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Sociotechnical Evaluation of the Safety and Effectiveness of Point-of-Care Mobile Computing Devices: A Case Study Conducted in India

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Abstract

The potential for health information technology (IT) to enhance quality of care is limited by unanticipated problems following adoption of new systems and technologies. Proactive assessment of system vulnerabilities can help improve existing systems and ease implementation of new innovations. We applied a comprehensive socio-technical model of safe and effective health IT use to the formative evaluation of a novel tablet-based device designed to support primary care practice in rural India. Based on our conceptual model, we developed an assessment guide for the tablet system that was informed by literature review, interviews, and observations of health workers and supervisors. Our assessment revealed and addressed both technical (functionality, content, usability, user interface) and non-technical (workflow, processes and policies etc.) areas of improvement.

Keywords:

User-Computer Interface; Medical Informatics; Patient Safety

Introduction

Several countries are aiming to transform their health care delivery systems with unprecedented economic investments in their health information technology (IT) infrastructures. Concurrently, policy initiatives in India and elsewhere have called for technology implementation to enhance health care quality and access [1]. Despite this momentum and commitment of resources, the pace of health IT adoption initiatives has been slower and more variable than expected [2]. Globally, only a few organizations have achieved successful transformation of their systems [3,4]. Many health care settings are just now beginning their health IT journey while others are using health IT partially and still modifying their work processes to make health IT fit[5,6]. The unexpected slower pace of health IT adoption could partially be explained by challenges to successful health IT implementation within the workflow of a complex health care system. For example, a number of unanticipated problems, including issues with patient safety and provider productivity [7-10] have occurred with IT adoption.

In view of the challenges that clinicians and organizations face with implementation of health IT, we previously developed an 8-dimension, socio-technical model of safe and effective IT use[11]. This model (see Figure 1) offers a comprehensive framework for evaluating the design, development, implementation, use, and monitoring of health IT within complex health care systems and was recently applied to electronic communication [12]. We are also using this model as a guide to proactively identify risks and opportunities to improve new and existing health IT systems [13]. Using this model to guide our current project, we sought to evaluate a mobile computing device in rural Indian healthcare settings.

Background

To reform India's highly fragmented healthcare system, one essential prerequisite is a safe and effective "health IT-enabled clinical work system" [14] that has potential to reach and improve the health of over one billion patients. In October 2010, the Planning Commission of India convened a High-Level Expert Group (HLEG) on Universal Health Coverage (UHC) and charged this Group to develop a framework for providing easily accessible and affordable health care to all Indians.[1] One of HLEG's recommendations was to develop a national health information technology network based on uniform standards to ensure inter-operability between all healthcare stakeholders. More than two-thirds of the population in India lives in rural areas where health care access is limited, technology penetration is low and physicians are scarce. Nevertheless, one possible method of outreach is through front-line non-physician health care workers who are technology-enabled and use mobile devices to collect/interpret basic clinical data. Globally, informaticians, and clinicians have always anticipated a small, inexpensive portable device that is capable

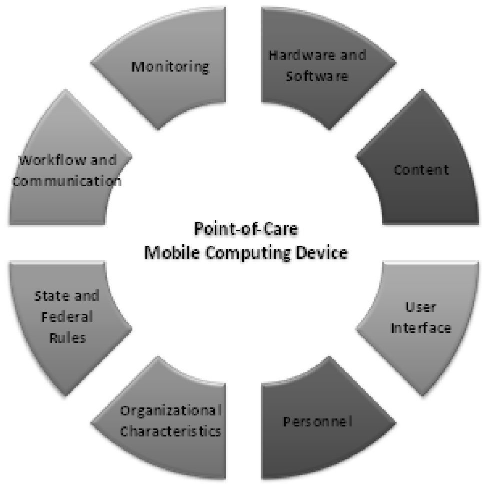

Figure 1 - 8-dimension socio-technical model used to identify and categorize the items in the guide

of collecting, interpreting, storing, and transmitting patient data from the point-of-care (POC) for clinical and administrative functions. The widespread availability of tablet computers with Bluetooth and 3G/4G networking capabilities has brought such tools within closer reach.

