

Original Article

Usability testing of a prototype Phone Oximeter with healthcare providers in high- and low-medical resource environments[✉]

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Summary

To increase the use of pulse oximetry by capitalise on the wide availability of mobile phones, we have designed, developed and evaluated a prototype pulse oximeter interfaced to a mobile phone. Usability of this Phone Oximeter was tested as part of a rapid prototyping process. Phase 1 of the study (20 subjects) was performed in Canada. Users performed 23 tasks, while thinking aloud. Time for completion of tasks and analysis of user response to a mobile phone usability questionnaire were used to evaluate usability. Five interface improvements were made to the prototype before evaluation in Phase 2 (15 subjects) in Uganda. The lack of previous pulse oximetry experience and mobile phone use increased median (IQR [range]) time taken to perform tasks from 219 (160–247 [118–274]) s in Phase 1 to 228 (151–501 [111–2661]) s in Phase 2. User feedback was positive and overall usability high (Phase 1 – 82%, Phase 2 – 78%).

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Pulse oximetry is an indispensable non-invasive monitor for anaesthetists who routinely use it to detect oxygen desaturation, allowing for early recognition and treatment of hypoxaemia. In high-income countries, pulse oximetry is used to screen patients presenting to an emergency department, is incorporated as intermittent routine monitoring of most patients admitted to hospital, is used continuously for patients in high care settings such as intensive care units (ICUs) and is considered a

minimum standard of monitoring during routine anaesthetic care [1]. In low- and middle-income countries, pulse oximetry is not routinely available. The World Health Organization has found that some 77 000 operating rooms around the world function without pulse oximetry [2]. It is noteworthy that anaesthesia-related death rates in these settings are 100–1000 times higher than in high-income countries [3–5]. Cost, user education, the need for routine maintenance and a

reliable mains power source are all barriers to wider adoption of pulse oximetry in low-income countries. The only indispensable monitor is the presence, at all times, of a person trained to provide safe anaesthetic care; however, the routine availability of pulse oximetry would undoubtedly be an asset. The availability of an inexpensive, portable and robust pulse oximetry device would be a significant incentive to wider adoption in low-income countries. Such technology could also be an asset outside of the operating theatre.

The advanced technological innovation and widespread global adoption of mobile phones can be harnessed to provide ubiquitously available pulse oximetry. Mobile phones are available to, and operated by, millions of people in low- and middle-income countries. Estimates from 2005 show that 1 in 11 Africans is a mobile phone subscriber, while more recent estimates put this figure even higher [6]. Mobile phones have high-density power storage, an integrated display and power-efficient processing capabilities suitable for the processing and analysis of oximetry signals [7]. Mobile phones are familiar, extremely portable and could be used both as an intermittent screening tool and as a continuous monitor of oxygen saturation.

Although pulse oximeters have been previously connected to mobile phones; they have not, to date, been designed for use in the operating theatre [8, 9]. They do not meet current pulse oximeter design standards, nor have they been developed using a goal-orientated interface design. The purpose of this study was to assess the usability of a prototype mobile phone interface, the 'Phone Oximeter', by evaluating the ease with which users with variable experience with pulse oximetry or mobile phone devices were able to perform a series of interactive tasks with the prototype device.

Method

The hardware used in this study was a 2nd generation iPod Touch® (Apple, Cupertino, CA, USA) hardwired via the serial port through the dock connector to a certified Xpod® OEM pulse oximeter module (Nonin, Plymouth, MN, USA) (Fig. 1). Assuming that touch-screen technology will soon dominate the global market, we chose a recent generation, but low-cost mobile device, the iPod Touch, for development of the early prototypes. The large and bright multi-touch LCD



Figure 1 The Phone Oximeter prototype consists of an Apple iPod Touch hardwired to a Nonin Xpod OEM pulse oximeter module. The *Home* tab displays PPG (photoplethysmograph) and S_pO_2 (oxygen saturation) (top), respiratory rate (bottom left) and heart rate (bottom right).

display (480×320 pixels) makes it ideal for application in the operating theatre. The Xpod module provides the raw photoplethysmograph waveform and processed trend values for oxygen saturation and heart rate in a serial data format.

