A Mobile Point-of-Care Diagnostic System for Low-Resource Settings

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Abstract
Disease detection and epidemiology in developing countries are hampered by a lack of convenient, affordable and usable diagnostic technologies. The goal of this research project is to design, deploy and evaluate a mobile system that uses computer vision algorithms running on a mobile device to capture, interpret and transmit point-of-care diagnostic tests for infectious diseases. Our system will provide health workers around the world with access to rapid and accurate diagnoses for their patients and public health officials with real-time, aggregated data and statistics regarding the numbers and results of tests administered via a centralized database. Our system is currently being evaluated with sixty health workers at five clinical research sites in Zimbabwe. Our findings and insights could inform the design of future mobile health systems and help ministries of health and other stakeholders to assess the viability of deploying mobile systems in similar environments.

Author Keywords
HCI4D; ICTD; Point-of-care diagnostics; smartphone; vision; image processing; mobile phone; healthcare.

ACM Classification Keywords
H.5.0 [Information interfaces and presentation (e.g., HCI)]: General.

Figure 1: A rapid diagnostic test (RDT) for malaria with a valid control line and a single valid test line that indicates a positive diagnosis.

Introduction

Developing technologies to improve the health of people in the poorest regions of the world remains one of today's greatest challenges. Providing accurate and timely disease diagnosis to patients living in these regions could facilitate the control of many infectious diseases. To address this challenge, low-cost, easy-to-use, point-of-care rapid diagnostic tests (RDTs) (see Figure 1) have been developed and are now commercially available throughout the world. Many developing countries, such as Zimbabwe, now routinely use RDTs to diagnose a variety of important infectious diseases, including HIV, malaria and syphilis.

However, although the potential benefits of RDT technologies are immense, little attention has been paid to the challenges faced by the health workers responsible for administering the tests and recording their results. As shown in Figure 1, an RDT result is usually indicted by the presence or absence of a series of colored lines on the test that are interpreted visually by the health worker. However, visual interpretation is subjective and health workers often lack confidence in their ability to read test results correctly. In addition, the numbers and positions of the test lines vary with different diseases and RDT brands, which increases the likelihood of human error. Many health workers in low-resource settings also have poor eyesight that could impair their ability to interpret the test. Furthermore, manually updating patients' medical records with the test results can be complex and time-consuming. Finally, in many countries, such as Zimbabwe, there is currently no mechanism for reporting the types and results of RDTs administered. Supplying governments and epidemiologists with timely and accurate statistics regarding the diseases detected could improve supply chain management, health-system evaluation, and global disease surveillance and control efforts.

To address these challenges, we are designing, deploying and evaluating a smartphone-based point-of-care diagnostic system. Users capture an image of an RDT using the device's built-in camera and computer vision algorithms running on the device automatically process the image and deliver the diagnosis. Data regarding the test is then automatically transmitted to a centralized database if and when connectivity is available, where it can be viewed, aggregated and analyzed by stakeholders.

From a patient management perspective, our system can provide an objective interpretation of diagnostic results to first make an accurate diagnosis and then help even minimally trained health workers administer appropriate treatment. From a public health perspective, by dramatically shortening the reporting cycle compared with paper, public health officials will be able to gather, assess, and respond to real-time disease occurrence for improved disease control. Results can be monitored to detect outbreaks or identify new and emerging threats. Changing burdens of specific diseases can be used to support evidence-based decision making. Accurate supply consumption data from widely dispersed clinics will better inform supply-chain managers, and aggregated data can be used to enhance transparency and improve monitoring and evaluation at all levels of the healthcare system.

This paper describes our mobile system and presents the design of a field study that we are conducting to evaluate the system with sixty health workers at five hospitals and clinics in Zimbabwe. Our goal is to provide findings to help ministries of health and other stakeholders assess the viability of deploying mobile systems to assist health workers in the field. In addition, our insights will guide future HCI researchers working to deploy mobile health systems in similar environments.

Related Work

A range of prior research demonstrates the potential for mobile technologies to strengthen healthcare systems in developing countries. Categories include informing people about health issues [2], improving adherence to medical protocols [5], providing remote medical consultation [8], and enabling data collection and retrieval [6]. There are also several projects that focus on interpreting diagnostic tests. Mudanyali et. al [7] developed a smartphone-based RDT reader that differs from our system in a number of ways. Each test requires a custom built holder that clips the test cartridge tightly to the platform. In contrast, our system uses a plastic stand (see Figure 2) capable of fitting many different RDT shapes and sizes. Mudanyali's system also requires an additional lens, three LED arrays, and two AAA batteries to control the environment in which images are captured. Our system does not require any of this additional hardware, which is advantageous since requiring additional parts increases the likelihood that a part will get lost or broken and lower the reliability of the system or render it non-functional.

