Developing, Implementing, and Evaluating Tuberculosis Laboratory Information Systems for Resource-Poor Settings

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Submitted to the Harvard-MIT Division of Health Sciences and Technology
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy in Medical Engineering
at the
MASSACHUSETTS INSTITUTE OF TECHNOLOGY
December 2008

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Abstract

Multi-drug resistant tuberculosis (MDR-TB) patients in resource-poor settings experience large delays in starting appropriate drug regimens and are often not monitored appropriately due to an overburdened health care system, communication delays, and missing or error-prone data. Medical information systems can be used to alleviate these problems by increasing the timeliness and quality of laboratory information available.

The research reported in this thesis developed, implemented, and evaluated two such systems in the urban, resource-poor setting of Lima, Peru in institutions with and without internet.

The first part addresses the electronic collection of tuberculosis (TB) laboratory information from multiple institutions without internet. A handheld computer-based system was developed and implemented. A cluster randomized controlled trial and before-and-after comparison showed that this system had a significant effect in reducing processing times from 23 to 8 days, the proportion of cultures with delays >90 days from 9.2% to 0.1%, the number of errors by 57.1%, and the work-hours necessary to process results by 60%. A cost and timeline framework was developed to allow other organizations in resource-poor settings to implement this technology.

The second part addresses a web-based system, e-Chasqui, developed to provide electronic communication and reporting of TB laboratory information to health care personnel within institutions with internet. A cluster randomized controlled trial showed that access to e-Chasqui resulted in significantly less time to receipt of test results, a 56% reduction in tests taking over 60 days to arrive and a 98% reduction of results that never arrived, as well as a significantly faster time to culture conversion among patients in intervention versus control centers.

These two parts describe verified medical informatics tools and an implementation methodology for settings both with and without internet connectivity.

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Acknowledgements

Me gustaria dedicar este trabajo a todos los pacientes peruanos con TB o TB-MDR que aun no conociendolos son la razon de mis esfuerzos.

I wanted to thank my doctoral committee that has been so amazing in supporting me through this process. Hamish Fraser, my initial inspiration for this work, thank you for always encouraging me to look further and for always promoting my work. Sonya Shin, I truly believe that this work would be a shadow of what it is now if it hadn't been for your help. I have learned how to work from watching you. Lucila Ohno-Machado and Peter Szolovits, thank you for keeping this work on track and for all of the thoughtful ideas and suggestions throughout the many hours we spent together.

Le querio mandar un gran agradecimiento a todos los usuarios de los sistemas que implementamos incluyendo el equipo de BK (Mayra Napa, Yrene Torres, Briam Chavez, y Veronica Albitres) y el personal de los centros de salud que usan e-Chasqui. También a Roger Huamani, Betty Palma, Pablo Rodriguez, y Wilmer Gomez por mantener los sistemas, hablar con los usuarios, y lidiar con tantas cosas. Al equipo de Metodos Rapidos por recolectar, editar, e ingresar todos los datos que he usado aquí y por todo el apoyo que me han dado.

Mis co-investigadores que han impulsado este trabajo: Martin Yagui, Gloria Yale, Carmen Suarez, Luis Asencios, Peter Cegielski, y todo el personal de los laboratorios de Lima Ciudad y Lima Este. Finalmente, Socios En Salud por haberme dado la estructura para poder trabajar en Perú y no haberme echado por todos los dolores de cabeza que les cause.

All the folks at Partners In Health who through advice or just a smile showed me how wonderful it is to work there. The EMR team: Mike and Darius, without whom I would not have had any systems to evaluate. Claire, for all those edits (I hope this is better than chippers). Ellen for being my second mom, and the rest of the team for making it so great to work there.

My statistical and SAS gurus, Jihoon Kim and Sid Atwood, without whom all of this would just be unintellible spreadsheets.

My family and friends who saw me through this entire process. And I'm going to apologize up front and blame my bad memory if I forget something, but that's just the story of my life.

Rocio y Francesca por todas las veces que me sacaron del trabajo justo cuando iba a explotar y me batieron hasta que me tuve que reir.

The Farrells for being my second family y por encarnar el estilo de vida que yo solo había podido soñar.

The SES volunteers for all of the great Limenian moments lived together (Melissa, Aldo, Holly, Chloe, Carlos, Brian, Kelsey, Collin, and others).

The River House crew for being my home in Boston and making it a true home.

The HST gang (Aaron, Roxanna, Jenny, Melissa, Phil, Blanca) who have seen me through all 8 years of this process.

Chris and Kathryn (and Adam) for being an amazing example of how passionate someone should be for their work, yet balance that with friends and family.

Jeannette, for showing me how to share life with someone again.
Cat and Charmaine, this is definitely worth another round of sangria.

My faith group for challenging me and supporting me all at the same time over sweets and wine.

Cata, por todas las uevas vividas juntos y a muchas otras aventuras entre gringolandia y chilito.

Paula, Esteban, Kenzo, Marigen, Andrés, y Mariela, por ser mi comunidad chilena aca en Boston.

Mark, for all the free advice.

Eduardo, compañero de frustraciones academicas y crisis de la vida. A pesar de nunca llamarte devuelta, tu sigues siendo mi amigo.

BB, Martin and Tomas, nunca lo he dicho, pero los quiero.

Mama y Papa, gracias por el amor nunca pronunciado pero siempre presente. Solamente ahora empiezo a reconocer mi suerte en haberlos tenidos como padres. Ustedes mas que cualquier otra cosa me han formado como soy.

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Table of Contents

List of Figures

List of Tables

1 Introduction

1.1 Motivation

Tuberculosis (TB) is a chronic infectious disease that kills over 2 million people per year in the developing world. According to the World Health Organization (WHO), tuberculosis is second only to AIDS as the most deadly infectious disease in the world. Multidrug-resistant tuberculosis (MDR-TB) is now recognized as one of the most significant emerging infectious diseases. MDR-TB has been documented in more than 100 countries throughout the world.[1] Transmission "hot spots" exist on several continents, and the problem of MDR-TB continues to grow.[2] In developed countries, programs to treat MDR have demonstrated cure rates of up to 90%.[3-6] Only recently have programs implemented in middle-income and poor countries also shown promising results.[7 8]

Multidrug-resistant tuberculosis in Lima, Peru

Incidence of TB in Peru is 162 per 100,000, second highest behind Bolivia.[9] In the densely populated periphery of metropolitan Lima, where half of all national cases are detected, the risk of infection with *M. tuberculosis* is estimated to be among the highest levels documented recently in any population.[10-12] Tuberculosis remains the leading cause of death among individuals between 15-59 years of age.[13]

Rates of MDR-TB are also significant, with a national prevalence of 5.3% among patients never before treated for TB (primary MDR-TB) and 23% among previously treated patients.[14] While directly observed standardized short-course chemotherapy (DOTS) has been successfully implemented in Peru since a reform in the early 1990's, the prevalence of MDR-TB continues to rise; thus, on-going transmission of these strains makes DOTS alone an insufficient strategy to control this epidemic.

The treatment of MDR-TB requires the use of second line anti-tuberculosis drugs, which are more costly, more toxic, and less effective than first-line drugs. For these reasons, the clinical management of these patients is complex and individual. The identification of patients with risk factors for drug resistance; timely diagnosis through drug susceptibility testing; individual

regimens based on test results; and close clinical monitoring all require specialized laboratory and clinical resources that are not easily implemented in resource-poor settings.

The motivation of this thesis is to improve patient care and reduce the transmission of drug sensitive and resistant TB in resource poor settings with a high burden of disease by providing a methodology for creating and implementing laboratory information systems, and performing randomized controlled trials to measure their impact under program conditions.

1.2 Problem Identification

As TB programs continue to address the growing burden of drug-sensitive and drug-resistant TB, there is increasing need for greater laboratory capacity and better information systems to manage patient data that can be employed in resource-poor settings. Drug sensitivity tests (DST) measure the medications to which the patient's TB is resistant. This test is fundamental in determining the appropriate drug regimen to be given to the patient. Bacteriology tests, smear and culture, comprise some of the most important clinical measures of treatment response. Each MDR-TB patient on treatment should leave a monthly sputum sample at his or her local health center for smear and culture tests.

Timeliness and accuracy of this data are essential to starting a patient on an appropriate drug regimen and monitoring them throughout their 2 year treatment period. An observational study in Peru has shown that despite the large increase in treatment capacity and decentralization of laboratory capacity, patients still experience risky delays of several months in starting the correct treatment and getting monitored appropriately.[15] For example, a Peruvian high school student with MDR-TB was not appropriately treated because doctors assumed she had drug-sensitive TB, a sample sent for DST was lost, and when she was started on an appropriate treatment, drug supply issues kept her from receiving the medications. Due to this delay of over 2 years, she now has permanent bilateral lung damage.[16] Our organization has seen many patients in this situation where the lack of information management has led to worse patient outcomes. Prompt treatment with individualized drug regimens based on DST improves patient outcomes[17] and reduces the risk of amplification of drug resistance and ongoing transmission[18 19].

Information systems could be used to alleviate both of these major problems. Appropriately designed web-based and off-line systems could virtually eliminate the time to communicate

results between different institutions and thus eliminate a major source of treatment start delays. Further, analysis and data quality tools within the system could radically improve quality control, eliminating lost results and delays in starting treatment. Decreasing the time to treatment and ensuring an appropriate drug regimen should lead to improved patient outcomes and reduce the transmission of this deadly disease.[20] As Raviglione and Smith comment in a recent editorial, "information is essential to build a response [to drug-resistant diseases], and only computerized information systems allow sufficiently rapid exchange of information within and between countries[21]."

A key area for research in medical information systems is evaluating the usability and impact of such systems. This is particularly important in assessing the impact on quality of care and patient outcomes. This thesis proposes to perform such an evaluation of systems that have the capacity to improve the quality of care provided to patients by increasing the timeliness and quality of information available. Few studies have been able to convincingly demonstrate such benefits in the US, and virtually none in resource-poor settings.[22-24]

1.3 Executive Summary

This thesis describes the design, development and deployment of two systems for TB laboratories. It then reports results of a formal evaluation of their effects in the target environment of MDR-TB care in Lima, Peru. Here I summarize the findings of the research chapters of the thesis.

Part 1: Improve the method of collecting laboratory data from a distributed group of non-networked TB laboratories by the use of a PDA-based system

1.3.1 Chapter 3 – Development and implementation of PDA-based system

This chapter describes the process of development and implementation of a PDA-based electronic data system to collect TB bacteriological results for current MDR-TB patients from a group of laboratories and health centers without internet in a low resource urban setting for clinical and research purposes. This electronic system uses PDAs as the initial point of data entry at the clinical site. The PDAs interface with the existing web-based medical record system (PIH-EMR) over the internet. A new section within the PIH-EMR, created for this project, contains pages to automate the validation of the data, generate the required forms, and transfer

data into the clinical section of the medical record system. This work was published in the Proceedings of the 2006 AMIA Annual Conference.[25]

1.3.2 Chapter 4 – Evaluation of PDA-based system

We performed a cluster randomized controlled trial in 93 health establishments to evaluate the effectiveness of the PDA-based system and compare this new system to the previous paper-based system. The PDA- and paper-based systems were evaluated based on processing times, frequency of errors, and number of work-hours expended by data collectors. Baseline data were collected for 19 months. Districts (n=4) were then randomly assigned to intervention (PDA) or control (paper) groups, and further data were collected for 6 months. Comparisons were made between intervention and control districts and within-districts before and after the introduction of the intervention.

The PDA-based system had a significant effect on processing times ($p<0.001$) and errors ($p=0.005$). The median processing time for cultures and smears was reduced from 23 to 8 days and 25 to 12 days, respectively, in the between-districts comparison. In that comparison, the proportion of cultures with delays >90 days was reduced from 9.2% to 0.1% and the number of errors was decreased by 57.1%. The intervention reduced the work-hours necessary to process results by 70% and was preferred by all users. This work was published in the International Journal of Infectious Diseases in 2008.[26]

1.3.3 Chapter 5 –Cost analysis of PDA-based system

The goal of this study was to assess the collection efficiency of each system and the resources required to develop, implement, and transfer the PDA-based system to a resource-poor setting. I performed a time-motion study of data collectors using the PDA-based or paper systems and a cost analysis of developing, implementing, and transferring the PDA-based system to a local organization and their further expansion of the system.

The study showed that work hours spent collecting and processing results decreased by 60% ($p<0.001$) when using the PDA-based system. Users perceived this decrease to be 70% and had no technical problems they could not fix. The total cost and time to develop and implement the intervention was US$26,092 and 22 weeks. The cost to expand to 9 other districts was $1,125

and to implement collecting patient weights was $4,107. This work was published in the International Journal of Tuberculosis and Lung Disease.[27]

Part 2: Improve clinical care by electronic communication and reporting of TB laboratory results in a resource-poor setting with internet

1.3.4 Chapter 6 – Development and implementation of e-Chasqui, laboratory information system

This chapter describes the web-based laboratory information system "e-Chasqui" that was designed and implemented in Peru to improve the timeliness and quality of laboratory data. It was deployed in the national TB laboratory, two regional laboratories and twelve pilot health centers. Using needs assessment and workflow analysis tools, e-Chasqui was designed to provide for improved patient care, increased quality control, and more efficient laboratory monitoring and reporting.

Since its full implementation in March 2006, 29,944 smear microscopy, 31,797 culture and 7,675 drug susceptibility test results have been entered. Over 99% of these results have been viewed online by the health centers. High user satisfaction and heavy use have led to the expansion of e-Chasqui to additional institutions. In total, e-Chasqui will serve a network of institutions providing medical care for over 3.1 million people. The cost to maintain this system is approximately US$0.53 per sample or 1% of the National Peruvian TB Program's 2006 budget.

This chapter shows that electronic laboratory information systems have a large potential to improve patient care and public health monitoring in resource-poor settings. Some of the challenges faced in these settings, such as lack of trained personnel, limited transportation, and large coverage areas, are obstacles that a well-designed system can overcome. This work was published in BMC Medical Informatics and Decision Making.[127]

1.3.5 Chapter 7 – Evaluation of e-Chasqui in reducing delays

This chapter describes the cluster randomized controlled trial performed to evaluate the effectiveness of e-Chasqui compared to the current paper-based system. The e-Chasqui and paper-based systems were evaluated based on the times to communicate a result, to start or change a patient's treatment, and for that patient to culture convert. The trial was conducted in 78 health establishments in Lima, Peru. Baseline data were collected for 15 months. Health centers

were then randomly assigned to intervention (e-Chasqui) or control (paper) groups, and further data were collected for at least 2 years. Comparisons were made between intervention and control groups, as well as before and after the introduction of the intervention.

This study showed that intervention health centers took significantly less time to receive both DST and culture results. They also had a significantly lower proportion of DSTs that had taken over 60 days to arrive. The time to start or change a treatment was not significantly different between control and intervention health centers, but those patients in intervention health centers did have significantly lower time to culture conversion.

1.3.6 Chapter 8 – Evaluation of e-Chasqui in reducing errors

This chapter describes the cluster randomized controlled trial performed to evaluate the effectiveness of e-Chasqui in reducing the number of communication errors compared to the paper-based system. The trial was conducted in the same 78 health establishments in Peru. However, here baseline data were collected every four months for 12 months before the health center randomization and then for the same months the following year. Comparisons were made between intervention and control districts and within-districts before and after the introduction of the intervention.

It was found that the major sources of errors in the paper results are missing results or charts, accounting for approximately 90% of all errors. When comparing the control and intervention HCs, there was no difference in the error rate for either cultures (21.5 vs. 21.9%, $p=0.07$) or DSTs (18.8 vs. 15.6%, $p=0.26$). However, when taking into account the online viewing of results by the intervention HC personnel, there is a significant decrease in errors in both cultures (1.9 vs. 21.9%, $p<0.001$) and DSTs (1.4 vs. 15.6%, $p<0.001$). A majority of users responded that they were missing at least 10% of results in the paper system (66% for control HCs, 55% for intervention HCs) and approximately the same proportion felt that this diminished the opportunity of treatment given to a patient. This showed that e-Chasqui reduced the number of missing laboratory results at point-of-care healthcare sites via electronic viewing, while the rate of missing results or errors on paper remained unchanged.

2 Background

This chapter provides the background on tuberculosis, the infectious disease targeted by these informatics tools. It describes the electronic medical records (EMR), laboratory system, and data collection systems implemented in developing countries and the evaluations that have been performed on them. It also summarizes the major findings of evaluations of these three types of systems in developed countries. The first section describes EMR implementations in developing countries. The second section provides a systematic review of evaluations performed on EMRs, laboratory information management systems (LIMS), and research or data collection systems that have been implemented in developing countries. It shows that although there is a rising trend in the number of evaluations performed, there are still few scientifically rigorous data on the effectiveness and cost-effectiveness of these systems in developing countries. The third section describes the evaluations of those systems in developed countries. In these settings, evaluations of different methodologies have been performed and have been shown to reduce delays, decrease errors, and positively impact patient care. Finally, the last section describes the Partners In Health EMR (PIH-EMR) that has been used for treating multi-drug resistant tuberculosis (MDR-TB) patients in Peru since 2001. Both the handheld and web-based systems described in this dissertation were built on this platform.

2.1 Tuberculosis

Tuberculosis (TB) is a common infectious disease caused by mycobacteria, the most common of which is *Mycobacterium tuberculosis*. In approximately 80% of cases, TB affects the lungs (pulmonary TB), but it can also affect many other parts of the body (extra-pulmonary TB), such as the central nervous system, gastrointestinal system, bones, or joints. The most common symptoms of TB are a chronic cough lasting at least two weeks[28] with or without blood, chest pain, weight loss, fever, and night sweats. Extra-pulmonary TB can have a variety of other symptoms depending on the organ affected.

Tuberculosis is spread through the air, when people who have the disease cough, sneeze, or spit. It has been estimated that a person with active but untreated tuberculosis can infect 10–15 other people per year. One third of the world's current population has been infected with *M. tuberculosis*,[29] however, most individuals will have an asymptomatic, latent infection. About one

in ten of these latent infections will eventually progress to active disease, which, if left untreated, kills more than half of its victims. In 2004, mortality and morbidity statistics included 14.6 million chronic active cases, 8.9 million new cases, and 1.6 million deaths, mostly in developing countries.[29]

The most common detection method for TB is smear microscopy because it is low cost, requires little training, and the result can be read in the same day. It involves collecting a biological sample (usually sputum or some other clinical material), fixing it thinly on a glass slide and then staining it with a dye that binds specifically to mycobacteria (making them easier to identify under a microscope).[29] Another type of test with higher sensitivity and specificity is a culture. There are different methods for cultures but all grow the mycobacteria in a liquid or solid medium for 20-60 days, then detect growth by evaluating the sample by visual exam or other modes of visualization to see if any mycobacteria can be detected. Both of these tests are used both to detect TB and to monitor a patient on treatment.

There are strains of TB that have become resistant to anti-tuberculous medications. Multi-drug resistant TB (MDR-TB) is TB resistant to the two most potent drugs, isoniazid and rifampicin. Extensively drug-resistant TB is resistant to isoniazid and rifampin plus resistant to any fluoroquinolone and at least one of three injectable second-line drugs (amikacin, kanamycin, or capreomycin).[30] To diagnose the resistance pattern of any strain of TB, a drug susceptibility test (DST) must be performed. Again, there are different methods, but the most commonly used in developing countries grow the TB strain in a liquid or culture medium with some concentration of the drug to be tested. Visual or automated detection then confirms if the strain grew in the presence of the drug and if so the strain is considered resistant to that drug.

2.2 EMRs in Developing Countries

Developing countries provide a greater challenge in the implementation of EMR systems than developed countries due to lower levels of infrastructure, communications and education. Despite these additional challenges, EMRs in developing countries are becoming more widely used, easier to implement, and more prominent in the public domain. Studies have shown the increasing availability of internet in developing countries and its increased use by health care professionals,[31-34] including the use of email and digital images for telemedicine.[35-39] A broad

range of robust and flexible devices are becoming available.[40] Governments are also becoming more aware of the need to develop clinical and reporting information systems[41] and to evaluate their use in health care.[42]

Several EMRs have been implemented and successfully used in developing countries. I conducted an exhaustive literature search in August 2006 to identify all published descriptions of EMRs, including those that were not peer-reviewed or were presented in conference proceedings. This search used a review of EMRs in developing countries[43] as a start and was supplemented by search of MEDLINE and Google Scholar using combinations of the terms: "electronic medical record", "electronic health record", "electronic patient record", "developing countries", "third world", "poor settings". We retrieved potentially relevant articles and reviewed their reference lists for additional articles. Further, we consulted colleagues to identify further unpublished systems. We restricted my search to only English articles.

- In Kenya, the Mosoriot Medical Record Systems (MMRS) has been implemented in a primary care rural health center.[44-46] The MMRS provides both patient registration and visit data collection functions. Data are collected on all patients seen in the medical clinic, including their laboratory test results and medications. Seven networked computers are linked to a single MS Access® database, which maintains information on over 60,000 patients.

- The Lilongwe EMR is a patient management information system for a wide range of clinical problems in the pediatric department of a central hospital in Malawi.[47] Data are collected on patient demographics, medication, laboratory tests and X-rays by using touch screens.[48] A centralized server, located in the hospital, connects all of the touch screens. This system contains information on over 160,000 patients.

- The Brazilian public health system uses the Computerized System for the Control of Drug Logistics (*Sistema de Controle Logístico de Medicamentos,* SICLOM) to deliver antiretroviral (ARV) treatments to over 100,000 patients.[49 50] This is by far the largest group of HIV patients whose treatment is tracked by an EMR in the developing world. Information about this system is limited; available literature indicates that the system registers the distribution of ARVs, helping both to maintain needed stocks of the drugs at the national

administrative agency and to ensure that ARVs are prescribed in accordance with national treatment and prescribing guidelines to maximize efficacy and minimize toxicity. A dial-up connection allows physicians—who each have separate data bases on their desktops—to periodically connect to the central server and update patient records. Another computer system, called System for Control of Laboratory Exams (*Sistema de Controle de Exames Laboratoriais*, SISCEL), established in 1997, gathers data from the public HIV laboratories nationwide and sends the information, online, to the central AIDS administration in Brasília.[50]

- The MEDCAB system was implemented in an urban primary health care practice in Cameroon.[51] Data are collected on patient demographics, medication and laboratory tests. The implementation team found that, after 14 months of usage, only 8 of the 16 users were still using the system. The main reasons for attrition included: (1) trained personnel left the practice; (2) changes in management, new leadership gave less attention to the project; (3) continual hardware breakdown; and (4) departure of most of the main investigators.

- CAREWare is an EMR developed by the US Department of Health and Human Services to support HIV treatment. It has over 350 US based sites and was deployed in Uganda in October 2003.[52] The MS Access® stand-alone database provides comprehensive tools for tracking HIV patients and their treatment, including clinical assessment, medications and billing data. Currently, the system contains information on thousands of patients in the USA and several hundred in their two sites in Uganda. An internet-accessible version has been developed and deployed.[53]

- FUCHIA was developed by Epicentre, the epidemiology group of Médecins Sans Frontières (MSF), to support their HIV treatment projects.[54] It supports clinical care and long-term follow-up of patients, including scheduling of visits; it includes data on medications and investigations and generates reports. It was developed as a stand-alone system using MS Access® and the Delphi programming language. This system is reported to be used in multiple sites where MSF provides care, although a list of sites was unavailable.

- An information system was developed to support the TB program in Botswana using EpiInfo, a free stand-alone program from the US Centers for Disease Control and Prevention (CDC)

designed for data collection and analysis in developing countries.[55] [56] This system was implemented in five pilot projects in Botswana and South Africa which have 8,000 and 16,000 TB cases annually, respectively. However, no further data on its use was available.

- An MS Access® based system was also used in Botswana to support that country's first public highly active antiretroviral therapy (HAART) outpatient clinic. It used optical character recognition (OCR) technology to scan three one-page data forms into the electronic database. They used this system for seven months to manage about 3000 patients on HAART and concluded that this OCR-based system combined ease of data entry and saving of physician time while not disrupting the patient-physician encounter.[57]

- The Patient Record Information System (PaRIS) was built in Indonesia for primary health centers spread over the thousands of islands which comprise the country.[58] Data collected include patient demographics, visit dates, medication, and disease category. The system uses a radio modem to connect 5 computers to a Postgres SQL database server on Linux machines. Each Linux machine has the database for local information as well as a copy of the entire global database. No information on the actual usage of this system was available.

- A recent report[40] includes other systems that have been implemented in developing countries including Therapy Edge,[59] [60] Care2x,[61] and World Vista, however, no other implementation information could be found aside from the list of countries where these systems have been used.

- EMR systems are also being implemented in Zambia (national EMR using smart cards),[62] Tanzania (MS Access® database for PEPFAR project), Haiti (pilot phase of data entry and reporting tool for PEPFAR and Global Fund reporting) and South Africa (use of cell phones to monitor adherence for the management of HIV/AIDS in patients on antiretroviral therapy).[63] However, no further information could be found in the literature.

2.3 Evaluations of EMRs, LIMS, and Data Collection Systems in Developing Countries

Despite the increasing number of EMR implementations in developing countries, no formal evaluations have been published of their impact on patient outcomes or clinical care,[22] [24] [64] and

only limited evaluations on their impact on improved productivity among health professionals exist.[65-67] These evaluations are essential in ensuring that the systems being implemented are safe, have a significant impact, and are not a waste of already scant resources.[66 68] A systematic review performed in 2004 of the use of IT in primary health care worldwide[22] found that most articles in the realm of eHealth "lacked any evaluation of their concrete application to health care." This echoes the conclusions of a 2001 review of the impact of computers on primary care titled "A descriptive feast but an evaluative famine,[23]" as well as separate systematic reviews of telemedicine applications' effect on patient care[69] and cost-effectiveness.[70]

We performed a systematic review of evaluations of EMRs, LIMS, and data collection systems in developing countries.[71] The goal of the review was to survey the evaluations that have been performed on these types of systems in developing countries to find their potential impact and to guide future implementations and evaluations of these systems.

2.3.1 Methods

2.3.1.1 Studies Eligible for Review

We included any qualitative or quantitative evaluation of EMR, LIMS, or data collection system as described below in developing countries. Developing countries were defined as those in the Emerging and Developing Economies List in the International Monetary Fund's World Economic Outlook Report[72]. Evaluations were excluded if (1) data completeness of the system was the only outcome, (2) the evaluation method was not described in the article, (3) the article was limited to describing the feasibility or technical evaluation of a system, (4) the evaluation was on attitudes towards or knowledge of eHealth (not an implemented system), or (5) it was only an educational tool[73 74]. In the cases of Uganda Health Information Network[75 76] and EHAS[77 78] where both systems were a health education and an eHealth system, we only report on the eHealth system.

2.3.1.2 Finding Relevant Studies

We conducted a worldwide review of the literature and requested submissions from researchers and implementers of eHealth systems in developing countries. Literature searches were completed through May 2008 without language restrictions through MEDLINE, EMBASE, Science Citation Index (Web of Science), Social Sciences Citation Index, The Cochrane Library,

and the Latin American and Caribbean Health Science Literature Database (LILACS). To find reports not in scientific journals or conferences, we also used Google Scholar. All citations were downloaded into EndNote X (Thomson ISI Research-Soft, Philadelphia, PA). For MEDLINE and EMBASE, terms were derived from the MeSH database and EMTREE tool, respectively. Among the terms used in the final strategies were *medical informatics applications, management information systems, telemedicine, telehealth, reminder system, geographic information system, hospital information systems, outcome and process assessment (Health Care), program evaluation, evaluation studies, attitude, costs and cost analysis, developing countries, poverty, Africa, Latin America, eastern Europe, central or southeastern Asia* (complete strategies available from the authors). An initial reviewer evaluated the eligibility of all studies identified in our search. A second reviewer confirmed all relevant articles and retrieved the full text of each article. Supplementary methods of finding evaluations included a review of article reference lists, informatics conference proceedings, information provided by primary study authors, requesting submissions from other researchers and implementers and searching the RHINO Literature Database[79] and other recent reviews.[22 43 80 81]

2.3.1.3 Data Abstraction and Synthesis

We extracted data according to recurring themes. We summarized these findings using tabular techniques and descriptive statistics. Reported analyses were too disparate to be pooled in a meta-analysis.

The systems described in the articles were placed into one of three categories:

1. Electronic Medical Record (EMR): an electronic record of health-related information on an individual that can be created, managed, or consulted by clinicians or staff. We have found that in the literature the term electronic health record (EHR) is used interchangeably and therefore will be used as a synonym for the purposes of this paper.

2. Laboratory Information Management System (LIMS): a system for laboratory specific activities or for reporting results to administrators and health care personnel.

3. Research or Data Collection System: any electronic system used for collecting data from different locations or for storing, managing, or reporting on data used for research purposes.

Evaluations were classified into two major categories: qualitative and quantitative. In this review, qualitative evaluations were those where users, patients, or staff gave their opinion regarding a system. These could take the form of questionnaires, focus groups, or interviews. This definition is different from the one proposed by Strauss and Corbin of "any type of research that produces findings not arrived at by statistical procedures or other means of quantification."[82] Quantitative evaluations were those whose outcomes were data quality, administrative changes, patient care, or economic assessment. The evaluation designs were grouped according to the definition by Friedman and Wyatt:[83] (1) descriptive (uncontrolled) study; (2) historically controlled (before-after) study; (3) case-control (retrospective) study; (4) prospective self-controls (subjects performing same action in both systems);[1] (5) simultaneous nonrandomized controls; (6) simultaneous randomized controls; and (7) externally and internally controlled before-after study. Two cost studies[84] [85] and two studies that modeled future medication requirements[86] [87] were categorized as self-controls, since the authors compared the impact of the system against the same situation without the system. Due to the inherent limitation of performing a case-control, descriptive, or qualitative study without statistics, we will not comment on the limitations of these studies in the results sections.

2.3.2 Results

Searches retrieved 1947 citations. Five of these articles were excluded because they did not have abstracts and full text versions were not available.[88-92] After the initial screening of article titles and abstracts, we found 154 articles that appeared relevant. An additional five articles were identified by hand searching bibliographies of eligible articles and prior reviews. Of these, 22 were deemed to fulfill the inclusion criteria of the review after full review of their abstracts, and are listed by type of system and evaluation in Table 2.1. For three of these articles, we were only able to retrieve the abstract, but still included them in the analysis.[93-96] Brief descriptions of outcomes and limitations are described under each category of system type in Tables 2.2-2.4. Though it is not in a developing country, we included an evaluation from the Indian Health Services in the U.S. since conditions were similar to those in developing countries.[97] If a system had multiple evaluations, only those with different outcomes are listed. If they had the same outcome, we took the one with the largest sample size. There were two articles reporting that an

1 This category was added by the authors

evaluation did not occur because of a failed system implementation.[24 98] These are not part of the results, but we considered it relevant to list them since articles on unsuccessful systems are not commonly published.

Eight articles performed qualitative evaluations and 18 performed quantitative evaluations. If an evaluation performed both types it was counted in both categories. Two qualitative and six quantitative evaluations performed some sort of statistical analysis on the results. Of all these evaluations, two of the qualitative and two of the quantitative were performed by an outside evaluator that was not the system developer. The number of evaluations has increased in the last few years.

Table 2.1 Number of total articles for the different eHealth categories by type of evaluation. If an article had both qualitative and quantitative studies or multiple types of systems, it was counted in both categories. Numbers are quantity of studies (percentage of total studies)

eHealth Category	Qualitative	Quantitative	
		Descriptive Studies	Controlled Studies
Electronic Medical Record (EMR)	4 (14)	1 (3)	4 (14)
Laboratory Information Management Systems (LIMS)	0	1 (3)	3 (10)
Research or Data Collection Systems	4 (14)	1 (3)	11 (38)
TOTAL	**8 (28)**	**3 (10)**	**18 (62)**

2.3.2.1 Electronic Medical Record (EMR)

EMRs are the core application on which other clinical systems such as computerized clinical decision support (CDSS), computerized order entry (COE), and sometimes telemedicine systems can be implemented and sustained. Because of this they usually need to encompass a variety of different functionality, making their implementations complex[99] and often prone to failure.[100] This complexity provides an additional challenge in evaluating these systems. In our search we were only able to find one evaluation that had a control group (Table 2.2); four were qualitative, with only one of them using statistics; two were case-control studies that could provide an insight into possible impacts, but had limited scientific rigor.[83]

The Vista system used by the Indian Health Services (IHS) was the most complete system, as it includes services for clinical reminders, radiology order entry, medication order entry, and lab order entry. Several of the other EMRs also incorporated multiple services,[44 101 102] however all of them will only be reported in the EMR sections because none performed evaluations on the separate parts of the system.

The MMRS evaluation provided data on the impact that an EMR could have on improving staff productivity and reducing patient wait times. The other evaluations gave insights into the ability of EMRs to improve staff satisfaction, providing higher quality data to relevant personnel, and ultimately improving the care provided to patients.

Table 2.2 Description of EMR evaluations in increasing order of evaluation strength with multiple evaluations of a single system placed together

System or Institution	Evaluation Type	Outcome
PDA-EHR[103]	Cost	Their system cost $750 dollars total for satellite communication for 2700 patients and a one-time fixed cost of a satellite phone ($500 plus monthly fees).
MCHS[104]	Case-control study	Over 4 years immunizations increased from 45.4% to 81.9% and 46.1% to 77.7% in DPT and polio vaccines; antenatal registration increased from 384 to 705 patients.
Nutrition Support-Philippines[105]	Case-control study	Decreased percentages of wrong entries and non-entries either of weight or height ($p<0.05$); Increases seen in nutrition support services ($p<0.05$); referrals to clinical dietitians ($p<0.05$), and dietician productivity ($p<0.05$).
HMIS-Korea[102]	Staff & patient surveys	Increased staff productivity and satisfaction. Did not increase staff persuasion and decision abilities. Increased visitors' satisfaction with services
Oman-EMR[101]	Physician survey	**Advantages:** Physicians recorded improved communication (95%); improved quality care (85%); accurate entry and retrieval of data (80%); easy access to data (70%); usable in physician liability cases (64%); reduced medical errors (67%); enhanced productivity (59%). **Disadvantages:** disease coding was a problem (70%); system was time consuming to use (67% agree); and too slow (60%).
IHS-Vista[97]	Physician survey	**Advantages:** EHR implementation was viewed positively (66%); improved quality of care (35%); 34% self-reported that EHRs improve quality, this was associated with increased utilization (odds ratio 3.03, 95% confidence interval 1.05– 8.8). IT could improve quality of care in underserved settings (87%) **Disadvantages:** decreased quality of patient–doctor interaction (39%).
MMRS[44]	User opinion	Hospital matron noticed a cluster of sexually transmitted disease and therefore dispatched a team to investigate. Also noted lack of child immunizations therefore dispatched nurses to that site. Reports that previously took a clerk two weeks, now takes minutes; allowed the director to reassign two clerks to other duties.
MMRS[44]	Before-after	Duration of visits dropped from 41 to 31 minutes; providers time with patients dropped by half, from a third to a sixth of their workday ($p = 0.004$); providers spent two thirds less time interacting with other staff ($p = 0.0002$) and tripled their time spent in personal activities ($p = 0.001$); clerks spent two thirds less time interacting with other staff and almost doubled their time registering patients.