The software implementation is designed to allow the majority of development to be performed outside the proprietary software development kit framework of typical mobile phone operating systems. This approach maximises the portability across the most common mobile phone platforms currently available. The backend was implemented in C and Scheme code and the graphics rendering in OpenGL, using only thin platform-specific wrappers to integrate with the underlying operating system. This minimised the power consumption of the device and made the prototype system easily portable to many other current and future platforms.

The Phone Oximeter software automatically detects the correct communication protocol upon connection of the pulse oximeter module. It uses custom algorithms to compute respiratory rate from the photoplethysmograph. It also collects the photoplethysmograph waveform, trend values, and sensor alarms and stores them in

a file on the device. This can be easily transferred from the phone to a computer for subsequent processing. The software is fault-tolerant, and allows the pulse oximeter module to be inserted and removed in ‘plug and play’ format.

The user interface design process was initiated by assembling 20 cardboard prototypes with physical dimensions identical to the iPod Touch device upon which images of different potential designs were printed. The layout of the first interface for the Phone Oximeter was created through a participatory design process that included discussions with the engineering team, usability experts and anaesthetists [10].

The design team then created the primary functional digital prototype that was to be used in the initial phase of the usability study (Fig. 2). Standard clinical auditory functions such as frequency modulating heart beats with oxygen saturation values were implemented. The parameters of heart rate, oxygen saturation and respiratory rate in the corresponding standard clinical colours were arranged on a *Home* tab of the display. The raw photoplethysmograph waveform was displayed with a digital display of oxygen saturation. A signal quality index, represented by coloured bullets, and a trend graph were incorporated for each parameter. Alarm threshold settings were incorporated as horizontal lines on the trend graphs. The patient’s characteristics (age, group and weight) and battery capacity were displayed on the *Top Bar* of the *Home* tab. The *Bottom Bar* was designed with touch icons to navigate between four tabs (*Home* tab, *Settings* tab, *Messages* tab, and *Powersaver* tab) (Fig. 3). The *Settings* tab allows for the adjustment

of characteristics and alarm thresholds. The *Messages* tab displays messages from the decision support engine, such as alarms and warnings. The *Power saver* tab would force the Phone Oximeter to enter a power-save mode, which turns off the screen. When this power-save mode is used, the auditory functions remain enabled so that users could continue to hear the heart rate and pitch of the oxygen saturation.

We hypothesised that the prototype would be usable if the device could be successfully operated by people familiar with pulse oximetry monitors, but not necessarily familiar with mobile phones or smartphones with multi-touch capability. Following institutional ethics approval in both Canada and Uganda, participants working in a hospital environment in Canada (Phase 1) were recruited. Subsequently, the research team took the updated prototype Phone Oximeter to Uganda, where the study protocol was repeated with Ugandan medical personnel recruited by word of mouth. Sample size was based on recommendations for usability studies [11].

All participants provided written informed consent and demographic information including age, sex, occupation, level of education, professional experience, previous use of the Apple iOS® operating system and pulse oximetry experience in days, months, or years. User familiarity with mobile phones was evaluated by asking participants to choose a label from the International Data Corporation (IDC) mobile phone user label system [12]. Users could select all, none, or any number of the descriptions they felt described their use of a mobile phone (Appendix 1).



Figure 2 The graphical user interface of the first prototype of the Phone Oximeter is composed of four tabs, which can be selected from the bottom bar (left to right): *Home*, *Settings*, *Messages* and *Power-saver* (not shown).



Figure 3 The second Phone Oximeter graphical user interface prototype as used in Phase II of the study. Visual changes made to the interface are highlighted in blue: (1) new signal quality indicator; (2) improved visual alert for alarms; and (3) improved icon for the trend line indicator.

