preferences will not be easily supported by a single stand-alone App, especially if the implementation is not a native App that is able to access all of the functions of the phone (e.g. the alarm clock).

If patients/users are using their own phones there are additional ethical concerns with respect to confidentiality compared with a study where phones are supplied by researchers. Modes of communication that are ethically acceptable are dependent on the security of the data handling and their burden on the user. Security concerns may limit the use of SMS texting or email as alternative modes of communication in contrast with more secure server-based methods that can be used via an App. Texting and voice calling to signal a patient may place an unacceptable burden on them if a high frequency of self-reporting is required. Ethics experts may therefore need to be included as stakeholders in the App development process before committing to particu-

lar aspects of technology or study design. Regulators are also clearly aware of the potential risks of Apps, especially those that are associated with medical devices.

A self-reporting task inevitably interacts with a user's lifestyle, which whilst it may not be a problem to some can cause difficulty, inconvenience or annoyance to others. Even if the self-monitoring task does not detrimentally affect their condition, as we found in our small asthma study, some users may become more aware of it and find this intrusive. However, this could be viewed as a positive effect that could result in better adherence to medication (as referred to by the user who was reminded to take his inhaler out more often during the study). Alternatively, users may believe that thinking about a symptom (e.g., a cough) can act to exacerbate it, although this effect was not reported.

Obtaining self-reported data on only half of all possible days in the asthma diary study was not entirely unexpected, since treatment adherence is known to be low for chronic conditions, but this clearly has implications for study designers who wish to ensure consistent data collection and achieve a statistically significant sample size. Adherence to self-reporting can also be affected by the intensity of the task. It is seen in the asthma diary case study that in the second week with more intensive testing (with the addition of physiological measurements), self-monitoring was found to be more inconvenient to some users and this is also possibly borne out by the smaller number of days of self-reporting, on average, compared to the first week (although this difference was not statistically significant). An intensity effect has also been noted in patient self-monitoring of blood glucose, where adherence was lower for more intensive self-monitoring during a research trial [13]. Such effects should be noted when introducing multiple measurements or more frequent sampling with a self-monitoring App, or if the App is used in parallel with other forms of data collection.

4 Acknowledgements

MC, KS and JC acknowledge support of this work through the MATCH Programme (EPSRC Grant EP/F063822/1) although the views expressed are entirely their own. MC was involved with both case studies, KS and JC with the IVF case study. HS and RM acknowledge support of a Xerox Research Centre Europe (Grenoble) donation for the support of studentships in Ubiquitous Computing within the Mixed Reality Laboratory at the University of Nottingham, for the asthma diary project. The IVF project and involvement of NRF, KV and AM was supported by Nurture Fertility.

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