REVIEW PAPER

A customized m-Health system for improving Tuberculosis treatment adherence and follow-up in south India

Padmanesan Narasimhan • Aishwarya Bakshi • Sathyapriya Kittusami • Suma Prashant • Dilip Mathai • Kasturi Bakshi • Chandini Raina MacIntyre • Pradeep Ray

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Abstract Tuberculosis is a major public health problem in India with more than 2 million new cases every year. With the growing crisis of inadequate healthcare workforce, monitoring of drug treatment for Tuberculosis is an arduous task. mHealth services (healthcare using mobile communication technologies) are gaining support as an effective tool to handle the situation, especially where technological and human resources are limited. This paper illustrates the delivery of a mHealth service with insights into the feasibility and applicability of deploying a voice call based reminder system for drug adherence in a resource limited setting.

Keywords mHealth · Tuberculosis · Drug adherence · Reminders · Mobile phones · Voice calls

P. Narasimhan (⊠) · C. R. MacIntyre School of Public Health and Community Medicine, The University of New South Wales, Room 217, Level 2, Samuels Building,

Kensington, Sydney, AustraliaNSW 2052 e-mail: padmanesan@unsw.edu.au

P. Narasimhan · A. Bakshi · C. R. MacIntyre · P. Ray Asia Pacific Ubiquitous Healthcare Research Centre (APuHC), Australian School of Business, The University of New South Wales, Sydney, AustraliaNSW 2052

S. Kittusami · S. Prashant

Rural Technology Business Incubator, Indian Institute of Technology Madras, IITM Research Park, Taramani, Chennai, India

D. Mathai

Apollo Institute of Medical Sciences, Apollo Health City, Jubilee Hills, Hyderabad, India

K. Bakshi

Kalyani Institute for Policy Action and Rural Change, Kalyani, West Bengal, India

1 Introduction

Tuberculosis (TB) is a potentially life threatening but curable disease which affects one third of the world's total population, primarily in developing countries. Global annual incidence of TB is estimated at 9.1 million cases, out of which 1.9 million cases, i.e. nearly one-fifth the global incidence, are from India [1]. Controlling TB in India is a challenge due to the shortage of human resources in the overburdened healthcare system [2]. This disease also affects economic development of the country, incurring US \$3 billion in indirect costs and US \$300 million in direct costs [3]. Further complications arise due to the emergence and spread of drug resistant TB and also Human Immunodeficiency Virus (HIV) co- infection.

On the other hand, due to the meteoric rise in the usage of mobile phones, even amongst the rural population, outreach to patients and access to information has never been easier. According to Telecom Regulatory Authority of India (TRAI), by the end of March 2012 there were 919.17 million mobile phone users in the country, with a tele-density of 78.66 (TRAI, 2012). To overcome the shortage of healthcare workers and improve the access to health care, mobile phones can be of great value for remote monitoring and information dissemination.

E-Health is the delivery or facilitation of health services and information through the Internet, telecommunications and related technologies [4]. e-Health is concerned with the application of Information and Communication Technologies (ICT) in healthcare. e-Health can play a vital role in extending healthcare to remote populations in the world where human resources are lacking, utilizing the rapid proliferation of mobile phones (World Health Organisation, 2005). With mobile (including satellite) technologies, healthcare and services can even be provided in remote settings where conventional telecommunication networks are either not available or have been disrupted. Mobile Health (mHealth) is a component of eHealth. WHO Global Observatory of eHealth defines mHealth as medical and public health practice supported by mobile devices such as mobile phones, monitoring devices, personal digital assistants (PDAs) and other wireless devices [5]. With the global proliferation of mobile phone services, it is now possible to develop and deploy m-Health services for reaching healthcare particularly in developing countries [6]. The world of information technology (IT) is now moving towards the concept of Software as a Service (SaaS) and Service Oriented Architecture (SOA) that defines IT services (including mHealth) as a service rather than a product.