A tutorial on the functioning of the Phone Oximeter was not given beforehand. Before interaction with the Phone Oximeter, users were provided with instructions on the use of a ‘Think Aloud’ method that encourages the verbalisation of mental processes [13]. A list of 23 tasks to perform with the Phone Oximeter prototype was then sequentially read to the users (Appendix 2). The tasks from the task list were typical of tasks performed with a pulse oximeter in clinical practice. There were also a number of perceptual tasks that required users to identify values or items displayed on the screen. The experiment was conducted in a quiet room with a moderator and observer present. The ability of the user to complete a task, any requirement for assistance, the types of errors made, the time taken to complete each task and the number of attempts to complete each task were recorded. Comments from users and observers were also recorded. During Phase 1, an audio recording was performed to facilitate time keeping and to aid in documentation of participant/observer/moderator comments (this was not universally available for Phase 2 in Uganda due to equipment failures).

Four written debriefing questions (Appendix 3) and a 55-question modified Mobile Phone Usability Questionnaire (hereafter referred to as the questionnaire) [14] were administered following the completion of the task list. The modified Questionnaire consisted of questions requiring categorical responses between 1 = strongly disagree, and 5 = strongly agree. A total of 22 questions were removed from the original

72-question Questionnaire, as they had limited relevance to the function and capacity of the Phone Oximeter prototype (example of question removed from the original Questionnaire: ‘It is it easy to use the phone book feature of this product’). Five questions were added to the Questionnaire to assess a number of functions specific to the Phone Oximeter (example of added question: ‘It is easy to change limits and alarm settings’).

Based on the results of Phase 1, the design team made modest enhancements to the Phone Oximeter prototype interface to be used in Phase 2 of the study. The most frequent user errors and Questionnaire responses guided the modifications to the prototype prior to undertaking Phase 2 of the study, with the same protocol, in Uganda.

Results

There were 20 participants in Phase 1 of the study, of whom nine (43%) had never used smartphones with multi-touch capability (Table 1). The remainder of participants had either exposure to or had regularly

Table 1 Characteristics of participants from Phase I and II. Values are number, mean (SD) or number (proportion).

| | Phase 1 (Canada) (n = 20) | Phase 2 (Uganda) (n = 15) |
|----------------------------------|---------------------------|---------------------------|
| Male:female | 13:7 | 11:4 |
| Age; years | 42.6 (10.2) | 32 (5.9) |
| Previous experience in using iOS | 11 (57%) | 4 (27%) |

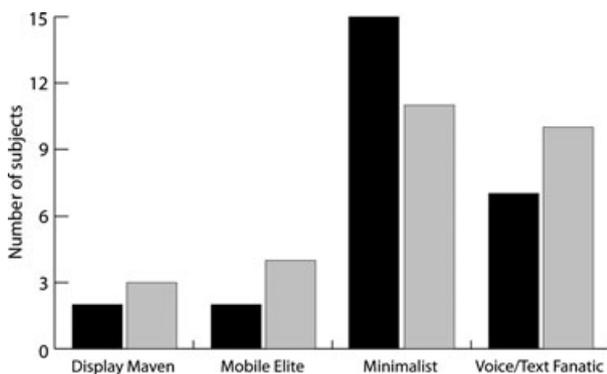


Figure 4 International Data Corporation (IDC) mobile phone user labels (Appendix 1) assigned to subjects from Phase I (black) and II (grey). Participants could choose any descriptor that they felt applied to their type of mobile phone use. Thus, more descriptors were ticked than there were participants.

used a smart phone with multi-touch capability. All participants had extensive prior experience with pulse oximetry. Ten anaesthetists, five postoperative care nurses, two anaesthesia technicians, one anaesthesia resident, one medical student and one cardiac surgeon participated. When choosing a label from the IDC mobile phone user label, 15 of the 20 participants (75%) described themselves as either entirely 'minimalists' or 'minimalists' plus one other parameter (Fig. 4).

Questionnaire analysis showed a high degree of overall satisfaction (82%) with the use of the Phone Oximeter. This percentage was calculated by pooling the individual score ranging from 1 to 5 (5 = strongly agree), assigned by each of the 20 participants in response to a total of 55 questions. This resulted in a maximum possible score of 5500 (5 possible points \times 55 total questions \times 20 participants). The total satisfaction

score in this phase was 4506 out of the possible 5500 resulting in 82% satisfaction (Table 2).