2.3.2.2 Laboratory Information Management Systems (LIMS)

There were only three evaluations of LIMS, of which only one had a control group. However they suggest two major benefits that a LIMS system can provide: (1) decreasing turn around times in the communication of results and (2) improving productivity of the laboratory. An additional impact, reduction in errors, has not yet been studied.

Table 2.3 Description of LIMS evaluations in increasing order of evaluation strength

System or Institution	Evaluation Type	Outcome
SGPGIMS[93]	Descriptive	Cholera was isolated in 22.6% (7/31) of samples sent to a central laboratory. Information was relayed to hospital and health authorities, who took strict measures to improve hygiene at a festival. Subsequently, the number of diarrhea cases during festival decreased and an epidemic was averted.
Tesilab[106]	Case-control study	Productivity indexes showed an increase by 41% in number of patients handled and 28% in number of tests processed.
VPN-LIS[107]	Before-after	Turn around times for routine samples decreased from 1 to half day; number of samples processed increased a factor of 2; annual laboratory revenue increased 4 times, from 55,000 to 220,000 euro per month.

2.3.2.3 Research or Data Collection Systems

Research or data collection systems had a large number of evaluations. All of these systems were on PDAs or used PDAs as the point of contact with the user and then had a back end database to collect and store data. Four RCTs showed that the main benefits of PDA systems were: data quality similar to paper systems[108 109] or higher,[25 110] less time to perform interviews,[110] and decreased data collection time.[25] Two of the RCTs compared the PDA system to paper, but not to a gold standard,[108 109] one had a small number of users (n=4), [25] and one was performed 17 years ago.

All three evaluations that had user surveys reported that users preferred the PDA system over traditional paper, two reported that users could fix most technical problems with the device, though technical support is still a critical need. Further, the organizations that implemented the PDA systems in Uganda[75 76] and South Africa[109] had experience with hundreds of users and over a dozen implementations combined, which empirically suggests the feasibility of these systems.

The cost-analyses showed that these systems were able to recuperate their high initial costs by providing increased efficiency and continuous material costs. The Uganda system[75 76] showed a cost savings of 91% over the paper system. The South African analysis[109] calculated that after using the PDA system for data collection in eight studies of medium scale, the system would equal the costs of paper. The system in Lima, Peru[25] would pay for its original development and implementation in 5.5 years, and for expansion to other health districts in 3 months.

Table 2.4 Description of research or data collection system evaluations

System or Institution	Evaluation Type	Outcome
PDA-Tanzania[111]	Descriptive	Collected data on 83,346 individuals over seven weeks with no PDA problems. Dataset was available within 24 hours. Median time to form

		completion was 14 minutes during training and nine minutes during survey.
Uganda Health Information Network[75 76]	User survey	87% reported that health content received helped them make faster more accurate diagnoses. 86% integrated PDA into other activities. 73% able to solve problems; 68% reported problems to health unit with only 41% of them being answered.
Uganda Health Information Network[75 76]	Cost analysis	System provides up to 91% saving per unit spending compared to paper-based HMIS data collection and reporting approaches. Reporting compliance to MOH improved from national average of 63% to 94-100% for districts using UHIN.
UN-Vodafone Partnership[67]	User survey	**Advantages:** Time savings (95 percent); the ability to quickly mobilize or organize individuals (91 percent); reaching audiences previously difficult or impossible to reach (74 percent); transmit data more quickly and accurately (67 percent); gather data more quickly and accurately (59 percent).
PDA-Gabon[112]	Self-controls	Rate of discrepant entries was 1.7%. Categorical data were more commonly discrepant than were continuous "typed in" data (2.4% versus 1.2%; p= 0.001).
PDCS-Nicaragua[113]	Self-controls	In 558 patient interviews accuracy of PDA and paper methods was 97.1% and 97.6%, respectively. For 1,543 field visits, accuracy rate for PDA and paper methods was 98.9% and 99.3%, respectively.
PDA-PREVEN[108]	Before-after (first survey), RCT (second survey)	First survey, almost perfect agreement between paper and PDA. Second survey, rates of responses to sensitive questions were similar between both kinds of questionnaires. PDA had 96% less inconsistencies (p = 0.0001) and 66% less missing values (p = 0.001) than paper.
HIV-PDA interview system[114]	Block RCT	There was no difference between participants' self-reported comfort across handheld and paper conditions. However, participants in the handheld condition were more likely to give socially desirable responses to the sexual behavior questions (p<0.01).
PDACT[109]	Cost analysis	Cost of PDA survey is slightly less than paper when cost of hardware is annualized over four studies and the programming cost excluded. When programming cost is included, upfront costs need to be discounted over eight studies to obtain a comparative cost with paper.
PDACT[109]	User surveys	85% of PDA users preferred PDA and 7% preferred paper for answering questions about sex. 53% of paper users preferred PDA and 28% preferred paper.
PDACT[109]	Simultaneous randomized controls	Intra-scale reliability and the test-retest reliability were found to be adequate and similar between paper and PDAs.
PIH-EMR PDA[26]	User Survey	User satisfaction higher for PDA (mean 5 of 5) than paper (3.5 of 5). PDA reduced mean work-time per result from 6.75 to less than 2 minutes. Mean 1.13 technical problems per month which could be fixed in the field (2 users) or back at the office (2 users).
PIH-EMR PDA[26]	Cost analysis	Work hours required decreased by 60% (p<0.001). Total cost and time to develop and implement was US$26,092 and 22 weeks. Cost to expand to 9 districts was $1,125 and to implement collecting patient weights $4,107.
PIH-EMR PDA[25]	Cluster RCT	PDA-based system had a processing time of 6.2 days, significantly lower than both the baseline and control site measurements of 54.8 and 64.4 days, respectively (p<0.0001). Reduced errors from 10.1% to 2.8%.
PDA-Gambia[110]	Cross-over simultaneous randomized controls	Handheld showed a 30% improvement for collection of identification data and a 100% improvement for dates and times [system automatically time stamped]. Significant reduction in inter-individual variability in data accuracy. By the third week the average interview times were 31% shorter for field workers who used handheld (p=0.007).

2.3.3 Discussion

This review shows that, with the exception of PDA data collection, there are still few scientifically rigorous data on the effectiveness and cost-effectiveness of these types of systems in developing countries.

These initial evaluations suggest that the following functions show a positive impact in developing countries:

1. Tools to decrease communication times of information within and between institutions.

2. Collection of clinical or research data using PDA.

3. Reductions in errors in laboratory and clinical data.

Evaluations of EMRs, LIMS, and data collection systems are challenging and require significant resources in addition to the creation and implementation of the system itself. Implementation should have evaluations built into the implementation process. This may provide useful feedback to improve the project and may also demonstrate the impact of the system.

There are benefits of electronic systems that are difficult to quantify. One is the ability to perform operational research with greatly reduced costs. During our search we found several articles that used electronic databases and probably could not have been performed if manual data collection were required.[115-122] Another benefit is the increase in communication across large distances of emergency data such as in a cholera outbreak[93] or refugee situations.[123]

However, more robust and better-evaluated information systems are going to be necessary to overcome the additional implementation challenges in developing countries. These systems must be evaluated to ensure that they are safe, effective, and have a reasonable cost. When looking at the software systems included in PEPFAR's ART Software Inventory Report[124] and EngenderHealth-OpenSociety software tools[125 126] comparison, only three systems, the PIH-EMR/HIV-EMR, MMRS and Vista, had any evaluations performed.

2.3.3.1 Challenges and biases in evaluating medical information systems

Carrying out successful evaluations of medical information systems is challenging in any environment as there are many factors that influence a system's effectiveness. Determining if an

improvement in data quality or clinical care is due to an information system requires carefully controlling for potential biases and confounders.[83] Historical controls (before and after studies) can be hard to interpret as healthcare delivery changes rapidly and improvements are often due to other factors. Studies with prospective control groups address this problem, but it is important to ensure the groups are equivalent. Selecting the appropriate unit of analysis can also be challenging, as it may not be appropriate to randomize the use of the system for some patients and not others in the same clinic, both from a practical and ethical stand point, and because there may be carry over benefits from the information system such as better access to information or laboratory data. Randomizing by clinic or hospital may be a better approach (cluster randomization), the main challenge being the need to include multiple clinics to have an adequate sample size. One pragmatic and fairly robust strategy for quantitative studies is to carry out before and after comparisons in the intervention sites and also include contemporary controls. This can be accomplished in a staged intervention where some clinics are randomized to get the system before the others.[26 127]

Another important potential bias is the "Hawthorne effect" where staff are aware that they are being monitored and therefore behave differently. This is particularly a problem if the intervention sites are aware they are being studied but the control sites are not. A related issue is when additional resources are invested in the intervention site such as training or better infrastructure. These biases can be minimized by treating the intervention and control sites as similarly as possible and just varying the information system or one of its components.

Both the software system implemented and the implementation process are extremely important in determining the impact that the system will have on clinical and administrative processes. Further, the system and implementation process used become even more critical as EMR systems begin to encompass more processes and users, or if the organizations adopting them grow in scale. In such cases, implementing systems that have been evaluated and shown to work in similar conditions can provide an initial, secure foundation.

For evaluations of information systems in resource poor environments all of the above issues need to be taken into account, as well as factors specific to the environment and staffing. Deploying an information system in a country like Haiti or Kenya first requires an assessment of

the feasibility and sustainability of running PCs and/or servers in the location and the ability to provide technical support and training. A simple and important test is if the system is still functional and in use one and three years after implementation. Measures of system usage and data completeness are also necessary both as an end in themselves and as an important prerequisite to a full evaluation study, otherwise a great deal of time and effort can be wasted.

It is clear from the evaluations reviewed here that none met all the criteria described above. However the system for drug order entry in Peru[128] was re-studied three years after implementation and was still in use and functional, generating warning alerts for 5.3% of medication orders. The Satellife[75] and On Cue Compliance Service[129] were shown to be well liked by users several years after implementation and, perhaps more importantly, by an independent evaluation team. The strongest evidence for beneficial impact of these systems on healthcare will come from long-term follow-up carried out by independent evaluators.

2.4 Evaluations of Electronic Laboratory Reporting Systems and Handheld Systems in Developed Countries

2.4.2 Electronic Laboratory Reporting Systems

Information systems have affected the manner in which laboratory data are handled, communicated and reported for over two decades and will continue to play a larger role in the future. The need to enhance communication between US health organizations was the impetus for the CDC's development of the Public Health Laboratory Information Systems (PHLIS)[130], a system still used both domestically and internationally. In the US, several state and local health departments have already made the transition to web-based electronic laboratory reporting and most will have such a system in the next 5-10 years.[131]

Even with this extent of adoption, the prompt and accurate reporting of laboratory test results, and the use of laboratory information systems and communication between all partners continue to challenge health care systems. Recent work has shown unresolved problems with data transmission, data completeness and accuracy, and user interpretation.[132-134] Furthermore, the CDC's National Plan for Tuberculosis Laboratory Services includes these data-related issues among the top five challenges to the development of an integrated national system that can

ensure prompt and reliable information flow among laboratory staff, clinicians, and TB-control officials.[135]

Integration of electronic laboratory-based reporting software has been shown to decrease communication time[136-139] and to increase the completeness of reporting.[136 138 139] These benefits have been shown in both non-randomized, prospective cohort (before and after)[136] and retrospective cohort studies that compare a paper based and an electronic system.[138 139]

Studies have also shown that such data can be used to warn doctors about important and urgent interventions.[140-145] The evaluation methodologies for these studies are varied. They include non-randomized, prospective cohort (before and after),[141 144] retrospective cohort,[145] prospective time-series,[143] and randomized controlled trials.[142] The benefits of these alerts include:

1. More clinicians ordering appropriate tests for their patients,[141 144 145]
2. Decreases in the time until an appropriate treatment is ordered for patients who had critical laboratory results,[140 142 143]
3. Improved functional tests performance by patients after a specified time,[143 144]
4. Fewer follow-up visits by patients.[145]

To date, there have been no studies of the impact of access to laboratory data in an EMR system on the quality of care provided to patients in developing countries.

2.4.2 Handheld Systems for Data Collection

The use of portable handheld computers, or personal digital assistants (PDA), in health care and clinical research is on the rise, with a corresponding increase in publications.[146 147] A review of sixty-seven studies found that approximately 60% to 70% of medical students and residents use PDAs for educational purposes or patient care.[148] Their use has been described in numerous research and clinical settings with a variety of uses including patient self-monitoring[149-153], patient assessment[154-157] and field data collection.[158-161]

Many of these studies have shown that handheld technology has several advantages over traditional paper modes of data capture. These include, but are not limited to:

1. data accuracy,

2. timeliness of data capture,

3. decreased time to fill out forms and adherence to protocols for data collection.

The evaluation methodologies have been varied including non-randomized, prospective cohort (before and after) and prospective cohort studies between a paper based and an electronic system,[152-155 161] and descriptive studies.[149 150 158 160] Also, several studies have been controlled studies where the same user performs the same task in both the paper and electronic form, with the order being decided in a random fashion.[154 156 159]

A review of 9 randomized controlled trials found that results favored handheld computers over paper for data collection among study participants, but the data are not uniform for the different outcomes. Handheld computers appeared superior in timeliness of receipt and data handling (four of four studies) and were preferred by most subjects (three of four studies). On the other hand, only one of the trials adequately compared adherence to instructions for recording and submission of data (handheld computers were superior), and comparisons of accuracy were inconsistent between five studies.[146]

2.5 The Partners In Health EMR (PIH-EMR) for sensitive & multi-drug resistant TB (MDR-TB)

Partners In Health (PIH), a 501(c)(3) nonprofit corporation was founded in 1987, two years after PIH co-founders established the Clinique Bon Sauveur in Haiti. It is linked with the Department of Social Medicine at Harvard Medical School and the Division of Social Medicine and Health Inequalities at the Brigham and Women's Hospital. They share PIH's mission to provide a preferential option for the poor in health care. By establishing long-term relationships with sister organizations based in settings of poverty, Partners In Health strives to achieve two overarching goals: to bring the benefits of modern medical science to those most in need of them and to serve as an antidote to despair. PIH has sister organizations in Haiti, Peru, Russia, Mexico, Guatemala, Malawi, Lesotho, and Rwanda which provide patient care, develop innovative approaches to the management of chronic diseases in developing countries and, in some cases, build and run clinics. PIH also has expertise in the procurement of drugs and other essential supplies, shipping

and pharmacy management. PIH has a team with extensive experience of management and finances and had a turn over of over $30 million in 2006.

In 1996, Partners In Health (PIH), with sister organization Socios En Salud (SES) in Lima and the Peruvian Ministry of Health (MINSA), created a pioneering treatment program for multi-drug resistant tuberculosis (MDR-TB) to complement DOTS. They showed that it is not only possible to treat such complex chronic diseases in developing countries, but cure rates can be as good as those achieved in the US. In 2005, treatment outcomes continue to be excellent with 77 percent of patients with fewer than two previous treatments cured of their MDR-TB. The remarkable successes in confronting an epidemic of multidrug-resistant tuberculosis in the slums of Lima have instigated major changes in global health policies.

In 2000, SES and MINSA became the hub of a multinational TB treatment project funded by the Bill & Melinda Gates Foundation. New support from the Global Fund to Fight AIDS, Tuberculosis, and Malaria since 2003 has enabled SES and MINSA to expand the cooperative treatment efforts and provide technical support to other countries starting similar programs.

The Partners In Health Electronic Medical Record (PIH-EMR) was developed within this project and is unique in providing a broad range of functions to support high quality patient care for sensitive and multi-drug resistant TB (MDR-TB) in a resource-poor setting. Functions include: (1) an electronic patient registry currently maintaining information for over 13,800 patients; (2) a web-based medication order entry system that has been shown to significantly reduce error rates and work load,[162] (3) a method for electronically archiving and displaying chest radiographs,[37 163] (4) tools for generating monthly reports for funders; and (5) tools to predict future drug requirements.[164] This system includes a substantial set of data entry and analysis functions for laboratory results including sputum smears, cultures, and Drug Sensitivity Tests (DSTs). The PIH-EMR can alert clinicians to abnormal laboratory results either when they log into the system, on specially formatted patient reports, or by email. The PIH-EMR has been integrated into the clinical and administrative workflow of Socios En Salud (SES), PIH's Peruvian sister organization. The Tropical Disease Foundation, a Non Governmental Organization in the Philippines, is also using the system to support the treatment of TB and MDR-TB in that country.

A second version of the system, the HIV-EMR, was deployed in rural Haiti in 2003 and in Rwanda in 2005 to support the treatment of HIV/AIDS.[165] [166] An offline component was developed to overcome unreliable internet communications in some sites. This component allows data entry and case viewing when the network is down and has proven reliable and popular with clinical staff. The HIV-EMR's important role in the management of over 4,200 patients on ARVs shows the feasibility of implementing a medical record system in remote clinics with virtually no infrastructure and limited technical expertise.

Other projects have shown that it is possible to create and deploy simple medical record systems in developing countries.[44] [47] [51] However, the PIH-EMR is unique in deploying its web-based design in very resource-poor regions, including extensive use of communications tools and alerts to track patient care in near real time.[43]

3 Development and Implementation of a PDA-based Bacteriology Collection System

The following sections detail the development and implementation of a PDA-based system to collect TB bacteriological data from over 100 health centers and laboratories in Lima, Peru, process them, and enter them into the PIH-EMR. Section 3.1, Organization and Collection Workflow, describing the institution adopting the technology and the initial workflow associated with collecting results. Section 3.2, System Description, details the technology used and the full system that was implemented. Sections 3.3 and 3.4, Results and Discussion, detail the implementation results and lessons learned from this project.

3.1 Organization and Collection Workflow

As mentioned in Section 2.5, Partners In Health and sister organization Socios En Salud (SES) provide treatment for thousands of MDR-TB patients. To monitor these patients, there exists a bacteriology team within SES that collects all results for those patients.

3.1.1 Bacteriology Collection Team at Socios En Salud

All patients on MDR-TB treatment must leave a biological sample every month at their local health center. Timeliness and accuracy of reporting results for these samples is essential to determine if the patient is responding to treatment and, if not, to change the medications being given[167]. This monitoring should result in shorter culture-conversion times, better treatment outcomes, and prevention of further transmission.

We surveyed the work flow performed by the bacteriology collection (BC) team and found two models of collecting information (Figure 3.1): (1) Single site model, where a patient's sample is processed for smear and culture at the same laboratory and therefore the BC team member is able to collect both results from one regional laboratory; (2) Dual site model, where a smear microscopy test is performed at the local health center. The sample, with the smear result, is then sent to the regional laboratory for a culture. A BC team member collects the primary smear result from the local health center. He/she then visits the regional laboratory and collects the culture result performed at the laboratory and also the result of the smear performed at the health center (secondary smear information). This secondary smear information is cross-checked with

the primary smear information obtained at the health center to ensure correct communication between the institutions.

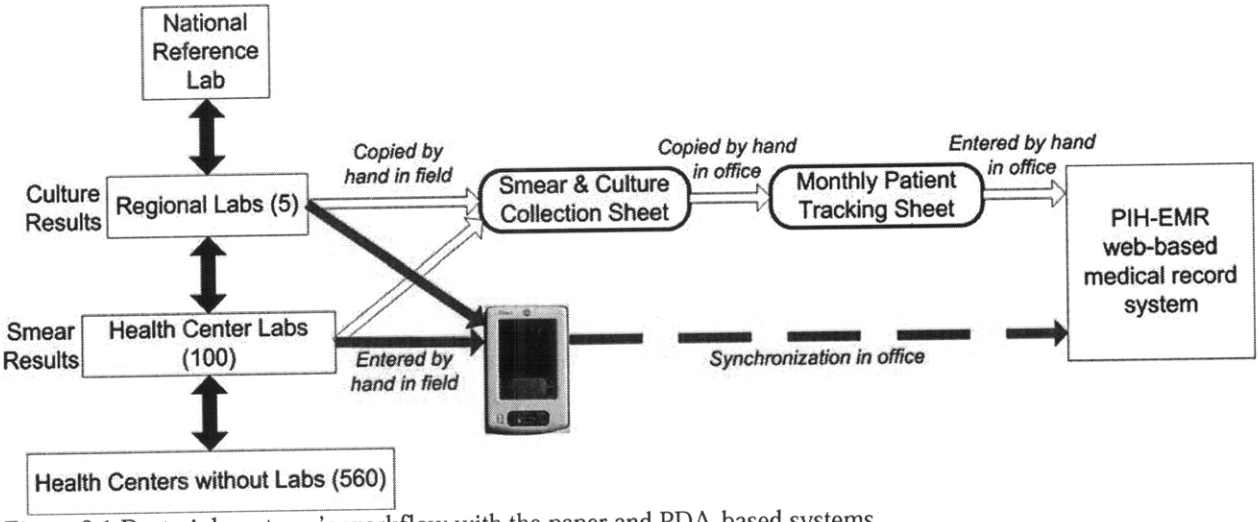
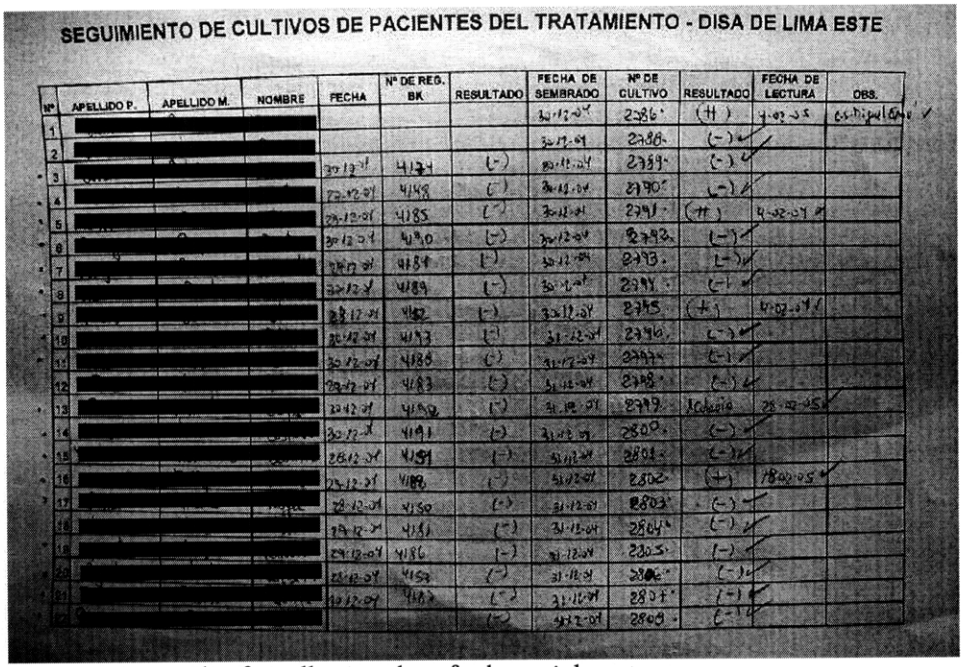


Figure 3.1 Bacteriology team's workflow with the paper and PDA-based systems

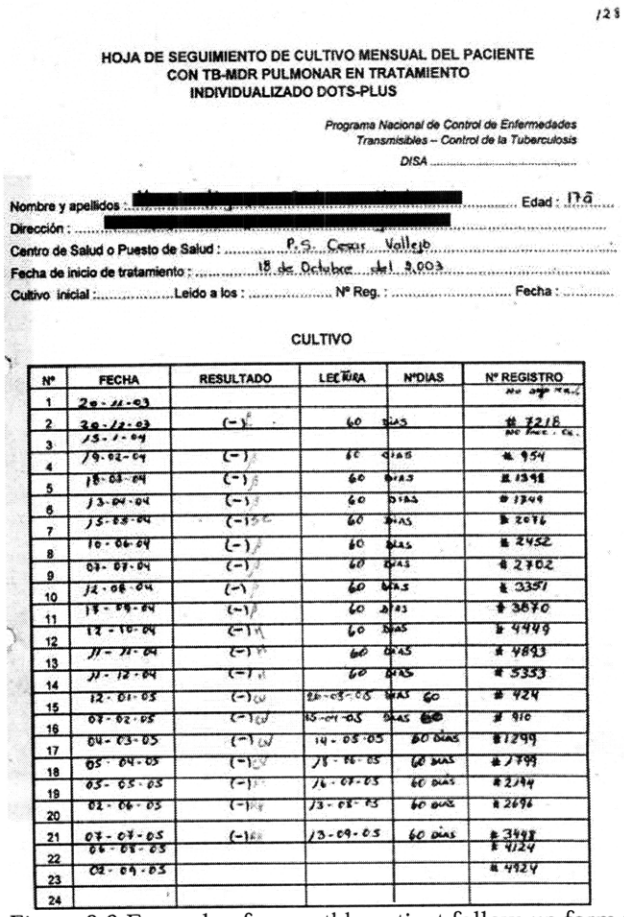
The four-member BC team visits approximately 100 of these health centers and 5 regional laboratories that care for MDR-TB patients and copy these results onto collection sheets (Figure 3.2). These sheets are then brought to the office, where the culture and smear results are verified for correctness. The information is then copied to a monthly patient follow-up for clinical purposes (Figure 3.3) and a second administrative form, and then typed into the PIH-EMR[168], a web-based electronic medical record system. For Lima, the team makes at least bi-weekly visits to all 105 sites distributed over 2,672 km^2. At the time of this study many of these laboratories and health centers did not have internet and an appropriate web-based laboratory information system did not exit. Because of this, a PDA-based system was the most appropriate technological solution.



SEGUIMIENTO DE CULTIVOS DE PACIENTES DEL TRATAMIENTO - DISA DE LIMA ESTE

Nº	APELLIDO P.	APELLIDO M.	NOMBRE	FECHA	Nº DE REG. BK	RESULTADO	FECHA DE SEMBRADO	Nº DE CULTIVO	RESULTADO	FECHA DE LECTURA	OBS.
1	[redacted]						30-12-04	2386	(+)	4-02-05	Es hígado Graz
2	[redacted]						30-12-04	2388	(-)		
3	[redacted]			30-12-04	4174	(-)	30-12-04	2389	(-)		
4	[redacted]			28-12-04	4148	(-)	30-12-04	2390	(-)		
5	[redacted]			28-12-04	4185	(-)	30-12-04	2391	(+)	4-02-05	
6	[redacted]			30-12-04	4190	(-)	30-12-04	2392	(-)		
7	[redacted]			30-12-04	4184	(-)	30-12-04	2393	(-)		
8	[redacted]			30-12-04	4189	(-)	30-12-04	2394	(-)		
9	[redacted]			28-12-04	4182	(-)	30-12-04	2395	(+)	4-02-05	
10	[redacted]			28-12-04	4193	(-)	31-12-04	2396	(-)		
11	[redacted]			30-12-04	4188	(-)	31-12-04	2397	(-)		
12	[redacted]			29-12-04	4183	(-)	31-12-04	2398	(-)		
13	[redacted]			29-12-04	4192	(-)	31-12-04	2399	Incluso	28-02-05	
14	[redacted]			30-12-04	4191	(-)	31-12-04	2800	(-)		
15	[redacted]			28-12-04	4181	(-)	31-12-04	2801	(-)		
16	[redacted]			29-12-04	4189	(-)	31-12-04	2802	(+)	18-02-05	
17	[redacted]			28-12-04	4180	(-)	31-12-04	2803	(-)		
18	[redacted]			28-12-04	4181	(-)	31-12-04	2804	(-)		
19	[redacted]			29-12-04	4186	(-)	31-12-04	2805	(-)		
20	[redacted]			28-12-04	4187	(-)	31-12-04	2806	(-)		
21	[redacted]			29-12-04	4182	(-)	31-12-04	2807	(-)		
22	[redacted]					(-)	4-02-05	2808	(-)		

Figure 3.2 Example of a collection sheet for bacteriology team



128

HOJA DE SEGUIMIENTO DE CULTIVO MENSUAL DEL PACIENTE
CON TB-MDR PULMONAR EN TRATAMIENTO
INDIVIDUALIZADO DOTS-PLUS

Programa Nacional de Control de Enfermedades Transmisibles – Control de la Tuberculosis

DISA .....

Nombre y apellidos : [redacted] Edad : 17a

Dirección : [redacted]

Centro de Salud o Puesto de Salud : P.S. Cesar Vallejo

Fecha de inicio de tratamiento : 18 de Octubre del 2003

Cultivo inicial : ..... Leído a los : ..... Nº Reg. : ..... Fecha : .....

CULTIVO

Nº	FECHA	RESULTADO	LECTURA	Nº DIAS	Nº REGISTRO
1	20-11-03				No aspp reg.
2	30-12-03	(-)	60	DIAS	# 7218
3	13-1-04				No Fuce - Cs.
4	19-02-04	(-)	60	DIAS	# 954
5	18-03-04	(-)	60	DIAS	# 1398
6	13-04-04	(-)	60	DIAS	# 1749
7	15-05-04	(-)	60	DIAS	# 2096
8	10-06-04	(-)	60	DIAS	# 2452
9	03-07-04	(-)	60	DIAS	# 2702
10	12-08-04	(-)	60	DIAS	# 3351
11	18-09-04	(-)	60	DIAS	# 3870
12	12-10-04	(-)	60	DIAS	# 4449
13	11-11-04	(-)	60	DIAS	# 4893
14	11-12-04	(-)	60	DIAS	# 5353
15	12-01-05	(-)	26-03-05	DIAS 60	# 424
16	08-02-05	(-)	15-04-05	DIAS 60	# 910
17	04-03-05	(-)	14-05-05	60 DIAS	# 1299
18	05-04-05	(-)	15-06-05	60 DIAS	# 1799
19	03-05-05	(-)	16-07-05	60 DIAS	# 2294
20	02-06-05	(-)	13-08-05	60 DIAS	# 2696
21	07-07-05	(-)	13-09-05	60 DIAS	# 3498
22	06-08-05				# 4124
23	02-09-05				# 4924
24					

Figure 3.3 Example of a monthly patient follow-up form that bacteriology team filled out in the office

The major disadvantages of this paper-based method are the delays in processing and entering a result, data quality issues, and the heavy work load involved in the process. A preliminary study found that the mean time from the test result date to entry in the PIH-EMR was 55.3 days. A routine quality control examination found error rates as high as 10.1%, and the bacteriology team was consistently backlogged with entry because of the increasing number of patients.

3.2 PDA-based System Description

To decrease delay time and errors, we designed and implemented an electronic bacteriology collection system using a PDA as the initial point of data entry at the clinical site[25]. The information is uploaded to the web-based PIH-EMR, where additional pages were created to automate the validation of the data, generation of the required forms, and data transfer into the PIH-EMR (Figure 3.4).

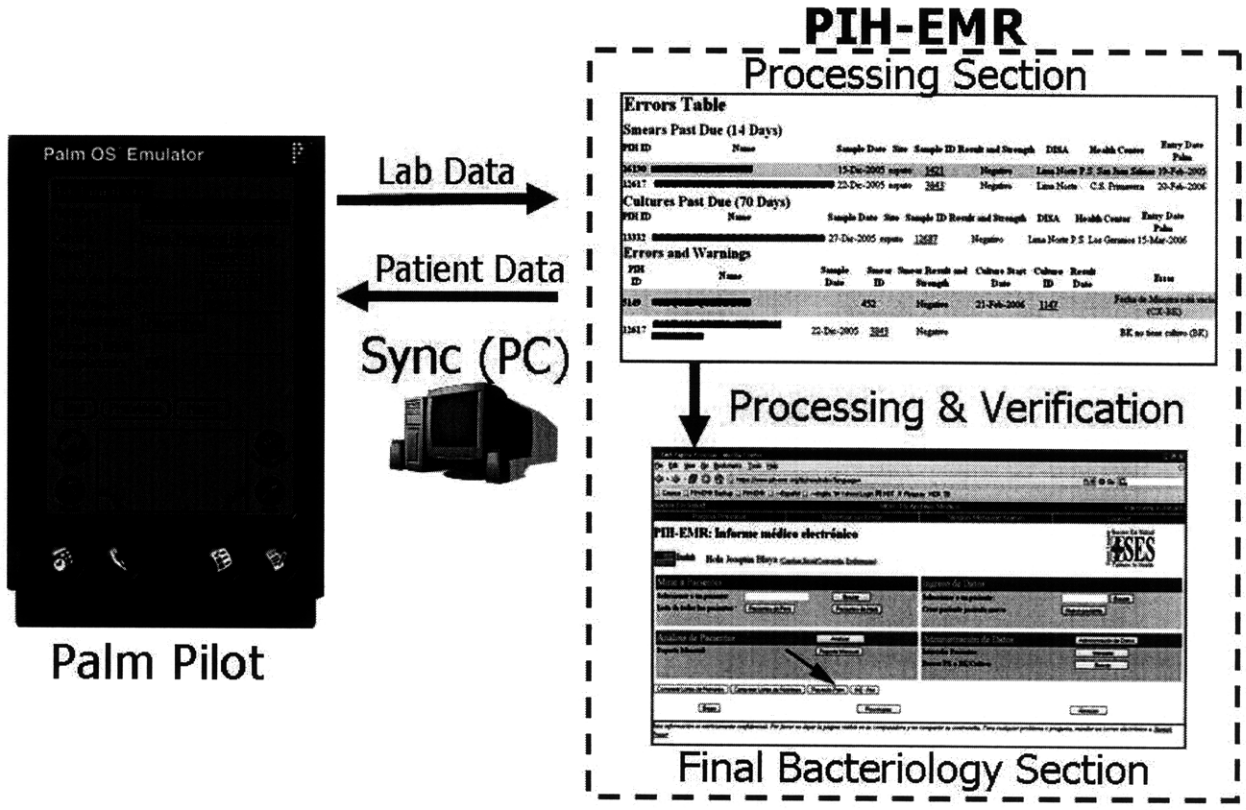


Figure 3.4 Overview of PDA-based system

3.2.1 Hardware and Software Selection

In selecting handheld computers, we compared Palm OS-based systems and Pocket PCs. We chose the low-end Palm OS-based systems (Zire 31, Zire 21, and Z22) due to their lower cost, smaller size and monochrome screens. In the poor areas where the bacteriology team collects their information, discretion is important. The Palms' smaller size made them easier to disguise within a notebook carried by the user and the monochrome screen called less attention.

