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Mobile Direct Observation Treatment (MDOT) of Tuberculosis Patients Pilot Feasibility Study in Nairobi, Kenya

Final Evaluation Report

March 2, 2009

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Executive Summary

World Health Organization guidelines for treatment of tuberculosis (TB) call for directly observed treatment (DOT) to monitor patient medication adherence (WHO, 2008; Frieden & Sbarbaro, 2007). DOT poses numerous structural barriers for both healthcare workers and patients. The purpose of this pilot study was to assess feasibility and acceptability among healthcare workers and patients in using video-enabled mobile telephones to monitor patient adherence to TB medication, as well as to assess patient response to having both text and video health messages sent to them via the mobile phone.

Mobile telephones capable of sending and receiving video and text messages were provided to 13 patients diagnosed with TB. Patients and their assistants (relatives or friends in the home) were asked to video-capture the patient taking his or her dose of TB medications with the mobile phone. The video was then immediately transmitted to a central database where healthcare workers viewed the video of patients taking their medications as prescribed by DOT protocol. Patients also received health messages including video and text on their mobile phones. These messages included vignettes portraying recovered patients, testimonials from physicians, and TB prevention messages.

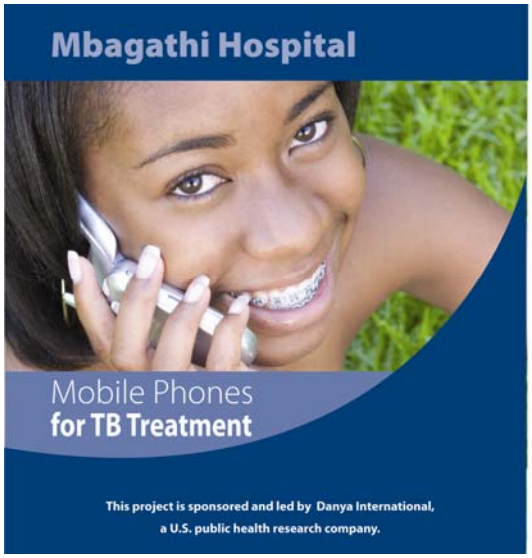

Figure 1. Patient Recruitment Brochure

Patients, patient assistants, and healthcare workers completed a brief questionnaire regarding their experiences at intake, 15 days, and 1 month post-intake. Participants rated their experiences in topic areas such as comfort levels with being videotaped, acceptability of receiving messages, types of messages most helpful, and technical issues with sending or receiving messages. Results showed that overwhelmingly, all participants were extremely satisfied with the study procedures and technology with a mean overall rating of 4.6 on a 5-point Likert scale, with 1 being “Awful” and 5 being “Great.”

This pilot study demonstrated technical feasibility of mobile technology as a viable means of remotely monitoring medication adherence for patients with TB. In addition, the study indicated positive acceptance by both patients and healthcare workers of using this technology for remote medication monitoring, health education, and communication. Further research is needed to assess the impact of this technology on medication adherence rates, as well as cost-effectiveness of implementing this technology on a wider scale to more patients as well as for other types of diseases.

Background and Introduction

Tuberculosis (TB), a highly contagious disease, currently infects about one-third of the world's population according to the World Health Organization (WHO). Left untreated, TB can lead to death. In 2005, TB resulted in 1.6 million deaths worldwide (WHO, 2007). Africa experiences both the highest number of deaths and the highest mortality per capita. People co-infected with HIV and TB are at an especially high risk of death, as each disease "speeds the other's progress."

Despite how grim the statistics sound, TB infection can be treated. Strict adherence to a prescribed medication regimen for a period of six months can lead to curing the disease. However, if medication adherence is not practiced—that is, if the patient misses doses of the medication—serious complications can occur in the form of drug-resistant organisms. When this happens, multidrug resistant TB requires a longer course of treatment with drugs that are more expensive and have more negative side effects.