Areas of the interface that caused difficulty included the icon bar at the top of the *Home* tab that displayed the current patient setting as an image (neonate, child, or adult), patient weight and battery life. When users were asked in task number 10 to change the patient's weight from 70 kg to 111 kg, a majority of users (as noted from observer comments) initially attempted to touch the 70 kg icon located on the *Top Bar* of the screen, which in the first prototype had no touch function. Eventually, all users realised that the *torso* icon on the *Bottom Bar* would take them to a new tab, entitled *Settings* where it was then possible to adjust the patient weight parameter (Fig. 2).

A second area of difficulty for those unfamiliar was the spinning wheel feature common to touch screens. Task 10 required the user to spin a digital wheel selector with sequential numbers to adjust the weight in kilograms on the *Settings* tab. From observer comments (Table 3), it was evident that a number of users had difficulty initiating the spinning wheel until it was either discovered incidentally, or after coaching from the moderator. Coaching was required by two of the nine (22%) of the non-smart phone users to initiate the spinning, versus one of 11 (9%) of participants who already had a degree of familiarity with smartphones with multi-touch capability.

When comparing consecutive tasks that required participants to undertake a very similar sequence of steps the median time taken decreased for subsequent tasks. For example, participants took a median (IQR [range]) time of 33 (26-53 [8-114]) s to complete task 10, which asked the participant to 'Change patient

Table 2 Mobile phone usability questionnaire analysis broken into question types [14]. Values are number/total possible (proportion).

| | No. of questions | Total score Phase 1 | Total score Phase 2 |
|--|------------------|------------------------|------------------------|
| Ease of learning and use | 21 | 1747/2100 (83%) | 1223/1575 (78%) |
| Helpfulness and problem-solving capabilities | 3 | 243/300 (81%) | 169/225 (75%) |
| Affective and aspect | 2 | 185/200 (93%) | 133/150 (89%) |
| Multimedia properties | 9 | 712/900 (79%) | 541/675 (80%) |
| Commands and minimal memory load | 6 | 480/600 (80%) | 351/450 (78%) |
| Control and efficiency | 8 | 668/800 (84%) | 466/600 (78%) |
| Typical task for mobile phone | 1 | 85/100 (85%) | 60/75 (80%) |
| Typical task for phone oximeter | 5 | 386/500 (77%) | 278/375 (74%) |
| Total | 55 | 4506/5500 (82%) | 3221/4125 (78%) |

Table 3 A selection of comments made by participants during Phase II.

1. Have other parameters in the settings page dim when you press on heart rate, weight, respiratory rate. This would then make it easier to identify the variable you are trying to adjust.
2. Fantastic concept; when non-invasive haemoglobin monitoring becomes available, incorporate this too.
3. The device does seem fragile, could you reinforce the connections?
4. The concept is great, I think because it is on a mobile phone platform it will be easily accepted.
5. Incorporate a numerical read-out, on a new tab, of 5-min variable values going back in time, such as is available on anaesthesia monitors for blood pressure, CO₂, heart rate, O₂ saturation.
6. Possibly remove the trend lines over time from the Home tab, and incorporate into a new tab (as above) that shows variable trends over time.
7. Attempt to make the spinning wheel function less sensitive; as it is too easy to over shoot the number you are trying to adjust to.
8. Incorporate a clock into the top bar of the Home tab.
9. Increase the thickness of the plethysmogram and trend lines; at this time it is too hard to see.

weight from 70 kg to 111 kg'. Subsequently participants took a median (IQR [range]) time of only 16 (12-22 [5-59]) s to complete task 13, which asks the user to

'Change Heart Rate UPPER limit to 128 beats/min', and which required a very similar set of steps as task 10 (Table 4). Both these tasks required a complex sequence of actions, including, but not limited to, switching between different tabs on the interface, and scrolling the spinning wheel control.

Based on participant comments during the Think Aloud process, errors made by participants, and notes made by the study observers, areas of the first Phone Oximeter interface that consistently caused users difficulty or delay were identified (Table 3). The Phone Oximeter interface was modified to overcome these limitations and render the system more intuitive to use before repeat usability testing of the modified prototype in Uganda – Phase 2 of the study.