In selecting software to use, we wanted to be able to do rapid prototyping of forms and be able to connect to the Oracle® database of the PIH-EMR. For these reasons we chose Pendragon® Forms, a commercial application that applies a modified client/server model to the PDA/PC relationship. It is based on a Microsoft Access® database on the PC and has the ability to "hotsync" to any Open Database Connectivity (ODBC)-compliant database. This system allowed us to quickly create forms for entering bacteriology data, as well as to download patient information and to upload completed bacteriology results to the web-based PIH-EMR using Microsoft Access® ODBC connection over the Internet.

3.2.2 PDA Forms

This bacteriology collection system was designed, developed, and tested with the BC team who had experience in collecting bacteriology results from all over Lima, Peru. At every step of development, we considered the current workflow and the role that an electronic system with decision support could have. The PDA forms were created to follow the workflow. Therefore two forms were created. The first was only for smear data (Figure 3.5a) which was used only if the smear was performed at the health center (dual site model). The second form was for both smear and culture data (Figure 3.5b) which was used at the reference laboratory in both the single and dual site models.

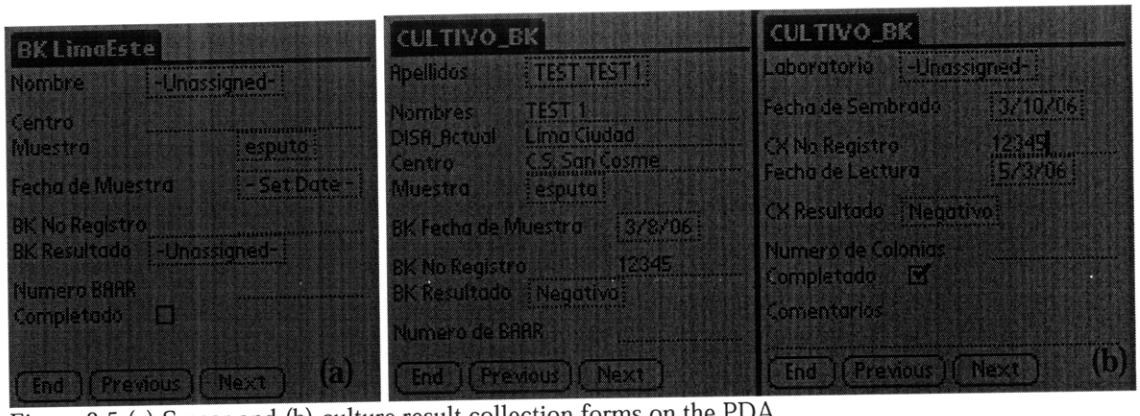


Figure 3.5 (a) Smear and (b) culture result collection forms on the PDA

We also found that the users had to carry a list of all patients on MDR-TB treatment to ensure that they searched for their monthly results. To eliminate the need for this list and to speed up the process of data entry we placed the list of all of these patients from the PIH-EMR on the collection form. This way the user could search for the name and on selecting a patient, their health district and center would be filled in automatically on the form.

The initial PDA forms had the same data as the paper forms that the BC team was using. However, as they discovered the ease of data entry, the leaders of the BC team requested that additional data fields such as the laboratory where the culture was performed and the type of specimen sent be added to the forms.

3.2.3 Decision Support System for BC Team in PIH-EMR

A module was added to the PIH-EMR which permitted the automated processing of data before transferring to the bacteriology section of the PIH-EMR for clinical and administrative use (Figure 3.6). This module included web pages which display information in a tabular format identical to the previous paper forms. They were created taking into account the workflow of the bacteriology team of data collection, verification of data, printing of additional forms and finally entry into the PIH-EMR. The pages were designed to decrease the time required to verify and enter data into the EMR as well as to improve data quality through decision support. Individual pages were created for each of the following requirements:

1. View smears results in a manner similar to the current paper form

2. View culture results and their respective smear result in a manner similar to the current paper form

3. Show errors and warnings for the entered data

4. Edit the entered data

5. Print forms for data that have been verified

6. Transfer the verified data to the bacteriology section of the PIH-EMR

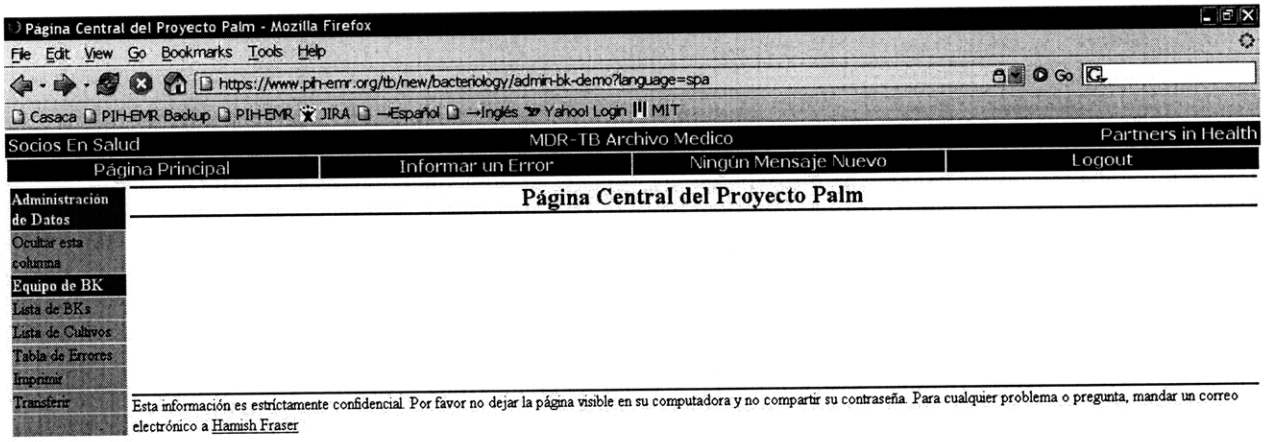


Figure 3.6 Main page of bacteriology module in PIH-EMR for bacteriology team to process results before transferring them to clinical pages of the PIH-EMR

The web page that allowed users to view all of the information in a table format identical to their previous forms can be seen in Figure 3.7. We found that these users, with low to moderate computer experience, preferred this view because (1) it allowed them to see all of the information at once, and (2) it was in a familiar format.

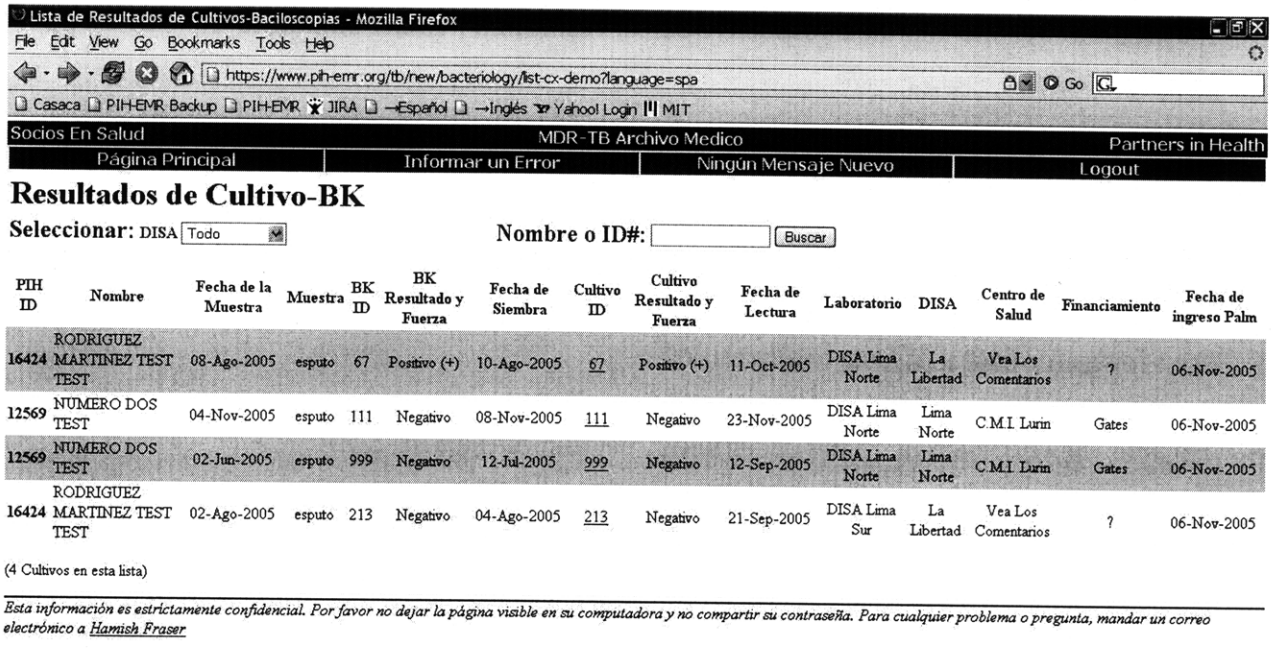


Figure 3.7 Table view of all culture and respective smears entered through the PDA-based system

The next web page performs data quality checks previously done by the team (Figure 3.8). They include:

1. Not allowing duplicate entry of a test result
2. Reporting any missing data for a specimen (first error in Figure 3.8)
3. In the dual site model, verifying that the primary and secondary smear information is identical
4. Checking that every culture has a corresponding smear and every smear a corresponding culture (second error in Figure 3.8)
5. Alerting for any overdue smear or culture that had not been transferred
6. Informing if a patient from a dual site institution is missing a smear from their health center
7. Color coding smears in the two site model to display if the smear information has been collected from both sites and cross-checked

Errors Table

Smears Past Due (14 Days)

PIH ID	Name	Sample Date	Site	Sample ID	Result and Strength	District	Health Center	Entry Date Palm
16130	[redacted]	15-Dec-2005	sputum	1421	Negative	Lima Sur	P.S. San Juan Salinas	19-Feb-2005
12617	[redacted]	15-Dec-2005	sputum	3843	Negative	Lima Ciudad	C.S. Primavera	20-Feb-2006

Cultures Past Due (70 Days)

PIH ID	Name	Sample Date	Site	Sample ID	Result and Strength	District	Health Center	Entry Date Palm
13332	[redacted]	27-Dec-05		12687	Negative	Lima Este	P.S. Los Geranios	15-Mar-2006

Errors and Warnings

PIH ID	Name	Sample Date	Smear ID	Smear Result and Strength	Culture Start Date	Culture ID	Result Date	Error
5149	[redacted]		452	Negative	21-Feb-2006	1147		Sample Date Missing (CX-BK)
12617	[redacted]	22-Dec-2005	3843	Negative				Smear with no culture

Figure 3.8 PDA-based system's decision support page in the PIH-EMR

Subsequently, the users print selected results on a standard layout and then transfer all the results to the bacteriology section of the PIH-EMR for clinical and administrative use (Figure 3.9). These web pages were color-coded depending on the test performed, whether the information had been cross-checked and whether there were remaining errors. If the data quality page detects an error or missing information in the result, it is displayed in gray and cannot be transferred.

Lista para Transferir BKs y Cultivos

Seleccionar: DISA [Todo] **Nombre o ID#:** [ ] [Buscar]

Hecho	PIH ID	Nombre	Fecha de la Muestra	Tipo	Muestra	ID de Muestra	Resultado y Fuerza	Fecha de Siembra	Fecha de Lectura	DISA	Laboratorio / Centro de Salud	Financiamiento	Impreso
☑	16424	RODRIGUEZ MARTINEZ TEST TEST	08-Ago-2005	BK	esputo	67	Positivo (+)			La Libertad	Vea Los Comentarios	?	No
☑	16424	RODRIGUEZ MARTINEZ TEST TEST	08-Ago-2005	Cultivo	esputo	67	Positivo (+)	10-Ago-2005	11-Oct-2005	La Libertad	DISA Lima Norte	?	No
☑	16424	RODRIGUEZ MARTINEZ TEST TEST	02-Ago-2005	BK	esputo	213	Negativo			La Libertad	Vea Los Comentarios	?	No
☑	16424	RODRIGUEZ MARTINEZ TEST TEST	02-Ago-2005	Cultivo	esputo	213	Negativo	04-Ago-2005	21-Sep-2005	La Libertad	DISA Lima Sur	?	No
	12569	NUMERO DOS TEST	04-Nov-2005	BK	esputo	111	Negativo			Lima Norte	C.M.I. Lurin	Gates	No
	12569	NUMERO DOS TEST	04-Nov-2005	Cultivo	esputo	111	Negativo	08-Nov-2005	23-Nov-2005	Lima Norte	DISA Lima Norte	Gates	No
☑	12569	NUMERO DOS TEST	02-Jun-2005	BK	esputo	999	Negativo			Lima Norte	C.M.I. Lurin	Gates	No
☑	12569	NUMERO DOS TEST	02-Jun-2005	Cultivo	esputo	999	Negativo	12-Jul-2005	12-Sep-2005	Lima Norte	DISA Lima Norte	Gates	No
☑	12568	NUMERO 1 TEST	04-Sep-2005	BK	esputo	123	Positivo (+)			Lima Ciudad	C.S. Juan Perez Carranza	GPAIM/CARE	No

[Transferir Bacteriologías Chequeadas]

Figure 3.9 PDA-based system's transfer page to the clinical section of the PIH-EMR

3.2.4 Additional Utilities

In the PIH-EMR, the bacteriology pages were modified to display which smear and culture results were entered through the PDA-based system. Figure 3.10 below shows the PIH-EMR's bacteriology page with several smear and cultures results marked as [palm] if they were entered by the PDA-based system.

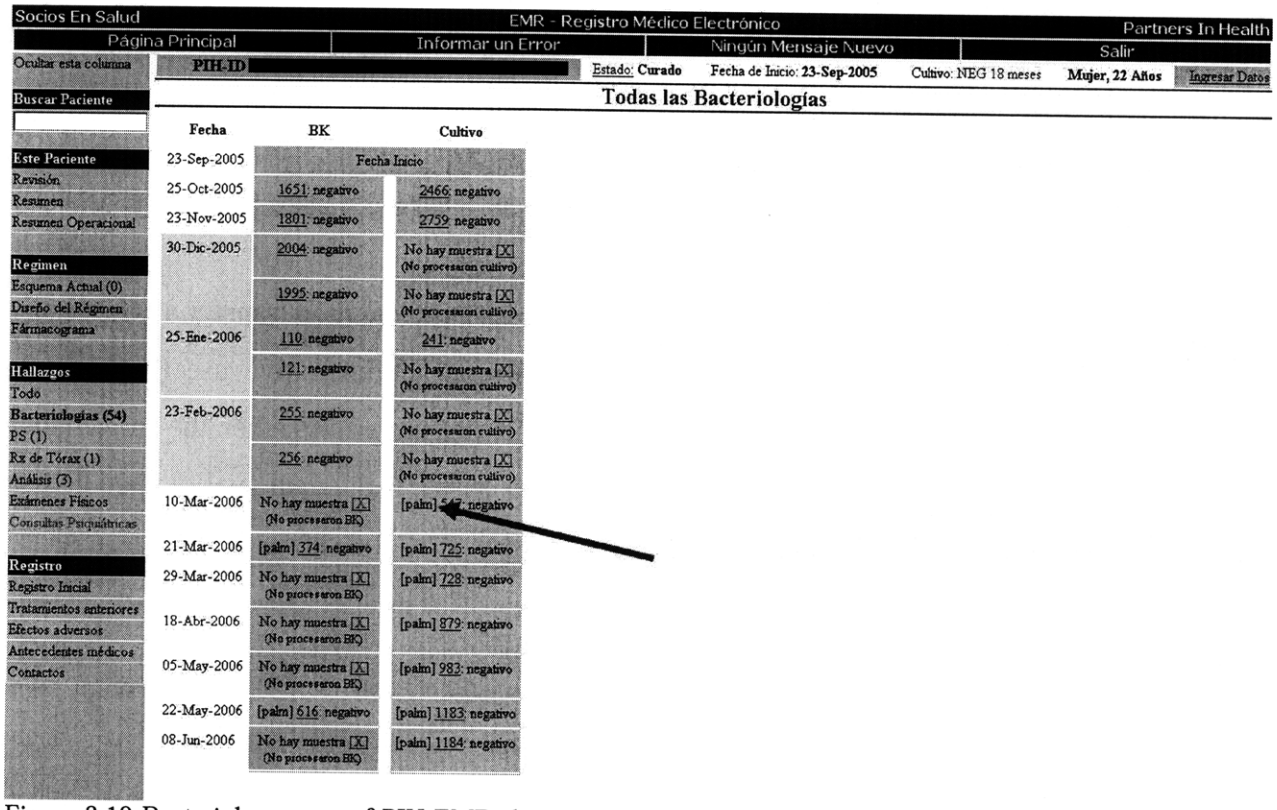


Figure 3.10 Bacteriology page of PIH-EMR showing results entered by PDA-based system marked with [palm] to the left of the sample ID (example marked with a red arrow).

Also, the leaders of the BC team had to report the number of MDR-TB patients who hadn't left their monthly sample so an additional page was implemented to facilitate this task, which showed patients who had or did not have a smear or culture result for the time period specified by the user (Figure 3.11).

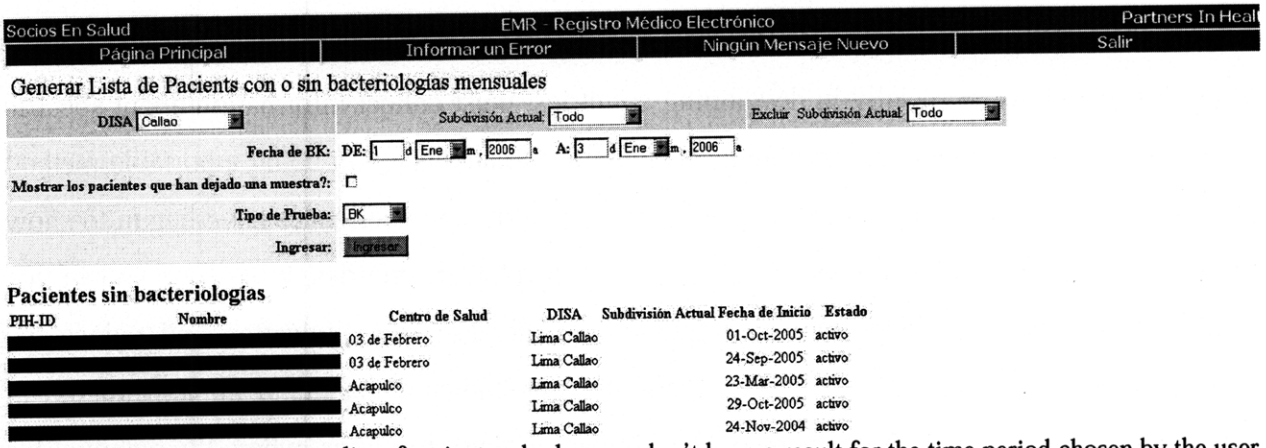


Figure 3.11 Page to generate a list of patients who have or don't have a result for the time period chosen by the user. The options on this page are to choose a health district (DISA) or any subdivision (Subdivision Actual), to exclude any subsection (Excluir subdivision actual), to choose the specific date range (Fecha de BK), show those patients who have left a sample (Mostrar los pacientes que han dejado una muestra?), and the type of test result either smear or culture (Tipo de Prueba)

3.3 Results

This system was implemented initially in September, 2004. Over the next twelve months, the system was piloted and iteratively improved for one year before a cluster randomized controlled trial and a time-motion study began.

Training for the use of this system consisted of the development of a user guide and four training sessions with the users of approximately four hours each. These sessions included training the team on the use of the PDA and web pages, as well as feedback to improve the system. The training time for new users should be considerably less. Further, there was frequent email and text messaging contact between the developer and users during the entire development and implementation periods. The frequency of contact decreased during the study period, once the system had been completed.

The user response to the electronic system was positive, although the team was initially apprehensive about its use. After 2-5 days, each of the users became comfortable with using the handheld to enter information and found that approximately the same time was required to enter information into the PDA as in the paper system. However, their most favorable response came from being able to quickly verify and transfer the bacteriology results electronically instead of having to work with large amounts of papers. Because of their experience the four users have asked to expand the system to all five health districts in Lima as soon as possible.

3.4 Discussion

Many organizations, especially in developing countries, must collect information about specific populations from a wide area. Handheld systems offer an advantage in being a portable method to digitize information at the initial point of contact and initial experiences have begun to show in what circumstances they are beneficial[75 169-171]. In developed countries, it has been shown that in clinical settings, handhelds have the potential to increase communication and reduce the number of discrepancies[172-175]. However, there are few studies of handheld implementation in developing countries, and almost none of their impact in these locations, where the potential for improvement is much larger than in developed countries.

This PDA-based laboratory result collection system allows users to gather results from many distinct health establishments and later synchronize them to a central database, to verify all the information and to transfer it to an electronic medical record system. Our hope is that the development of our PDA-based system will help others implement similar systems. We have come into contact with many organizations and researchers with similar requirements for collecting data from multiple sources in different locations. We feel that one of the key factors to success was the careful study of workflow, and the close relationship between the developers and end-users.

4 Evaluation of PDA-based System

This chapter describes the cluster randomized controlled trial performed on the PDA-based system and its results showing the system's impact. The first section describes the need for evaluations of systems for remote data collection in developing countries. The Methods section describes the methodology used for the study, the parameters studied, and the statistical methods used for this analysis. We then show how the PDA-based system was able to significantly reduce processing times and errors, as well as to be preferred by the users over the current paper system. Finally, we discuss the implications of this evaluation and conclude that a well-designed PDA-based system to collect data from institutions over a large, resource-poor area can significantly reduce delays, errors, and person-hours spent processing data.

4.1 Introduction

Clinical and research organizations often must collect data from large numbers of patients who are distributed over large geographic areas. New technologies may play an important role in ensuring that high-quality data can be quickly and reliably collected under these challenging field conditions. Ideally, organizations or individuals that need to record large amounts of data in dispersed locations would be able to electronically capture these data at the point of collection. In clinical and research settings within developed countries, personal digital assistants (PDAs) have shown some promise as a new technology which can increase the quality and efficiency of data collection, though performance has varied between studies[149 150 152-156 158 159 161 172-175]. This heterogeneity may suggest that the design and implementation of the PDA intervention play a key role in a system's success. In resource-poor settings, initial experiences have demonstrated several situations in which PDAs[75 111 112 160 169-171 176-179] and cellular phones[180 181] are of benefit. However, to date, we have found no quantitative studies of the impact of mobile technologies on the time to collect and process data, the frequency of discrepancies, or the number of person-hours required for data collection.

As described in the previous chapter, we worked with Socios En Salud, an organization that monitors multi-drug resistant tuberculosis (MDR-TB) patients in Peru, to implement a PDA-based system and study the impact of this system on data collection. The major disadvantages of this paper-based method are the delays in processing and entering laboratory results, data quality

issues stemming from multiple opportunities for transcription errors, and the heavy work load involved in the process. A preliminary study found that the mean time from the test result date to entry in the PIH-EMR was 55.3 days. A routine quality control examination found error rates as high as 10.1%, and the bacteriology team was consistently backlogged because of the increasing number of patients on treatment.

The study described here evaluated a PDA-based system which we implemented in an attempt to alleviate these problems[25]. The specific aims of this study were:

1. To compare the processing time using the electronic system to the paper-based system;
2. To compare the frequency of errors entered with and without the electronic system;
3. To assess the system's usability and its acceptability by users.

4.2 Methods

4.2.1 Study Design and Parameters

After collecting baseline data for 19 months from four of five health districts in Lima, Peru, we randomly assigned two to the intervention while two were maintained as controls. During the intervention period, we collected data on the same endpoints in both control and intervention arms (Figure 4.1). This allowed us to perform a prospective comparison between the intervention and the control arms (between-districts comparison) as well as a historical comparison comparing each arm to itself before the intervention began (within-districts comparison). This complementary design using two comparison groups allowed us to minimize the risk that the changes measured were due to secular changes in the regions studied or to baseline differences between the arms. Since the potential sources of bias should be independent, observing similar effects in both comparisons should offer reassurance that our conclusions are valid.

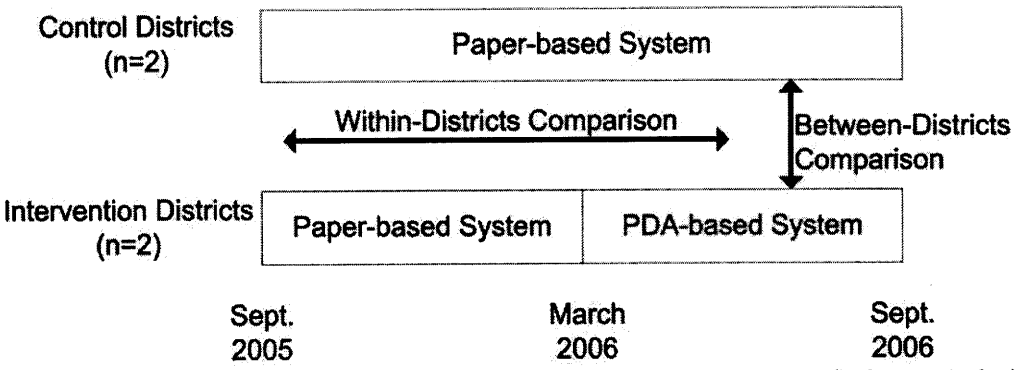


Figure 4.1 Cluster randomized controlled trial schema with within-districts (before and after) and between-districts comparisons

4.2.2 Processing Time

We defined the processing time as the number of days from the date of the bacteriology result to its entry into the PIH-EMR (Figure 4.2). The activities included within the processing time were visiting the health establishment to collect the information, processing and verifying that information at the office, and entry into the PIH-EMR for clinical and administrative use. A part of the processing time was the collection time, from the date of the bacteriology result to its collection by the team. The collection time was not affected by the intervention, but was included in the processing time because it could not be separated in the retrospective data used for the within-districts comparison. We analyzed the between-districts data and found that there was no statistically significant difference between collection times in the intervention and the control districts.

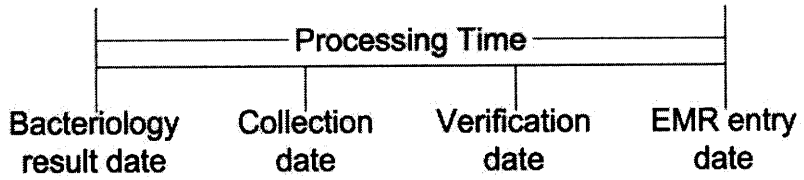


Figure 4.2 Definition of processing time

4.2.3 Collection Errors

We defined a collection error as an occurrence when information entered into the PIH-EMR did not match the original laboratory notebook (gold standard). We recorded all variables collected for cultures and smear microscopies. These included result date, identification number, result, and if the result was assigned to the wrong patient (misidentification errors).

We expected a decrease in all types of errors since data had to be entered only once in the PDA-based system compared to three times in the paper-based system. The additional forms in the paper-based system were necessary to organize the information for both clinical and administrative purposes. In the PDA-based system, these forms were placed online and generated automatically. Further, the PDA-based system had a full patient list from which the user could select a patient name. We believed that having this utility would reduce the number of misidentification errors since the users would not have to remember all active patients when they searched for results.

4.2.4 Usability and Acceptability of System

A survey that had been previously used in Peru[180], was administered to measure the usability and acceptability of the system (Appendix A). The survey was modified for our intervention, validated with other employees from our organization Partners In Health and Socios en Salud, and given to the bacteriology team. The responses were short answers or given on a five-point Likert scale anchored by 1=very negative, 5=very positive. The survey examined four themes: the amount of time each user spent collecting information, the amount of training required for each of the two systems, the effect of the PDA on the user's interaction with health care personnel, and the quantity of technical problems.

4.2.5 Data Abstraction

For the between-districts comparison, we collected all culture and their respective smear microscopy results for the six months after the full implementation of the PDA-based system (result dates between March 24 and September 24, 2006).

For the within-districts before-and-after comparison, we collected all culture and smear microscopy results entered into the PIH-EMR during the routine operation of the bacteriology team before the intervention from January 1, 2004 to July 31, 2005. Two exclusion criteria were used and the quantities and percentage of results eliminated are shown in parenthesis: (1) The PIH-EMR entry date was before the result date (2 smears 0.01%, 18 cultures 0.2%); (2) The processing time was greater than 1 year. This eliminated results collected during retrospective searches and not during routine collection (100 smears 0.8%, 223 cultures 2.1%).

We compared the data entered in the PIH-EMR with the original laboratory register by visiting each clinical site. Twenty five percent of results were reviewed a second time and we found excellent agreement (99%) with the original data. All questions about errors were resolved by a consensus between the bacteriology team and me.

4.2.6 Statistical Analysis

To compare processing times, we used a random effects model.[182] [183] There were two fixed effects: intervention and period (pre- and post-implementation) in the model. District was used as a random effect since the individual observations within the district might be correlated. To test the fit of the random effects model, we looked at the residual and QQ plot (Figure 4.3). For the residual plots in both culture and smears, the equal distribution of the residuals above and below zero shows that there are no data points that will be unusually influence the outcome of the test. For the Q-Q plots for cultures and smears, the distribution approximates a straight line. Only the far edges deviate and therefore we accepted the null hypothesis that the data were normally distributed after log transformation.

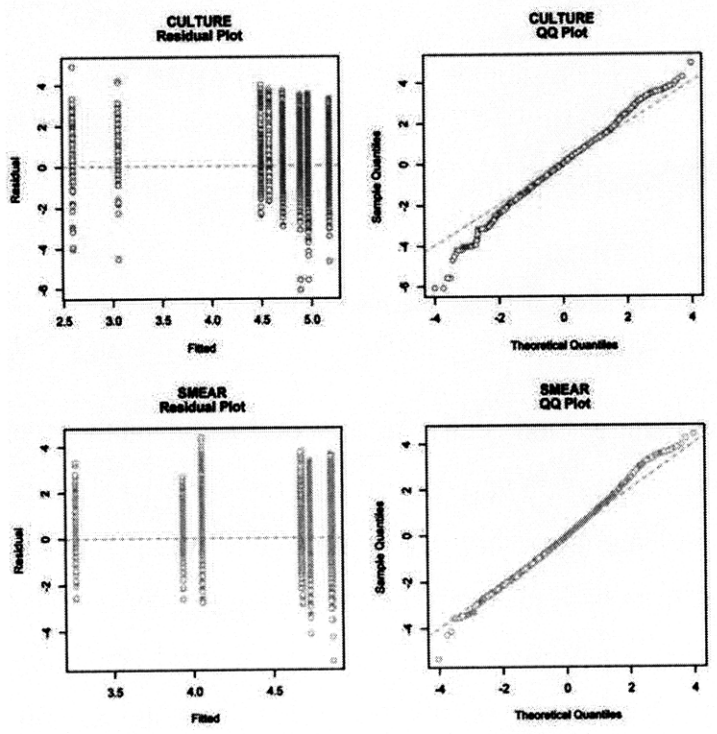


Figure 4.3 Diagnostic plots for random effects model used to compare processing times

The response variable, processing time, was log transformed as it had a right-skewed distribution (Figure 4.4). The intervention effect was tested with the period as a block in the model. The intracluster correlation coefficients (ICCs) calculated for culture and smear microscopies were 0.025 and 0.102, respectively. For the collection errors, we fit a Generalized Linear Mixed Model (GLMM)[184 185] to test for the effect of the intervention since response variable 'collection error' and 'misidentification error' were binary (1 for presence of error, 0 otherwise). In the second model, ICC's were 0.049 and 0.064.

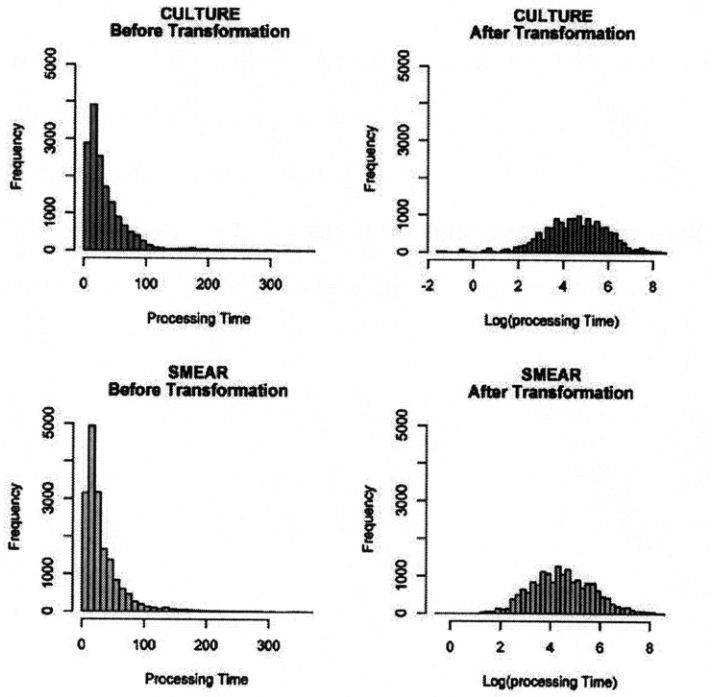


Figure 4.4 Log transformation of processing time for both culture and smear microscopies

As the collection processes differed for cultures and smear microscopies, the analysis of processing time was done separately. Smear microscopy was usually performed at a local health centre and the result communicated to a regional laboratory where the culture was performed. The smear microscopy data were collected from both locations and cross-checked before being entered into the PIH-EMR. Culture results were always collected from the regional laboratory. For the collection errors, both the process of extracting results from clinical settings and the variables collected were similar, so culture and smear microscopy results were combined. Additional data fields were implemented in the PDA system at the request of the users; however, these fields were not taken into account for the collection errors.

4.3 Results

Characteristics of the intervention and control districts are summarized in Table 4.1. The number of monthly results collected by the bacteriology team since 2004 (pre-intervention) has increased for both sets of districts. The control districts had more health centres from which data were collected (58 vs. 35) and more monthly results collected (2255 vs. 785) compared with the intervention districts. The number of years working in the bacteriology team (mean 4.5 vs. 4.9 years) and years of internet experience (mean 4.3 vs. 4.6 years) were similar before and after the PDA-based system was implemented, primarily because three team members participated in all periods of the study.