Current WHO guidelines for the treatment of TB call for directly observed treatment (DOT) in certain instances to monitor patient medication adherence practices (WHO, 2008; Frieden & Sbarbaro, 2007). DOT consists of an observer watching the patient swallow his or her tablets in a way that is sensitive and responsive to the patient's needs and to ensure that the patient takes the right drugs, in the right doses, and at the right intervals.

Yet, the implementation of DOT can pose significant structural barriers for both healthcare workers and patients. DOT can put an additional burden on an already overburdened healthcare system. Requiring patients to go to a clinic or hospital to be observed taking their medication or healthcare workers to make home visits to patients may not be the most efficient use of a healthcare worker's time. For patients, especially those living in developing countries, going to a hospital or clinic even three times a week, much less on a daily basis, can put a significant strain on an individual's working ability and lifestyle. For those patients who are poor or living in poverty, the cost of transportation to and from the clinic can be prohibitive or just plain impossible. Furthermore, in many rural areas with poor to non-existent roads, the time to travel long distances may take the better portion of a day.

Telemedicine, in particular wireless mobile telephone technology, may provide an innovative and effective means of controlling some of the costs associated with DOT and at the same time address some of the structural barriers that health professionals as well as patients face. Recent advances in hardware and network capacity provide a mobile infrastructure capable of capturing and transmitting video clips with resolution as high as 176 x 144 pixels and transmission as fast as 30 frames per second. If patients equipped with mobile phones enabled with video capabilities were to video-capture themselves while taking their TB medication and then send those video clips to a corresponding healthcare facility, time and cost could be drastically reduced for both the healthcare industry as well as the patients themselves.

Study Goals and Objectives

The goal of this pilot study was to test the feasibility of implementing mobile direct observation treatment (MDOT) via mobile telephones for patients with TB and to assess the acceptability of this type of technology from both the healthcare worker and patient perspective. Because of the lack of published

literature in this area, technological issues, video-capture of ingesting medication, acceptability of text and video health education messages, and the image quality of the videos for healthcare workers to adequately assess medication compliance as prescribed by DOT protocol were all topic areas for which there is little guidance on whether this type of telemedicine practice might be feasible. To achieve the study goal, the following objectives were identified:

1. To test the quality of video capture (resolution, etc.) with mobile phones
2. To test the reliability of the transmission of video and text messaging
3. To assess the receptiveness of patients to the use of video capture techniques
4. To assess the receptiveness of patients' assistants to the use of video capture techniques
5. To assess the receptiveness of patients to receiving health messages on their mobile phones
6. To assess patient preference of the modality of the messages, video versus text messages
7. To assess patient preference as to the content of the messages

Research Methodology

Study Population

Participants—including patients, patient assistants,[1] and healthcare workers—were recruited from the Mbagathi District Hospital in Nairobi, Kenya. Patients who receive outpatient TB care typically have a member of their household or close friend (called "patient assistants" or "treatment supports") who have been trained to assist them with following their medication treatment regimen. Patients were recruited by handouts available in the healthcare facility.

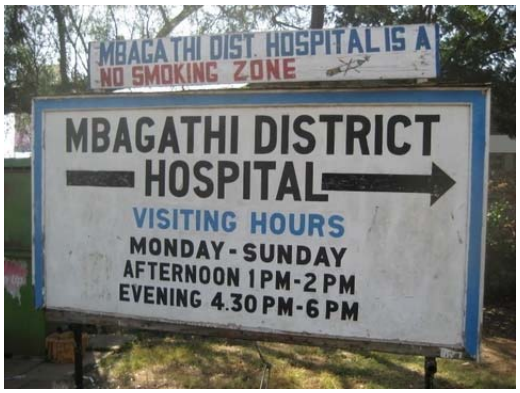

Figure 2. Mbagathi District Hospital TB Clinic where patients were recruited and area treated

Eligibility criteria for patients were: a) between the ages of 18 to 64; b) have a regular patient assistant who was also willing to participate in the study; and c) was currently in outpatient care treatment for TB. Patient assistants were enrolled in conjunction with the patients. Criteria for these individuals included: a) were between the ages of 18 to 64; and b) had experience acting as a TB medication compliance treatment support for a TB patient. The healthcare workers were individuals who were trained in DOT and worked regularly with patients in the TB clinic.