Modifications to the prototype included a brighter red flashing colour for a visual alert when an alarm condition was present. Touch functionality was added to the icons on the top bar of the *Home* tab (touching the patient's weight or the neonate/paediatric/adult icon would now take the user to the *Settings* tab). An improved icon was added on the *Settings* tab for the trend line indicator. A redesigned signal quality indicator bar, that more closely resembled existing industry

Table 4 Time to completion of each task. Values are median (IQR [range]) in seconds.

| Task | Description of task | Phase 1: Canada | Phase 2: Uganda |
|------|--|--------------------|--------------------|
| 1 | Place sensor on finger | 1 (1-1 [1-1]) | 1 (1-1 [1-1]) |
| 2 | Start Phone Oximeter from iPod menu screen | 13 (10-18 [2-33]) | 1 (1-10 [1-10]) |
| 3 | Identify what value is alarming | 5 (4-8 [1-34]) | 5 (2-10 [1-120]) |
| 4 | Silence alarm generated | 2 (1-5 [1-20]) | 6 (5-13 [1-180]) |
| 5 | View alarm details | 2 (1-6 [1-21]) | 5 (1-5 [1-300]) |
| 6 | Identify the cause of the alarm – i.e. wrong patient mode, wrong limit values, etc | 3 (2-15 [1-38]) | 10 (5-25 [1-300]) |
| 7 | Change patient mode from neonate to adult | 12 (8-25 [1-42]) | 10 (8-20 [3-600]) |
| 8 | Back to Home screen | 1 (1-1 [1-1]) | 1 (1-5 [1-15]) |
| 9 | Identify the weight of the patient from the Home screen | 2 (1-2 [1-3]) | 4 (1-5 [1-30]) |
| 10 | Change weight from 70 kg to 111 kg | 33 (26-53 [8-114]) | 25 (15-55 [6-75]) |
| 11 | Back to Home screen | 1 (1-10 [1-1]) | 1 (1-1 [1-1]) |
| 12 | Identify the heart rate upper limit from the Home screen | 3 (2-5 [1-34]) | 12 (5-28 [1-120]) |
| 13 | Change heart rate upper limit to 128 beats/min | 16 (12-22 [5-59]) | 19 (14-35 [5-240]) |
| 14 | Back to Home screen | 1 (1-1 [1-1]) | 1 (1-1 [1-5]) |
| 15 | Identify the relative signal quality for the heart rate | 13 (5-28 [1-42]) | 15 (7-38 [1-300]) |
| 16 | Change trend line length to 3 min | 21 (12-37 [4-85]) | 20 (14-50 [5-400]) |
| 17 | Back to Home screen | 1 (1-1 [1-1]) | 1 (1-3 [1-12]) |
| 18 | Identify O ₂ saturation lower limit from Home screen | 2 (1-3 [1-33]) | 5 (1-16 [1-60]) |
| 19 | Change O ₂ saturation lower limit to 85% | 9 (6-12 [2-20]) | 10 (8-18 [5-160]) |
| 20 | Restore the default values for adult | 14 (8-19 [2-56]) | 17 (10-35 [2-240]) |
| 21 | Change patient mode to child | 3 (2-5 [1-15]) | 5 (4-6 [1-10]) |
| 22 | Back to Home screen | 1 (1-1 [1-1]) | 1 (1-1 [1-5]) |
| 23 | Shut down the Phone Oximeter | 1 (1-1 [1-1]) | 1 (1-5 [1-10]) |

Table 5 Design improvements made to the first Phone Oximeter prototype.

| Phase 1 error/complaint | Number with errors/complaints | Improvement made by design team |
|--|-------------------------------|--|
| While on the Home tab users were unclear which parameter was alarming. | 10 | Brighter colour red introduced, flashing alarm state introduced |
| Users tried to press the top bar to access Settings tab. | 19 | Touch functionality added to top bar of the Home tab |
| Users were unclear which icon represented the trend line. | 14 | New icon for trend line in Settings tab introduced |
| Users were unclear about the meaning of the original SQI* symbols. | 11 | Redesign of SQI to resemble existing industry standards more closely |
| Users felt that the alarm limits were too faint and unclear. | 7 | Colour-coded alarm limits added on Home tab |

*SQI – signal quality Indicator.

standards, and colour-coded alarm limits were added to the *Home* tab (Table 5) (Fig. 3).