Table 4.1 Descriptive statistics of samples for study

	Before		After	
	Intervention Districts	Control Districts	Intervention Districts	Control Districts
Smear microscopies for processing time	5846	6376	2791	3435
Cultures for processing time	4876	5954	2890	3263
Smears and cultures for collection errors	677	N/A	1112	970
Health centres from which data were collected	35	58	35	58
Mean monthly smear and culture results collected	315	460	785	2255
Mean years as team member	4.5	4.5	4.9	4.9
Mean years using Internet	4.3	4.3	4.6	4.6
Culture Collection Time (days)				
Mean	43.2	43.2	9.9	35.1
Standard Deviation	39.8	40.3	10.1	45.6
Median	30.5	30.7	7.7	22.5
IQR	35.2	41.5	7.7	26.1
Smear Collection Time (days)				
Mean	32.6	42.5	15.0	34.3
Standard Deviation	34.0	43.2	12.2	38.2
Median	21.5	27.7	11.6	24.6
IQR	30.1	40.7	11.3	19.8

Bacteriology team member characteristics are identical within the before and after comparisons because users were the same and they rotated between the intervention and control districts.
IQR = interquartile range

4.3.1 Processing Times

The effect of the intervention on processing time was highly significant in both culture and smear ($p<0.001$, $p<0.001$). In the random effects model for cultures, the period effect was also significant ($p<0.001$) and the ICC was 0.025 implying relatively small variability compared to

the random error. For the smears the period was also significant ($p<0.001$) but the ICC was slightly bigger, 0.102.

Median culture processing time for the intervention districts was 65.8% less (7.7 vs. 22.5 days) in the between-districts comparison and 74.8% less (7.7 vs. 30.5 days) in the within-districts comparison (Figure 4.5a). For smears, the PDA-based system was associated with a 52.8% (11.6 vs. 24.6 days) and 45.8% (11.6 vs. 21.5 days) reduction in delay measured in the between-districts and within-district studies, respectively (Figure 4.5b). We also found that the control districts had a decrease in processing times for both cultures (22.5 vs. 30.8 days) and smears (24.6 vs. 27.7 days) after the PDA-based system was implemented in the intervention districts.

Furthermore, the timing of data entry with the PDA-based system was more predictable than the paper-based system. The interquartile range (IQR) for culture processing time in the intervention districts (7.7 days) was smaller than that for the between-districts (26.1 days) and the within-districts (35.2 days) comparisons. This effect was also observed for the smear microscopy results (11.3 vs. 19.8 and 30.1 days, respectively).

Finally, this system was able to almost eliminate outliers defined as processing time of over 90 days (Figure 4.5c and d). At baseline, 9.2% and 8.2% of cultures had a processing time of at least this long for the intervention and control districts, respectively. This decreased to 0.1% in the intervention district post-implementation compared to 5.4% in the control district post-implementation. The same phenomenon was observed for smear results where the pre-implementation values were 6.0% and 9.1% for the intervention and control districts, respectively, and they decreased to 0.1% and 4.8% post-implementation.

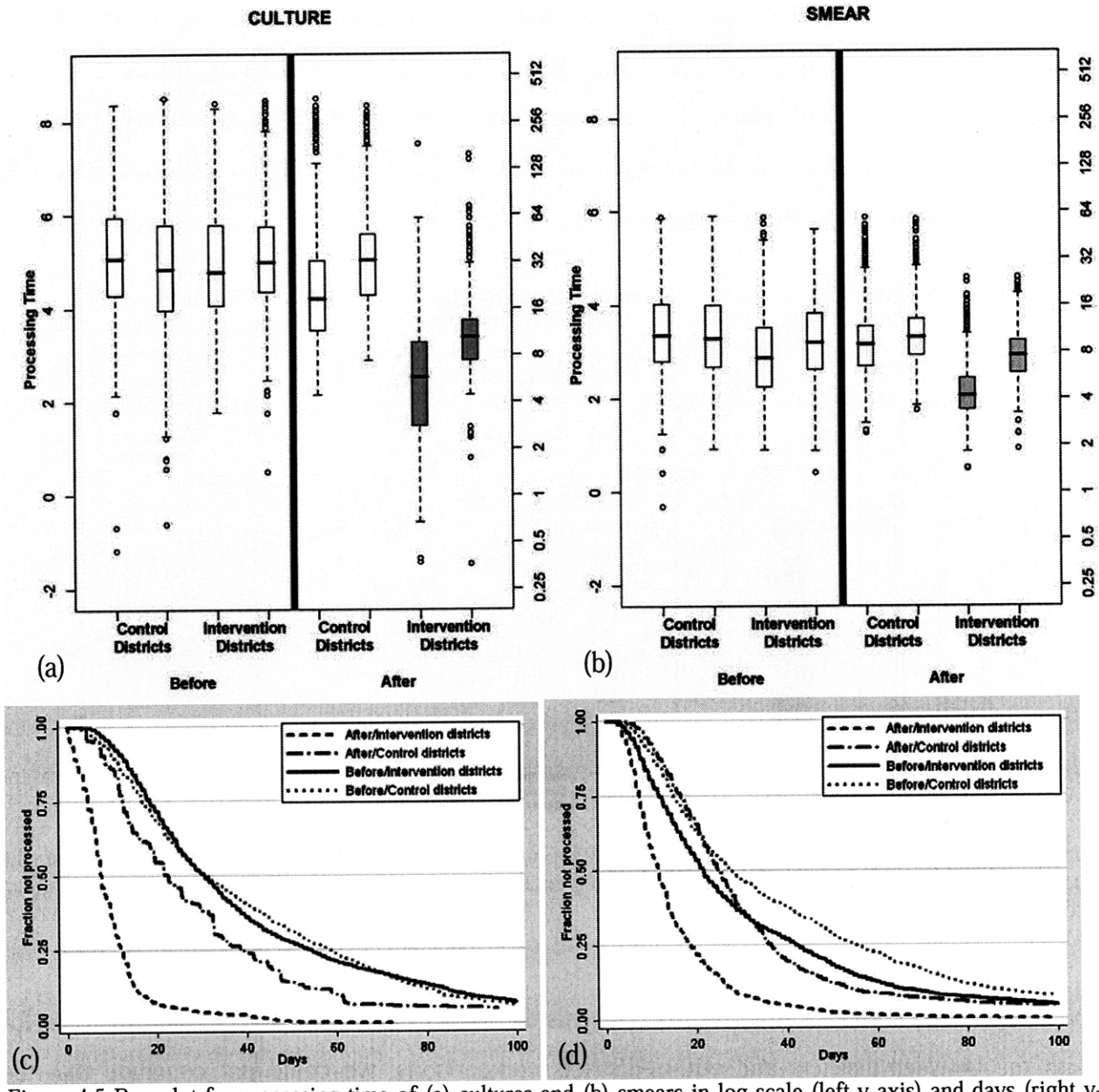


Figure 4.5 Box plot for processing time of (a) cultures and (b) smears in log scale (left y-axis) and days (right y-axis). These show that for both culture and smear results there was a statistically significant decrease ($p<0.001$) in the processing time with the PDA-based system (intervention districts after) compared to the same districts before the implementation (intervention districts before) and districts with the paper-based system (control districts after). The Kaplan Meier survival curves for the initial 100 days for (c) culture and (d) smear microscopy show that the PDA-based system was able to drastically decrease the number of outlying results with a processing time of over 90 days.

4.3.2 Collection Errors

After fitting GLMM's, we found that the intervention had a significant effect on the total frequency of collection errors (p=0.005); the fraction by which errors were reduced was 57.1% for the between-districts comparison and 39.1% for the within-districts comparison. The proportion of results with errors in the intervention districts was 2.6% (29 of 1112 results) compared to 6.1% (59 of 970 results) and 4.3% (29 of 677 samples) in the control districts and the baseline intervention districts, respectively (Figure 4.6).

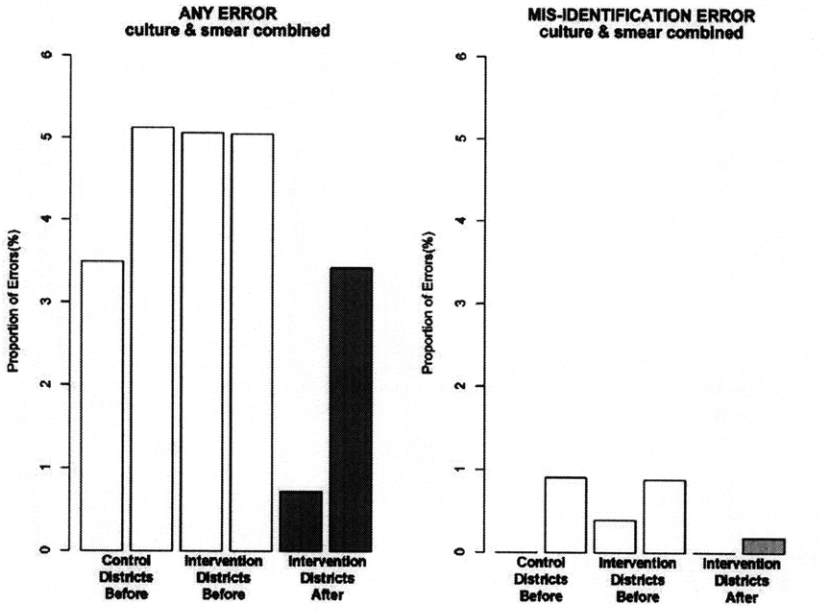


Figure 4.6 Proportion of total and misidentification errors comparing the intervention districts after the implementation to the historical control group (intervention districts before) and the prospective control group (control districts before).

Despite finding 80-85% fewer results with misidentification errors in intervention districts for both the between-districts and within-districts comparisons, we could not conclude that the intervention significantly lowered the frequency of this serious type of error (p=0.074). This is largely attributable to small numbers of these types of errors overall; intervention districts had an error rate of 0.09% (1 in 1112 samples) compared to 0.62% (6 in 970 samples) in the control districts and 0.44% (3 in 677 samples) in the baseline data for the intervention districts. Unlike processing time, the period effect was not found to be significant for either type of error (p=0.554, p=0.064). The ICCs were small for both collection errors (0.049) and for misidentification errors (0.064).

4.3.3 Usability and Acceptability of System

The user feedback about the electronic system was positive, with all four users preferring the PDA-based over the paper-based system. After less than five days of practice, each of the users became comfortable with using the PDA to enter information. The users noted the ability to quickly verify and transfer results electronically instead of working with large amounts of paper and to access an updated patient list automatically uploaded to the PDA instead of having to manually create it every week as favourite features of the electronic system. The users asked to conclude the study early so that the system could be expanded to all health districts in Lima as soon as possible.

All users found it easier to learn to use (mean 4.0 out of 5) than the paper based system (mean 3.5 out of 5), to collect results with the PDA (4.5 vs. 3.5), and to process results (4.75 vs. 3.0). All users said that the intervention affected their relationship with the local health centre personnel in a positive or very positive way. Two of the users expressed that it improved their relationship because it seemed more professional and they could explain its use.

4.4 Discussion

Many organizations must collect information from a population which is distributed over a large area. In a previous publication, we reported on the design and implementation of a PDA-based system to collect TB bacteriological data from many institutions[25]. In this full evaluation, we found that the use of this system was associated with a substantial reduction of the delays from collection to entry of laboratory results, a decreased frequency of errors, and a reduced workload for those involved in data collection and processing.

This system was able to reduce the median processing time by 46-74% depending on the type of result and comparison. Also, the intervention almost eliminated large delays of over three months from between 6-9% to 0.1%. The intervention districts had 39% and 57% fewer errors than the baseline intervention and control districts, respectively. We believe this improvement resulted from eliminating manual data entry and providing electronic verification tools. Finally, the intervention lowered the person-hours spent processing and verifying data and was well-liked by users. One user wrote "With the paper system our work was always late. With the PDA system our work is up to date." Providing more timely and accurate bacteriology data to

clinicians should allow them to monitor their patients better and reduce the amount of time that patients are infectious. This is the first quantitative evaluation showing that a user-friendly PDA-based system to collect data in resource-poor settings can significantly reduce processing time, decrease the frequency of collection errors, and lower the effort required for processing.

We also found that the control districts had a decrease in the mean delay of 27% and 11% for cultures and smears, respectively, compared to the pre-intervention delay. In reviewing the results with the team, they asserted that the main reason for this decrease was that they had more time to work in the control districts because their work load in the intervention districts was reduced.

Another possible measure of the success of this system is its continued use and expansion. After the study period, the PDA-based system was transferred to our Peruvian partners. This process consisted of training their technical team and providing monthly technical advice via phone. At the request of the users, they have expanded the system to the control districts, one additional district in Lima and five provinces of Peru. Additionally, four new users have been added with the leaders of the bacteriology team preparing and performing the training. Finally, at the request of the clinical staff, the same system is currently being extended to incorporate the collection of patient weight and height data. All activities and costs for these additional activities are described in Chapter 5.

4.4.1 Limitations of study

Though this study is small, with four users in four health districts, the use of dual comparison groups (between-districts and within-districts before-and-after) helped us to minimize potential biases due to secular trends and baseline between district differences. Further, we took other steps to reduce sources of bias by rotating the users of the system and ensuring that no other changes in collection were made during the study. Finally, this was a formative, rather than summative, evaluation since the developers were involved, although the expansion and continued maintenance of the system by local staff independent of the original developer shows its sustainability.

4.5 Conclusion

This study shows that a well designed PDA-based system can provide large improvements in community data collection for clinical and administrative purposes, even in resource-poor settings. These systems can provide higher quality data with fewer communication delays and person-hours required, though the effort, time, and attention to detail required to create these systems must be taken into account. These benefits might also be seen in the use of cellular phones, especially smart phones. However, their user interface and connectivity with a larger record system must be studied further. Organizations working at the community level or requiring data from institutions spread over a large area should consider the advantages of using mobile data collection systems.

5 Cost Analysis of PDA-based System

This chapter describes a cost analysis and time motion study performed on the PDA-based system. Here we evaluated the system's effect on users' workloads and their perception of the system's effect. We also performed a cost-analysis of implementing and expansion of this system. Finally we provide a framework and case-study of how to implement PDA-based systems in resource-poor settings.

5.1 Introduction

Many clinical and research organizations must collect data from locations distributed over a large area to monitor patients, conduct surveys, or perform research. Although there is still some debate in developed countries, many studies have shown that personal digital assistants (PDAs) can increase communication and reduce discrepancies for these purposes[149 150 152-156 158 159 161 172-175]. In resource-poor settings, implementations of PDA-based systems for data collection are increasing[75 111 112 160 169-171 176-179 186 187], however, to date, we have not found any quantitative studies of the development and implementation costs and potential savings associated with using these technologies for data collection. There are many important unanswered questions for institutions or projects considering using these technologies. Among them are: what are the initial and recurring costs of using these types of systems? How long will it take to implement? What are the processes required to create and implement a functional system? Will the investment in information technology pay for itself?

5.2 Methods

5.2.1 Study Design and Data Collection

To assess the intervention's effect on the team's work, we performed a time-motion study, described below, during a prospective controlled trial, described in Section 4.1, where four of five health districts in Lima, Peru were selected by chance to the PDA intervention or the current paper system. Since team members spend little time on any individual task, we chose a type of time-motion study formerly used at the Regenstrief Institute for Health Care[188].

The time-motion study was performed six months after full implementation of the PDA-based system (March 24-Sept. 24, 2006) and consisted of a single observer following the team

members during routine data collection. The assistant assigned all tasks to one of the pre-established set of categories (Table 5.1). Each task was visually identified when it began, without verbal explanation by the team member. It was timed using a stop watch and results rounded to the nearest half minute. The observer then recorded the task, start, and end times. Since there was continual observation of users there were no missing data. There are fewer categories for the PDA-based system because many paper processes were automated or eliminated. For example, sheets with patient names were eliminated since this information was in the PDA. Also, manual entry of results into the PIH-EMR was replaced with an automated transfer feature. If multiple identical tasks were performed consecutively, the time for the group was recorded. All materials used by the BC team were also logged.

To calculate the average time per result for collection, the total number of minutes for all processes was divided by the total number of results collected. In order to calculate average processing time, the total number of minutes for all processes was divided by the total number of results entered into the PIH-EMR. The total number of results collected or entered were used for the denominator since all of the other processes were performed on a sub-group of there results. Thus, this average time per result for collection or processing includes all processes required on any sample.

Cost data on the development and implementation of the intervention were collected from the beginning of the project, one year before the study. Data on the technology transfer and expansion were collected for one year after the study. All costs are in 2006 US$.

Table 5.1 Time-Motion study results for collection and processing tasks showing the number of samples, mean minutes per sample, the change caused by the PDA-based system, and corresponding p-value for each task.

	Paper System		PDA-based System			
Task	Samples	mean minutes per sample	Samples	mean minutes per sample	Estimate of change (difference)	p-value
Recording smear result	709	1.08	594	1.51	0.43	0.07
Verifying smear result	12	3.67	128	2.26	-1.41	0.78
Recording new culture test	319	0.53	483	0.78	0.26	0.89
Recording culture result	552	0.38	639	0.42	0.05	0.90
Verifying culture result	18	2.50	3	4.33	1.83	
Waiting (total minutes)		301		138	-163	
Total smear collection time	**709**	**1.36**	**594**	**2.11**	**0.75**	**0.12**
Total culture collection time	**552**	**1.04**	**639**	**1.15**	**0.11**	**0.31**
Enter smear to PIH-EMR	970	0.77	1277	0.06	-0.71	< 0.001
Process smear	193	1.06	230	1.45	0.39	0.12
Copy smear	887	3.03				
Enter culture to PIH-EMR	1134	0.77	1442	0.06	-0.71	< 0.001
Process culture	198	1.04	353	1.36	0.32	0.02
Copy culture	575	2.50				
PDA synchronization			29	7.90		
Create new patient sheet	44	6.59				
Update patient list	458	0.71				
Prepare materials	364	1.01				
Photocopy collection sheet	165	0.67				
Total smear processing time	**970**	**4.09**	**1277**	**0.41**	**-3.68**	**<0.001**
Total culture processing time	**1134**	**3.68**	**1442**	**0.47**	**-3.21**	**<0.001**
Total smear time		**5.45**		**2.52**	**-2.93**	**0.01**
Total culture time		**4.72**		**1.62**	**-3.10**	**0.01**

To calculate the average time per result for collection, the total number of minutes for all processes was divided by the total number of results collected. In order to calculate average processing time, the total number of minutes for all processes was divided by the total number of results entered into the PIH-EMR. The total number of results collected or entered were used for the denominator since all of the other processes were performed on a sub-group of results. Thus, this average time per result for collection or processing includes all processes required on any sample.

5.2.2 Statistical Analysis

We used a t-test for two independent samples to analyze the differences in the means of the time-motion study with the Satterthwaite's approximation for the degrees of freedom because of the unequal variances between the groups. Two-sided p values < 0.05 were considered statistically significant.

5.2.3 Costing

We collected the tasks and costs of developing, implementing and transferring the PDA-based system to the local organization (Table 5.2). Since system requirements were developed

iteratively, development and implementation occurred simultaneously. However, we have separated them for clarity.

Personnel costs were approximated from standard salaries at non-profit organization in each respective country. A US-based developer's hourly rate is $30 ($60,000 annually) and an advanced US-based programmer's $35 ($70,000 annually). The average annual salary of a Peruvian data collector, information technology (IT) technician, and developer are $3,000 (average Peruvian salary is $2620[189]), $12,000, and $18,000, respectively.

The paper system had been in use at the local organization for over 7 years, so it was not possible to measure its development costs. For recurring costs, we collected data on the functioning of the BC team. This included the time-motion study and recording all materials used.

Table 5.2 Processes and costs of developing and implementing PDA-based system, 2006 US$

Process Name	Description	Costs	
		Paper (US$)	PDA-based system (US$)
Workflow Assessment			
Site Visits	1 two-week Peru trip by developer: flight, hotel, food		$1,500
Learning workflow	2 week full-time developer		$2,400
Meetings with team members	2 two-hour meetings, developer with 4 person BC team		$152
Development			
Learning PDA software	2 weeks half-time developer		$1,200
Learning software for PIH-EMR	2 weeks full-time developer		$2,400
Training on PIH-EMR by advanced programmer	5 days half-time advanced programmer		$700
Creation of PDA forms, decision support & transfer modules in PIH-EMR	10 weeks half-time developer		$6,000
Consults to advanced programmer	4 days half-time advanced programmer		$560
Writing of user manual	2 full-time days developer, 1 full-time day BC team member		$496
Deployment			
Site Visits	2 two-week Peru trips by developer: flight, hotel, food		$3,000
Installation	3 days full-time developer, 2 days full-time Peruvian developer		$912
Trainings	2 two-hour meetings, developer with 4 person BC team		$152
Troubleshooting	4 weeks half-time, 8 weeks quarter-time developer, 12 weeks 0.1-time BC team member		$4,875
Technology Transfer			
Writing technical manual	1 full-time day developer		$240
Training technical personnel	1 two-hour meeting, developer with 2 Peruvian developers, 10 one-hour Skype conversations		$480
Materials			
PDAs, accessories, software	3 work & 1 backup PDAs, accessories, Pendragon Forms license, Oracle software		$1,025
Office supplies	Folders, Filing cabinets, paper	$279	
TOTAL		$279	$26,092

5.2.4 User's perception

A survey, used previously in Peru[190], was employed to assess users' time spent on each sample and the technical problems experienced. The survey was modified, validated with other employees, and given to the team after study completion (Appendix A). Responses were on a five-point Likert scale (1=very negative, 2=negative, 3=neither negative nor positive, 4=positive, 5=very positive) or short, numeric answers. For Likert scale responses, scores were averaged across all users. The short, numeric answers, such as number of technical problems per month, were also averaged across all users.

5.3 Results

Baseline characteristics are summarized in Table 5.3. The control districts had more health centers (58 vs. 35) and more monthly results collected (2,255 vs. 785). The BC team's work experience (mean 4.9 years) and years of internet experience (mean 4.6 years) are identical between intervention and control districts because all team members rotated between districts.

Table 5.3 Sample sizes for smear microscopies and cultures collected during study, number of health centers, mean monthly results, and average experience of users for control districts (current paper system) and intervention districts (PDA-based system).

	Intervention Districts	Control Districts
Collected smear microscopies	594	709
Collected cultures	639	552
Processed smear microscopies	1277	970
Processed cultures	1442	1134
Health centers from which data were collected	35	58
Mean monthly smear and culture results collected	785	2255
Years as BC team member		
Mean	4.9	4.9
Minimum	1.5	1.5
Maximum	7	7
Years using Internet		
Mean	4.6	4.6
Minimum	1.5	1.5
Maximum	8	8

BC team member characteristics are identical because all users rotated between the intervention and control districts before and after the implementation of the PDA-based system.

5.3.1 Time-Motion Study

Overall, time spent collecting and processing results decreased by 54% (5.45 to 2.52 minutes) for smear microscopies and by 66% (4.72 to 1.62 minutes) for cultures (Table 5.1). If the PDA-based system were expanded to all sites, the time saved would be 221 person-hours per month. To further analyze this, processes were divided into either collection or processing categories.

In the collection categories, the PDA-based system had a larger average collection time for both smear microscopies (1.36 to 2.11 minutes) and cultures (1.04 to 1.15) than the paper system (Table 5.1). This was partly due to additional collection fields implemented in the PDA. For smears, this increase was largely due to more verified smears in the intervention than control districts (128 to 12 samples) though the average time was less for the PDA (2.26 to 3.67

minutes). This difference was due to additional regulations in the intervention districts adopted by the control districts after the study.

In the processing categories, the PDA-based system required 90% less time for smear microscopies (4.09 to 0.41 minutes) and 87% for cultures (3.68 to 0.47 minutes) than the paper system. The major contributor was the elimination of office processes such as creating new patient sheets and of duplicate entry at the clinical site and then into the PIH-EMR.

5.3.2 Costs

The total cost of implementing, developing and transferring the PDA-based system was $26,092 (Table 5.2). These costs included a US-based developer travelling to Peru to learn the team's workflow and deploy the system. It also included software development (12 weeks), testing and troubleshooting (12 weeks), and writing instructions (2 days). There were frequent emails between the developer and users during these periods, which decreased considerably after full implementation. Materials for the system totaled $1,025 and included 3 PDAs with accessories and Pendragon Forms licenses (Table 5.2). Training for the use of this system consisted of writing a user guide and two four-hour training sessions. Finally, the US developer trained a Peruvian IT technician and programmer to maintain and update the system.

This Peruvian technical team expanded the PDA-based system to the three remaining health districts in Lima and to nine health district in other provinces in Peru. The total time and cost for this expansion was three months and $1,125 (Table 5.4). It took this long because the technicians needed to learn to both troubleshoot and expand the current forms. Also, at the request of the clinical team, the Peruvian technical team created an additional data collection form for patient weights. This took five months and cost $4,107. The initial creation took two months, however they encountered a bug in Microsoft Access® which took three months to solve. We therefore believe this example over-estimates the cost of implementing additional collection forms. Additionally, six new users were trained by the leaders of the original BC team.

The paper system costs consist of fixed costs such as filing cabinets and folders ($279) and recurring monthly costs of photocopies and printouts ($32). Development costs could not be measured since it had been implemented for over 7 years.

Table 5.4 Costs of expanding PDA-based system to 9 additional districts and implementing additional data collection form by Peruvian personnel, 2006 US$

Process	Description	Cost (US$)
Development		
Learning to manage system	10% time information technology (IT) technician 3 months	$288
Expanding forms for new districts	5% time IT technician 3 months	$144
Deployment		
Installation	2 hours IT technician	$12
Trainings	3 trainings led by original data collection team for 6 community health workers, 3 hours each	$113
Troubleshooting	5% time IT technician and data collection team member 3 months, 8 hours Peruvian Programmer	$182
Materials		
PDAs, accessories, software	2 palms (1 additional, 1 replacement), accessories, 2 additional Pendragon Forms licenses	$387
TOTAL		$1,125
Development		
Creating requirements for additional form	2 leaders of data collection team 1 day	$25
Learning and creating additional form	40% time IT technician 2 months	$768
Solving technical problem with lack of decimal point	30% time IT technician and Peruvian programmer 3 months	$2,160
Deployment		
Installation	2 hours IT technician	$12
Trainings	1 hour training by IT technician, 3 hours training by original data collection team	$22
Materials		
PDA, Computer	1 PDA for performing testing by IT technician, 1 PC to act as additional synchronization station	$1,120
TOTAL		$4,107

5.3.3 Break-even Point

The break-even point, at which savings on personnel and materials costs equal intervention costs, for the development and implementation of the system was 66.3 months or 5.5 years (Table 5.5). More importantly, the break-even points to expand from two to eleven districts and create additional forms were 2.9 and 10.4 months, respectively (Table 5.5). These calculations assume identical monthly savings.

Table 5.5 Sensitivity analysis for break-even point of implementing and expanding PDA-based system. All costs are in 2006 US$.

Item	Quantity/Cost
Average monthly tests entered by BC team	4,406
Average time saved per test (minutes/result)	3.01
Monthly work hours saved (hours)	221.01
Average monthly salary of BC team (US$)	$264.03
Monthly savings from increased efficiency (US$)	$364.71
Monthly savings from materials (US$)	$29.00
Total monthly savings (US$)	$393.71
Months to break-even Implementation	
Materials only	2.6
Total Cost	66.3
Months to break-even Expansion	
Expansion of Current System to 9 districts	2.9
Implementing Additional Collection Forms	10.4

5.3.4 User's perception

Overall user satisfaction was higher for the PDA (mean 5 out of 5) than for the paper (mean 3.5 out of 5). Users responded that the intervention reduced mean time per result from 6.75 to less than 2 minutes. Over the six month implementation period users experienced, on average, 1.13 technical problems per month which they themselves could fix in the field (2 users) or back at the office (2 users).

There were also role changes because each SES team member was able to collect and enter their own data without having to rely on other team members or additional data entry personnel. One user said "Now it's faster because we verify and enter the data ourselves."

5.4 Discussion

The previous chapter showed that a PDA-based system to collect bacteriological data from many institutions without internet could reduce processing delays and errors[25]. In this chapter, we showed, in a time-motion study, that it reduced the person-hours required to process samples by over 50% compared to the paper system and that users felt this reduction was 70%. We also provided a framework to develop, implement, and transfer such a system to a local organization in a resource-poor setting. This framework identifies the personnel, processes, and costs required to either create a new system or to expand the one described in this thesis.

In the time-motion study, the increase in collection time by the PDA-based system for smears occurred mostly because of two reasons. The first is a baseline difference due to a legal policy in the intervention districts requiring communication of smear results from health centers to regional laboratories. This meant that the SES team had to verify the communicated results. During the time of this study only the intervention districts had this policy, though it is now active in all districts. The second reason was that 3 or 4 additional fields were implemented in the PDA for culture and smear results, respectively, at the request of the SES team.

The implementation times and processes described here should be broadly generalizable to organizations having at least one individual with basic IT experience. For the costs of the project, however, local wages should be substituted to arrive at the actual cost. The majority of the PDA-based system's cost was the US-based developer's salary. It for 86% ($22,439) of the total project cost of $26,092. A more cost-effective model would develop the system locally rather than in the US. Both system expansions described here were performed by local developers. The number of work-hours were 20% less than original development (539 vs. 670 hours), but the cost was 80% less ($5,232 vs. $26,092).

Three essential parts of the development framework that should be emphasized are: user appropriation of the system, iterative development cycles, and a prolonged technology transfer period. First, having users appropriate the system is crucial to its ability to foster improvement and its sustainability. A thorough workflow assessment is essential to this process [191] because it involves future users at the beginning of the development process. Also important for user appropriation is their constant input when troubleshooting the system. Conversations with users of the PDA-based system confirmed their sense of ownership because they participated in the entire development and implementation processes. Second, iterative cycles between development and deployment are required to have all functionality working appropriately; however if a thorough workflow assessment is performed at the beginning, fewer cycles (and less development time) can be expected. For most systems, if there is a single design period, it will not be able to meet all user needs and have a higher chance of failure. Finally, transferring technology for local administration of a system consists of more than a well-written user manual and a few meetings conducted within a short time frame. There must be planning from the

beginning of the project and continued conversations over time (probably months, if not years) when unforeseen issues arise.

There were limitations to this study. A few costs could not be accounted for, such as the external data entry personnel required to enter backlogged data or the time required to create reports. All of these unmeasured costs were related to the paper system and therefore would have made the PDA-based system more affordable in comparison. Also, the PDA-based system was partly created in the PIH-EMR, an already-implemented medical record system. However, a simpler system could be created using MS Access®. Finally, this was a formative, rather than summative evaluation since the developers were involved, though the expansion and maintenance by local staff shows the system's sustainability.

More organizations should be able to use this or similar systems since the technical barriers and costs of local development of PDA-based data collection systems are currently being lowered. For example, Epihandy (www.epihandy.org), a PDA form creation tool, has recently been programmed to connect to the medical record system OpenMRS (www.openMRS.org). A similar effort is underway with EpiSurveyor (www.datadyne.org), another PDA form creation tool. All are open source software that are available free on the Internet and offer a potentially low cost and sustainable system, though more development may be required to match the flexibility of Pendragon Forms®.

5.5 Conclusions

This chapter describes the processes and costs of implementing a PDA-based system to collect data and its ability to significantly decrease collection and reporting times. It also shows the cost savings resulting from expanding the existing system and shows the time and resources required for this expansion. These results should guide organizations that need to collect data from many locations and provide an estimate of the time, costs, and personnel requirements for the implementation of an electronic system. With the methodology described, local developers, and free, open source software becoming more available, many organizations could reap the benefits of this technology.

6 Design and Implementation of e-Chasqui, a Web-based Tuberculosis Laboratory Information System

This chapter describes the design and implementation of a web-based TB laboratory information system to communicate data between a national laboratory, two regional laboratories, and 12 health centers (HC) in Lima, Peru. This system was designed to support a national TB laboratory network connecting all participating institutions. We then describe the expansion of the system at the request of the public administration. Finally, we examine broader issues of implementing these types of systems in resource-poor settings including costs and sustainability.

6.1 Background on organization

SES, Harvard Medical School, and the US Centers for Diseases Control and Prevention (CDC), in collaboration with the Peruvian Ministry of Health (MINSA), are performing a study "Operational Assessment of Rapid Diagnostic Methods for MDR-TB in Lima, Peru" to decentralize drug susceptibility tests (DST) and increase regional laboratory capacity. This implementation of decentralized, rapid DST is underway as part of nationwide efforts to scale up services for detection and treatment of MDR-TB and extensively drug resistant TB (XDR-TB)[192]. Whereas initially only the Peruvian National Reference Laboratory (NRL) performed DST, the capacity of the regional laboratories has expanded to include rapid and conventional first-line DSTs. The typical flow of a suspected TB patient's sputum sample from the initial treatment site through the laboratory network is depicted in Figure 6.1. Each test result is communicated serially, and in each step, there are delays and the potential to lose the result.