Figure 2: A plastic stand holds the mobile device in a convenient position above the RDT.

There are also several commercial RDT reader systems that have recently been developed. For example, Skannex [9] marks each test with an identifying barcode that makes it easy to identify the type of RDT being captured but precludes reading RDTs that do not have barcodes. The FIO Corporation [1] markets an Android-based RDT reader but requires users to purchase the company's proprietary devices and cloud-based services. By contrast, our system is open-source software that allows users to add their own tests to the system and use a variety of Android devices or backend storage options. Finally, in previous work we built a mobile application to automatically quantify time-sensitive diagnostic data on a smartphone [4]. We targeted an experimental diagnostic test and showed that a smartphone was capable of analyzing time-sensitive data and quantifying the result. Although we plan to incorporate complex tests like this in the future, they are not yet ready to be field-tested or marketed commercially. Therefore, this project targets simple, commercially available RDTs, and we have designed the system to be able to handle more complex tests as they become available. Our goal is to have a stable, usable and tested platform already in place to which new and sophisticated tests can easily be added.

Design and Implementation

The goal of this research project is to design, deploy and evaluate a mobile smartphone system that captures, interprets and transmits point-of-care diagnostic test results for important infectious diseases. Our approach has been enabled by the widespread adoption of two technologies over the last decade. First, low-cost, easy-to-use, point-of-care rapid diagnostic tests (RDTs) are now commercially available throughout the world. An RDT is typically a small plastic cartridge that contains all of the elements necessary for processing a biological sample, such as a blood sample, at the point of care. Second, the rapid growth of global cellphone networks and the availability of reasonably priced smartphones have enabled real-time reporting of data from remote locations. Smartphones are portable, battery-powered and can handle intermittent power. In addition, users with little computer experience find smartphones easier to use than desktops because of their intuitive touchscreen interfaces.

Leveraging these technology trends we designed an Android-based mobile system that uses computer vision algorithms running on the device to automatically interpret a variety of commercially available RDTs. To add a new RDT to the system, a user creates a simple text file that provides several parameters and the size and location of regions of interest on the RDT. After uploading this file to the device, users can capture images of RDTs using the device's built-in camera. Captured images are processed on the device and the results are displayed on the screen for inspection and validation. In addition to interpreting RDTs, users can also collect any relevant patient data. The data (including an image of the captured test) is stored on the device and transmitted to a central database if and when connectivity is available. The data from all mobile users is then collected, aggregated, and made available through a secure server.

Our initial system implementation and details of our image processing algorithms have been described in a prior research paper [3]. However, we did not evaluate the system in the field or explore the challenges associated with integrating the system into the health workers' clinical workflow. Thus, the study described below builds on our initial technical work to provide a detailed field evaluation of the system under real clinical conditions experienced in low-resource settings.

Study Design

We are conducting a two-month field evaluation at five clinical sites across Zimbabwe. This study is the first time that the system has been evaluated with health workers in low-resource settings. We chose to target the capture and analysis of diagnostic tests for malaria since they are routinely used in Zimbabwe. Our field evaluation focuses on three important research questions: (1) the impact of the mobile system on health workers patient care routines, (2) the impact of poor infrastructure on system usage and data collection, and (3) the equivalency between human and software interpretation of RDT results. Our findings could inform the design of other mobile health systems and help to support ministries of health and other stakeholders working to deploy mobile health systems in similar environments.

Research Sites and Participants

Working with the Ministry of Health and Child Care in Zimbabwe we identified five deployment sites: one provincial hospital, two district hospitals, and two rural health centers. We deliberately targeted health facilities that ranged in size from large hospitals to small rural clinics to explore how system workflow and usage might vary at different levels of the healthcare hierarchy. We recruited a total of 60 health workers (47 female) across the five research sites ranging in age from 24 to 64 years ($M = 35$). The majority of health workers owned basic mobile phones, but 31 had never used a touchscreen device before and another 15 had less than six months experience using touchscreen devices.