For Phase 2 of the study, the Ugandan phase, there were a total of 15 participants, 4 women, 11 men, and mean (SD) age of 32 (5.9) years, in this phase of the study (Table 1). Multi-touch smartphones had never been used by 11 of the 15 (73%) of participants before enrolment in the study. Of the four participants who had used smartphones with multi-touch capability before participation in the study, only one owned an iOS device, the other three had exposure limited to a few days or hours. All participants had prior experience with pulse oximetry, although for some participants (first-year anaesthesia residents and anaesthetic officers in training), the experience had been mostly theoretical, and their hands-on experience in intra-operative monitoring, silencing alarms and adjusting limits was limited to less than two months. The 15 participants consisted of eight anaesthesia residents (five in their second month of anaesthesia training), three anaesthesia consultants, two anaesthetic officer students who were in the second month of their clinical year (the second year of their two-year programme), one ICU consultant and one ICU nurse.

Eleven of the 15 users (73%) chose more than one descriptor from the IDC mobile phone metric. However, 10 out of the 15 of participants (67%) included the descriptor ‘Minimalist’ in defining their typical mobile phone use. The Questionnaire analysis showed a high degree (78%) of overall satisfaction: 3221 out of a possible 4125 (5 possible points \times 55 total questions \times 15 participants) with the use of the Phone

Oximeter across the 55 questions in the Questionnaire (Table 2).

Participants took less time and had less reported difficulty with the first part of Task 10 (‘Change weight from 70 kg to 111 kg’) in the improved prototype. The *displayed weight of the patient* icon at the top of the *Home* tab was initially touched by 12 out of the 15 participants (80%), which had now been touch-enabled and initiated a switch to the *Settings* tab. Median (IQR [range]) time to complete task 10 in Phase 2 was 25 (15–55 [6–75]) s, compared to a median time of 33 (26–53 [8–114]) s taken to complete task 10 in Phase 1. However, completion of Task 10 still required users to change the patient’s weight setting from 70 kg to 111 kg using a spinning wheel selector. It is noteworthy that times were recorded from a wristwatch by the observer in Phase 2 study because of failure of the audio recording device, which may have resulted in less accurate time keeping.

According to observer comments, 10 out of the 15 participants (67%), and 11 out of the 11 participants (100%) unfamiliar with smartphones with multi-touch capability had difficulty with initiating the scroll function to change the patient’s weight from 70 kg to 111 kg. However, only four out of the 15 (27%) participants required help or hints to initiate the scroll, thus 11 out of the 15 (73%) discovered the scroll function rapidly enough that they did not feel that they needed to ask for assistance. Despite the novice users’ apparent difficulties with concepts such as alarm limits, and changing alarm limits to suit a particular clinical situation (e.g. neonate vs adult patient), feedback from these participants was still positive. Even those who struggled with some aspects of

the prototype embraced its concept, as reported in their answers to the debriefing questions (Appendix 3).

Discussion

The prototype Phone Oximeter was found to be very usable both by medical staff in a developed world setting and by a range of anaesthesia and medical care providers in the developing world. Testing of the first prototype Phone Oximeter in Canada identified specific failings in the interface design. The improvements in design reduced the number of errors in the tasks, even though the users in Uganda were generally less experienced medical personnel. Despite the identification of specific improvements needed, the overall usability in Phase I and II was still high. The feedback from participants in the study was very encouraging and participants, despite encountering some areas of difficulty, embraced the concept unanimously.

The goal of the design process was to develop an interface that could be used universally by both expert and less experienced users, as well as making it language-independent. The performance, in testing, was not significantly influenced by familiarity with the use of mobile phones or pulse oximeters. The level of training required to use the interface was minimal. However, the expertise to interpret the results and make specific clinical decisions is likely to take much longer to develop. We plan to integrate expert knowledge and clinical guidelines into future versions of the device.