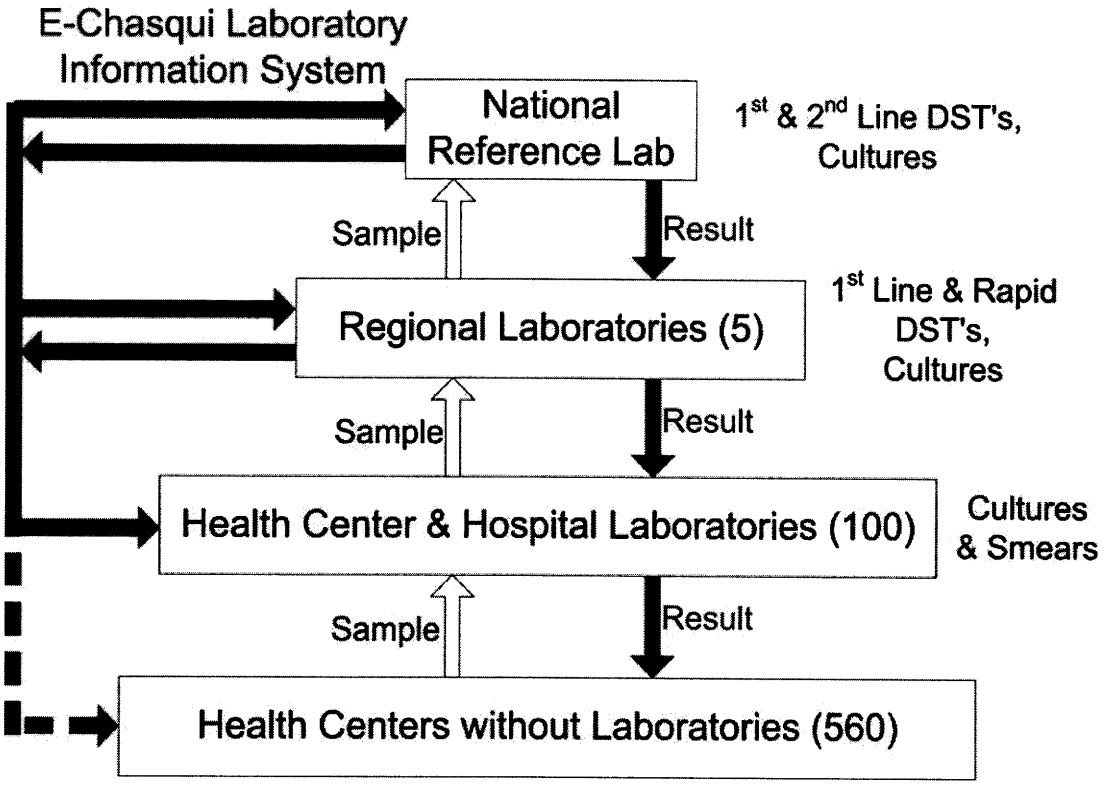


Figure 6.1 Tuberculosis laboratory structure/workflow in Lima and locations of e-Chasqui implementation

A study of turn-around-times (TATs) for cultures and DSTs within the Peruvian public health system suggests that patients could still experience risky delays despite availability of decentralized, rapid DST unless programmatic aspects are also addressed[15]. In addition to reducing communication delays, minimizing lost and erroneous results is essential for reducing morbidity in these high-risk patients. To improve these aspects, we developed and implemented the laboratory information system described herein.

6.2 Methods

6.2.1 Needs Assessment

The first step in creating the laboratory information system was to conduct a needs assessment of the major stakeholders: the personnel in the HCs, regional, and national laboratories. After working with the director, laboratory technician and data entry staff in the participating laboratories and the TB clinician, nurse and local laboratory technician in several key HCs, a list of information requirements was created, shown in Table 6.1. While most requirements were identified during this initial period, others emerged during the implementation process.

Table 6.1 Needs assessment of health centers and laboratories

Health Centers
All information displayed to mirror paper forms
Find patient by name despite constant misspellings
Fast access despite low bandwidth
Easily access patient's individual result and history of all results
For a sample view all tests performed and date when sample was taken
View all recent results by HC
Track all tests pending by HC
Access information on samples collected in other institutions (e.g. while hospitalized, prior to transfer to their HC)
Email notification of new test results
Print out a test result in the official MINSA format
Display trend in DST requests by HC
Show MDR-TB patients not appropriate treatment
Current patients failing treatment
Access latest information on evidence-based TB treatment
Laboratories
Integrate into laboratory workflow with minimal disturbance or increased work
Search for sample by ID number
Individual results printed in current paper form
Aggregate reporting for all tests entered
Ability to view all culture and DST results reported within an arbitrary time period
Improve quality control of test results
Ability to modify or "grow" system with continual requirements
Compatibility with existing computerized information systems

6.2.2 Integration into Laboratory Workflow

The laboratory information system needed to be integrated within the workflow of the busy regional and central laboratories. We performed a thorough workflow analysis of each laboratory's systems of information, each staff's responsibilities, quality control, and tests performed, and designed the system to follow the current workflow of intake, processing, and reporting. However, the integration of the information system still required workflow adjustments to incorporate data entry, digital verification, and printing of results from the system. This was done through iterative discussions with the laboratory directors followed by an hour-long training session for all laboratory personnel. These changes in workflow, however, did not result in increased time demands; instead the revised system resulted in greater efficiency for most laboratory personnel, since the database (with reliable back-up) obviated the need to photocopy and maintain physical copies of all results at the laboratory.

Finally, the laboratory information system had to integrate with current laboratory reporting systems being used. During the implementation of e-Chasqui the NRL moved from using the PHLIS laboratory reporting system,[130] to an in-house developed laboratory management system. To communicate data between these systems, a tool was created to manually export all results; we are currently defining other inter-system communication methods.

6.2.3 System Design

The electronic laboratory information system, called e-Chasqui[2] (Figure 6.2), supports the decentralized entry and viewing of bacteriological tests (smear microscopy, cultures, species identification, and DSTs). In addition, it includes applications to assess quality control, generate aggregate reports, notify health centers of new results or contaminated samples, and track both enrolled patients and the status of pending laboratory tests. e-Chasqui extends the web-based TB electronic medical record system, PIH-EMR, that has been in use in Peru since 2001[168 193]. To protect patient's confidentiality, e-Chasqui incorporates extensive encryption and web security features for medical records of the PIH-EMR[68]. Furthermore, all users sign a confidentiality agreement before being given access.

2 The Chasquis were agile and highly-trained runners that delivered messages, royal delicacies, and other objects throughout the Inca Empire and are a source of pride in Peru.

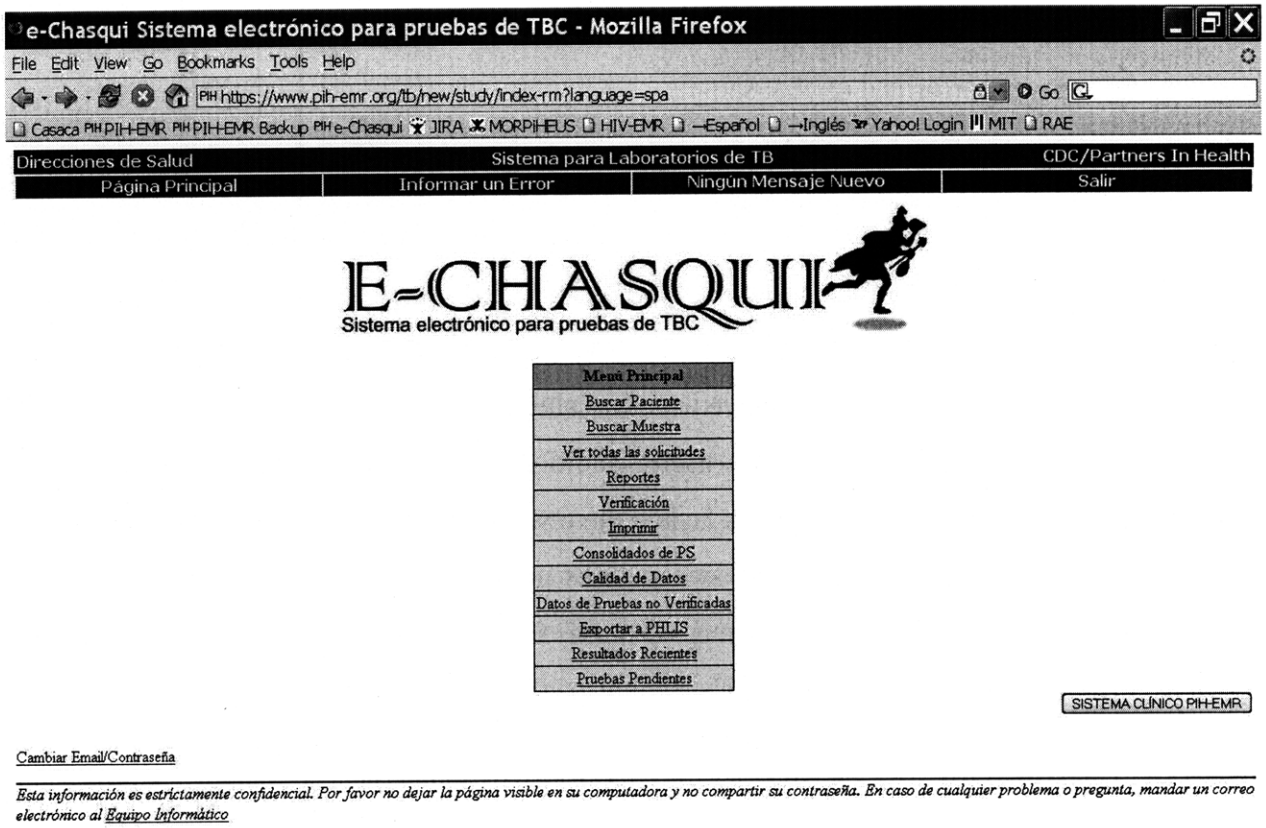


Figure 6.2 Main page of e-Chasqui showing all of its functions: search for patient by name (Buscar Paciente), search for patient by sample id (Buscar Muestra), show all results entered by lab for last 2 months (Ver todas las solicitudes), create laboratory reports (Reportes), verification of results by laboratory director (Verificación), print a batch of recently verified results (Imprimir), list of DST performed for laboratory (Consolidados de PS), quality control page (Calidad de Datos), unverified results (Datos de Pruebas no Verificadas), export data to PHLIS (Exportar a PHLIS), recent results for health center personnel (Resultados Recientes), and tracking samples for health center personnel (Pruebas Pendientes).

We worked with the national and regional district and laboratory directors to define the access profiles for the different types of users. Clinical personnel have individual access to all patients under their responsibility, e.g. single HC, multiple HCs, or a full district. Examples of clinical personnel include HC staff, the regional TB program director, and the regional treatment approval committees, composed of pulmonologists and clinicians. Laboratory personnel have both an individual and aggregate view of laboratory test results. Defining the types of access, getting all stakeholders to agree, and building the flexibility into the system was one of the most difficult tasks in building e-Chasqui.

The ultimate goal of the system is for all laboratories, including those at HCs, to enter tests they've performed and use the system to order further tests. However, in the initial phase all data were entered at the NRL and regional laboratories with "read-only" access provided to HCs.

Therefore when the first e-Chasqui laboratory receives a sample, personnel there enter all previous test results performed on that sample.

6.2.3.1 Patient Care

The core of the e-Chasqui interface is a single patient page containing the history of all tests performed for the patient on a left sidebar, and the details for any single sample on the main part of the page (Figure 6.3). For a single sample, tests can be performed by up to four different laboratories. All test results are displayed in this single page to give the full history of the sample. This novel tracking ability is a useful addition; prior to e-Chasqui's implementation, laboratory and clinical personnel systems lacked the test request date or the smear or culture data when they received a DST result. The system uses a flexible search algorithm by either the patient's names (including partial names, Figure 6.4a) or by any of the sample's test identification numbers (Figure 6.4b). This patient page, like all others, contains only text and uses optimized SQL queries to load quickly even in areas with low bandwidth.

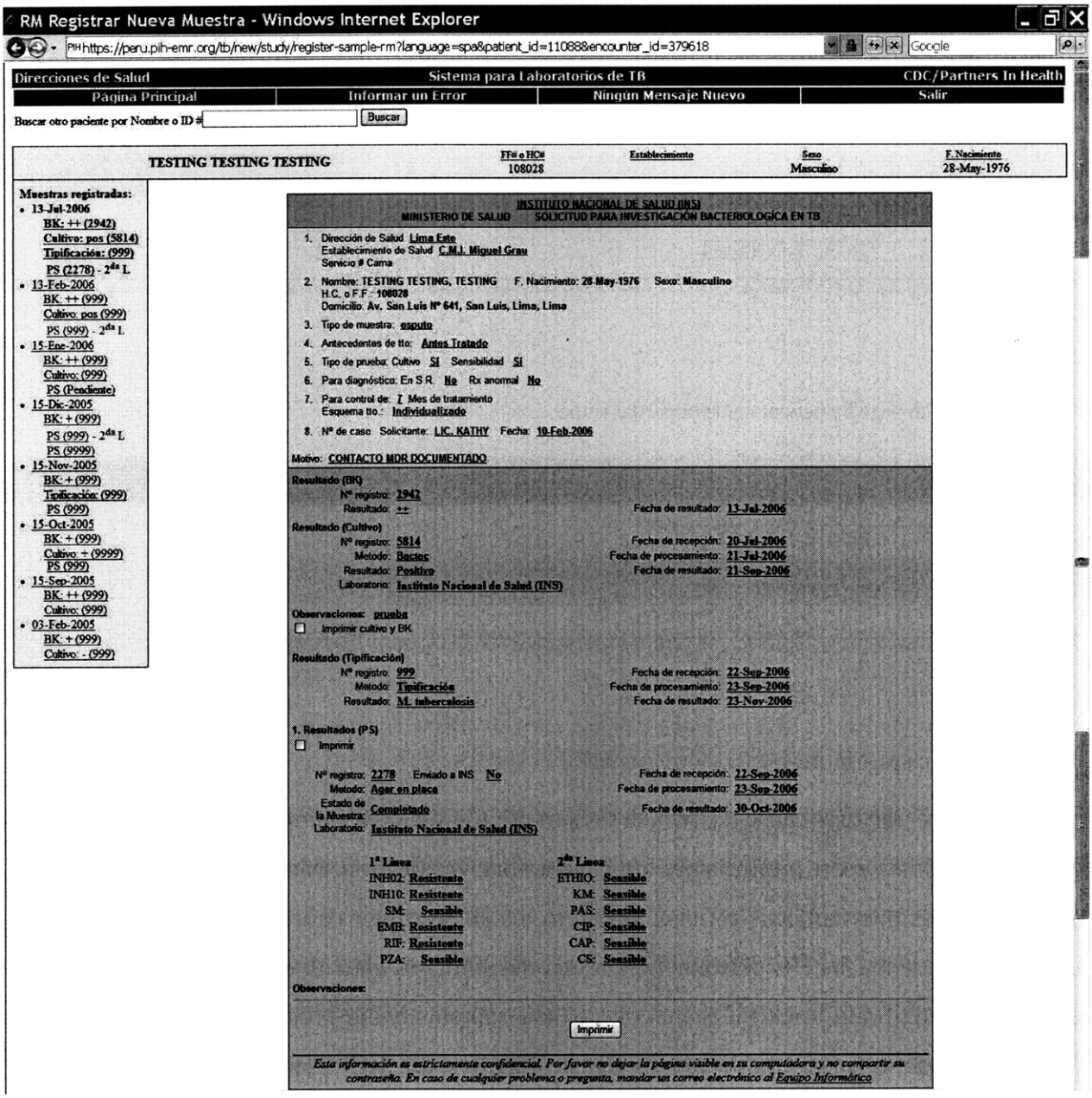


Figure 6.3 e-Chasqui main patient page which shows the patient's full bacteriological history on the left sidebar and with bolded sample date for the sample whose results were being displayed on the main part of the page

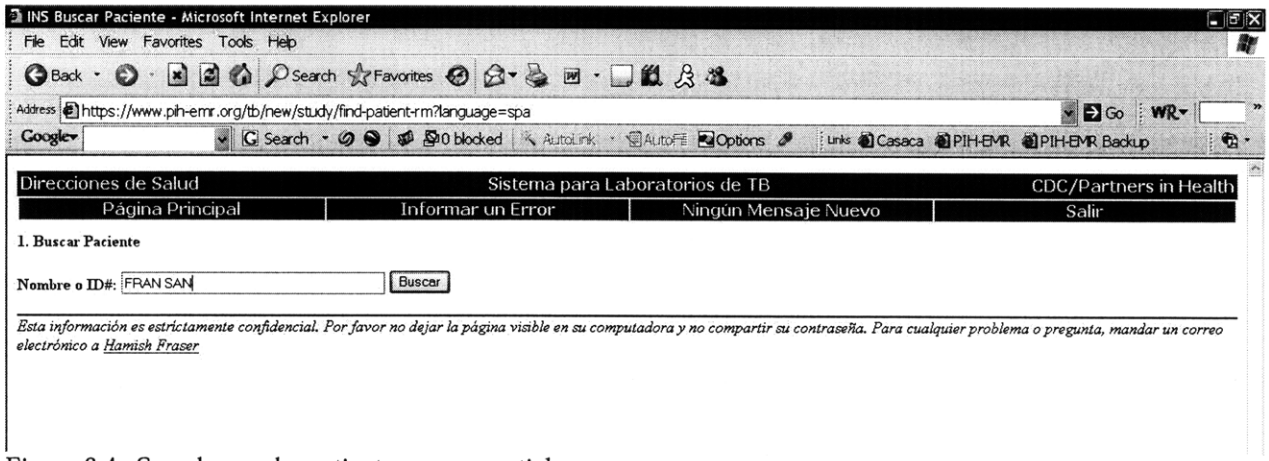


Figure 6.4a Search page by patient name or partial name

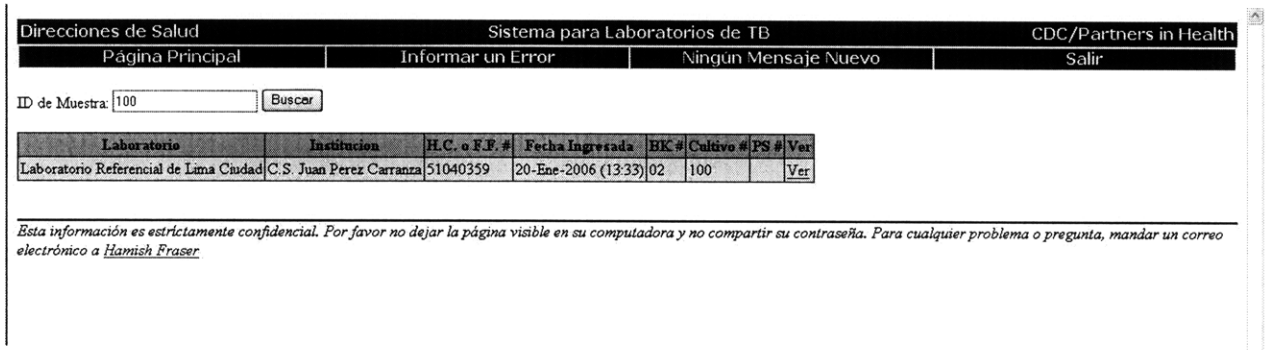
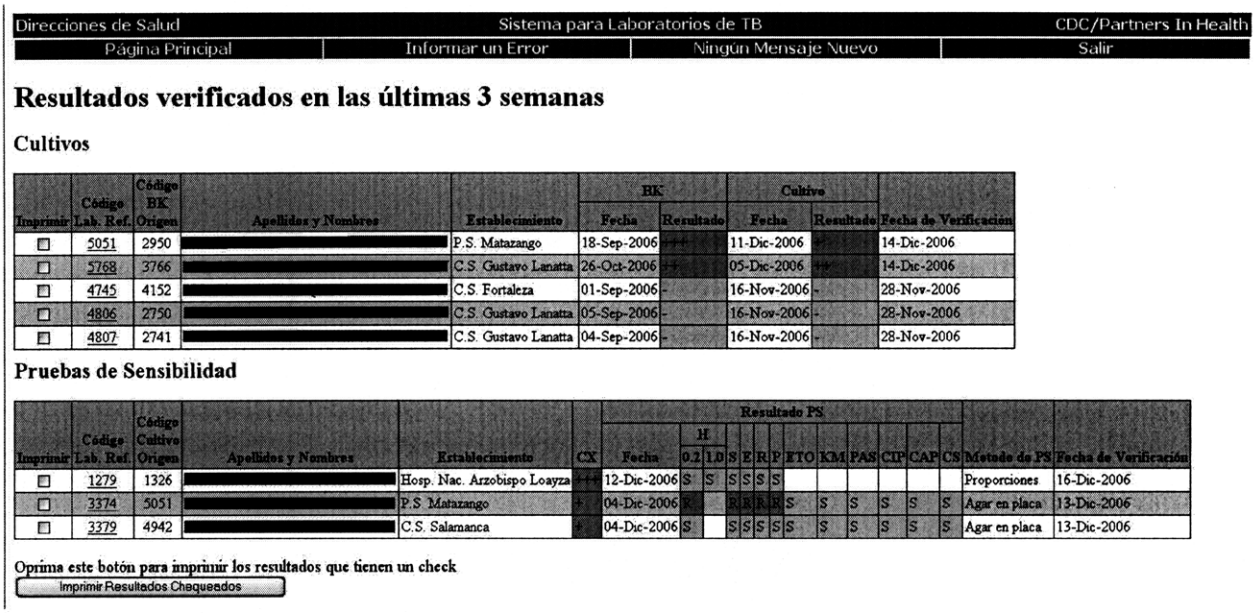


Figure 6.4b Search page by sample ID showing results

From this page, the user can select which tests to print in the official report format. Athough each HC can print the report immediately after laboratory verification, each laboratory also prints a copy and sends this stamped "official" report to the HC for their paper records. Due to the high load of TB patients, the HC personnel requested the ability to view their latest results on a single page (Figure 6.5) and track the status of all their samples being processed (Figure 6.6). Tools were designed to meet these requirements. Finally, all HC users receive nightly email notifications for new test results on patients attending their HC.



Direcciones de Salud | Sistema para Laboratorios de TB | CDC/Partners In Health

Página Principal | Informar un Error | Ningún Mensaje Nuevo | Salir

Resultados verificados en las últimas 3 semanas

Cultivos

Imprimir	Código Lab. Ref.	Código BK Origen	Apellidos y Nombres	Establecimiento	BK		Cultivo		Fecha de Verificación
					Fecha	Resultado	Fecha	Resultado	
☐	5051	2950	[redacted]	P.S. Matazango	18-Sep-2006	+++	11-Dic-2006	+	14-Dic-2006
☐	5768	3766	[redacted]	C.S. Gustavo Lanatta	26-Oct-2006	++	05-Dic-2006	++	14-Dic-2006
☐	4745	4152	[redacted]	C.S. Fortaleza	01-Sep-2006	-	16-Nov-2006	-	28-Nov-2006
☐	4806	2750	[redacted]	C.S. Gustavo Lanatta	05-Sep-2006	-	16-Nov-2006	-	28-Nov-2006
☐	4807	2741	[redacted]	C.S. Gustavo Lanatta	04-Sep-2006	-	16-Nov-2006	-	28-Nov-2006

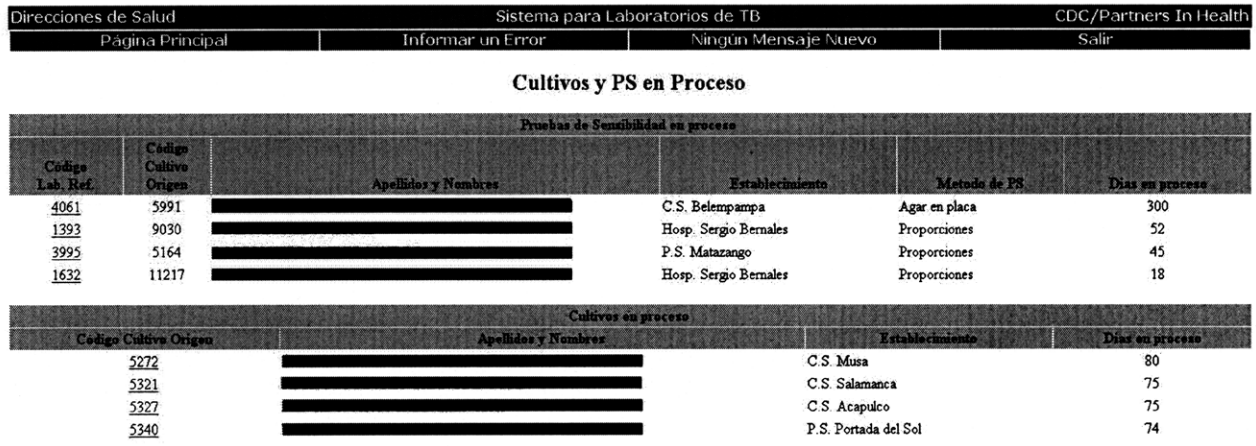
Pruebas de Sensibilidad

Imprimir	Código Lab. Ref.	Código Cultivo Origen	Apellidos y Nombres	Establecimiento	CX	Resultado PS													Método de PS	Fecha de Verificación
						Fecha	H		S	E	R	P	ETO	KM	PAS	CIP	CAP	CS		
							0.2	1.0												
☐	1279	1326	[redacted]	Hosp. Nac. Arzobispo Loayza	+++	12-Dic-2006	S	S	S	S	S	S							Proporciones	16-Dic-2006
☐	3374	5051	[redacted]	P.S. Matazango	+	04-Dic-2006	R		R	R	R	R	S	S	S	S	S	S	Agar en placa	13-Dic-2006
☐	3379	4942	[redacted]	C.S. Salamanca	+	04-Dic-2006	S		S	S	S	S	S	S	S	S	S	S	Agar en placa	13-Dic-2006

Oprima este botón para imprimir los resultados que tienen un check

Imprimir Resultados Chequeados

Figure 6.5 Multiple results view page designed at the request of the health center personnel



Direcciones de Salud | Sistema para Laboratorios de TB | CDC/Partners In Health

Página Principal | Informar un Error | Ningún Mensaje Nuevo | Salir

Cultivos y PS en Proceso

Pruebas de Sensibilidad en proceso

Código Lab. Ref.	Código Cultivo Origen	Apellidos y Nombres	Establecimiento	Metodo de PS	Dias en proceso
4061	5991	[redacted]	C.S. Belempampa	Agar en placa	300
1393	9030	[redacted]	Hosp. Sergio Bernales	Proporciones	52
3995	5164	[redacted]	P.S. Matazango	Proporciones	45
1632	11217	[redacted]	Hosp. Sergio Bernales	Proporciones	18

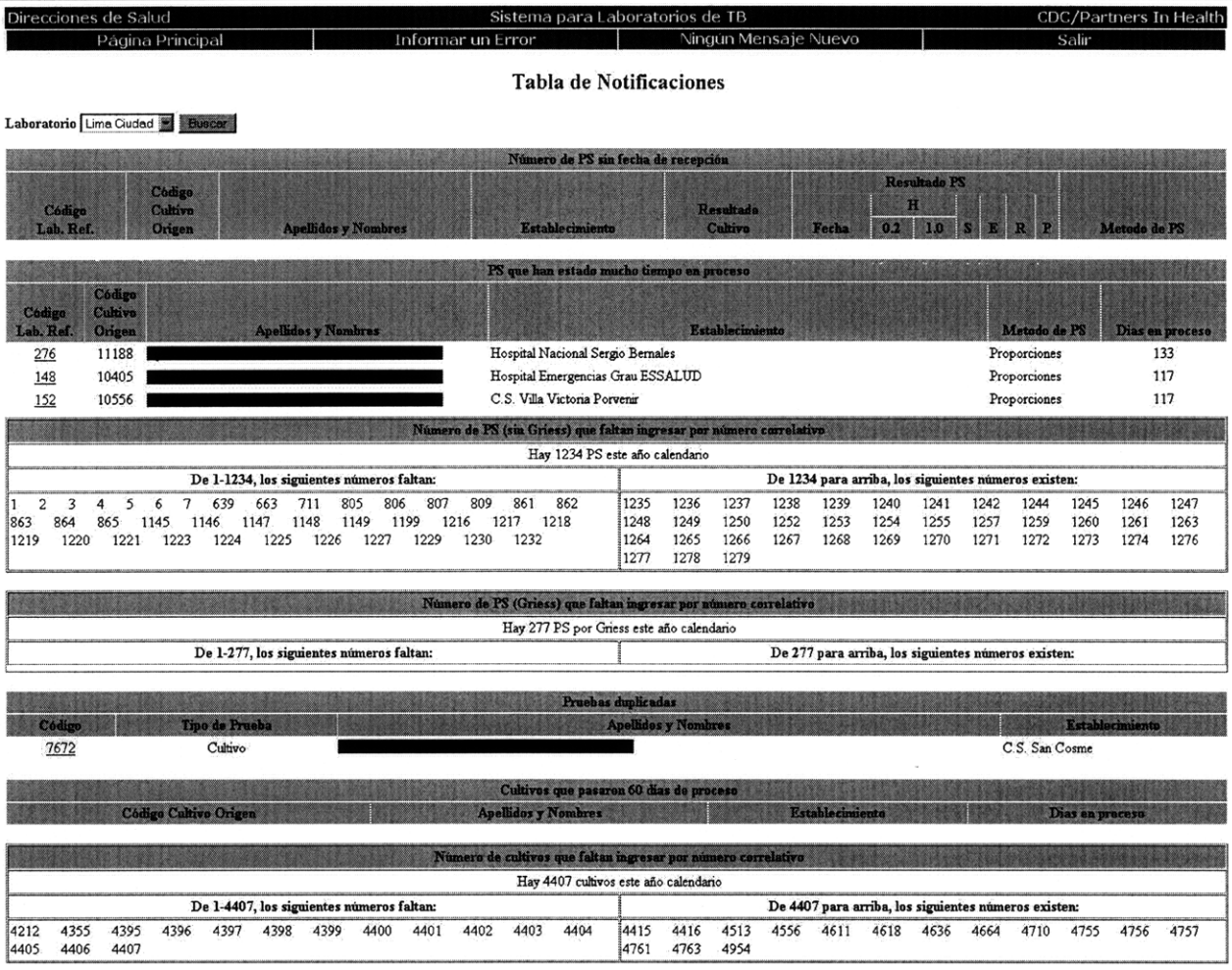
Cultivos en proceso

Código Cultivo Origen	Apellidos y Nombres	Establecimiento	Dias en proceso
5272	[redacted]	C.S. Musa	80
5321	[redacted]	C.S. Salamanca	75
5327	[redacted]	C.S. Acapulco	75
5340	[redacted]	P.S. Portada del Sol	74

Figure 6.6 Cultures and DSTs in Process page designed at the request of the health center personnel

6.2.3.2 Laboratory Quality Control

The laboratory personnel described long-standing problems with ensuring the timeliness of reporting results. Since a culture or DST result takes 20 to 60 days to be read, some tests "fell through the cracks" and were not read, or were read late. Furthermore, they also requested ways to ensure all results had been entered, to minimize duplicate tests, and to monitor the contamination rate. Therefore, the system was expanded to incorporate quality control tools to remind personnel to read samples on a regular basis, flag duplicate or missing results, and report contamination rates (Figure 6.5).



Direcciones de Salud | Sistema para Laboratorios de TB | CDC/Partners In Health

Página Principal | Informar un Error | Ningún Mensaje Nuevo | Salir

Tabla de Notificaciones

Laboratorio: Lima Ciudad — Buscar

Número de PS sin fecha de recepción

Código Lab. Ref.	Código Cultivo Origen	Apellidos y Nombres	Establecimiento	Resultado Cultivo	Resultado PS: Fecha	H 0.2	H 1.0	S	E	R	P	Metodo de PS

PS que han estado mucho tiempo en proceso

Código Lab. Ref.	Código Cultivo Origen	Apellidos y Nombres	Establecimiento	Metodo de PS	Dias en proceso
276	11188	[redacted]	Hospital Nacional Sergio Bernales	Proporciones	133
148	10405	[redacted]	Hospital Emergencias Grau ESSALUD	Proporciones	117
152	10556	[redacted]	C.S. Villa Victoria Porvenir	Proporciones	117

Numero de PS (sin Griess) que faltan ingresar por número correlativo

Hay 1234 PS este año calendario

De 1-1234, los siguientes números faltan:	De 1234 para arriba, los siguientes números existen:
1 2 3 4 5 6 7 639 663 711 805 806 807 809 861 862 863 864 865 1145 1146 1147 1148 1149 1199 1216 1217 1218 1219 1220 1221 1223 1224 1225 1226 1227 1229 1230 1232	1235 1236 1237 1238 1239 1240 1241 1242 1244 1245 1246 1247 1248 1249 1250 1252 1253 1254 1255 1257 1259 1260 1261 1263 1264 1265 1266 1267 1268 1269 1270 1271 1272 1273 1274 1276 1277 1278 1279

Número de PS (Griess) que faltan ingresar por número correlativo

Hay 277 PS por Griess este año calendario

De 1-277, los siguientes números faltan:	De 277 para arriba, los siguientes números existen:

Pruebas duplicadas

Código	Tipo de Prueba	Apellidos y Nombres	Establecimiento
7672	Cultivo	[redacted]	C.S. San Cosme

Cultivos que pasaron 60 días de proceso

Código Cultivo Origen	Apellidos y Nombres	Establecimiento	Dias en proceso

Numero de cultivos que faltan ingresar por número correlativo

Hay 4407 cultivos este año calendario

De 1-4407, los siguientes números faltan:	De 4407 para arriba, los siguientes números existen:
4212 4355 4395 4396 4397 4398 4399 4400 4401 4402 4403 4404 4405 4406 4407	4415 4416 4513 4556 4611 4618 4636 4664 4710 4755 4756 4757 4761 4763 4954

Esta información es estrictamente confidencial. Por favor no dejar la página visible en su computadora y no compartir su contraseña. En caso de cualquier problema o pregunta, mandar un correo electrónico al Equipo Informático

Figure 6.7 Quality control page for laboratory showing the number of DSTs without reception dates (Numero de PS sin fecha de recepcion), DSTs in process for too long (PS que han estado mucho tiempo en proceso), number of DSTs by proportions method that have not been entered (Numero de PS que faltan ingresar por numero correlativo), number of Griess DSTs that haven't been entered (Numero de PS Griess que faltan ingresar por numero correlativo), duplicate tests (Pruebas duplicadas), cultures in process over 60 days (Cultivos que pasaron 60 dias de proceso), and number of cultures that have not been entered (Numero de cultivos que faltan ingresar por numero correlative).

Verification of results was also part of the current workflow in the laboratory using the paper system. To follow this workflow, we implemented a page so that the laboratory personnel could digitally verify results before they were communicated to the health centers, as seen in Figure 6.8.