This paper will explore a mHealth service where a simple and inexpensive mHealth application can be used to facilitate a chronic disease management i.e., TB treatment. The system will primarily use the Short Message Service (SMS) and voice call facility available in nearly all mobile phones and can be used in resource limited settings as it is cost effective. The rest of the paper is organized as follows. The background information and motivation to develop the mHealth system is provided in section 2. In section 3 we discuss the potential of mHealth in improving healthcare systems. In section 4 the methodology used to develop the project is discussed. In section 5 we discuss the service design. In section 6 we discuss the service implementation and analysis techniques. In section 7, we discuss the limitations and generalizability of the service and section 8 concludes with a summary and future work.

2 Background

India has the highest number of TB cases in the world, with 1.98 million new cases of TB and 330,000 tuberculosis deaths occurring in 2011, and accounts for 20 % or one fifth of the total TB cases worldwide [7]. Also, India has an estimated 2.3 million HIV infected patients, which makes it the third highest HIV burdened country in the world. As TB is the most opportunistic infection in people living with HIV, there is a high risk of the TB epidemic worsening unless treated early. Without HIV, the lifetime risk of developing TB in TB-infected people is 10 %, compared to at least 50 % in HIV co-infected. TB also accelerates the progression of AIDS and reduces the survival chance of patients with HIV infection. TB in HIV-infected persons is also a transmission risk to non-HIV affected persons and can accelerate the TB epidemic [8].

India has currently adopted the highly successful Directly Observed Treatment Short-Course (DOTS) to tackle TB in the country and even though it is proven effective, it is complicated by several factors like shortage of healthcare workers to monitor the large number of patients, lack of drug adherence to the 6 month schedule and social stigma. DOTS requires the patients to be regularly monitored and their treatments to be supervised by either health workers or any person willing to take the responsibility to do so (e.g. community volunteer). Due to the large number of TB patients and shortage of healthcare workers, individual supervision often becomes burdensome. This situation is further worsened by the social stigma associated with the disease where it is often considered as a 'death penalty', a 'dirty disease' or 'only affecting the guilty' [9]. Despite the benefits of DOTS therapy, the rigid supervision of treatment may also increase the stigma associated with the disease, as it implies distrust of the patient. Patients often isolate themselves to avoid infecting others and to avoid uncomfortable situations such as being shunned or becoming the subject of gossip [10].

Inspired by the growth of mobile communication technologies, global health policy-makers and providers are strengthening mHealth as a new tool to tackle the global crisis in inadequate workforce and patient monitoring [11]. Also, mHealth in the follow up and management of TB patients can provide a secondary benefit in addressing the issue of stigma by avoiding face to face contact [12], and as a result better results of the treatment can be expected. The massive penetration of mobile phone networks, especially in developing countries, (i.e., about 4 billion people have mobile phones) potentially enhances access to ubiquitous healthcare services. This is an encouraging sign for the use of mHealth with mobile phone networks as a cost-effective alternative to the more traditional web based eHealth applications to facilitate TB treatment.

The Asia-Pacific ubiquitous Healthcare research Centre (APuHC-www.apuhc.unsw.edu.au) at the University of New South Wales, Australia has been leading an evidence-based study on the Assessment of eHealth for Health Care Delivery (eHCD) for WHO since 2006 in a number of Asia Pacific countries including India and China

3 Potential use of m-Health

m-Health describes the application of mobile telecommunication and multimedia technologies in mobile and wireless health care delivery systems [13]. Broadly, it involves using wireless technologies to transmit and enable various data contents and services which are easily accessible through mobile devices such as mobile phones, smart phones, PDAs, laptops and tablet PCs [14].

In many developing countries, health services are often inadequate as they are generally neither accessible nor costeffective. The situation is worse due to a major shortage in health work force to handle large populations [13]. Even when health services are available, they are mostly of poor quality and do not cater to the actual needs of the patients [15]. Table 1 reflects the poor quality of healthcare available to people in developing countries [16].