Overall, this usability study was able to demonstrate that a fully functional interface can be implemented on a mobile phone-sized screen without losing the practical usefulness of standard pulse oximetry. The ease of navigation and parameter manipulation could also be maintained. This early exploration of the usability of a phone based pulse oximeter has allowed us to investigate the potential use for oxygen saturation monitoring in many other healthcare settings. In a world where mobile phones are rapidly being adapted to uses previously not thought possible, i.e. mobile phone banking in Africa, the mobile phone with its already highly usable and familiar user-interface, long battery life, affordability and ubiquitous availability has potential for application in healthcare [15].

The ultimate goal of this project is to make the Phone Oximeter compatible with a variety of mobile

phone platforms, which would reflect the actual market availability and variability of mobile phones and their use in different regions of the world. This conceptual adaptation will enable this technology to be inexpensive, personalised and a readily available adjunct to medical device users around the world. When the mobile phone-compatible pulse oximeter unit (probe and adapter cable) can be produced and sold for an affordable fee, wider adoption is possible. We anticipate the consumer cost to be less than £13 (€15; or \$20). The user, who already is an owner of a mobile phone device, can simply have his or her own personal Phone Oximeter immediately available for use. Volunteer community health-care workers, anaesthetic officers, nurses, physicians or even the patients themselves could use Phone Oximeters in varying clinical roles. Less expensive and with a very different and complementary scope for patient assessment than a stethoscope, the concept has far-reaching potential. The goal is also eventually to have software updates available for downloading. If broad adoption can occur, it will in turn have a trickle-down effect on those less familiar with the triage, diagnostic and monitoring potential of pulse oximetry, aiding in making pulse oximetry globally more ubiquitous and understood.

This is one of the first applications of pulse oximetry on a mobile phone. In this study, we have developed a new user interface based on tested hardware (the XPod pulse oximeter module and the iPod Touch mobile device). The application of the device may eventually be significantly different from current applications of pulse oximetry in the operating theatre. The battery life may limit the duration of monitoring to select periods of anaesthesia (such as induction and recovery) or to intermittent measurements. The other uses of the phone (such as phone calls) may also limit the capability for continuous monitoring. The rapid check of oxygen saturation outside the operating theatre, such as for monitoring of oxygen therapy or screening for congenital heart disease or respiratory illness, would be easily achieved with a mobile phone-based device, as continuous monitoring is not a requirement for these applications.

The global improvement in the safety and quality of anaesthesia has been supported by recent efforts to produce international standards of anaesthesia practice

[16]. The introduction of minimum standards of monitoring, including the routine use of pulse oximetry, has been included in the Surgical Safety Checklist [17]. While universal availability of pulse oximetry alone may not make anaesthesia safer [18], accompanied by education and a systematic change in culture and practices this intervention is much more likely to prove successful. The use of a mobile device will offer additional flexibility in providing information on standards and guidelines and delivering educational content.

There were a number of limitations of this study, including the potential for observer bias. Most of the data were collected in the presence of researchers, and participants may have forwarded inappropriately positive feedback, in order not to offend (observer-expectancy effect). In addition, using the prototype in a research setting where the concept of the prototype was explained before its use could have biased the participants to have found the device more usable. However, the research team endeavoured to keep instruction about its capacities to a minimum before testing.

The aggregate intervals of time may not have reflected the complexity of the times taken by participants to complete various tasks in the task list. Many of the tasks included multiple steps and were scored in a single unit of time. The observer and moderator subjectively identified the specific difficulties. This limited the degree to which time taken to complete various tasks could be used to compare groups or study phases; specifically, task 10 in the protocol asked users to 'Change weight from 70 kg to 111 kg'.