Prior to study implementation, both the Danya Institutional Review Board and the Kenyan Medical Review Board reviewed the study protocol to ensure that both countries' standards for human subjects' protections were met. Once individuals agreed to participate in the study, they were informed that their participation was voluntary, they could withdraw from the study at any time, and that their responses to the study questionnaires would remain confidential. All

[1] In Nairobi, Kenya, patient assistants are referred to as *treatment supports*. For clarity, these individuals will be called *patient assistants* in this document.

participants signed an informed consent which described in detail these conditions.

Study Design

During the initial intake visit of the study, patients were issued a mobile telephone with video-capture technology. Each telephone was pre-loaded with 200 free multi-media messages (MMS) and text messages (SMS), so that patients could capture their videos of medication ingestion, send these videos to the project database at a remote location, and review text (SMS) and video messages sent by the project staff. At the intake visit, project staff taught the patient and their assistant how to use the telephone to send and receive video and text messages.

Patient assistants were asked to video capture the patient taking his or her dose of TB medication as prescribed with the mobile phone. Once the video was recorded, the patient or their assistant immediately transmitted the data to a secure central database using a number pre-programmed into the phone. All video data was time and date-stamped upon receipt into the database. A text message was automatically sent back to the patient's mobile phone confirming receipt of the data.

After the video was received at the central database, a healthcare worker trained in DOTS protocol reviewed the video clips to assess patient adherence to medication compliance as prescribed by DOTS protocol requirements. Danya project staff also sent to patients a series of short health messaging video clips (approximately one per week) to watch on their mobile phone. These videos were developed and reviewed by behavior change communications experts. For example, one video showed an actor portraying a former TB patient providing testimony of how he was cured when he faithfully followed the prescribed medication regimen. In addition, text messages were sent to the patients with other information about TB, positive reinforcement for taking medications as prescribed, and reminder messages if a video clip was not received from the patient for that day.

Instruments to assess the perceptions of the technology were designed for patients, patient assistants, and healthcare workers by the study team. These instruments consisted of Likert-like responses and open-ended questions asking the participants about their perceptions of the use of this type of technology for monitoring medication adherence. Participants rated their experiences in topic areas such as comfort levels with being video recorded, acceptability of receiving messages, types of messages most helpful, and technical issues with sending or receiving messages. All participants made these ratings at three time points: 1) intake into the study; 2) 15-days post-intake and 3) one month (30 days) post-intake.

Results

At intake, 13 patients, 5 patient assistants, and 3 healthcare workers completed study questionnaires. Eleven (11) patients completed 15-day and one-month follow-up questionnaires. For the patient assistants, 8 completed the 15-day follow-up and 7 completed the one-month follow-up. All three healthcare workers completed the intake, 15-day and one-month follow-up questionnaires. Due to the small sample sizes, data at the three data collection timepoints were considered as discreet groups, and all available data was used in the analysis. To further clarify, the following table represents the number of participants at each point in time.

Table 1. Sample sizes at data collection points.

Participant Type	Baseline (Intake) n	15-day follow-up n	30-day follow-up n
Patients	13	11	11
Patient Assistants	5	8	7
Healthcare Workers	3	3	3

Patients were about evenly split in terms of gender (5 males and 6 females). All healthcare workers were female. The average age for patients was approximately 28 years of age; healthcare workers were approximately 43 years of age. All participants in the pilot were Kenyan and all were fluent in English.