Seventy percent of the population have access to mobile phones [17] and the numbers are growing extremely fast. Bangladesh

UK

USA

Countries	Infant mortality rate (per 1,000) in 2006	Maternal mortality (per 100,000) in 2005	Years of life lost due to communicable disease (%) in 2002	Births attended by skilled health personnel (%)
India	57	450	58	47 (2006)
Pakistan	78	320	70	54 (2006)

60

10

9

Table 1 Health indicators of countries

52

5

7

Indeed, mobile phones, as an ICT platform, have far greater penetration than computers, and are potentially capable of meeting the health needs of patients. The exponential growth in mobile phone usage in India is reflected in Fig. 1 [17].

570

8

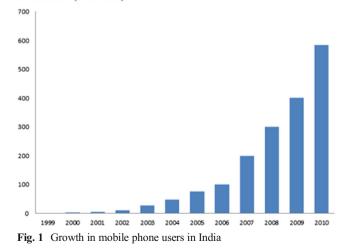
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A recent study by WHO Global observatory on eHealth states that nearly 83 % of the WHO member states reported offering at least one type of mHealth services and most of these projects are in the pilot or informal stage [2]. These programs are gaining strong support across regions as well as from different stakeholders like technology providers, government and academia. Different types of mHealth services are in practice, which include text (SMS) & video contents and voice (medical call centres) service. TB patients in Thailand were given mobile phones so that healthcare workers could call these patients on a daily basis to remind them to take their medication. Medical compliance rates reached 90 % due to the introduction of this remote monitoring application [18]. Such a system would be of great help in a country like India but due to a much larger patient base.

4 Methodology

The mHealth Service Development in this project is based on the 8-stage iterative methodology [19], shown in Fig. 2, which

Subscribers (in millions)



helps us gradually improve the design of software and service with time. For example, we can improve the contents and frequency of the messages substantially to motivate patients better.

20 (2006)

99 (1998)

100 (2004)

Hospital beds

(per 10.000)

9 (2003)

12 (2005)

3 (2001)

39 (2004)

32 (2005)

The eight-stage service design and management methodology captures and illustrates important process in the development and management of services, including e-business services. This model has evolved in the AT and Ts service development over the last decade or so and is very useful in the formulation of qualitative service management requirements, and their top-down quantification.

The first stage of this model defines service needs based on customer requirements. In the second stage designers and customers come together to finalize some kind of performance benchmark for service. This benchmark is then incorporated into Service Level Agreements (SLAs). The third stage involves the generation of concepts for design purposes. This helps in developing the design framework. The next stage is to develop the design in more detail. Of course at every level one needs to be as quantitative as possible. Stage 6 involves implementation of the design. Stage 7 entails the measurement of design performance, and assessment of customer satisfaction in relation to the initial requirements. Finally, in Stage 8, one can go ahead with improving performance, based on the satisfaction level measured in Stage 7. So the Eight-Stage model is an iterative loop of 8 stages (Fig. 1), which help us design and refine a service and work out management strategies.

Stages 1–4 of this methodology are primarily design steps. Stages 5–8 are primarily the management of service. Thus this model provides a way of integrating design and management functions of any service. The advantage of this model is that it is generic and can be used for any type of service, including airline service, banking service, restaurant service, health care or telecommunication services. It is applicable to a wide variety of e-business management situations. This methodology uses Total quality Management (TQM) techniques.

House of Quality (HoQ) matrix: In order to translate the vague terms like "right" or "good" to quantitative values, it is necessary to use some kind of systematic modeling tactics. For this purpose, we use by way of example the quality function deployment matrix or QFD matrices, which have

Total health

14 (2003)

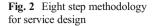
12 (2003)

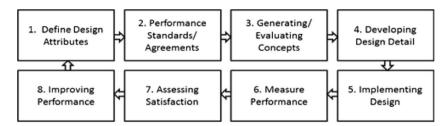
5 (2001)

75 (2001)

125 (1999)

workers (per 10,000)





been used extensively in the area of Total Quality Management (TQM). These matrices help resolve issues in the quantitative formulation of design and management specifications from the qualitative attributes that we saw in Section 2. There is a wide range of matrices used for this purpose, the most common being the House of Quality (HoQ) matrix (see Fig. 3).