Verificación de Resultados por Jefe de Laboratorio

ID de Muestra: DISA Lima Ciudad Buscar

Cultivos

Verificar	Código Lab. Ref.	Código BK Origen	Fecha de Siembra	Apellidos y Nombres	Establecimiento	BK		Cultivo		Tiene PS?
						Fecha	Resultado	Fecha	Resultado	
☑	2903	941	27-Mar-2008	[redacted]	C.S. Juan Perez Carranza	24-Mar-2008	-	23-May-2008	-	No
☑	2960	535	27-Mar-2008	[redacted]	C.S. San Sebastian	25-Mar-2008	-	23-May-2008	-	No
☑	2966	568	27-Mar-2008	[redacted]	C.S. San Sebastian	25-Mar-2008	-	23-May-2008	-	No
☐	3407		10-Abr-2008	[redacted]	C.S. Villa Maria del Triunfo			26-May-2008	-	No
☐	3408	2067	10-Abr-2008	[redacted]	Hospital Emergencias Grau ESSALUD		2	26-May-2008	++	No

5 Cultivos que verificar

Tipificación

Verificar	Código Lab. Ref.	Código BK Origen	Fecha de Siembra	Apellidos y Nombres	Establecimiento	Resultado

0 Tipificaciónes que verificar

Pruebas de Sensibilidad del Laboratorio

Verificar	Código Lab. Ref.	Código Cultivo Origen	Fecha de Recepción	Apellidos y Nombres	Establecimiento	Resultado Cultivo	Resultado PS							Metodo de PS
							Fecha	H 0.2	L0	S	E	R	Z	
☑	G247		09-May-2008	[redacted]	C.S. Tahuantinsuyo Alto		22-May-2008	S				S		Griess
☑	675	1898	12-Mar-2008	[redacted]	C.S. Ermitano Alto	+	24-May-2008	S	S	S	S	S	S	Proporciones
☐	706	1928	12-Mar-2008	[redacted]	Hospital Nacional Sergio Bernales	+++	26-May-2008	S	S	S	S	S	S	Proporciones
☐	708	1747	12-Mar-2008	[redacted]	Hospital Nacional Sergio Bernales	+	26-May-2008	S	S	S	S	S	S	Proporciones
☐	710	1766	12-Mar-2008	[redacted]	Hospital Nacional Sergio Bernales	+++	27-May-2008	S	S	S	S	S	S	Proporciones

Oprima este botón cuando ha puesto un cheque al lado de todos los resultados verificados

Verificar Datos Chequeados

Figure 6.8 Verication page by laboratory personnel for cultures (Cultivos), speciation (Tipificacion), and DSTs (Pruebas de Sensibilidad del Laboratorio)

Finally, to ensure the timelines of entry of results by the data entry personnel at the laboratory, prompt verification of those results by the laboratory director, and to measure the time until health centers viewed those results, we created a page to display the average of each of those times for any specified date as seen in Figure 6.9.

Tiempos en Comunicacion de Resultados

Fecha de Lectura: DE: 17 d Dic m , 2006 a A: 17 d Oct m , 2007 a

Laboratorio [redacted]

Buscar

LEYENDA

El tiempo de demora apropiado es **menos de 1.5 dias,** aceptable es **menos de 2.5 dias** , y [redacted]

Pruebas de Sensibilidad

Días entre Fecha de Lectura y Fecha de Digitación (Promedio [Rango])	1.14 [.35-31.71]
[redacted]	
Total de PS	2116

Centro de Salud	Días entre Emisión de Resultado por LR y la Visualización en el Establecimiento de Salud (Promedio [Rango])	Total de PS
[redacted]	1.15 [0-4.18]	48
[redacted]	2.37 [0-9.26]	75
[redacted]	2.15 [0-11.81]	114
[redacted]	1.96 [0-16.24]	28
[redacted]	2.05 [0.01-11.55]	37
[redacted]	1.45 [0.01-5.41]	30

Figure 6.9 Communication times for results

6.2.3.3 Laboratory Monitoring/Reporting

An initial reporting tool was created for the regional laboratories to view all results. Further monitoring and reporting tools were created as the needs arose throughout the implementation process. The type of reports can be seen in Table 6.2, below. The page to find each report can be seen in Figure 6.10.

Table 6.2 Reports generated by e-Chasqui

Report	Informed	Purpose	Type of Access
Frequency of e-Chasqui access by HC personnel	Regional laboratory and TB director	Encourage frequent utilization of IS to access real-time laboratory data	Monthly report prepared by data administrator
Number of laboratory results entered at regional laboratory	Regional laboratory and TB director	Identify delays in data entry	Monthly report prepared by data administrator

Number of laboratory results verified and released to providers	Regional laboratory and TB director	Identify delays in verification	Monthly report prepared by data administrator
DST results for any specified period grouped by every variable in request form	Regional and INS laboratory director	Report and identify trends in laboratory performance	Constant access**
Culture results for any specified period grouped by every variable in request form	Regional and INS laboratory director	Report and identify trends in laboratory performance	Constant access**
Individuals with a positive culture for any specified date	Regional and INS laboratory director	Report to regional TB program	Constant access**

**Constant access means that the laboratory users could view this information in the system at any time. Some reports let the user specify the start and end dates.

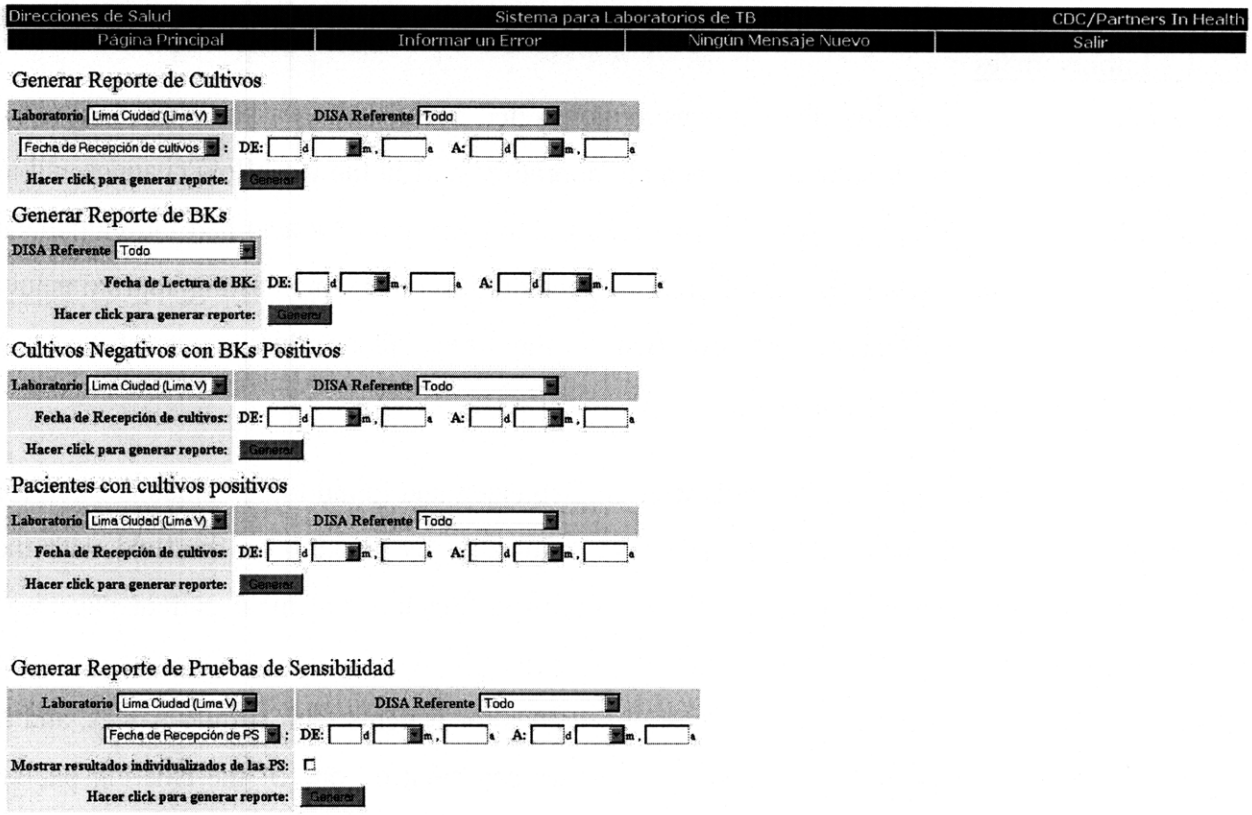


Figure 6.10 Reports page showing how laboratory personnel can create reports of cultures performed (Generar Reporte de Cultivos), reports of smears they have received (Generar Reporte de BKs), find negative cultures with positive smears (Cultivos Negativos con BKs Positivos), pacientes with positive cultures (Pacientes con cultivos positivos), and create reports of DSTs performed (Generar Reporte de Pruebas de Sensibilidad)

6.2.4 Implementation

Though described separately from the needs assessment and system design, the deployment of e-Chasqui in the laboratories and HCs was complementary and overlapped as the use and functionality of e-Chasqui grew.

6.2.4.1 Information Technology Assessment

The initial step of implementation consisted of an assessment of the information technology status at each HC and laboratory, performed by the regional health districts, and included data such as the number and condition of computers in each HC, physical security, and internet access. The assessment identified key deficits, and we were able to coordinate with each health district to perform corrections such as donating or fixing computers and providing or improving internet access.

6.2.4.2 Laboratories

The commitment of the health districts was demonstrated by providing a part-time data entry person specifically for e-Chasqui. We trained all laboratory staff in the workflow changes and in the use of e-Chasqui during a single 1-hour group training session. We also had individualized sessions for each user since each had different responsibilities, on average lasting approximately 1.5 hours. After several months of use, two of the three laboratories requested that the technicians also have e-Chasqui access.

For data entry several simple design tools were implemented and found to be valuable. First, for ease of data entry each data field can be accessed not only by clicking on the field with the mouse, but also by sequential tabbing through the page. Second, the main patient page was identical to the test request form from which the data entry occurred. To avoid duplicate patients when a new patient is being created, e-Chasqui searches for patients with similar names, and if any are found a warning is displayed where the user can click on one of the existing patient names or click the "Create New Patient" button. Also, a tool to merge patient records was created to handle duplicates. Duplicate sample records are handled using data quality tools, explained previously in the Laboratory Quality Control section.

The system had to be continually expanded and adapted to the needs encountered during the pilot phase. During the first eight months after implementation, functionality to generate lists of

reported DSTs and quality control tools were created. In the following 3 months, we added pages for the HC users to view the tests currently being processed and a consolidated view of the last 3 weeks of results. In Sept. 2006, 11 months after initial implementation, the NRL began to use this system and required changes to accommodate its specific workflow. At the same time we modified the system, at HC users' request, to send only one email at night if results had been verified that day, as opposed to an email for every result verified.

6.2.4.3 Health Centers

Once a HC had a computer with internet access that could be used by the TB personnel, all users were trained in a single 1-hour session in computer use, confidentiality procedures, and use of e-Chasqui. The e-Chasqui data administrator then performed follow-ups every third week. In most HCs, we identified at least one "champion" who uses the system frequently. However, rarely did we find this champion promoting the system to others.

Throughout the implementation, we had to troubleshoot problems. Most of the problems were administrative or hardware related such as having to create a new windows XP user, ensuring that HC users were viewing their results in e-Chasqui in a timely fashion, replacing a stolen computer, and providing six web access points to TB programs within HCs that lacked computer access (Baobab Health Partnership)[47].

6.2.4.4 Controlling Permissions of System

Once a HC had a computer with internet access that could be used by the TB personnel, all users were assigned appropriate permissions to see patients within the health centers or districts according to the previously explained rules set with the DISAs. Figure 6.11 shows the page within e-Chasqui used by the data administrator to set the permissions for the different users.

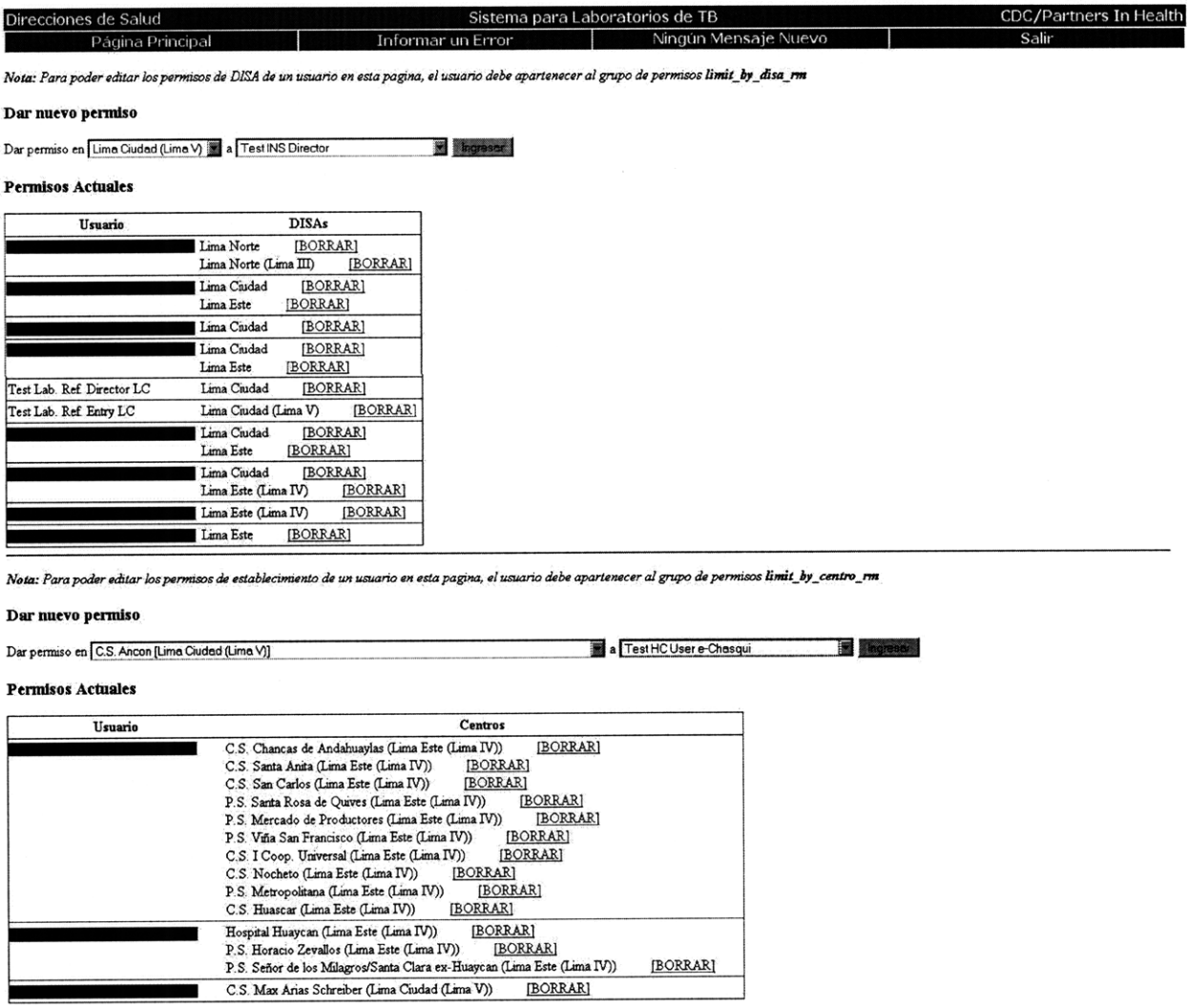


Figure 6.11 Sample of page to give users permissions to health districts (top half) and to health establishments (bottom half)

6.3 Results

The needs assessment and workflow analysis began in June 2005, with the first user testing in July 2005, January 2006, and May 2006, for each of the two regional and the national laboratories, respectively. Full implementation occurred in March 2006, August 2006, and September 2006, respectively.

6.3.1 System Usage

Our system has been successfully integrated into program operations. Since its initial implementation, 29,994 smear microscopy, 31,797 culture and 7,675 DST results have been entered. In 2006, 99.5% of all DST results and 98.8% of all culture results for the 12 pilot HCs

were viewed online. The average number of pages viewed by the HCs in each of the two health districts (Lima Ciudad, Lima Este) can be seen in Figure 6.12. The large increase in pages viewed in August 2006 occurred because e-Chasqui was fully implemented in both the Lima Este regional laboratory and the NRL.

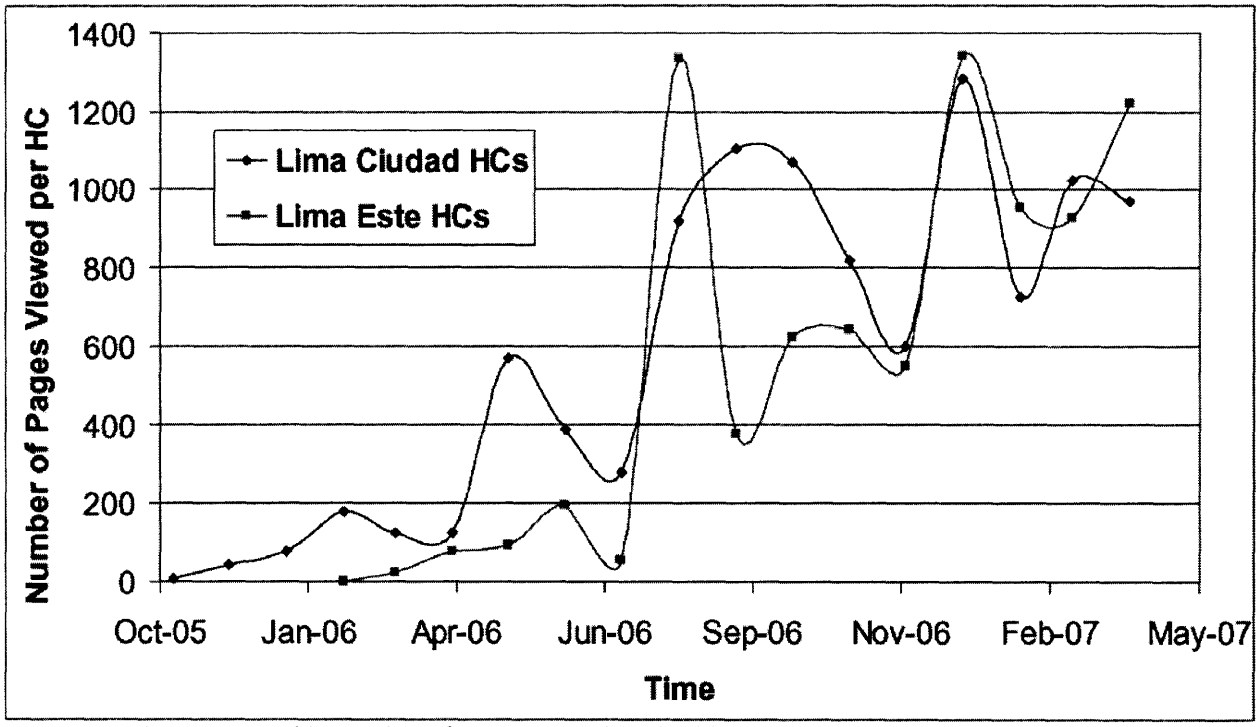


Figure 6.12 Average monthly number of pages viewed by health centers in each of the two health districts. Full implementation occurred in March 2006 (Lima Ciudad) and August 2006 (Lima Este).

This is an online transaction processing system and since it is used in sites with low to medium internet bandwidth, this is a major factor in its performance. Due to e-Chasqui's simple, text-based design all sites can use it during routine clinical and laboratory work. In 2006, the system performed on average 1865 transactions per day including page views, data entry, and analysis. In 2007, it has increased to 4501 daily transaction and the system's performance has not been appreciably affected.

Feedback from users has been positive. This feedback has been in the form of conversations by the research staff with the clinical and laboratory personnel, increased usage of the system by intervention sites, and requests for expansion of the use of the system by the district and laboratory administrators. Importantly, we have been careful to respond to critical comments and suggestions to enhance the system and maintain user "buy-in." A strong indicator of the system's

utility is that district administrators have requested expansion of the system to additional institutions. In response, we are expanding access to three laboratories, 2 hospitals and 11 HCs that administer 47 other health centers. In total, e-Chasqui will serve a network of institutions providing medical care for over 3.1 million people.

6.3.2 System Costs

In quantifying the costs of designing and implementing this web-based system in Peru, we have found the annual recurring cost to be US$34,738 total or US$0.53 per sample entered. More details can be found in Table 6.3. This figure includes the cost of full internet access to all e-Chasqui institutions and a US based system manager. Since HCs use the internet for other purposes, including the national health register, we feel the system should incur 50% of the internet cost. Also, if the system manager were Peruvian with a local salary, the annual recurring cost would reflect the approximate cost of implementing e-Chasqui in all major health centers in the two health districts. For comparison, the e-Chasqui health districts had 1103 MDR-TB patients on standardized or individualized treatment in 2006. The annual cost of these treatments are approximately US$2,900 and US$3,000, respectively[194]. Another comparison is that these health districts accounted for 53% of TB and MDR-TB patients in a national program whose 2006 budget was close to US$10 million[195]. In either case, this system to communicate all vital laboratory data for TB and MDR-TB treatment accounted for approximately 1% of the budget for those districts.

Table 6.3 Fixed and monthly costs of implementing e-Chasqui

	Calculation	Fixed Cost	Monthly Cost
Infrastructure Building			
Computers, web access points and installation	8 x $458 (average cost)	$3,666.00	
Printers	4 x $150	$600.00	
Server		$2,500.00	
Internet for health centers and labs	12 HCs & 2 labs x $41 monthly		$574.00
Internet for headquarters with server	1 HQ x $400 monthly		$400.00
Total		$6,766.00	$974.00
System Design & Development			
Peruvian Clinician	80 hours x $21/hour	$1,680.00	
System Manager	500 hours x $22/hour	$11,000.00	
Faculty Consulting	40 hours x $59/hour	$2,360.00	
Programmer	100 hours x $40/hour	$4,000.00	
Total		$19,040.00	
System Implementation			
System Manager	620 hours x $22/hour	$13,640.00	

Faculty Consulting	80 hours x $59/hour	$4,720.00	
Programmer	450 hours x $40/hour	$18,000.00	
Total		$36,360.00	
Data Entry & Management			
System Manager	1/4 time		$937.50
Peruvian Data Administrator	2/3 time		$253.33
Peruvian Data Entry (one per lab)	3 x 2/3 time		$580.00
Transportation for Data Administrator	1.5 monthly visits to every site		$150.00
Total			$1,920.83
System Advocacy			
Peruvian Clinician	100 hours x $21/hour	$2,100.00	
Faculty Consulting	50 hours x $59/hour	$2,950.00	
System Manager	200 hours x $22/hour	$4,400.00	
Total		$9,450.00	
Grand Total		**$71,616.00**	**$2,894.83**

We have divided the costs into five categories: infrastructure building, system design and development, system implementation, data entry and management, and system advocacy. For infrastructure, the objective is to have every health institution with a computer, printer and intermittent, if not constant, internet connection. System advocacy has consisted of meetings and discussions, usually with national or regional administrators, to discuss the system's potential benefits, provide updates on its status, and train users on the system's abilities since this was the first time a web-based clinical system had been implemented. The costs incurred by a new program implementing e-Chasqui should be reduced as they will not include system development.

All costs are in 2007 U.S. Dollars.

Unless explicitly stated all staff are US based.

6.3.3 Additional Benefits

Several additional benefits were seen in implementing this information system. The first was the ability to survey the clinical staff at the health establishments. The first implementation of this was a questionnaire to find out why duplicate DSTs were ordered for the same patient. The Peruvian National norm states that a second DST should not be ordered for a patient within 6 months of the sample being taken for the first one unless there is a relevant clinical reason for it. Currently, the Reference Laboratories perform duplicate DSTs for the same patient within this 6 month period. The system e-Chasqui was able to quantify the number of duplicate DSTs performed, something previously unavailable from the paper system. To investigate the reasons why the e-Chasqui pilot health centers order multiple DSTs an online survey was implemented. When a laboratory entered a duplicate DST within e-Chasqui, an email was sent to all the personnel at the health center to fill out the online survey. The email survey displayed the

previous DST results and their current request (Figure 6.13). It also asked the user to check the reason they had ordered this duplicate DST. The choices were:

1. When I ordered the DST, I didn't know that a DST was currently being performed
2. The result of the first DST doesn't agree with the clinical status and/or radiologic findings of the patient
3. Patient has worsened clinically and deserves a second DST
4. There are different results for DST ordered previously
5. I have not received the first DST result
6. I have a Griess result which shows resistance
7. I do not know who ordered this DST
8. Other, please specify _____

Esta es la información sobre las pruebas de sensibilidad hechas en los **últimos 6 meses**

Código Lab. Ref.	Fecha de recepción	Apellidos y Nombres	Establecimiento	Resultado PS							Metodo de PS
				Fecha	H 0.2	H 1.0	S	E	R	Z	
G049	19-Ene-2007	[redacted]	C.S. San Juan de Amancaes	20-Feb-2007	R				R		Griess
200	13-Feb-2007	[redacted]	Hospital Nacional Sergio Bernales	09-Abr-2007	**Recién Ordenada**						Proporciones
9345	05-Mar-2007	[redacted]	C.S. San Juan de Amancaes	17-Abr-2007	R	S	S	S	R	S	Agar en placa

Por favor, indique la razón por que solicitó la prueba de sensibilidad recién ordenada
(SU RESPUESTA SERÁ CONFIDENCIAL y solo sera manejada por el administrador del sistema)

- ○ 1. Cuando solicite la prueba de sensibilidad, **desconocía que había otra** corriendo o hecha anteriormente
- ○ 2. El resultado de la primera prueba no esta de acuerdo con el **estado clínico** y/o radiológico del paciente
- ○ 3. El paciente ha **deteriorado clínicamente** y amerita una segunda prueba de sensibilidad
- ○ 4. Hay **discordancia** entre las pruebas de sensibilidad hechas anteriormente
- ○ 5. El resultado de la primera prueba de sensibilidad **no me ha llegado**
- ○ 6. Tengo un **resultado de Griess** que muestra resistencia
- ○ 7. **Desconozco quien solicitó** esta prueba de sensibilidad
- ○ 8. **Otra razón**, por favor ingrésela aquí

Ingresar

NOTA: Cuando ingrese su respuesta lo llevara a la última PS realizada

Figure 6.13 Example of online survey sent to health center personnel when a duplicate DST was entered into e-Chasqui

During the 10 month study period, 178 of the 180 surveys sent were answered (98.9%). Of those, 37 were answered by the TB program clinician, 137 by the nurse or nurse assistant, and 4 by the laboratory technician. The responses to these surveys can be seen in Table 6.4. Of the 178 responses, 106 (59.6%) were not clinically appropriate for a second DST. They are highlighted in Table 6.4.

Table 6.4 Results of online survey

Answer	Number	Percentage
Not Aware of other DST	16	9.0%
DST inconsistent with patient status	19	10.7%
Patient Clinically Worse	42	23.6%
Conflicting previous DSTs	2	1.1%
DST results not received	23	12.9%
Resistant Griess Result	9	5.1%
Don't know who ordered DST	28	15.7%
Other		
- Want 2nd line results	5	2.8%
- New treatment	9	5.1%
- Multiple sample to get results	4	2.2%
- Patient has a TB contact	5	2.8%
- Other	16	9.0%
Total	**178**	**100.0%**

Additionally, during the pre and post survey period, 25 and 35 DSTs were not processed, respectively, because the lab personnel at the laboratory checked that there was a previous DST within e-Chasqui.

Another benefit of the system was the ability to perform operational research to improve the work of the laboratory and provide data for academic publications. Due to e-Chasqui, we have been able to implement quality control tools within the laboratory and perform real-time assessment of the performance of a novel, rapid DST, the Griess method, using programmatic data from the reference laboratory and the Peruvian Instituto Nacional de Salud (National Institute of Health).

6.4 Discussion

6.4.1 Challenges and Obstacles

Creating a system with enough flexibility to meet all stakeholders' needs that arise during implementation. Though e-Chasqui has focused functionality, the need to create many types of users and to define methods of communication between institutions took much work and time. There were two main reasons for this. First, the inexperience in implementing clinical information systems among stakeholders meant much learning about this topic had to take place. As a result, the technical requirements of e-Chasqui were constantly revised. For example, some stakeholders were unfamiliar with the concept that different users see information in specific manner such as individual or aggregate views. Therefore some exhibited initial skepticism about the system's ability to keep information confidential. Second, defining appropriate user accesses was a balance between patients' confidentiality and the users' informational needs. Again due to e-Chasqui's novelty, both the developers and the institutions have had to learn what the appropriate user permissions were. The web-based architecture allows e-Chasqui to track all users' actions. This capability was highly valued by all stakeholders since many of them asked about data confidentiality and security.

Maintaining both high data quality and timeliness with limited staff. The balance between opportune entry of results and electronic verification with high data quality continues to be a problem. The mean number of days between a DST result being read, its entry, and verification is 5.8. Though we believe that the additional step of result verification ensures higher data quality, we are still working to minimize these delays. On the other hand, the average number of days from laboratory verification to the HC personnel viewing their result in e-Chasqui is 2.2 which shows their interest in updated results.

Strengthening public infrastructure. To ensure e-Chasqui had lasting impact on patient care, it was necessary to integrate this system within the public health structure. This can mean additional work in terms of agreements with the different national and regional institutions, as well as providing additional services. However, the long lasting benefits, such as sustainability and implementation at a national level, usually outweigh this additional work.

6.4.2 Lessons learned

TB programs trying to improve communications, monitoring, and patient care by implementing electronic information systems face a task that can sometimes seem overwhelming. We have learned several lessons from our experience developing a nation-wide electronic laboratory information system in Peru.

All important stakeholders must contribute to the design and implementation. This is the only way to ensure the system addresses the actual user needs and to have user appropriation. To identify key system attributes during the design, medical and laboratory personnel must be involved from the beginning. Furthermore, developers must create a system easily integrated into the existing workflow with minimal disruption and sufficient advantages to gain "buy-in" such as easy usage for people with little computer experience. Lastly, branding the system appropriately, perhaps with a familiar name, makes it more recognizable. During the system's implementation, users must be constantly asked if they have questions or problems and their suggestions for fixing them. Problems that are outside the system's scope, such as not having access to a computer with internet, personal conflicts with other personnel who would like internet access, or equipment failures, should be addressed with administrative personnel.

Political support is integral to the system's dissemination. Unless there is will from the administration to implement an electronic information system, promote its use, and allocate resources to maintain it, there is little chance of success. This system was implemented as part of a scale up strategy between the National Tuberculosis Program and NRL to expand the laboratory network. Political support in this case was demonstrated by the support of the regional health administration and by laboratories providing data entry staff.

Provide adequate training in the system's use and benefits. Training should be focused on the benefits that it provides to the users. In Peru, most previous health information systems have required HC personnel to enter data for reporting purposes without receiving any feedback. While implementing e-Chasqui, we saw reticent users become enthusiastic when they realized the system would provide *them* with useful information. Training must also be provided continually, and the system's use monitored to ensure it continues to meet user's needs.

Ensure the system's sustainability. Sustainability in our experience is maintained by generating user confidence in the system's quality and usability, creating a flexible system able to adapt to changes within the public system, and providing evidence of system benefits. To have user confidence, the system must actually save time and be perceived as a *consistently* useful tool after the initial novelty has worn off. Three main factors to promote sustainability include (1) providing and maintaining a functional internet access point at their HC, (2) ensuring the quality and promptness of data, and (3) providing support to all users. Support to all users usually took the form of technical assistance at the laboratories and up-to-date results to HCs.

Implement the system as part of a larger structural improvement. We believe that the implementation of an information system is enhanced if it is an integral part of larger improvements in the clinical or laboratory infrastructure. That way the system can not only help improve communication but also be part of a more general improvement in workflow. In the case of e-Chasqui, it was incorporated into national project to decentralize DSTs.

6.5 Conclusions

Electronic laboratory information systems have much potential to improve patient care and public health monitoring in resource-poor settings. Some of the challenges described, such as lack of trained personnel, limited transportation, and large coverage areas, are obstacles that a well-designed information system can overcome. However, creating well-designed information systems is a difficult task necessitating appropriate resources, expertise and time to be successful.

e-Chasqui has the potential for creating a national TB laboratory network in Peru to facilitate the communication and analysis of all bacteriological results country-wide. We have already begun to see additional benefits to this system such as having the test always available during clinical decision making, reducing duplicate tests performed, and reducing the time and money spent by staff checking the status of their samples. Studies have been initiated to quantify these benefits. We are also conducting a prospective and retrospective evaluation study to measure e-Chasqui's effect on reducing mean delays, "lost" results with excessive delays, and errors of laboratory reporting. Furthermore, this same system or one similar could more easily be implemented in other countries facing similar problems of test tracking. In our efforts to make these systems

available, we are implementing the core functionality of e-Chasqui as a module in the OpenMRS system[196] [197]. With colleagues in the US and Africa, we have developed OpenMRS, a general purpose medical record system architecture to support TB and HIV treatment programs. OpenMRS is being rolled out in eight countries[198] with support from the US Centers for Disease Control and Prevention and the World Health Organization.

7 Impact of e-Chasqui on Delays

This chapter describes the evaluation performed on e-Chasqui described in the previous chapter. This chapter focuses on the impact of e-Chasqui in the time to communicate results between laboratories and health centers, to place a patient on an appropriate MDR-TB regimen, and to have patients become culture negative after a drug resistant DST result.

7.1 Introduction

Laboratory information systems in developed countries have been shown to decrease turn-around-times (TAT) of laboratory results,[199-201] reduce redundancy in resource utilization,[200 202 203] and provide faster and more complete notification for public health purposes.[134 136 204] Shorter TATs have been associated with decreased treatment time, mortality, morbidity, and length of hospital stay.[205 206] However, a systematic review found no reports of evaluations of these systems in resource-poor settings.[71]

We conducted a cluster randomized controlled trial to evaluate the effectiveness of the e-Chasqui laboratory information system in reducing delays within the TB program in Peru. We also performed a before-and-after comparison to evaluate additional effects of the system.

7.2 Methods

A cluster randomized controlled trial (RCT) tested the effect of the laboratory information system e-Chasqui in reducing the time to communicate patients' test results, start them on appropriate treatment, and have them culture convert. The trial is reported according to the CONSORT statement.[207] As a secondary study design, we also conducted a before-and-after trial. Both trials were performed within a larger observational study evaluating the impact of expanded laboratory capacity in the district laboratories.[15] All data for both the RCT and before-and-after trials was collected prospectively.

7.2.1 Study Settings

This study was carried out in two health districts of Lima, Peru: Lima Ciudad and Lima Este. Lima Ciudad includes 45 health establishments (24 HCs, nine health posts, and 12 hospitals) serving a population of 1,577,090 in an area of approximately 100 km^2. Lima Este includes 134

health establishments (42 HCs, 87 health posts, and 5 hospitals) serving a population of 1,088,515 in an area of approximately 6340 km^2. Smear microscopy is used to diagnose active TB, while culture and DST are reserved for individuals with confirmed TB and at least one risk factor for MDR-TB according to National Tuberculosis Program (NTP) Norms.[28] Smear microscopy is performed in Level I laboratories in HCs and hospitals. Health posts send sputum samples to their closest HC for smear microscopy. For patients with MDR-TB risk factors, smear-positive samples are sent to the district Level II laboratory for culture and/or 1st line DST (Table 7.1). DST results resistant to isoniazid or rifampicin or both are sent to the NRL for 2nd line DST. Results on paper are sent from the NRL back to the district laboratory for registration and subsequent transmission, directly or indirectly, to the point-of-care health centers and posts. The patient is then routinely seen by a pulmonologist at the local hospital to review the DST results and if necessary modify the TB regimen. In patients with drug-resistant isolates, an expert committee reviews the case to approve enrollment into MDR-TB therapy (Figure 7.1).