Figure 3. TB Clinic in Kenya

The majority of the patients (82%) had been diagnosed with TB between one and three months before the pilot. Patient assistants had either less than one week (33%), between 1 and 3 weeks (33%) or between 6 and 9 weeks (33%) worth of experience in assisting patients with their medication regimen. The patient assistants also had either considerable (33%) or very much (66%) experience in the use of mobile phones. All healthcare workers had over 12 years of experience in the healthcare field, and two workers had between 3 and 6 years of experience in TB medication compliance; one worker had between 9 and 12 years of experience.

Overall Findings

All participants were extremely satisfied with the MDOT program. Figure 1 shows the average ratings by participant category for the intake, 15-day and one-month follow-up assessment. All participants rated their overall satisfaction

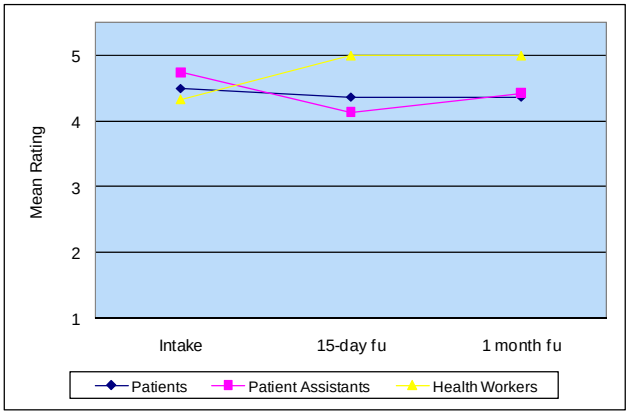

Figure 4. Mean overall satisfaction ratings by participant group.

with the program on a 5-point Likert scale with 1 being "Awful" and 5 being "Great." As shown in Figure 1, healthcare workers were extremely pleased, especially at the follow-up interviews. These later ratings are probably a better indication of overall satisfaction since participants were able to experience the study protocol for a month. Although both patient and patient assistant ratings did drop slightly at the follow-up interviews when compared to the intake assessment, average ratings for these participant groups were 4.36 and 4.33 respectively out of a maximum score of 5. Thus, although patients and their assistants may have experienced some frustration, their overall satisfaction with the MDOT protocol was highly positive.

In addition, as Figure 2 shows, all participants felt that recording a patient taking their medication was a good option instead of meeting with someone in person. Healthcare workers were unanimous in their agreement

giving this question a rating of 5 (strongly agree) for all three time points. Patients and patient assistants also agreed, despite the fact that patient ratings dropped slightly at the 15-day follow-up. However, by the one-month follow-up, both patients and their assistants rated this question at 4.27 and 4.29 respectively, indicating that they also agreed that recording was preferable to meeting someone in person.

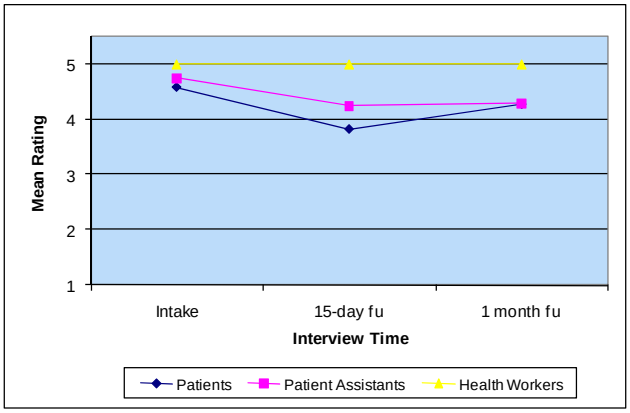

Figure 5. Average agreement ratings for the following statement: *Recording people while they take their medications is a good option instead of meeting with someone in person.*