House of Quality conceptualizes the process of arriving at user needs, and service specifications, from a set of visual rules. The rules are as follows: The process of specifications is:-talk to the customer in Room #1 (away from technical designers). Then take the designers or the implementers of the systems (technical people) into another room, Room #2, and talk to them separately about the competing services available for that purpose. If the two groups are brought together it is quite possible that the user group may feel inhibited due to the lack of technological knowledge, and not spell out the requirement clearly. Similarly, a less than optimal technological solution, specified by some users, may inhibit the technical design group. One can combine the data generated from the consultations with the customer and technical people and using some simple calculations, to be specified later, arrive at the requirements. The visual paradigm of HoQ is organized in eight compartments of thinking (rooms). This compartmentalization and subsequent systematic correlation

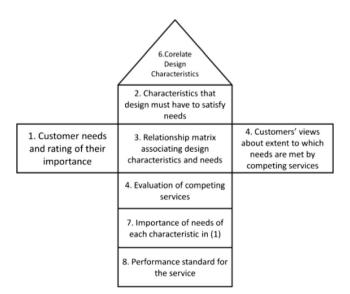


Fig. 3 House of quality (HoQ) matrix

helps in deriving the specification in an unattached, objective manner.

The next step, in Room #3, is to rank the needs according to their levels of importance. Let us say that most important for this diagnosis, is the x-ray or the scans, or the pathology test. One can assign some kind of a notional value, or a ranking factor to each of these needs. Relationship matrices are defined with design characteristics as rows, and needs as columns. This is followed by deliberations in Room #4 (with customers) on the extent to which the already ranked needs are satisfied by competing services (e.g. fax and Internet).

Once that is done, move into Room #5 where one needs to ask the viewpoints of the designers. This is followed by deliberations in Room #6 where designers are asked to define the alternatives against some criteria for comparison.

Once that is done, customers view the matrix in Room #7 to check on the extent to which needs are met by the competing services. Finally, in Room #8 quantitative benchmarks are specified for the management of the service under consideration.

Therefore, QFD matrices (as shown with HoQ), provide the following benefits:

- a) A structured method for defining quality standards early in the design process
- b) A system for incorporating quality standards in the service design methodology
- c) A technique for the propagation of the quality throughout the service lifecycle
- d) Establishment of quality relationships at different levels of service parameters

5 Objectives/expected outcomes of the service

5.1 Objective

To facilitate effective implementation of the national TB program through a mobile phone based intervention

5.2 Expected outcomes

1. To develop and maintain a digital registry of patient information using a form on the mobile phone

- To motivate, remind and educate patients for treatment adherence by sending voice and text reminders with customized messages
- To monitor the progress of anti-tuberculosis treatment using mobile form updates of lab results and data available on web interface

6 Rationale for the design and methodology

- Stages 1 (define design attributes) and 2 (perfora. mance standards/agreements): Based on the 8-stage iterative methodology, stages 1 and 2 i.e. the initial requirements and benchmarking attributes for the system were framed and developed by APuHC, UNSW, Australia in collaboration with doctors and technical experts from Christian Medical College (CMC) Vellore, India, Rural Technology and Business Incubator (RTBI), Indian Institute of Technology Madras (IITM), Chennai, India and Kalyani Institute for Policy Action and Rural Change (KINSPARC), Kalvani, India. The system development and planning involved communication between partners from both countries via email, phone and organized visits. The requirements were eventually found to be development of a system to remind patients periodically to adhere to their medication and a mobile based registration system. Also a gateway for easy communication between the patients and health workers needed to be created. The design attributes includes user friendliness and a simple interface to capture all the required information.
- b. Stage 3, where the need of such a system is evaluated, involved carrying out surveys in one of the pilot locations (Kalyani West Bengal). It was found that, out of all the families surveyed (n=50), 74 % (n=37) of the families had access to a mobile phone. Also, when asked if they would find such a system useful, 74 % (n=37) responded with yes, 8 % (n=4) did not believe it would help while 18 % (n=9) were unsure.
- c. Stage 4: The barriers to mHealth implementation in India include diverse population across the country. There are officially 14 languages in India, but in reality there are over 20 widely used languages and dialects. Most of the population, especially in rural areas have no exposure to English and hence any system that does not incorporate local languages will have difficulty in reaching out to the audience. Tuberculosis is a major infectious disease affecting mainly individuals who belong to the lower socio economic strata. Drug adherence is an important problem as it requires 6 months supervised treatment.