The study was also limited in its capacity to compare participants in Phase 1 and Phase 2. Essentially different prototypes were used for the two Phases, as improvements were made to the prototype after Phase 1. In addition, the participants for Phase 2 of the study were medical personnel with, on average, significantly less clinical experience, whereas the majority of participants in Phase 1 were seasoned clinicians or nurses with years of experience in patient monitoring. This aspect of the study did, however, highlight the importance of prior experience with similar monitors and the familiarity of concepts introduced by industry for medical monitoring. It is essential that medical devices are designed with due consideration for the specific uses and user expertise. The use of a simple interface may reduce

the need for extensive expertise or training. The interpretation of the monitoring information, within the specific clinical context, can be supported by the design of the interface. In future versions of the software, we plan to incorporate 'just in time' [19] teaching as an integral feature of the Phone Oximeter. The Phone Oximeter could also utilise educational materials made available by the World Health Organization and World Federation of Societies of Anaesthesiologists' Lifebox programme [20]. The Lifebox initiative, which is making thousands of pulse oximeters available to low- and middle-income countries, has a series of multimedia pulse oximeter support modules in multiple languages on its website (see <http://www.lifebox.org/>).

It is not difficult to envision the usefulness of this device; it will enable clinical data gathering and then transmission of the data to a higher referral centre. The Phone Oximeter could complement strategies already underway around the world using mobile phones to aid healthcare workers, such as the Mobile Medic Program in Malawi [21]. Mobile phone-compatible decision support built into the Phone Oximeter application will help community workers with decisions around treatment options or possible need for further referral, thus enabling an even greater degree of independence for healthcare workers when centralised support is not available. The anaesthetic officer or anaesthetist, in a developing world healthcare setting, who now owns his or her own pulse oximeter, would bypass an inefficient and resource-scarce medical system where new equipment does not get purchased, and old equipment is either left unmaintained or simply disappears. Personnel working in the 77 000 operating theatres worldwide that do not have pulse oximetry would undoubtedly do more for the health and safety of their patients if there were an easily available, inexpensive and user-friendly way to measure oxygen saturation. The Phone Oximeter could be a link in bridging this gap.

The development of low-cost medical devices, previously confined to the hospital setting due to their high cost before, is a dynamic and rapidly advancing field of research. The quality and safety of the engineering solution are important to ensure widespread adoption of these potentially valuable devices. Poor quality will not only introduce risk to patients but also reduce reliance and adoption when the healthcare

providers do not observe any clinical advantage. The interface of the device remains an essential component when quality, safety and adoption are considered.

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Competing interests

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Appendix 1: International Data Corporation Mobile Phone Use Metric [12].

Instruction: This metric is designed to quantify your use of mobile phones and similar devices. Check all the Labels that you feel apply to your personal use of mobile phones.

| Label of user | Description | Check all that apply |
|---------------------|---|----------------------|
| Display Maven | Users who primarily use their devices to deliver presentations and fill downtime with entertainment applications to a moderate degree | |
| Mobile Elites | Users who adopt the latest devices, applications and solutions, and also use the broadest number of them | |
| Minimalists | Users who employ just the basics for their mobility needs; the opposite of the Mobile Elites | |
| Voice/Text Fanatics | Users who tend to be focused on text-based data and messaging; a more communications-centric group | |

Appendix 2: Task List

- 1 Place sensor on finger
- 2 Start Phone Oximeter from iPod menu screen; wait a moment for programme to load and values to appear
- 3 Identify what value is alarming
- 4 Silence alarm generated
- 5 View alarm details
- 6 Identify the cause of the alarm – i.e. wrong patient mode, wrong limit values, etc
- 7 Change patient mode from Neonate to Adult
- 8 Back to Home Screen
- 9 Identify the weight of the patient from the Home Screen
- 10 Change weight from 70 kg to 111 kg
- 11 Back to Home Screen
- 12 Identify the Heart Rate UPPER Limit from the Home Screen
- 13 Change Heart Rate UPPER limit to 128 beats/min
- 14 Back to Home Screen
- 15 Identify the relative signal quality for the Heart Rate
- 16 Change Trend Line Length to 3 min
- 17 Back to Home Screen
- 18 Identify O₂ Saturation LOWER limit from Home Screen
- 19 Change O₂ Saturation LOWER limit to 85%
- 20 Restore the default values for Adult
- 21 Change patient mode to Child
- 22 Back to Home Screen
- 23 Shut Down The Phone Oximeter

Appendix 3: Debriefing Questions

- 1 What did you think of the overall design?
- 2 What would like to see added or removed?
- 3 What did you like the most about this product?
- 4 What did you like the least?