Patient Acceptance of Methodology

One of the objectives of this study was to assess the acceptability on the part of patients in particular as to whether they would feel comfortable being video recorded while taking their medication. It was unknown at the beginning of the study if patients would find this methodology too intrusive in the privacy of their home. Furthermore, it was also unknown whether patients would be accepting of their patient assistants video-recording them while taking medication. Results showed that all of these turned out to be non-issues. Almost all patients at all three points in time either agreed or strongly agreed to the statement "I felt comfortable with being video recorded while I took my TB medication." Only one patient gave this statement a "neutral" response at the 15-day follow-up. At both follow-ups, almost all patients reported that they felt comfortable having someone (presumably the patient assistant) present during the video recording process. The exception was at the 15-day follow-up when two individuals gave a neutral response to this question. However, by the one-month follow-up, all patients were comfortable being recorded and having someone present. Patient assistants and healthcare workers were also asked to rate how comfortable the patient seemed to them while being recorded. At both the 15-day and one-month follow-up, all patient assistants and healthcare workers agreed or strongly agreed that patients seemed comfortable in the study. These findings are shown in Figure 3.

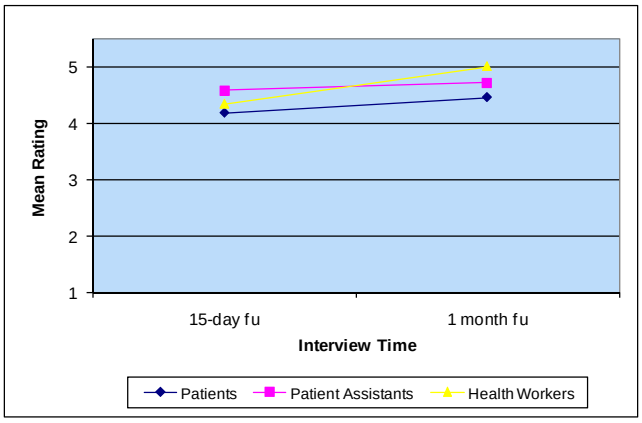

Figure 6. Comfort levels of patients, and perceptions by patient assistants and healthcare workers.

The only area in which patients expressed discomfort was in video recording themselves taking their medications without help from anyone. That is, about 70% of the patients either strongly disagreed or disagreed when asked if they would feel comfortable doing the video recording by themselves. Patients seemed to prefer having their assistants support help them with the recording process.

Finally, patients were asked to rank-order their preferences on how TB medication compliance can be monitored by rating the following options: a) going to a clinic or hospital; b) having someone [healthcare worker] make a home visit to monitor compliance; and c) using a mobile phone camera to record TB medication. As shown in Figure 4, the majority of patients preferred to use the mobile phone camera to record TB medication compliance, followed by going to a clinic or hospital. Those who chose the option of going to a clinic at intake changed their minds by the follow-up interviews and instead preferred the mobile phone methodology. Patient assistants were also asked this question and their responses mirrored the patients. However, it is interesting to note that none of the patient assistants chose home visits as the most preferred method of monitoring medication adherence.

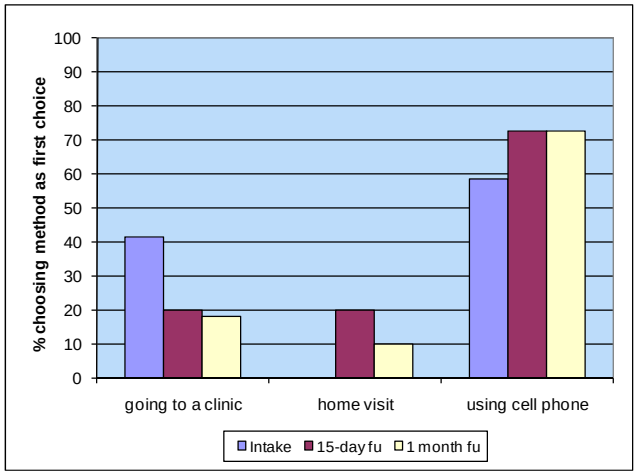

Figure 7. Patients' preferred method of TB medication adherence monitoring.