The m-health system that has been developed addresses the following issues.

The system has the following main functions

- i) Mobile based recording/enrolment for TB patients Currently there is a paper based format (treatment card) for enrolment purpose where in basic demographic information, TB status, treatment schedule and sputum smear results are recorded. This will be replaced by a mobile based recording system, where all relevant details from the RNTCP treatment card will be recorded through a mobile phone and stored securely in a central server.
- ii) Maintaining Patient database

The patient database contains information relating to a particular TB patient. It contains personal details like name, age and sex and medical history relevant to the TB. The most important data items from the eHealth perspective will be the mobile number of the patient, the preferred language of communication, preferred mode of messages (SMS or voice calls) and the timing of the messages. With this information all future interactions with the patient are carried out in the specified language whenever possible. The database also contains the medication schedule of the patient which varies based on their previous history of TB treatment.

iii) Sending reminder messages

Drug adherence to the 6 month long TB therapy is a major problem. Patients start feeling a little better after few weeks of the TB treatment as the drug therapy is designed to kill maximum number of organisms during first 2 months (intensive phase). Some patients stop taking their medications and increase the risk of developing drug resistant TB as the treatment has to be strictly followed in the continuation phase (next 4 months). TB medication is also known to cause many side-effects which include nausea, vomiting, dizziness, etc. This problem can easily be avoided if the patients understand the risks and follow their drug regime rigorously. This also requires constant motivation to complete the course.

The purpose of this module is to assist the patients in following their drug regime by sending timely medication reminders in their language of preference. Even though DOTS requires health workers to visit patients and supervise each dose, sometimes it is difficult to do so due to the disproportionate health worker-patient ratio. There might be cases where the health worker taking care of a particular group of patients becomes unwell or the patient is out of iii)

station. In either case, it is essential that medication continues and the reminders aid in doing so. Motivating the patients to continue therapy is an essential part of this module with additional features such as counseling available at their request.

Depending on the medication schedule of the patient, the system retrieves reminder messages from the message database in the patient's preferred time of communication and sends reminder messages to the patient reminding them to take their medication. *Tracking drug adherence response from patients*

Once the reminders are sent, the system looks for responses from the patients for the rest of the day. The system maintains a daily list of all the patients to whom the reminder messages are sent and they are taken off the list the moment a positive response is received. If the patient fails to attend the call in the first attempt, the call will be sent again within an interval of 15 min. Three attempts were made to reach the patient. Field investigator will call those patients who do not respond on their phone to find out the patients' problems and why they did not respond to the message. If the patient fails to respond regularly or does not respond to the phone calls, the field investigator will visit the patient personally to sort out the issue and encourage the patient to follow the drug routine. Figure 4 shows the flow of the reminder service.

This allows the health workers to monitor drug adherence amongst patients regularly and helps them assist the patients in maintaining their drug routine with timely action. It also lets them target their focus on individual patients who resist following the regime and are more susceptible to relapse. In the long run, the drug adherence information collected based on region can help the healthcare agencies distribute health workers better.

- iv) Sending out motivational and awareness messages From time to time, awareness and motivational messages in the patient's preferred language are sent with the hope of educating the patients about their disease and removing the stigma associated with it. Once the patients understand the disease better and are aware of the facts related to their disease, they are able to face society with greater confidence. Figure 4 shows the flow of the reminder system.
- v) Channel for remote communication between patient and health worker

Often patients are not confident of speaking about their problems face to face with the health workers due to their inhibitions regarding the disease. This system allows the patients to talk to the field investigator regarding their queries or problems.