Table 7.1. Number of tests performed annually in district laboratories using e-Chasqui

	2003	2004	2005	2006	2007	2008 (anticipated)
Cultures						
Lima Este			5,416	6,981	6,037	6,960
Lima Ciudad	8,256	8,288	9,611	10,168	11,784	12,833
DSTs						
Lima Este	0	0	0	493	1,645	2,807
Lima Ciudad	0	0	946	1,893	2,721	3,514

The two health districts organize transmission of paper results to HCs differently. In Lima Ciudad, all 24 HCs are "direct HCs" that receive results directly from the laboratory and present patients to the district MDR-TB treatment committee, which determines the treatment plan. In Lima Este, 17 direct HCs use the identical process as HCs of Lima Ciudad. The other 25 HCs and 87 health posts are "indirect HCs" whose results are communicated to one of the 17 direct HCs, which in turn sends results to the indirect HCs. The indirect HC then compiles and submits patient information to the direct HC, which presents the case to the MDR-TB treatment committee for development of a treatment plan, which the direct HC returns to the indirect HC for treatment initiation (Figure 7.1).

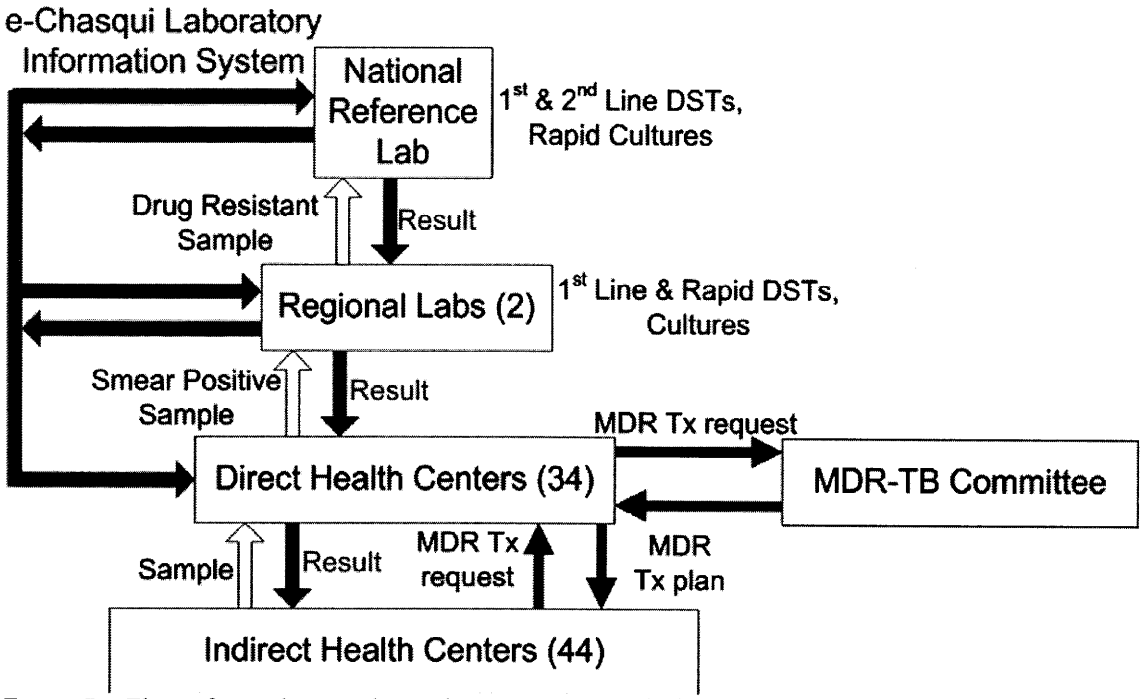


Figure 7.1 Flow of samples, results, and MDR treatment (Tx) requests and plans within the Peruvian National TB Program

7.2.2 Study Design

e-Chasqui was implemented at two levels: at the district & national laboratories and at the health establishments. First, the system was implemented at the two district laboratories and NRL. These laboratories served all of the health establishments. After full implementation in the laboratories, 12 of 32 HCs were randomized to utilize e-Chasqui. The cluster RCT evaluated the effect of HC access to e-Chasqui. Because randomization did not occur at the laboratory level, we used a before-and-after analysis to evaluate the effect of district laboratory access to the system.

We prospectively collected baseline data for 12 months from the two health districts. We then implemented e-Chasqui in the laboratories and randomly assigned six HCs from each health district (12 total) to the intervention (Figure 7.2). In Lima Ciudad, these six were randomized from the 20 highest incidence HCs. In Lima Este, they were randomized from the 12 direct HCs within Lima city limits. Indirect HCs (n=44) belonged to the study arm that was assigned to their corresponding direct HC (Figure 7.1). Therefore, the six direct intervention HCs in Lima Este had 17 indirect intervention HCs and the 6 direct control HCs had 27 indirect control HCs (Table 7.2). After the intervention was implemented, we collected data on the same endpoints in both

control and intervention arms. The Lima Este district laboratory did not perform DSTs before the implementation of e-Chasqui, hence there is no pre-implementation data for that district.

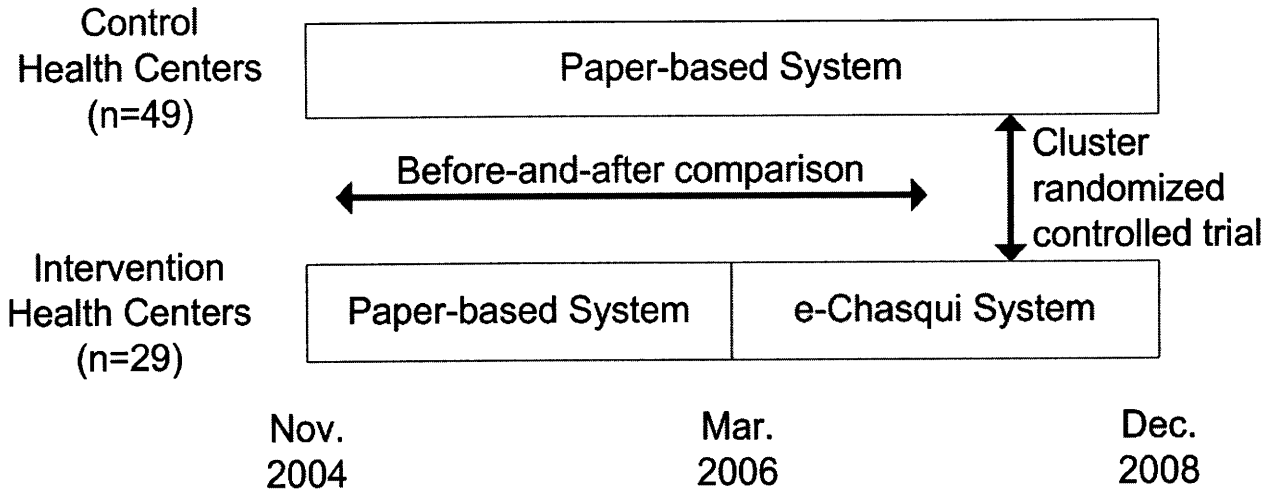


Figure 7.2 Cluster randomized controlled trial schema with before and after comparison

During the study (October 2006), the Lima Este health district re-organized their HCs. All direct intervention HCs remained the same. One direct control HC was re-allocated to an indirect intervention HC, three indirect intervention HCs to indirect control HCs and three indirect control to indirect intervention. The samples and patients in these "cross-over" HCs maintained their original assignment in the analysis since it only affected 17 data points for the primary outcome. Patients in the study were assigned to the HC where they were first captured. If a patient transferred or left a sample at another HC, they and their sample would be assigned to the initial HC. If a patient transferred from a control to an intervention HC, the intervention HC staff would have access to all of that patient's bacteriological history in e-Chasqui. Both of these problems may have the effect of weakening the impact of the intervention.

This study was approved by the Partners Healthcare Human Research Committee and the Peruvian National Institute of Health.

7.2.3 Study Population

All individuals who lived within the catchment area of one of the two district laboratories and had at least one MDR-TB risk factor as defined by the Peruvian NTP Norms were included in this study.[28] For Lima Ciudad, only individuals in the 20 HCs with highest incidence were

included. For Lima Este, only tests performed for the 12 direct HCs within Lima city limits (and their respective indirect HCs) were included. There were no exclusion criteria for enrollment into the study. Because all sputum samples of patients who have at least one MDR-TB risk factor are sent to the district laboratory for DST, subjects eligible for enrollment into the study were identified by this referral.

7.2,4 Outcomes

The primary outcome of the study was the laboratory turn-around-time (TAT), defined as the number of days between a test result date and the date that result was received by the HC (Table 7.2). For the electronic system, the date received at the HC was the earliest of the reception of the paper result or when the result was viewed online by a TB staff member. This primary outcome was calculated for both cultures and DSTs. Secondary outcomes were: (1) the proportion of DST results with a laboratory TAT greater than 60 days among all samples requested and emitted to the same health establishment, and (2) treatment TAT, defined as the number of days between the result date of the first DST resistant to INH, RIF or both and the date of a new regimen or change in regimen (Figure 7.3).

Table 7.2 Outcome definitions and sample

Outcome	**Definition**	**Sample**
Culture Lab TAT	Number of days between a culture result date and the date that result was received by the HC	All cultures performed on participants belonging to study clusters
DST lab TAT	Number of days between a DST result date and the date that result was received by the HC	All DSTs performed on participants belonging to study clusters
DST lab TAT > 60 days	The proportion of DST results with a laboratory TAT greater than or equal to 60 days	All DSTs performed on participants belonging to study clusters
Treatment TAT	Number of days between the result date of the first DST resistant to INH, RIF, or both and the date of a new regimen or change in regimen	All patients with a DST resistant to INH, RIF, or both
Culture conversion TAT	Number of days between the result date of the first DST resistant to INH, RIF, or both and the sample date of the first of two negative consecutive cultures taken at least 30 days apart	All patients with a DST resistant to INH, RIF, or both who had a positive culture six month before or two months after the DST result date

Although the study was not designed to have sufficient power to detect differences in time to culture conversion, we collected data on the culture conversion of patients. We calculated the

number of days between the result date of a DST resistant to INH, RIF, or both and the date of the first of two negative consecutive cultures taken at least 30 days apart (culture conversion TAT).[208] Patients in this cohort must have had a positive culture six months before or two months after the DST result date.

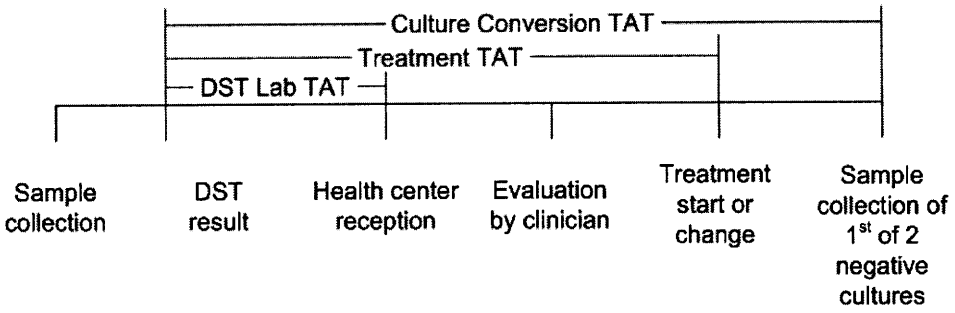


Figure 7.3 Diagram of turn-around-time (TAT) outcomes

7.2.5 Intervention

We designed and implemented the web-based laboratory information system "e-Chasqui" that was described in Chapter 6.[127] It was deployed in the NRL, two district laboratories, and 12 intervention HCs.

7.2.6 Sample Size

Previously we measured the treatment TAT to be approximately 65 days.[15] Assuming that the effect estimate of e-Chasqui would reduce this delay by 20 days, based on 0.8 power, and an α of 0.05, 165 subjects in each group (330 total) were required.

7.2.7 Usability and Acceptability of System

An anonymous survey previously used in Peru[180] was applied to measure the usability and acceptability of the system. The survey was modified for our intervention and validated with employees from our organizations, Partners In Health and Socios en Salud. After the intervention was completed, HC personnel with e-Chasqui access were given the same survey as those without access with two additional sections for questions about e-Chasqui. When personnel without access were asked about an electronic system the question referred to "an electronic laboratory information system" and not specifically to e-Chasqui. The responses were multiple choice, short answers or given on a five-point Likert scale anchored by 1=very positive, 5=very negative. The survey examined two themes: the frequency of missing results in the paper and e-

Chasqui systems and the security of both systems. Examples of both the control and intervention HC questionnaire can be found in Appendix B.

7.2.8 Data Abstraction

Baseline data were collected 15 months prior to the implementation of e-Chasqui (Jan 1, 2005-Mar. 30, 2006 for Lima Ciudad, May 1, 2005-Aug. 18, 2006 for Lima Este). Data were prospectively abstracted by a team of trained collectors who used standardized forms. For the RCT the study period started on the date of implementation of e-Chasqui and ended on August 31, 2008. Data are included from only those laboratories that implemented e-Chasqui (the NRL and the two district laboratories). Equivalent variables between the e-Chasqui and the study database were compared for data quality. Discordant results were verified at the laboratory that had emitted the result. If the end date for any TAT was missing, we censored that time using the date the patient left the study.

7.2.9 Statistical Analysis

We examined the effect of the intervention at a sample and an individual level, adjusting for the impact on variance of the clustering in the study design. We used multivariate regression models (marginal model with generalized estimating equations) to investigate the effect of the intervention on the TAT outcomes as a function of covariates and to account for the clustering at the HC level.[209] To investigate whether the intervention was associated with a reduction in the number of DST results with laboratory TAT greater than 60 days, we used a generalized linear mixed model[184 185] with HC as a random effect and health district and period (pre- and post-implementation) as fixed effects.

Due to the different structures of the laboratory and HCs within each district, we stratified our analysis by the health district (Lima Este and Lima Ciudad). For Lima Este, we further stratified by type of HC (direct or indirect). All stratification was done in the cohorts and not in the multivariate models. To adjust for possible HC differences that may have been unequally distributed despite randomization, we included the median pre-intervention TAT per HC for each of the TAT outcomes (as a proxy for HC variance) and number of HC staff changes. At the individual level for the treatment and culture conversion TAT, we also adjusted for HIV status and pediatric status.

To analyze the differences in the means of survey responses we used a t-test for two independent samples with the Satterthwaite's approximation for the degrees of freedom because of the unequal variances between the groups. We used SAS version 9.1 (SAS Institute, Cary, NC, USA) for all analysis and checked all models using R.[210]

7.3 Results

During the trial, 89% (1671/1888) of all eligible patients were enrolled (Figure 7.4). The intervention HCs had a significantly greater number of study participants per HC. If separated by district, these differences existed only in Lima Ciudad. The intervention HCs also had younger patients, a higher proportion of female patients, and a larger number of personnel changes in the TB clinician per HC. There were no significant differences in the number of patients per indirect HCs, number of co-infected with HIV, number of TB nurse changes during the study, number of patients who had a smear or culture positive or had a drug resistant DST by study arm (Table 7.3). 98% of all culture results and 100% of all DST results available in e-Chasqui were viewed by the intervention HCs.

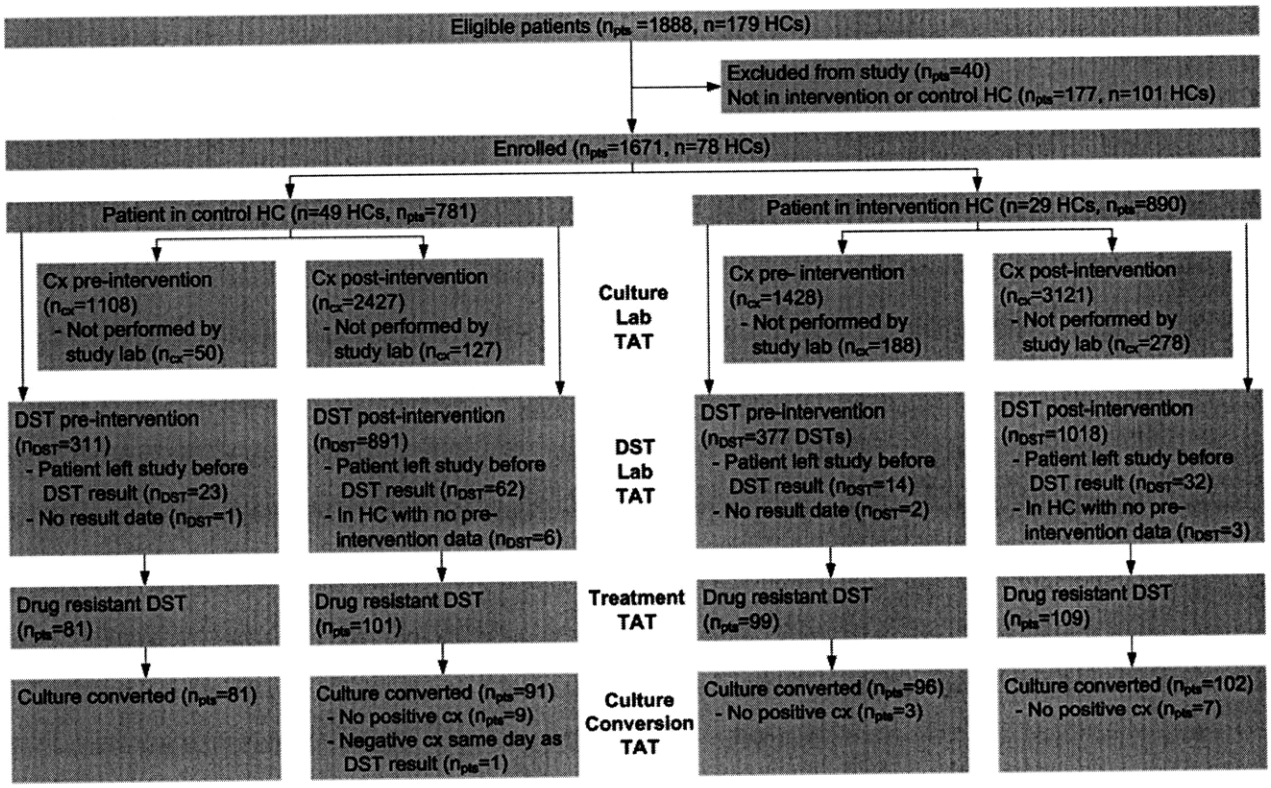


Figure 7.4 Flow of participants (n_{pts}), cultures (n_{cx}) and DSTs (n_{DST}) through trial

Table 7.3. Characteristics and outcome measures for all study health centers (HCs) and participants. Values are mean (SD) unless stated otherwise.

Characteristic	Control	Intervention	p-value
Total # direct HC	22	12	
Total # indirect HCs	27	17	
Total # (%) participants in Lima Ciudad	357 (46)	462 (52)	
Total # (%) participants in direct HCs	548 (70)	650 (73)	
Total # (%) participants in indirect HC	233 (30)	240 (27)	
Participants per HC	16.3 (16.9)	29.7 (32.6)	0.04
Participants per direct HC	26.1 (18.2)	54.2 (39.1)	0.02
Participants per indirect HC	8.6 (10.9)	13.3 (10.5)	0.10
Smear or culture positive patients per HC	12.8 (13.7)	23.7 (29.5)	0.08
Patients with drug resistant DST per HC	4.9 (4.8)	8.3 (11.7)	0.73
Age (years)	33.5 (16.0)	31.1 (16.5)	0.001
Total # (%) female	257 (33)	340 (38)	0.02
Total # (%) co-infected with HIV	100 (13)	94 (11)	0.15
Changes in TB clinician per HC during study	2.1 (1.1)	1.7 (1.1)	0.04
Changes in TB nurse per HC during study	1.6 (0.9)	1.4 (0.9)	0.34

7.3.1 Laboratory TAT

Intervention HCs took significantly less time to receive both DST (median 10 vs. 18 days, p<0.001) and culture (5 vs. 8 days, p<0.001) results (Table 7.4, Figure 7.5). For cultures, the same pattern is seen where direct HCs in both districts have lower laboratory TATs (Lima Ciudad p<0.001, Lima Este p=0.004), but indirect HCs have a higher TAT (9 vs. 8 days, p=0.02). For DSTs, the district with all direct HCs (Lima Ciudad) had a significantly lower TAT (median 9 vs. 16 days, p<0.001). In Lima Este, it was significantly lower for direct HCs (14 vs. 19 days, p<0.001), but not for indirect HCs (27 vs. 22 days, p=0.658). For the analysis of DST laboratory TAT, diagnostic plots of the marginal model showed that it did not fit the data well. To confirm the results for that outcome, we performed the same analysis using a mixed effects model with only the uncensored data. This model provided approximately the same estimate and p-value as the marginal model. For all other outcomes, the marginal model diagnostic plots showed a good fit.

Table 7.4 Primary and secondary outcomes with stratification factors of health district and HC type. Figures are median (IQR) unless stated otherwise.

Outcome	Control HCs	Intervention HCs	Adjusted Hazard Ratio (95% CI)	p-value
Culture laboratory TAT	**8 (6)**	**5 (5)**	**0.64 (0.60-0.67)**	**<0.001**
Lima Ciudad	8 (6)	4 (4)	0.50 (0.47-0.53)	<0.001
Lima Este direct HCs	7 (8)	4 (6)	0.59 (0.48-0.73)	0.004

Lima Este indirect HCs	8 (10)	8 (11)	1.36 (1.17-1.56)	0.02
DST laboratory TAT	**18 (23)**	**10 (15)**	**0.60 (0.55-0.67)**	**<0.001**
Lima Ciudad	16 (18)	9 (13)	0.54 (0.48-0.61)	<0.001
Lima Este direct HCs	19 (26)	14 (26)	0.62 (0.42-0.93)	0.004
Lima Este indirect HCs	22 (31)	27 (32)	1.07 (0.76-1.49)	0.658
% of DST laboratory TAT > 60 days	**17.7**	**7.9**	**0.51 (0.27-0.97)**	**0.04**
Lima Ciudad	13.2	4.0	0.26 (0.13-0.52)	<0.001
Lima Este direct HCs	18.9	12.1	0.33 (0.08-1.48)	0.122
Lima Este indirect HCs	32.3	35.4	1.07 (0.37-3.09)	0.901
Treatment TAT	**50.5 (62)**	**66 (71)**	**0.92 (0.63-1.33)**	**0.539**
Lima Ciudad	40 (57)	66 (64)	0.98 (0.61-1.58)	0.882
Lima Este direct HCs	69 (57)	70 (125)	0.36 (0.09-1.5)	0.161
Lima Este indirect HCs	48.5 (169)	24 (97)	1.63 (0.63-4.2)	0.31
Culture conversion TAT	**85.5 (81.5)**	**67.5 (96)**	**0.61 (0.38-0.99)**	**0.043**
Lima Ciudad	85.5 (79)	70 (79)	0.82 (0.48-1.4)	0.473
Lima Este	54 (100)	19 (10)	0.18 (0.04-0.72)	0.015

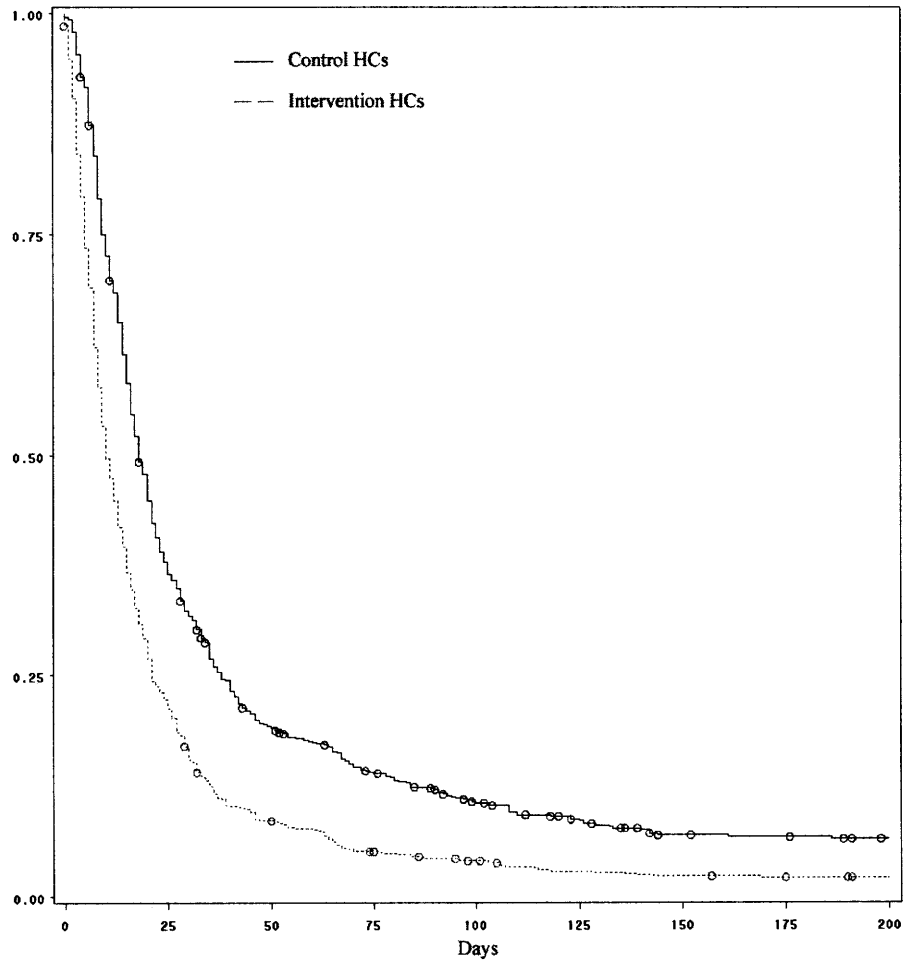


Figure 7.5 Kaplan-Meier survival curve for DST laboratory TAT for RCT showing first 200 days

In the before-and-after comparison, all HCs in the district had a significantly lower TAT post implementation overall (6 vs. 8 days, p<0.001), in Lima Ciudad (6 vs. 7 days, p<0.001), Lima Este direct HCs (5 vs. 9 days, p<0.001), and Lima Este indirect HCs (8 vs. 12 days, p<0.001).

For DSTs, Lima Ciudad (12 vs. 15 days, p=0.02) also had a significant decrease post-implementation.

7.3.2 Laboratory TAT > 60 days

Intervention HCs had significantly less DSTs that had a laboratory TAT over 60 days compared to control HCs (p=0.04). There was a significant decrease in Lima Ciudad (4.0 vs. 13.2%, p<0.001), but not in Lima Este direct HCs (12.1 vs. 18.9%, p=0.122) or indirect HCs (35.4 vs. 32.3%, p=0.901). 57.5% (42/73) of DST with laboratory TAT over 60 days never arrived compared with 83.6% (112/134) for the control HCs. In the before-and-after comparison, the decrease after the implementation for the full cohort (12.4 vs. 24.9%) and in Lima Ciudad (7.8 vs. 15.4%) were both highly significant (p<0.001).

7.3.3 Treatment TAT

For a total of 210 participants (109 in the intervention HCs, 101 in the control) treatment TAT did not significantly differ in the intervention versus control HCs: overall (median 66 v. 50.5 days, p=0.539), in Lima Ciudad (median 66 vs. 40 days, p=0.882), in Lima Este direct HCs (70 vs. 69 days, p=0.161), or in Lima Este indirect HCs (24 vs. 85 days, p=0.31) compared to control HCs (Figure 7.6). In the before-and-after comparison, there was a significant decrease overall (60 vs. 62 days, p=0.014), but not within any of the stratifications: Lima Ciudad (59.5 vs. 52 days, p=0.09), Lima Este direct HCs (70 vs. 68 days, p=0.383), Lima Este indirect HCs (24 vs. 48 days, p=0.44).

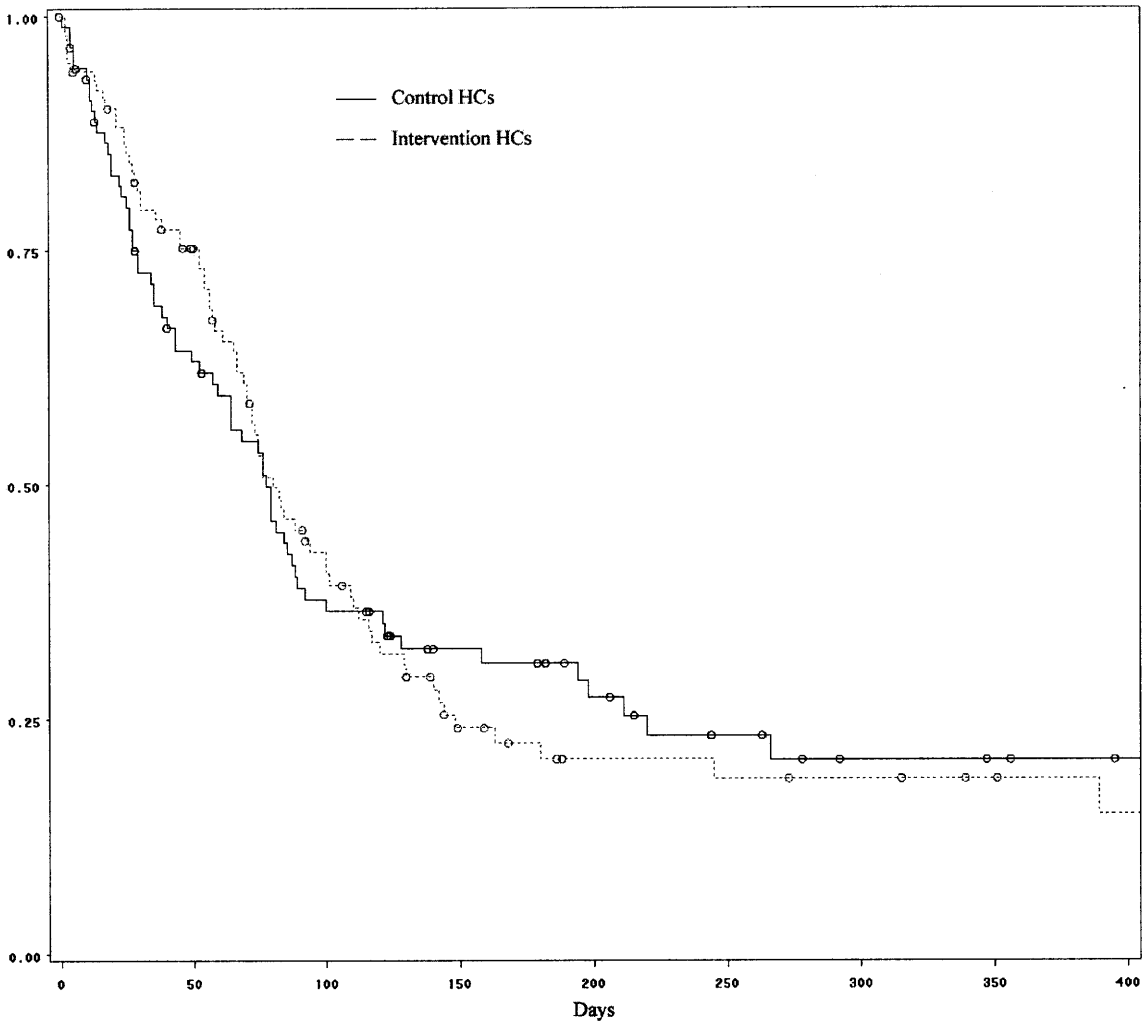


Figure 7.6 Kaplan-Meier survival curve for treatment TAT for RCT showing first 400 days

7.3.4 Culture Conversion TAT

Among 193 participants included in analysis for culture conversion TAT (102 in intervention HCs, 91 in control), those in the intervention HCs had a significantly lower TAT than those in the control HCs for the full cohort (p=0.043) and in Lima Este (19 vs. 54 days, p=0.015), see Figure 7.7. In Lima Ciudad there was no significant difference (70 vs. 85.5 days, p=0.473). Since there were only seven patients in Lima Este, we did not stratify by HC type. In the before-and-after comparison, there was a significant increase in culture conversion TAT overall (70 vs. 37 days, p<0.001) and in Lima Ciudad (76 vs. 35.5 days, p<0.001). The opposite, however, was seen in Lima Este (19 vs. 38 days, p<0.001).

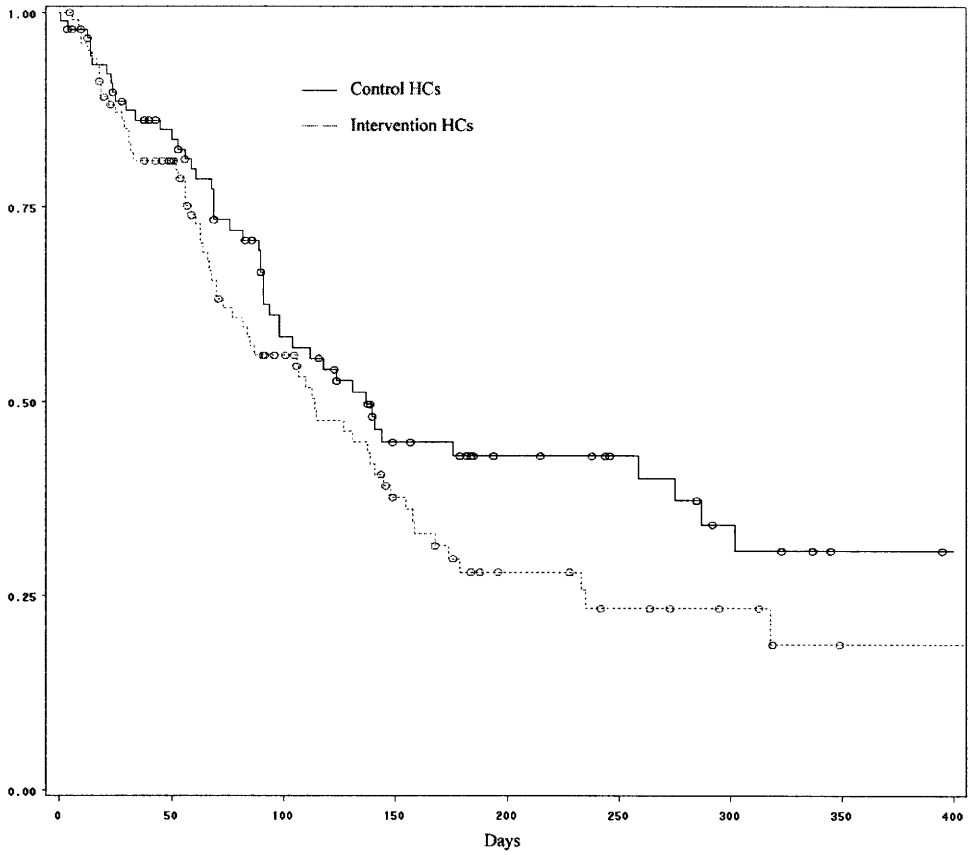


Figure 7.7 Kaplan-Meier survival curve for culture conversion TAT for RCT showing first 400 days

7.3.5 Usability and Acceptability of System

The response rate among intervention HC users administered the survey was 94% (29 of 31). 23 users were not administered the survey because they were not present at their HC during the visit. The response rate among control HC users was 93% (108 of 116). Of the intervention HC users, 48% (n=14) were clinicians or nurses in charge of the patients treatment (Table 7.5). The intervention HC users had, on average, more years of internet usage and had accessed the internet more frequently from the TB office or laboratory. Both of these can be attributed to e-Chasqui since the survey was given after three years of using the system and the district office had prioritized internet access for those TB offices in intervention HCs.