With this vision, the Public Health Foundation of India, Division of Health Technologies, developed the "Swasthya Slate," [15] a state-of-the-art Android-based tablet computer that is designed to collect and process administrative, demographic, and physiologic data relevant to all aspects of primary care, including maternal and child care [16]. The Swasthya Slate system was designed primarily to empower frontline health workers to deliver high quality care. This system provides a seamless interface to the electronic medical record, which, when combined with cloud computing technologies, can ***automate data reporting*** to central authorities, reducing the burden of secondary data entry. Additionally, using global positioning satellites (GPS) and images, it is possible to ***validate and authenticate care delivery***. For example, a supervisor who oversees 5-6 providers at different primary health centers can review the GPS locations at which visit data were entered and review pictures for authentication.

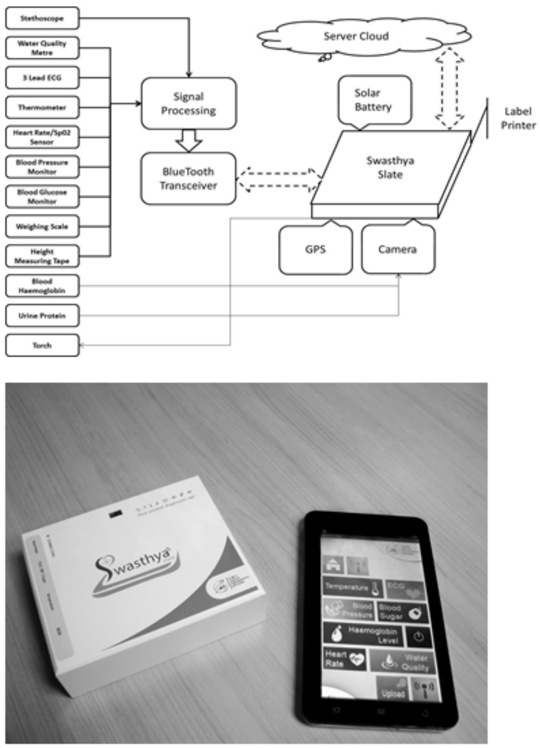

Figure 2 - Swasthya Slate Hardware Block Diagram and system (see www.swasthyaslate.org)

Swasthya Slate Functionality

In addition to supporting manually entered information, Swasthya Slate enables digitization of test data and ***point-of-care-diagnostics.*** For example, Bluetooth-enabled blood pressure monitors and blood sugar monitors can transmit data directly to the device [17]. The tablet can also image and analyze reactive test strips to diagnose, for instance, high levels of blood glucose and anemia [18].

The system further facilitates the provision of high-quality healthcare by including ***clinical decision support (CDS) systems*** as part of the tablet. CDS systems use artificial intelligence algorithms or basic logical flowcharts that encode guidelines from governmental health agencies to provide healthcare workers with on-the-spot help in delivering care. These systems can also provide ***logistical support*** to the healthcare workers, for example, by enabling them to easily access daily plans, plot their care delivery routes, get reminders, and access emergency services and learn about resources at nearest care facilities to properly guide the patient.

The peripherals used with the Swasthya Slate are equivalent to those used in standard practice in the Indian public health system and include: 1. stethoscope; 2. water quality meter; 3. 3-lead ECG; 4. digital thermometer; 5. heart rate and $Sp0_2$ sensor (for oxygen saturation); 6. blood pressure monitor; 7. hemoglobin color scale; 8. urinalysis test strips; 9. blood glucose monitor; 10. digital weight scale; 11. flashlight; and 12. measuring tape. Thus, the device could enable a non-physician health care worker to collect many of the basic parameters for a medical assessment of common conditions.

To ensure that the robust functionality of this system fits within the social context of India's health system, we developed a sociotechnical assessment tool for its formative evaluation. Our study objective was to apply our sociotechnical model to develop a comprehensive evaluation strategy for the Swasthya Slate and use this evaluation to address both technical and non-technical areas of improvement during the all-important design, development, and usability testing phases of user-centered design. Our ultimate goal was to ensure the device's safe and effective, large-scale use in rural India.