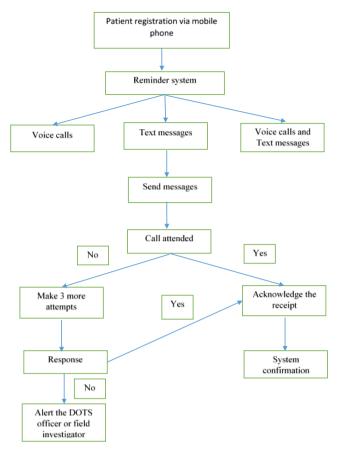


Fig. 4 Reminder service flow

vi) Evaluation methodology and questionnaire

We evaluated the information obtained from patients during their registration into the system. Information from the RNTCP treatment card (such as demography, medical and TB history, lab results and treatment) were collected in addition to the mobile number of the patient, mobile phone ownership details preferred method for receiving messages i.e whether they would like to receive only voice calls or only text messages or both; and their convenient time for receiving reminder messages were also collected. Known risk factors for medication compliance such as alcohol, tobacco and substance abuse were also recorded. In addition to the information collected from patients at the start of the study, lab results and treatment outcome were collected from DOTS centres through the process and at the end of the treatment. Call records such as call attendance rate, attempt in which the call was attended including duration of the call attended etc was obtained from the database.

d. Stage 5: Service Implementation

The study was performed in Vellore, Tamil Nadu where the primary language is Tamil. People with active

TB were allocated to receive standard care, which comprises DOTS and the m-health initiative to assist with TB management. DOTS involves the direct administration of medication by a health worker/family member/ community volunteer of the patient, who then observes the patient swallowing the pills. This ensures adherence with treatment.

Officers in charge at the DOTS centres who have been informed about the study are requested to provide necessary information about newly detected TB cases to the investigation team. On receiving patient details, a study investigator discussed with the patients about the study design and explains to the participants the risks and benefits of participating in the trial in their local language (Tamil). If they consent to participate, they are administered informed consent (translated in local language) and asked to sign the same.

This study evaluated the efficacy of an m-health initiative as an additional access point to improve control of TB without altering the current program practice. Our pilot data show that often patients, faced with long travel times and difficulties of access to care, may default from treatment. If an alternative were available, such as access to advice by mobile phone, this may improve treatment outcomes. At the end of the study, the following outcomes were measured

- Treatment completion and cure rates (as defined by W.H.O)
- Treatment adherence rates
- Adverse drug reaction rates
- Stigma associated with TB
- Patient satisfaction
- Usage of the m-health initiative

Implementation-phase 1

In this stage we assessed the acceptability and feasibility of a SMS based intervention. We approached consecutive TB patients seeking care from the DOTS centres. A predesigned questionnaire was used to collect the demographic details, information on phone usage, ability to read and write SMS and preferred time for receiving the messages. More than 34 % (n=53/157) of study participants refused to participate in the study. On further analysis we found that 62 % (n=33/53) did not own a mobile phone. In the subgroup who owned a mobile phone but refused to participate (20/53) nearly 75 % (n=15/20) cited illiteracy as the barrier to access text messages. The detailed results are summarised elsewhere [20].

This study highlighted the mobile ownership patterns in this setting, with a statistically significant association between illiteracy and ownership (p=0.002), with 63 % of illiterates not owning a mobile phone. Elderly (\geq 65 years old) were less

likely to own a mobile phone compared to the younger age group.

Based on these findings a voice call based reminder system was developed in collaboration with RTBI-IITM and the same was implemented in the next stage.