Messaging

Another objective of this study was to determine which kinds of messages resonated with patients on a variety of aspects. Patients were asked to check which of the following messages were most valuable to them:

- Testimonials from recovered patients
- Testimonials from doctors
- Testimonials from patients who were noncompliant and developed MDRTB
- Explanation of compliance
- Healthy behavior education

Figure 5 shows the percent of responses for each of the above message types. Clearly, the testimonials from recovered patients made the greatest impact on the patients participating in this study. Another interesting finding is that although healthy behavior education was a popular choice at intake or the 15-day follow-up, by the end of the study it was the second most valuable message after the recovered patient testimonials. The testimonials from doctors were initially popular, but seemed to lose some of their appeal by the end of the study.

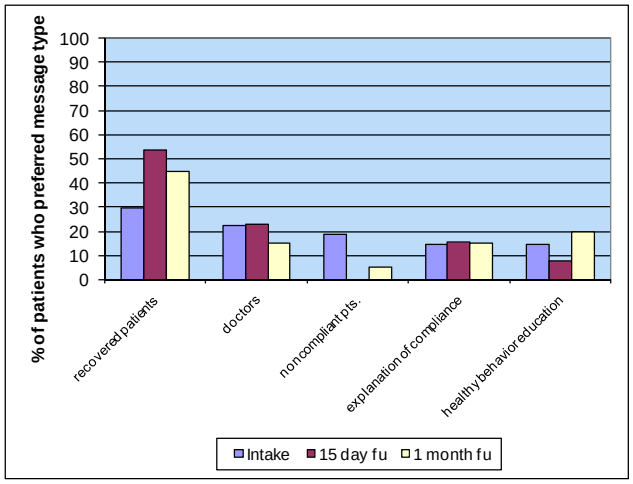

Figure 8. Types of messages most valuable to patients.

Patients were also asked to rate how they felt about receiving text and video messages on the mobile phone. Using a 5-point Likert scale, with 1 being "Strongly disagree" and 5 being "Strongly agree," patients made ratings pertaining to both text and video messages for the following statements:

- I was uncomfortable receiving messages on the mobile phone.
- I changed my behavior because of a message.
- The messages were easy to understand.
- I learned something new from the messages.
- The messages made me feel optimistic about my condition.
- I looked forward to receiving the messages.
- I would like to continue receiving the messages.
- I know someone who would benefit from the messages.

Figure 6 displays the average patient ratings made at the 30-day follow-up interview for each of the above statements. As shown in the graph, there are few differences between text and video messages. That is, patients seemed to have no preference as to whether the messages they received were in text or video format. Patients indicated that they looked forward to receiving the messages and they wanted to continue receiving the messages, again another indication of their satisfaction with the mobile methodology. Although patients most likely did not change their behavior because of the messages, this may be explained by the short time period of the follow-up interview, i.e., 30 days. Usually in behavioral change studies, a much longer time period, six months to a year, is necessary before any change is seen. One additional point that should be noted is the interpretation of the first set of bars in the graph. Although the mean rating represented by these two bars is toward the lower end of the scale, recall that the scale is graded from disagree to agree with a 1 being "Strongly disagree" and 5 being "Strongly agree." Thus, the lower mean rating for the statement "I was uncomfortable receiving messages" indicates that patients either strongly disagreed or disagreed with the statement. Lower scores indicate that patients were *not* uncomfortable receiving the messages.

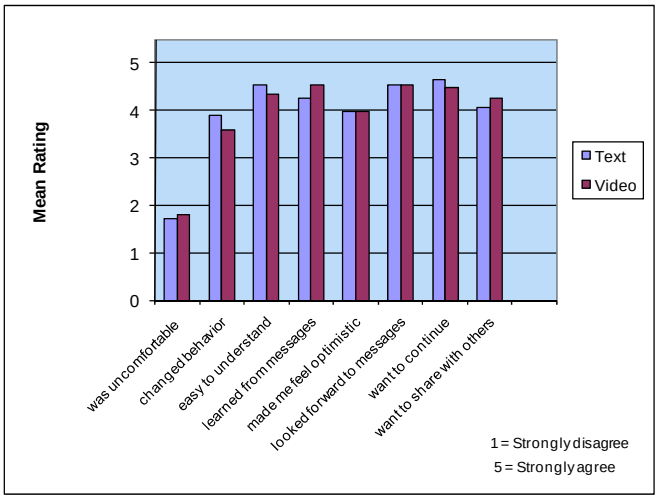

Figure 9. Preferences between text and video messages.