Materials and Methods

Development of a "Sociotechnical" Assessment Guide

First, we developed an itemized assessment guide to identify potential risks or challenges to safe and effective use of the tablet under realistic clinical practice conditions. Item content was derived from several sources: 1. an extensive review of the literature, 2. interviews with experts in clinical care and health IT implementation, 3. surveys of challenges and opportunities to user acceptance of these types of devices, and 4. field observations of primary care workers with various levels of clinical and computing expertise working with these and similar devices.

1. Literature reviews: We reviewed the literature relevant to each of the eight dimensions of our model to identify items that were applicable to safe and effective use of IT, particularly those which were directly applicable to tablet devices.

2. Interviews: We conducted interviews in both the US and India with experts in public health, medicine, and health IT. We focused to a large degree on frontline health workers, who bear the burden of delivering most clinical care in rural India. Interviews with health workers were important to identify potential improvements to the system in terms of usability (user interface), training requirements, compliance with local, regional and national laws and reporting requirements for specific clinical conditions (e.g. pregnancy), workflow and communication, and supervision and monitoring by physicians. We interviewed administrators to further understand legal, monitoring, and workflow issues which could pose as barriers and facilitators to implementation of such a device. Finally, we interviewed physicians regarding issues of clinical content (knowledge, rules and logic embedded into the device) and whether the communication and reporting channels under development and supervision mechanisms of front-line personnel collecting data would be aligned with their expectations.

3. Documenting/observing user acceptance: We administered the IsoMetrics Usability Inventory [19] to frontline healthcare workers to document usability in the following 7 domains: 1. suitability for the task; 2. self-descriptiveness of the system (e.g. functions of the system are self-explanatory); 3. controllability of the system; 4. conformity with user expectations; 5. error tolerance; 6. suitability for individualization; and 7. suitability for learning. We also administered a custom developed questionnaire to evaluate how well the system fulfilled the reporting requirements of selected conditions such as pregnancy.

4. Field observations: Field observations were used to examine the effectiveness of training of trainers and evaluate the durability of the tablet. It also helped us study how environmental factors (e.g., temperature, rain, direct sunlight) affect the usability of the system.

Mobile Computing Device Evaluation Guide

An initial set of evaluation items from each of the eight sociotechnical dimensions was created from the results of the literature search and interviews. The items were then refined based on additional expert opinion, user acceptance testing, and observations. The following items (under each dimension) were determined to be most relevant to the safety and effectiveness of the device (and potentially other similar devices) and were included in the final draft of the guide.

Hardware and software

Reliable hardware and software is essential for any mobile POC mobile device. The following items were found to be most relevant for safety and effectiveness of POC devices.

- The tablet will run the required software applications for at least 4 hours on battery power.
- The device has a protective case to reduce breakage or damage and prevent entry of dust into the system.
- The device is water-resistant; the screen can be cleaned with liquid disinfectant.
- The device has up-to-date virus protection software.
- The device's hardware interfaces have been tested with all external, ancillary devices (i.e., thermometer, water quality gauge, blood glucose monitor, etc.).
- The device is password protected.
- The device's hard drive is encrypted and can be erased by remote command in the event the device is lost or stolen.
- The device can connect to the Internet through a variety of means (e.g., either a wireless LAN or 3G/4G connection) and has a way to store data locally and then upload it at a later time in the event that Internet connections are not available.

Clinical content

Up-to-date clinical content (i.e., data, information, and knowledge) is required to encode the user entered information as well as provide clinicians with reference information at the point of care.

- Required clinical content has been loaded on the device.
- Clinical content can be updated remotely.
- Clinical guidelines and CDS content are up to date.
- Clinical content is available in one of the native languages of the user. (An example of the system in Hindi appears in Figure 3 below.)

Human-computer user interface

The user interface enables users to interact with the data, information, and knowledge required to understand the patient's physiologic state and document their findings and intended actions.