Implementation-phase 2

The activities implemented in this stage included

- a. Mobile phone based registration of TB patients which included a customised registration form on mobile phone equivalent to the government RNTCP card. A unique ID was generated for each patient and the registration system included a drop down menu format which can be uploaded via GPRS to a central database.
- b. SMS and/or voice call reminder enabled treatment adherence support system- Voice messages were sent in local language to overcome the barrier of illiteracy. The content was customised to motivate the patients, maintain routine medications and encourage them to make scheduled visits for diagnosis. The schedule was tailored to patient's preferences and also the RNTCP schedule (alternate day schedule for 6–9 months).
- c. Real time reporting and monitoring- Patients lab results were updated every 2 months using the appropriate form on mobile phone along with treatment progress. These information were also made available using web interface for continuous monitoring and analysis purpose.
- e. Stage 6: Measure performance

Of the 104 patients recruited, 100 patients were followed up until their treatment outcome was known. As the remaining 4 patients have been transferred out to a different DOTS unit beyond the scope of our study, their results have not been included in the analysis. However, it is important to note that, these patients continued to receive the reminder calls and have known to have completed their treatment successfully. Of the followed-up patients, 88 % have completed their full course of treatment, treatment outcome recorded as success for 84 % (includes completed and cured), 5 % of the patients have been identified as default i.e. patients who stopped taking medication midway for a consecutive period of 2 months due to medical, societal or family reasons; while 7 % were notified as deceased.

It has been found that more than 77 % of the patients exhibited greater than 60 % of call attendance with a demonstrated association between their call attendance percentage, not only with treatment completion but also their possibility of being cured of the disease.

Four patients who were registered in the system under the patient category of 'after default relapse failure' have successfully completed their treatment and have been cured. This is a significant finding as these are patients who were identified as 'default' in their first course of treatment, after which they relapsed back into TB treatment for the second time and during this course had become 'treatment failure'. The finding that these categories of patient who have a higher probability of treatment failure or defaulting have been cured in their third round of treatment in the presence of our mHealth intervention is noteworthy. Similarly, patients who have been identified to be co-infected with HIV, making the management of two very challenging health conditions further complicated (Ministry of Health and Family Welfare, Government of India, 2012), have fared well in our study.

Figure 5 shows a graph which has been plotted for the percentage of calls attended during the course of the treatment against the treatment completion status comprising of 'treatment complete' and 'incomplete treatment' (includes default and dead). Figure 1 show that as the call attendance percentage increases, the number of patients who have completed the treatment also increase significantly when compared to those who have not completed the treatment. This indicates that the calls have aided in ensuring that the patients who enrol in the treatment also completed the course. 94 % of the patients who have successfully completed treatment have also regularly attended the calls.

A correlation analysis reveals that here is a high degree of correlation (0.848) between the percentages of calls attended by the patients to their completing the treatment, confirming that these variables move in tandem. Taking the analysis a step further, logistic regression for the treatment completion and other factors likely to impact the same were considered. These factors included gender, age, marital status, patient type, site of TB infection, smoking, alcohol consumption and reminder type preference (call/text/both). The regression results for the above mentioned factors were not significant. Logistic regression was also done for treatment completion and call

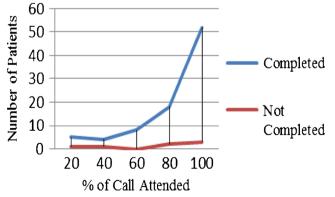


Fig. 5 Percentage of calls attended vs. treatment completion

attendance percentage which was split into intervals of low (0–30 % calls attended), medium (30–70 % calls attended) and high (70–100 % calls attended). The logistic regression showed that people with a high call attendance percentage were 5 times more likely to complete treatment than those with a low call attendance percentage with significance of 0.093.

Qualitative study consisted of in-depth interviews among patients from different treatment outcomes. The interviews brought out the extent to which voice calls acted as a reminder/trigger to take medication; their role in improving awareness about TB and its management and finally the support system provided by the intervention throughout the process of treatment. The interviews threw light on the patients' felt need for a medium expressing care and concern on their health; the promptness and regularity of the reminder calls was received among the patients as showing constant care and empathy.

f. Stage 7 Assessment of customer satisfaction:

Our qualitative analysis proved that the mHealth system acted as a support system for TB treatment with a personalised care. Patients referred to this system as 'inspiring' and 'useful' to complete their course of treatment.