Technical Issues

As expected, participants did encounter some technical difficulties with the mobile phones during the course of the study. When this occurred, patients initially felt frustrated when their videos were not going through; they resolved these issues by calling or sending a text message to the healthcare workers. However, from their reports the incidence of these difficulties was not significantly detrimental to the overall study. One out of the 13 patients had difficulty during the training in understanding how to use the mobile video phone procedures, but after a few additional hours of training was able to master them. At the 30-day follow-up only 2 patients agreed, and 2 patient assistants strongly agreed, that they had technical difficulties using the video recorder. Over 70% of patients and patient assistants said they had trouble recording with the phone and sending video messages half the time or less. Over 80% of the patients said

they had trouble retrieving messages on the phone or accessing videos half the time or less. These findings are not surprising considering that for many patients they had little or no experience using video applications on a mobile phone prior to participation in the study. One promising and positive finding was that the healthcare workers all agreed that the quality of the video was adequate for them to observe the patients taking their medication according to DOTS protocol via videos sent over mobile phones as opposed to in-person observation.

The most challenging issue during the pilot study was the technical integration of all of the technology systems required to implement MDOT. Most services were provided as in-kind contributions, and ensuring the mobile phone video software, database software, mobile data services, and the Internet access at the hospital were all working simultaneously required fairly extensive technical management oversight and trouble-shooting. Challenges included figuring out how to use the various video quality settings, compression formulas, and determining how to deal with software bugs that arose from the transfer of files from a computer to a mobile handset. In addition, at times there was no network service and occasionally the internet was slow. All of the issues were ultimately resolved by working with local technology providers and through trial and error.

Another challenge had to do with the videos themselves. There is a standard size limitation of 200–300 KB for transferring files through the mobile services provider's server, which is approximately 8–10 seconds of video on the default video quality settings. It became clear that a more specific protocol for the length of the videos was needed, as well as more clearly defined steps for recording the video. For example, to tell if the patient was taking the medication, the healthcare workers suggested that it was useful to have the patient assistant first record the patient showing the medication in their hand, putting the medication in their mouth, drinking water, and then finally, showing their tongue. It would be helpful to have a demonstration video of how this should be done. Also, more specific directions would be helpful regarding the distance of the phone to the patient and how much light is required in the room while recording the video.

Conclusion

Results of this pilot feasibility study showed that mobile telephone technology is a viable alternative to direct observation to monitor patient adherence to TB medication. Overwhelmingly, patients, patient assistants, and healthcare workers were highly satisfied with the methodology. Patients found the process of their assistant video-recording them while they took their medication as very acceptable. Patients also preferred mobile technology as a means for direct observation treatment as opposed to going to a clinic or having a healthcare worker come to their house to observe medication compliance.

Figure 10. Nokia Video Phone

Patients were highly receptive to receiving both text and video messages on their mobile phones.

In fact, most indicated a desire to continue receiving such messages once the study was completed. Besides receiving the pre-recorded health messages designed for this study, informal reports from patients revealed that they also had two-way communication with their healthcare worker occasionally. This direct communication between patient and healthcare worker was advantageous for both parties. Healthcare workers were able to explain and address patients' concerns about taking TB medication, provide more health information, and encourage patients on treatment adherence. One specific incident occurred when a patient experienced an unfamiliar side effect of the medication. The patient immediately sent a message to the healthcare worker, who in turn replied that the symptoms were common side effects and there was no need for alarm. Furthermore, it saved the patient a trip to the doctor, which in this case, travel time was considerable.