- Users can see the information on the screen in direct sunlight.
- The fonts are large enough for middle-aged and older health care workers to read without difficulty.
- The touch screen is properly registered (i.e., when the user touches an item on the screen, the device recognizes that object has been touched).
- The device cannot be used with gloves on.
- The required software applications can be used with a finger or a stylus.

Figure 3 - Health maintenance reminders for maternal and child health are installed and working

- The application allows both freehand and keyboard-based data entry.
- The device and key software applications provide multi-language support.
- Using the applications on the device requires limited text interface with audio support.
- The applications are easy to learn and text-based, audio, or video support is readily available.
- The software does not create tasks that are superfluous to the user's normal daily routine.
- The software adds value to the user's daily life.
- The software automatically produces reports and letters of discharge and referrals to minimize administrative work.

Personnel

People are required to design, develop, implement, use, and manage all aspects of the IT-enabled healthcare system.

- All health care workers have had at least 2 hours of training on how to use the tablet in their native language.
- Centralized IT support personnel are accessible via cellphone or Voice-over-IP to health care workers.
- Health care workers are able to answer healthcare questions that are frequently asked by patients in rural areas who are unfamiliar with similar types of data collection instruments.

Workflow and communication

Modern healthcare requires extensive collaboration between disparate members of the healthcare team. Meeting the needs of various healthcare workers continues to be a challenge.

- Workflow observations are conducted and recorded prior to local implementation of the tablet.
- Indications for referral are clearly specified and sent to the referring provider either via paper, fax, email, etc. [20].

Organizational policy, procedure, culture, & environment

In organizations that are involved with implementing and using the mobile device, policies and procedures and the culture and physical environment should empower workers and not burden them with constraints. Items that address this include:

- Standard operating procedure documents specify the scope and indications for use of the tablet.
- Procedures for maintenance and technical problem-solving are clearly delineated.

External rules and regulations

Local, regional and federal rules and regulations (i.e. those that originate outside of the organization) also have a significant impact on the safe and efficient functioning of the organization. This was addressed by the following items:

- Laws and provisions created by the government are adequate to protect the use of the tablet for its intended purposes and to prevent fraud and theft.
- Regulations create mechanisms to strictly reinforce the delivery of expedited clinical care and referrals for patients who are found to need urgent medical attention.

Measurement and monitoring

The key to improving the safety and efficiency of the IT-enabled healthcare system is to measure and monitor important details. This was addressed by the following items:

- The demographics interface is able to validate patient identity through a legitimate source such as user identification (UID), ration card, etc.
- Calibration of all physiologic or chemical sensors is performed every 3 months.
- 5% of data collected are validated for accuracy (e.g., 5% of automated EKG interpretations should be verified by a clinician).
- Outcome assessments are conducted using random samples of 5% of patients should be conducted to ensure that the tablet is serving its intended purpose (e.g., a positive diabetes screening should consistently prompt a referral or treatment).

Results

Use of the guide for formative evaluation of the Swasthya Slate system resulted in several product enhancements and considerations of how the device fit within the larger social context of the health system. For instance, the tablet case was redesigned in response to feedback generated from these items (see Figure 4). The initial design emphasized the technology focus, but the final design aims to provide a more robust look with better protection against environmental factors.