The customised platform using voice calls was the first study to correlate the effectiveness of voice calls with successful TB treatment outcomes. Our system also showed that the role of the field investigator can be easily taken up by the DOTS provider and the mobile phone recording system can replace the paper based recording system.

g. Stage 8: Improving performance

The service design throws light on two important aspects with respect to the use of mobile technology in health services-demonstrate that mHealth interventions need to be understood from the end user perspective before deployment in the field and the design should be malleable to be able to adapt to field realities and changing needs. The project also shows how an iterative methodology, which helps us gradually improve the design of software and service with time, can be applied to achieve the same. The project also presents how 'voice based applications' can overcome the hurdles of illiteracy and reach out to the patients in their own local language, particularly relevant in a country like India which has people speaking diverse range of languages and dialects. To improve performance, a pre pilot phase for implementing the service design for understanding the needs of the recipients/end users. A qualitative analysis even at the pilot stage will be useful to understand the barriers and concerns for deploying the design in a field setting.

7 Discussion

Our study is the first attempt to examine the usefulness of mHealth intervention for a major infectious disease in India (i.e. Tuberculosis). Our systematic activity has shown positive results in both our qualitative and quantitative analysis. We were able to show in our stage 1 that illiterates and elderly individuals have limited access to mobile phones. We were also able to demonstrate that mHealth interventions need to be understood from the end user perspective before deployment in the field. Our stage 2 study showed that a voice call reminder system may improve drug adherence and in turn augment treatment outcomes among TB patients. Mobile based registration system may supplement the paper based registration and follow up system for real time monitoring of patients. Qualitative analysis throws light on the patient's perspective on their illness and the stigma related issues in the field [21].

The evidence obtained from this research study has a strong policy implication placing emphasis on the role of ICT interventions in facilitating better implementation and management of the Government of India's Revised National Tuberculosis Control Programme (RNTCP) employing Directly Observed Treatment Short course (DOTS) as its operating strategy for the management of TB. This need becomes much stronger with RNTCP's 'National Strategic Plan (2012-2017)', aimed at strengthening its implementation, recommending the incorporation of ICT for better patient monitoring and treatment completion. Implementing this low cost and simple application involving DOTS centres in a phased manner with an objective to scale will enable followup of all the patients who have been enrolled with RNTCP. This set up can be customized and seamlessly incorporated into any healthcare system that aims at the control of Tuberculosis and further to any other disease of public health concern.

Limitations The mHealth system is dependent on the prompt updates by the field investigator on the sputum smear results and treatment outcomes. A similar level of commitment cannot be expected from a DOTS health worker who has other commitments. We were unable to follow up patients who were transferred out from this particular DOTS unit. This initiative was tested only in a small scale therefore a larger sample in different settings is required to understand the feasibility of this program.

Generalizability The primary purpose of this service is to develop a channel of communication between patients and health workers and therefore does not have to be limited to TB treatment. It can be applied to tackle almost any illness where a strict or long term drug regime is prescribed e.g. chronic diseases like diabetes, high blood pressure, etc. Similarly, this low cost service can also be developed to assist in other

interventions such as smoking cessation and obesity prevention where it can help patients remember their medication schedule and also provide an alternate channel of communication between clinics and patients where the patients can ask questions, report problems and drug reactions, etc. It will be useful to perform future studies on the efficacy of this service in controlling diseases in different environments.

8 Conclusion and future work

In this paper we have discussed the delivery and evaluation of a mHealth service to monitor TB patients in south India. The system works on a widely and cheaply available technology i.e. mobile phones with voice call and SMS facility and is extremely user-friendly with minimal training required for operation. We conclude that text messages are not widely accessible among lower socio-economic groups, especially among illiterates and elderly. Individuals were more likely to accede to receiving voice calls for medication reminders in our study. Higher rates of treatment success of TB patients with mHealth voice call reminder system shows the efficiency of the system. Large scale studies are needed to assess the applicability in a diverse setting.

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Conflict of interest The authors declare that they have no conflict of interest.

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