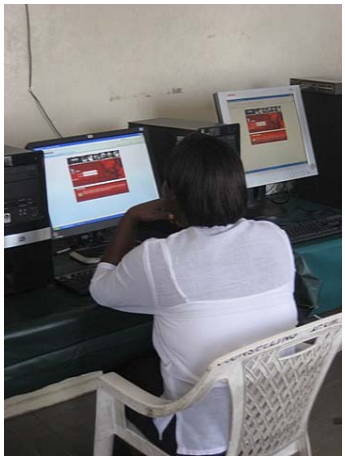

Figure 11. Healthcare worker at Mbagathi District Hospital's TB Clinic Computer Lab

Individuals who assisted the patient with their medication, as well as healthcare workers were highly enthusiastic about the mobile technology. All thought that recording a patient taking their medications was a good alternative to direct observation. Healthcare workers found that quality of the video adequate so that they could remotely assess DOT protocol.

When interviewed, patients commented that they liked participating in this study and testing this new methodology. In many cases, it gave patients more immediate access to their healthcare worker with the convenience of two-way communication via text messaging. Often patients feel a sense of isolation when diagnosed with TB, and this technology provided them with a means of staying in touch with their healthcare worker. Many patients also said that they learned new information from the health education messages, and that the mere act of taking the video reminded them to take their pills. The testimonial messages, especially from recovered patients, gave the patients in this study hope and optimism about a cure for themselves. One patient stated "*I liked the messages and video clips very much because I thought no one in this world cares about people with TB…*"

The purpose of this feasibility study was to investigate whether mobile technology could be applied to TB medication adherence monitoring and if it would be acceptable to patients suffering from TB. The results of this study showed that this methodology is viable. One issue that did arise during recruitment for study participation was some concern over protecting an individual's privacy. Many potential participants (patients) were hesitant to take part because of uncertainty about the security of sending the videos, where the videos would be stored, and who might have access to the videos. They had a misperception that videos might make their way to public sites on the Internet so that the video could be viewed by the general public. Once this fear was allayed by project staff, patients were more comfortable to participate.

However, there are many limitations from these results due to the small number of participants; further research is needed to answer broader questions. These questions should be addressed by conducting a larger scale scientific study including a much larger sample of participants. Suggestions for future research include conducting the study over a longer time period, so that the entire medication regimen interval (i.e., six months or as long as medication is prescribed by the physician) is included in the study. While the present pilot study showed that the technology was acceptable for a one-month period of time, daily practice over a much longer time frame may show a decline in satisfaction due to redundancy, mundane activity, and boredom. The "newness" or novelty may wear off after a longer period of time. Other broader questions to be answered by more detailed research include what is the effect of mobile direct observation treatment on medication adherence rates among a larger sample of patients. Does this type of methodology improve medication adherence? Could this technology be used to monitor other types of diseases that require a daily medication regimen such as HIV/AIDS?

A cost-benefit analysis of the technology should also be undertaken. Cost savings should be studied from both the consumer (patient) and health industry perspective. In developing countries where transportation systems are crude and healthcare facilities are located a great distance from rural patients, cost savings for the patient in terms of their time and transportation costs to and from the clinics would be useful information. On the other hand, savings for the healthcare system should also be analyzed. For example, is there a significant time savings in terms of the healthcare worker reviewing video clips instead of in-person direct observation? What is the impact on quality of care? Does the lack of direct interaction between healthcare worker and patient have any detrimental effects on the patient-provider relationship? What kinds of cost savings does this technology have for clinic or hospital operations? Does this technology reduce the burden on already over-crowded health facilities?

Mobile direct observation treatment is a promising methodology for health-related applications. It should be given serious consideration to be added to the complement of other telemedicine techniques already being used by patients and healthcare providers.

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