Apparatus

Each site was issued with Samsung XCover 2 Android devices that were chosen because they were readily available and moderately priced in Zimbabwe. The XCover 2 has a 1 GHz dual core processor, a 5 mega-pixel built-in camera, a 4 inch capitative touchscreen and a plastic cover to protect the device from dust and moisture damage. The provincial and district hospitals received four devices each: one for the maternal and child health clinic, the outpatient clinic, the maternity clinic and the opportunistic infections clinic. Since rural health centers typically employ fewer health workers than hospitals, each health center was issued with one or two devices to cover their patient load. In total, we deployed 15 devices across the five sites. Each device was accompanied by a simple plastic stand (see Figure 2) designed to provide stability and a fixed focal length for the phone's camera.

Figure 3: A training session with health workers at a district hospital.

Figure 4: A health worker using the system at a rural clinic.

Procedure
Before starting the study we visited Zimbabwe to assess the study sites and understand the health workers' current routines. During this visit, we identified the RDTs that the sites currently use. Then a clinical laboratory expert at Global Solutions for Infectious Diseases, San Francisco, USA, created and tested system files for three different malaria RDTs. Encouragingly, adding new RDTs to the system was relatively quick, taking approximately 30 minutes per test. Rigorously testing the system parameters for each test took longer, typically several days, although the process was made simpler by creating a version of the system that could batch process a variety of different test images and parameters at once. This allowed the laboratory user to quickly narrow in on the optimal parameters for each RDT.

After adding the RDTs to the system, we conducted participant training sessions at each research site (see Figure 3). Each session lasted approximately 60 minutes and began by demonstrating the system to a group of participants. Participants were then separated into pairs and given time to read user manuals, ask questions and practice capturing and transmitting RDTs. The amount of practice that participants required varied depending on their familiarly with technology, although all participants were able to master the system within the training session. During each training session, we explained that this was the first time the system was being tested and that all patient care should continue to be based on their human-interpreted visual RDT diagnosis and not on the software's diagnosis. Comparing the visual and software diagnoses is one of our primary study goals.

After the training sessions, participants were asked to integrate the system into their patient care routine and to capture and transmit data every time that they performed an RDT (see Figure 4). At the larger hospitals, we explained that each of the main clinical departments would receive one device and that participants working in these departments would share the device accordingly. We conducted follow-up visits to each site one week and six weeks after the training sessions to assess how easily participants had been able to integrate the technology into their clinical workflow. We observed participants using the system and collected data regarding participants' opinions and experiences.

Results and Discussion

We are currently in the process of finalizing data collection and starting analysis. Thus, we are not yet able to draw any final conclusions regarding the overall study goals. Instead, we describe some interesting preliminary findings.

Participants captured and reported a total of 1828 malaria tests during the two-month study period. Health workers at all sites used the system consistently for the duration of the study to collect extensive amounts of test data after only sixty minutes of training. For the first time, the Ministry of Health in Zimbabwe has reliable statistics regarding the numbers and results of RDTs from each location. This data could transform resupply processes, inform supervisors of overworked clinics, and focus disease control efforts to where they are most needed.

In addition, in the first week of the study we validated the potential for the system to be useful for quality control. We noticed several transmitted images with dark red backgrounds (see Figure 5). This may result from health workers using too much blood on the test or reading the test result too early. The extra color could easily obscure a weak positive result and the test should be discarded.

Figure 5: An image of an RDT that contains too much red background to yield a valid diagnosis.

Instead, health workers were incorrectly reporting these tests as valid, usually negative, diagnoses. We alerted the relevant hospital supervisor who immediately reviewed the RDT manufacturer's guidelines with the health workers.

There are a variety of different usage scenarios in which our system could prove useful. For example, if health workers have been well trained, the system could simply be used to focus quality control efforts on RDTs in which the human diagnosis differs from the software diagnosis. Alternatively, in situations where health workers may be less experienced, the system could provide a second opinion and thereby increase a health worker's confidence in the diagnosis. Finally, in situations in which health workers have not received the necessary training, the system could perform the diagnosis and tell the health worker the result. It will be interesting to explore these different usage scenarios in the coming months.

Future Work and Conclusion

Our goal is to design and evaluate a mobile system that captures, interprets and transmits diagnostic tests for infectious diseases. Our work highlights several important challenges that arise when health workers in low-resource settings integrate a mobile system into their clinical workflow. Our findings could help ministries of health and other stakeholders working to deploy mobile health systems in similar environments. In the future, we plan to conduct a larger study across an entire province or country to assess the scalability and sustainability of the system. In addition, we want to incorporate a variety of more sophisticated diagnostic tests, such as tests that require quantification or time-sensitive analysis. Finally, we want to integrate the system with other mobile data collection and sensor-based systems to create a generalizable mobile medical platform for users in low-resource settings.

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