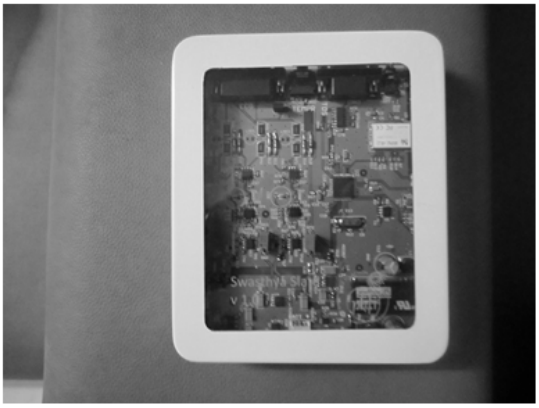

Figure 4 - Earlier box design

Software reliability was significantly improved as well. The user interface was also improved by focusing on both affect (i.e., making it look more "sophisticated") and functionality. We utilized Microsoft's new "metro interface" design language emphasizing typography and large text on large buttons to catch the user's eye. This allowed users with limited education to use the tablet easily. We developed the reporting system to be in line with the reporting requirements of the government. For example, one of the requirements was that health workers complete a registry with a list of mothers. We interfaced the Slate with a label printer to automatically generate stickers for applicable cases, which the health worker could in turn simply stick on the register to save time and reduce omission or transcription errors. Following the ethnographic observations, the workflow was modified so that the upfront diagnostics were performed before the checkup which fit the user's workflow better as well as minimizing the time the kit needed to be turned on, maximizing the battery life. To comply with legal directives (external rules and regulations), our decision support system (content) was designed to limit interventions by frontline health workers to those that are non-pharmacological, i.e. so they didn't receive specific CDS interventions about prescribing medications beyond their expertise. We also identified skill sets specific to the types of personnel that would be using the device.

Quantitative data were also collected and analyzed with a specific focus on improving the usability of the tablet. To date, we have surveyed 100 community health workers, 50 nurse midwives, and 50 equivalent health workers in the private sector for our usability study. A composite scoring system was developed for each of the 7 usability domains. The mean usability rating across all of the domains was 8.9/10 (SD = 0.6). The lowest domain score was for user customization (mean 7.8/10, SD 1.1), although this was not unexpected because, by design, customization was limited to avoid potential interference with best practices. The highest domain score was suitability for the task (mean 9.2/10, SD 0.6).

Average learning time to first correct execution of the software was 10 minutes, and by 45 minutes users were able to use the apps with less than 1% "slip" errors (e.g., accidental pressing of buttons, etc.). Our training, which lasts 1 day, has been very successful in ensuring the full use of the system.

As the device is implemented more widely, we will continue to conduct additional iterative evaluation to inform device use as well as add additional items to the guide if needed for its subsequent use in other types of settings.

Discussion

We developed a "sociotechnical" assessment guide for safe and effective use of a mobile computing health care device in India. A sociotechnical assessment can be used to help prevent unintended consequences of using mobile IT and for helping proactively detect, mitigate, and ameliorate unintended consequences and potential failures associated with the use of such devices. Our evaluation was grounded in our previously used multifaceted socio-technical model of health IT implementation and use. Based upon the work we conducted, others planning to collect and interpret data at the point of care in rural settings could consider similar formative evaluation methods to ensure successful design, development, implementation and use of these devices. Health information technology is changing the way we deliver health care and can be used in reforming health care and improving health care access especially in developing countries. In India, there is a large deficit of physicians in rural settings, and thus point of care mobile devices that can be used by trained non-physician health care workers to collect data can assist with providing primary health care needs. However, there might be little benefit of data collection and point of care devices unless the data is used successfully to improve clinical care in terms of improving quality, safety and efficiency. Thus, these devices must be integrated within the social context of the health system where they are implemented and used. We envision that stakeholders planning to use such devices would assemble multidisciplinary assessment teams to conduct such a comprehensive evaluation which will ensure that the device fits within the broader context of health care delivery and improvement.

Our study limitations include absence of outcome data on how Swasthya Slate impacts care processes or outcomes of clinical conditions. Nevertheless, the Slate is being pilot tested in several rural settings in India and data on impact will be available in the future. In addition, our evaluation might only be generalizable to certain types of rural healthcare settings.

Conclusion

To better leverage health IT, a sociotechnical approach is necessary to avoid unexpected challenges and failures [21]. This includes both technical and non-technical formative and summative evaluations of health IT devices to ensure that they fit within the social context. Our evaluation strategy facilitated a comprehensive sociotechnical assessment and improvement of a promising point of care computing device in India. Our assessment revealed and addressed both technical (functionality, content, usability, user interface) and non-technical (workflow, processes and policies etc.) areas of improvement.

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