Table 7.5 Survey respondent characteristics

Characteristic	Controls (n=108)	Intervention (n=29)
Gender		
Male	27 (25)	12 (41)
Clinical background		
Physician	20 (19)	6 (21)
Nurse	35 (33)	8 (28)

Laboratory staff	9 (8)	3 (10)
Nurse technician	36 (34)	10 (34)
Other	5 (5)	2 (7)
Years of Internet usage		
0	26 (25)	2 (7)
1-5	47 (44)	18 (62)
6-10	25 (24)	6 (21)
>10	1 (1)	1 (3)
Location of Internet usage		
TB office/laboratory	16 (15)	15 (52)
Office in health center	17 (16)	4 (14)
House	56 (53)	12 (41)
Internet cabin	36 (34)	7 (24)
Other office	17 (16)	3 (10)
Other	3 (3)	0
Health district		
Lima Ciudad	88 (83)	17 (59)
Lima Este	17 (16)	12 (41)

Even though intervention HC users were more satisfied with the paper system than the control HC users (p=0.005), they still preferred e-Chasqui (p=0.009). Users liked all tools provided in e-Chasqui with nightly email notification of results and easy access to the system being the favorites. Of the clinical users, 71% (10 of 14) used e-Chasqui in the presence of their patient at least a quarter of the time. The same number reported at least one in 10 patients expressing to them an unsolicited positive opinion about the system. When asked about a nation-wide implementation, all e-Chasqui users thought it appropriate to expand the system and that it would improve the quality of patient care.

Table 7.6 User satisfaction with paper and e-Chasqui systems and opinion on a national TB laboratory information system. Responses are mean of five-point Likert scale anchored by 1=very positive, 5=very negative or number (percentage) of option chosen

Question	Controls (n=108)	Intervention (n=29)
How satisfied are you using the paper system to communicate results?	3.0	2.2
How satisfied are you using e-Chasqui to communicate results?		1.4
Which system do you prefer to view your results?		
e-Chasqui		20 (69)
Paper		1 (3)
Both are the same		6 (21)
How many times do you access e-Chasqui?		
Multiple times daily		3 (10)

Once daily		10 (34)
Once weekly		8 (28)
Once monthly		5 (17)
Almost never		2 (7)
Benefit of (mean of responses, 1=Very Beneficial, 5=No Benefit)		
Email notification of results		1.11
List of pending tests		1.32
View my patients' results from other health centers		1.28
Easy access		1.15
Do you use e-Chasqui during patient visits? (n=14 clinical users)		
More than half of patients		8 (57)
Less than half		2 (14)
Less than a quarter		1 (7)
Very few		2 (14)
Never		1 (7)
If so, what quantity of patients have expressed that they find e-Chasqui beneficial? (n=14 clinical users)		
1 of 2 patients		5 (36)
1 of 4		2 (14)
1 of 10		3 (20)
1 of 50		1 (7)
1 of 100		1 (7)
None		1 (14)
Is it feasible to implement a web-based system to communicate lab results at a national level?		
Yes	102 (96)	
No	1 (1)	
Would this system improve patient care?		
Yes	101 (95)	
No	1 (1)	
Do you think it appropriate to expand e-Chasqui to other health districts?		
Yes		29 (100)
No		0
How do you think using e-Chasqui in other health districts would impact the quality of care of patients?		
Improve greatly		25 (86)
Improve a bit		3 (10)
Neither improve nor worsen		0
Worsen a bit		0
Worsen greatly		0

7.4 Discussion

The e-Chasqui laboratory information system considerably reduced the time to communicate results of cultures and DSTs to local HCs and the proportion of results that had an excessive delay or never arrived. The patients in the intervention HCs had the same time to treatment as those in control HCs, but they did have a significant decrease in the time until they culture converted.

The prospective, randomized nature of this trial allowed for rigorous evaluation of the effect of e-Chasqui within the National TB Program. There have been no prior evaluations reported of the impact of an electronic system in decreasing delays in a resource-poor clinical setting and the results of this study show that it can have a large effect in the communication time of critical laboratory data. This effect might be even more apparent if this system were used in rural areas since the obstacles to communication usually encountered (long travel times, infrequent transport, or weather) are easily surpassed if there is a reliable internet connection. Perhaps more importantly, the system prevented results from arriving too late or never arriving. We found that, without e-Chasqui, approximately 1 in 8 DST results arrived late or never arrived at the HC before our intervention. This means that without a system like e-Chasqui, of the approximately 950 MDR DST results performed in 2008 by the district labs, 120 would probably never have been seen by the treating physician and the patient might not receive the appropriate treatment. This "break" in the patient care process can be easily overlooked when evaluating a TB program. If the laboratory network reports the number of MDR DSTs and the TB program reports the total number of patients on treatment, without an electronic system, it would be difficult to see how many patients had "fallen through the cracks" between these two institutions.

The differing organization structures of the two health districts allowed for an analysis of how information systems like e-Chasqui would impact a region where HCs communicated in an "indirect" fashion. Many countries have a system with "indirect" HCs and it is important to note that though e-Chasqui had a positive impact on the district as a whole, there was little to no effect on these establishments. The results here would suggest that the greatest benefit can be achieved by providing these indirect HCs with internet so that they can reap the advantages of the information system, even if organizational structure remains the same.

The randomized trial strongly supports the positive impact of e-Chasqui on reporting efficiency. However, we feel that the randomized trial only reflects a portion of the impact of the system. Since e-Chasqui affected the entire laboratory through several quality control and reporting tools, we performed the before-and-after trial to evaluate the system's effect on the district as a whole. These data suggest that, indeed, additional benefits may have been gained. For instance, the proportion of DSTs with laboratory TAT greater than 60 days decreased by more than 50% and there was a small, but significant decrease in treatment TAT. However, this system was implemented within a larger project to improve laboratory capacity and as such many other strategies were implemented during this study period; therefore we cannot attribute the historical trends solely to e-Chasqui.

There was no significant difference in treatment TAT between the intervention and control HCs. There are several possible explanations for this, including several factors which weakened the impact of e-Chasqui. These factors included a) that patients and their samples were assigned to their initial HC even if they transferred to another HC and b) since e-Chasqui was implemented programmatically, access to both control and intervention HCs was given to the district director and all clinicians in the MDR-TB treatment approval committee. Other possible explanations include that clinicians in the higher burden intervention HCs took longer to have their patients' MDR-TB regimens approved by the MDR-TB committee or that patients are getting started on effective standardized regimens and do not need to be modified based on a DST result.

Few prospective, randomized trials have shown that an information system can have a clinical impact. Here, we find that the patients in the intervention HCs had undetectable levels of TB after their DST 18 days earlier than those in the control HCs, a 21% decrease in culture conversion TAT. The mechanism of this impact, however, is unclear since it is not due to an earlier start of appropriate treatment. We believe that the culture conversion TAT measures not only the effect of the drug regimen, but other factors that we did not measure directly. Some of the ways e-Chasqui could contribute to the clinical impact are: 1) improved monitoring of patients because clinicians have greater access to their bacteriological history; 2) increased ability to prioritize regimen changes for the patients who would benefit most; 3) improved adherence by patients because they believe they are receiving better treatment when their doctor

uses a computer (as seen by the positive patient opinion expressed in the survey); 4) a greater sense of responsibility because their doctor can monitor them more closely.

The positive user opinions also showed that e-Chasqui had benefits for the HCs users. For example, despite the fact that half did not have computers at their office, 72% of all users accessed e-Chasqui at least once a week. Also, 90% of users preferred e-Chasqui or found it as useful as the paper system. We found that the control HC staff had a favorable opinion of the benefit of using electronic systems nation-wide and that e-Chasqui users maintained that opinion.

Another possible measure of the success of this system is its continued use and expansion. During the study period, over 120 users from 79 HCs not in the study cohort were trained in the use of the system at the request of district administrators. Since the end of the study period, another 118 users from 68 control HCs have been trained and are using e-Chasqui. In total, e-Chasqui serves a network of 159 institutions serving a catchment area of over 4.2 million people and providing treatment to approximately 9,600 TB and 800 MDR-TB patients every year. We are currently working with the Ministry of Health to transfer the system to their control.

Limitations

There were fundamental baseline differences between the intervention and control HCs despite the randomized nature of this trial. These differences could introduce bias into the analysis, but in all cases we used pre-implementation values in our models to account for this. The study was conducted in the two most populous health districts in Peru. Therefore the generalizability of these results should be treated with caution. Being in an urban area provided the project with mostly consistent power and internet, as well as geographic proximity to provide technical support, which is not the case in many resource-poor settings. Therefore groups implementing these systems should ensure that the appropriate infra-structure is in place. Also, the data used in this study is on 1600 of the 1800 patients enrolled in the study. Finally, this was a formative, rather than summative, evaluation since the developers were involved.

7.5 Conclusion

A carefully designed and implemented web-based tuberculosis laboratory information system reduced the time to communicate results between laboratories and health establishments spread throughout a large, peri-urban area. It also prevented many results from taking over two months

to reach their destination or never arriving. This system was also endorsed by users despite limited support available and difficulties in accessing the internet. Patients in intervention HCs had the same time to treatment as those in the control HCs, but they had their first negative culture after a DST 18 days before those in the control HCs (21% earlier). Such a system in other resource-poor settings should be considered as a component of laboratory infrastructure to support TB and MDR-TB care.

8 Impact of e-Chasqui on Data Quality

In previous chapters, we have described the e-Chasqui laboratory information system and its impact in reducing delays in communication of results from laboratories to health centers, changing medication regimens, and having patients culture convert. In this chapter, we analyze its impact on reducing the number of errors in the laboratory results communicated between the laboratories and health centers—in other words, its impact on data quality. The description of the setting and study is similar to the previous chapter. We conducted a cluster randomized controlled trial to evaluate the effectiveness of the e-Chasqui laboratory information system in reducing the number of errors in laboratory results used by clinical personnel in the TB program in Peru. We also performed a before-and-after trial to evaluate additional effects of the system.

8.1 Methods

A cluster randomized controlled trial (RCT) tested the effect of the laboratory information system e-Chasqui in reducing errors in communicating test results from district laboratories to health centers. As a secondary study design, we also conducted a before-and-after trial. Both trials were performed within a larger observational study evaluating the impact of expanded laboratory capacity in the district laboratories.[15]

8.1.1 Study Settings and Design

This study was carried out in the same two health districts and format as described in the previous chapter. The intervention, e-Chasqui, was described in Chapter 6.

We prospectively collected baseline data for 12 months from the two health districts. We then implemented e-Chasqui in the laboratories and randomly assigned six HCs from each health district (12 total) to the intervention. In Lima Ciudad, these six were randomized from the 20 highest incidence HCs. In Lima Este, they were randomized from the 12 direct HCs within Lima city limits (Figure 7.2). Indirect HCs (n=44) belonged to the study arm that was assigned to their corresponding direct HC. After the intervention was implemented, we collected data on the same endpoints in control and intervention arms. This allowed us to perform a prospective comparison between the intervention and the control arms (cluster randomized controlled trial) as well as a historical comparison comparing the full district pre- and post-implementation (before-and-after

trial). This complementary design using two comparison groups allowed us to minimize the risk that the changes measured were due to secular changes in the regions studied or to baseline differences between the arms. Since the potential sources of bias should be independent, observing similar effects in both comparisons should offer reassurance that our conclusions are valid. The Lima Este district laboratory did not perform DSTs before the implementation of e-Chasqui, hence no baseline DST data for that district is available.

8.1.2 Outcomes

An error was defined as an occurrence when information from the laboratory register did not match the result found in the clinical chart at the HC. We recorded all relevant variables collected for DSTs and cultures, including patient name, result date, identification number, result, and if the result or clinical chart were found at the HC. For the purposes of this thesis, we only report what we defined as major errors: (1) a change in the patient's name that could result in mis-identification of the result, (2) difference in result type (negative to positive) or strength (paucibacillary, +, ++, or +++), (3) paper result not found in the patient's chart, (4) chart not found at the HC. For the comparison of the patient's name we considered the chart at the HC to be the gold standard, and the laboratory register was the gold standard (for the result).

We performed a primary analysis comparing the results found on paper in the laboratory register and the chart at the HC. For purposes of this analysis, if a result or chart was not found at the HC we did not take into account if it had been viewed in e-Chasqui. We performed two secondary analyses. First, we analyzed the same data, but counted a result as not missing if it had been viewed in e-Chasqui by the intervention HC staff. Second, we eliminated all missing result or chart errors and only considered those results that had reached the HC. We analyzed this cohort for the number of errors resulting from a wrong name or result.

We expected a decrease in all types of errors. For the randomized controlled trial, we expected the intervention HCs to have fewer errors because they would have access to all results in e-Chasqui and therefore should have no missing results. In the before-and-after trial, all data had to be verified by the laboratory director before being displayed in the web-based system, therefore we expected that e-Chasqui implementation at the laboratory should decrease errors for the full district.

8.1.3 Sample Size

In an earlier study of a collection method for cultures in Peru we had measured the error rate to be 4%.[26] Assuming that the effect estimate of e-Chasqui was to reduce this error rate to 2%, based on 0.9 power, and an α of 0.05, 262 samples subjects in each group (1048 total) were required; we collected 2962 cultures and 1743 DSTs.

8.1.4 Data Abstraction

For cultures, we sampled results every four months the year before and after the intervention was implemented. In Lima Ciudad, the pre-implementation collection dates were the first two weeks of March, July, and November 2005. The same dates in 2006 were collected for the post-implementation comparison. In Lima Este, pre-implementation collection dates were the first 23 days of May 2005, September 2005 and January 2006. A higher number of days were sampled because the Lima Este laboratory performs fewer tests than Lima Ciudad. The same dates the following year were sampled for post-implementation. For DSTs, we sampled all DSTs performed pre-implementation and post-implementation in Lima Ciudad (Jan. 17- Dec. 2005 and Feb. 1-Dec. 31, 2006). No pre-implementation DSTs were performed by Lima Este; we collected post-intervention DSTs in Lima Este (Dec. 1, 2006-Nov. 15, 2007) to meet our sample size requirement.

8.1.5 Statistical Analysis

We examined the effect of the intervention at a sample level, adjusting for the impact on variance of the clustering in the study design. We used a generalized linear mixed model (GLMM)[184 185] with HC as a random effect and pre-intervention mean error rate per HC (as a proxy for HC variance), DST method and number of changes of the TB clinician and nurse per HC as fixed effects. The pre-intervention error rate should adjust for possible HC differences that may have been unequally distributed despite randomization. We stratified the analysis by health district (Lima Este and Lima Ciudad).

8.2 Results

Characteristics of the intervention and control HCs are summarized in Table 8.1. There was no significant difference in the total number of cultures and DSTs between the intervention and controls HCs. The only significant difference was the higher number of clinician changes in the

intervention HCs. 98% of all culture results and 100% of all DST results available in e-Chasqui were viewed by the intervention HCs.

Table 8.1. Characteristics measures for all study health centers (HCs). Values are mean (SD) unless stated otherwise.

Characteristic	**Control HCs**	**Intervention HCs**	**p-value**
Total # direct HC	22	12	
Total # indirect HCs	27	17	
Monthly cultures per HC	12.3 (11.1)	26.3 (28.6)	0.06
Monthly DSTs per HC	2.0 (2.0)	3.4 (3.8)	0.06
Changes in TB clinician per HC during study	1.7 (1.1)*	2.1 (1.1)	0.04
Changes in TB nurse per HC during study	1.4 (0.9)	1.6 (0.9)	0.34
Sample Sizes			
Cultures Sampled	539	780	
DSTs Sampled	584	765	
	Before	After	
Cultures Sampled	1643	1319	
DSTs Sampled	394	1349	

8.2.1 Primary Analysis

When looking at the paper results, the major source of errors are missing results or charts, which account for 88-92% of all errors depending on the comparison (Tables 8.2 and 8.3). When comparing the control and intervention HCs, there was no significant difference in the error rate for either cultures (p=0.07) or DSTs (p=0.26). For cultures, the Lima Ciudad intervention HCs had significantly fewer errors than control HCs (p=0.02), though there was no difference in Lima Este (p=0.35) as seen in Table 8.4. For DSTs, there are no significant differences between control and intervention HCs (Table 8.6).

In the before-and-after trial for effects of e-Chasqui implementation at the laboratory level, DSTs in Lima Ciudad had significantly fewer errors after the implementation (p=0.02, Table 8.7). No significant change was seen in cultures (Table 8.5)

Table 8.2 Number of errors by type in cluster randomized controlled trial

	Control		**Intervention**	
	Number	%	**Number**	%
Culture Patient Name	7	1.2	14	1.8
Culture Result	4	0.7	1	0.1
Culture Colonies	0	0.0	0	0.0
Culture not found in chart	66	12.2	70	9.0
Chart not found (Culture)	41	7.6	83	10.6
Total	**118**	**21.9**	**168**	**21.5**

DST Patient Name	10	1.7	11	1.4
DST Result	1	0.2	4	0.5
DST not found in chart	57	9.8	73	9.5
Chart not found (DST)	23	3.9	56	7.3
Total	**91**	**15.6**	**140**	**18.8**

Table 8.3 Number of errors by type in before-and-after trial

	Before		**After**	
	Number	**%**	**Number**	**%**
Culture Patient Name	51	3.1	21	1.6
Culture Result	4	0.2	5	0.4
Culture Colonies	0	0.0	0	0.0
Culture not found in chart	139	8.5	136	10.3
Chart not found (Culture)	195	11.9	124	9.4
Total	**389**	**23.7**	**286**	**21.7**
DST Patient Name	15	3.8	21	1.6
DST Result	1	0.3	5	0.4
DST not found in chart	55	14.0	128	9.5
Chart not found (DST)	60	15.2	79	5.9
Total	**131**	**33.2**	**233**	**17.3**

8.2.2 Secondary Analysis

We used the event log of e-Chasqui to count all of the results that had been viewed online by at least one staff member in the intervention HCs. If the result was viewed online then it was not counted as missing. All DST results and 98% of culture results were viewed online.

The intervention HCs had significantly fewer errors than control HCs for both cultures and DSTs (Tables 8.4 and 8.6, see Error Rate with e-Chasqui). This decrease remained significant in both health districts. In the before-and-after trial, there was a significant decrease in errors in all comparisons after the implementation of e-Chasqui. This includes the overall analysis (cultures $p<0.001$, DSTs $p<0.001$), in Lima Ciudad (cultures $p<0.001$, DSTs $p<0.001$), and in Lima Este (cultures $p<0.001$).

Table 8.4 Primary and secondary analyses stratified by health district for cultures in RCT. Figures are percent of samples with at least one error unless stated otherwise.

Outcome	Control	Intervention	Hazard Ratio (95% CI)	p-value
Paper Error Rate	**21.9**	**21.5**	**0.74 (0.53-1.02)**	**0.07**
Lima Ciudad	27.6	15.2	0.4 (0.18-0.89)	0.02
Lima Este	14.6	27.1	1.49 (0.61-3.64)	0.35
Error Rate with e-Chasqui	**21.9**	**1.9**	**0.07 (0.02-0.24)**	**<0.001**

Lima Ciudad	27.6	0.5	0.003 (0.002-0.10)	<0.001
Lima Este	14.2	3.2	0.22 (0.06-0.79)	0.02
Wrong Name or Result	**1.9**	**1.9**	**1.28 (0.42-3.93)**	**0.65**
Lima Ciudad	0.7	0.5	Model did not converge	
Lima Este	3.2	3.2	1.32 (0.39-4.46)	0.63

Table 8.5 Primary and secondary analysis stratified by health district for cultures in the before-and-after trial. Figures are percent of samples with at least one error unless stated otherwise.

Outcome	Before	After	Hazard Ratio (95% CI)	p-value
Paper Error Rate	**23.8**	**21.5**	**0.89 (0.73-1.07)**	**0.21**
Lima Ciudad	23.3	20.7	0.83 (0.64-1.08)	0.16
Lima Este	24.2	22.4	0.94 (0.72-1.22)	0.63
Error Rate with e-Chasqui	**23.8**	**9.9**	**0.36 (0.28-0.47)**	**<0.001**
Lima Ciudad	23.3	12.5	0.48 (0.36-0.65)	<0.001
Lima Este	24.2	7.3	0.25 (0.17-0.36)	<0.001
Wrong Name or Result	**3.3**	**1.9**	**0.56 (0.34-0.92)**	**0.02**
Lima Ciudad	2.6	0.6	0.20 (0.07-0.55)	0.002
Lima Este	3.9	3.2	0.77 (0.43-1.39)	0.39

In the second analysis, we compared the error rates among results at the HCs (Wrong Name or Result in Tables 8.4-8.7) by excluding the missing results and chart errors. No difference was seen between control and intervention HCs in the overall or health district comparison for cultures (Table 8.4) or DSTs (Table 8.6). In the before-and-after trial, cultures had a significant decrease post-implementation in the overall analysis (p=0.02) and in Lima Ciudad (p=0.002, Table 8.5). No significant difference was seen in Lima Este. For DSTs, there was a decrease in the overall analysis (p=0.05) and in Lima Ciudad (p=0.02) post-implementation (Table 8.7).

Table 8.6 Primary and secondary analysis stratified by health district for DSTs in the RCT. Figures are percent of samples with at least one error unless stated otherwise.

Outcome	Control	Intervention	Hazard Ratio (95% CI)	p-value
Paper Error Rate	**15.6**	**18.8**	**1.21 (0.87-1.70)**	**0.26**
Lima Ciudad	18.2	16.3	1.2 (0.36-3.93)	0.75
Lima Este	13.0	21.9	1.6 (0.75-3.38)	0.21
Error Rate with e-Chasqui	**15.6**	**1.4**	**0.11 (0.06-0.22)**	**<0.001**
Lima Ciudad	18.2	1.2	0.12 (0.02-0.97)	0.047
Lima Este	13.0	1.2	0.08 (0.03-0.24)	<0.001
Wrong Name or Result	**1.9**	**1.9**	**1.23 (0.49-3.05)**	**0.66**
Lima Ciudad	0.7	2.4	4.67 (0.16-139.8	0.19
Lima Este	2.9	1.5	0.42 (0.13-1.38)	0.15

Table 8.7 Primary and secondary analysis stratified by health district for DSTs in the before-and-after trial. Figures are percent of samples with at least one error unless stated otherwise.

Outcome	Before	After	Hazard Ratio (95% CI)	p-value
Paper Error Rate	**33.2**	**17.3**	**0.41 (0.30-0.57)**	**<0.001**
Lima Ciudad	33.2	17.0	0.45 (0.32-0.65)	<0.001
Lima Este		17.7		

Error Rate with e-Chasqui	**33.2**	**7.8**	**0.18 (0.12-0.27)**	**<0.001**
Lima Ciudad	33.2	8.6	0.19 (0.12-0.29)	<0.001
Lima Este		7.0		
Wrong Name or Result	**4.1**	**1.9**	**0.50 (0.26-0.99)**	**0.05**
Lima Ciudad	4.1	1.7	0.41 (0.19-0.89)	0.02
Lima Este		2.1		

Errors in the after group include both control and intervention HCs post-implementation and therefore the error rates average the errors of both the electronic and the paper system..

The RCT in the previous table measures the impact of HC access to e-Chasqui, whereas the before-and-after trial in this table measures the impact of e-Chasqui on the laboratory and hence all of the HCs in the district.

8.2.3 Usability and Acceptability of System

The response rate among intervention HC users administered the survey was 94% (29 of 31), though 23 users were not administered the survey because they were not present at their HC during the visit. The response rate among control HC users was 93% (108 of 116). Of the intervention HC users, 48% (n=14) were clinicians or nurses in charge of the patients treatment (Table 8.8). The intervention HC users had, on average, more years of internet usage and had accessed the internet more frequently from the TB office or laboratory. Both of these can be attributed to e-Chasqui since the survey was given after three years of using the system and the district office had prioritized internet access for those TB offices in intervention HCs.

Table 8.8 Survey respondent characteristics with number (percentage) of users

Characteristic	Controls (n=108)	Intervention (n=29)
Gender		
Male	27 (25)	12 (41)
Clinical background		
Physician	20 (19)	6 (21)
Nurse	35 (33)	8 (28)
Laboratory staff	9 (8)	3 (10)
Nurse technician	36 (34)	10 (34)
Other	5 (5)	2 (7)
Years of Internet usage		
0	26 (25)	2 (7)
1-5	47 (44)	18 (62)
6-10	25 (24)	6 (21)
>10	1 (1)	1 (3)
Location of Internet usage		
TB office/laboratory	16 (15)	15 (52)
Office in health center	17 (16)	4 (14)

House	56 (53)	12 (41)
Internet cabin	36 (34)	7 (24)
Other office	17 (16)	3 (10)
Other	3 (3)	0
Health district		
Lima Ciudad	88 (83)	17 (59)
Lima Este	17 (16)	12 (41)

A majority of users were missing at least 10% of results in the paper system (66% for control HCs, 55% for intervention HCs) and approximately the same proportion felt that this diminished the opportunity of treatment given to a patient. All of these users in the intervention HCs found results in e-Chasqui they did not have on paper.

Control HC users thought that an electronic system would be more complete, confidential, and secure than the current paper system. This same pattern is seen in the responses of the intervention HC users when asked about e-Chasqui.

Table 8.9 User opinion of paper and e-Chasqui systems. Responses are mean of five-point Likert scale anchored by 1=very negative, 5=very positive or number (percentage) of option chosen. Percentages are calculated from total surveys even if question was left blank.

	Frequency (%)	
	Controls (n=108)	Intervention (n=29)
How often were you missing a culture or DST result for a patient? (paper system)		
1 of 2 patients	27 (25)	2 (7)
1 of 4	21 (20)	3 (10)
1 of 10	22 (21)	11 (38)
1 of 50	13 (12)	2 (7)
1 of 100	2 (2)	0
Never	17 (16)	7 (24)
Do you believe this diminished the opportunity of treatment?		
Yes	80 (75)	16 (55)
No	20 (19)	6 (21)
Did you find information in e-Chasqui that you would not have had without the system?		
Yes		20 (69)
No		9 (31)
In which system do you believe the information is more complete (the requests are filled out better)?		
Electronic / e-Chasqui	83 (78)	21 (72)
Paper	0 (0)	1 (3)
Both are the same	18 (17)	6 (21)
In which system is the information more confidential (accessible only to the appropriate personnel)?		
Electronic / e-Chasqui	77 (73)	27 (93)
Paper	4 (4)	0

Both are the same	21 (20)	1 (3)
In which system is the data more secure (will not lost)?		
Electronic / e-Chasqui	84 (79)	26 (90)
Paper	4 (4)	0
Both are the same	12 (11)	2 (7)

8.3 Discussion

This study showed that there was no significant difference in the number of errors in the paper results found at HCs with or without e-Chasqui. Missing results or patient charts account for approximately 90% of these paper errors. When taking into account the online viewing of results by the intervention HC personnel, there is a substantial decrease in errors. Intervention HCs had a 91% reduction in errors for both cultures and DSTs as compared with control HCs. This confirms that e-Chasqui access at the HC level had a significant impact in reducing the error rate, mostly by providing access to results otherwise unavailable in the paper system.

When the missing results or patient chart errors were eliminated, the error rate found at all HCs post-implementation was lower for both cultures and DSTs—that is to say, if the result was found at the HC, it was more likely to be correct after e-Chasqui implementation. This confirms that e-Chasqui access at the laboratory level (which affects the entire district) had a significant impact in reducing the misspelling of names and reporting of wrong results.

In surveys, a majority of control and intervention HC users reported that they were missing at least 1 in 10 results. This validates our study's results where we found that 15.4 to 29.2% of all culture and DST results were not found at the HC. More importantly, almost 70% of e-Chasqui users reported finding results electronically that had been missing in paper form. This may be the system's largest impact.

We have not found reviews of the number of errors or missing results in other resource-poor settings, but our experience working in developing countries makes us believe that they are of the same or greater magnitude than what we have found here.[165 211 212] A high rate of missing results can occur easily within a paper system. This is aggravated by many factors found in the public health care system in most developing countries. Among some of the likely causes are a high patient load, lack of staff to support the administrative requirement of a paper system, inconsistent transportation of samples and results between HCs and laboratories, and the lack of

storage space or organization for charts. The results of this study show that the electronic system did not improve the proportion of paper results found at the HC. The fact that all DSTs and 98% of cultures in the system were viewed online by point-of-care healthcare providers demonstrates that electronic medical record reporting systems like e-Chasqui can improve not only the timely delivery of results, but also the quality of results, which facilitates, in turn, quality of care.

Limitations of study

The data were collected at approximately the same time for both pre and post implementation phases. Because of this, the pre-implementation data needed to be stored longer at HCs and therefore was more likely to be missing. Though this is a disadvantage of any paper system, it does imply a bias in the before-and-after trial. The study was conducted in the higher burden HCs in the two most populous health districts in Peru, therefore the generalizability of these results should be treated with caution. We think that a higher rate of missing results can be expected for a paper system in more rural or sparsely populated settings, though this should not be the case for an electronic system. A more rural setting however can imply less consistent power or internet availability, making it harder to access an electronic system. Finally, this was a formative, rather than summative, evaluation since the developers of e-Chasqui were involved.

8.4 Conclusion

An electronic system substantially reduced the number of missing laboratory results at point-of-care healthcare sites via electronic viewing, while the rate of missing results or errors on paper remained unchanged. Clinical users reported that the system provided them with results that were not received via the paper system. Further studies are required to investigate the impact of this online availability on patient outcomes.

9 Conclusions and Future Work

9.1 Conclusions

This work had two major goals.

1. To develop informatics tools and an implementation methodology for those tools to improve the communication of tuberculosis laboratory results in resource-poor settings with and without internet.

2. To evaluate those tools, using randomized controlled trials with a before-and-after comparison, to show their impact on decreasing communication delays, improving data quality, and reducing the time for patients to show clinical improvement.

9.1.1 Developing Informatics Tools and Implementation Methodologies

The two systems developed as part of this work show that laboratory information systems can be implemented in a resource-poor, peri-urban area. Both systems used a common implementation methodology which we believe account for a large part of their successful implementation. The major themes are:

1. Implement healthcare technologies within larger collaborations that improve the overall public health infrastructure even if this means additional work and time.

2. Create a system technically flexible enough to meet the stakeholder's needs that will be discovered throughout the implementation process.

3. Involve all personnel who will be using or be impacted by the system. In a public health context this especially includes the end users such as clinicians, nurses, and data entry personnel, who can be easily left out of the process.

4. Have local political support for the project from its conception. Unless there is will from the administration to implement an electronic information system, promote its use, and allocate resources to maintain it, there is little chance of success.

5. Focus on the needs of the users. Trainings should be focused on the benefits the system provides the users. In Peru, most previous health information systems required users to enter data for reporting purposes without receiving any feedback. In this work, we saw reticent users become enthusiastic when they realized the system would provide *them* with useful information.

6. Share the lessons learned of the process. This could be done by making available the plans, times, and costs of implementing any system available through academic publications or internet sites focused on resource-poor settings such as the Global Health Delivery online communities.[213]

9.1.2 Evaluation of the Impact of the Informatics Tools

Any medical informatics tool implemented should be evaluated to ensure its safety and the impact it has on patient care. This work showed that well-designed and implemented electronic systems can provide for major improvements in a peri-urban, resource-poor setting. Among the improvements were:

1. Reducing the median time to communicate a result, in the case of the handheld system from 23 to 8 days.

2. Reducing the proportion of tests with large communication delays, in the case of the handheld system, from 9.2% to 0.1%.

3. Ensuring that results reach the clinician. Approximately 20% of results could not be found on paper at the e-Chasqui health centers, yet all were viewed in the system by the staff.

4. Reducing the work load on already overburdened clinical and administrative personnel. The handheld system reduced the number of work-hours necessary to process results by 60%. E-Chasqui virtually eliminated clinicians phone calls to the laboratory to enquire about the status of their sample by providing them with the ability to track their samples online.

9.2 Recommendations for Future Work

The need to improve communications and treatment in settings of poverty is both dire and daunting. This thesis presented data on how laboratory information systems can be implemented in resource-poor settings with and without internet and shows their impact on clinical and administrative criteria. However, much more work needs to be done in developing robust medical information systems for these harsh settings, creating methodologies to ensure their successful implementation, and performing quantitative evaluations to determine their impact on clinical care.

For developing robust systems, factors such as intermittent internet and power, little to no computer experience, and high staff rotation, need to be taken into account and provide additional challenges to the already difficult task of successfully implementing medical informatics applications. One factor that will help in this process is the philosophy of open source software and community. There are already three major open source projects developing systems and communities that are empowering projects in resource-poor settings. The goals are to provide better clinical care, but also to empower them to become more self-sustainable by promoting the creation of local businesses and developers and giving them tools on which they can build without being dependent on companies in the developed world. One such movement is centered around OpenMRS, [196] [197] a general purpose medical record system architecture we have developed with colleagues in the US and Africa to support TB and HIV treatment programs. We have also seen this occur with our local Peruvian organization, Socios En Salud, which has developed the technological capacity to manage the systems developed during this thesis and to be able to implement them in other areas or countries in need.

Implementation methodologies are also needed so that resource-poor settings do not make the same mistakes as many developed countries. These methodologies should focus on both the local and national level. For local institutions they should describe the holistic approach of implementing information systems. This holistic approach includes understanding the information flows throughout their organization, standardizing forms and terminology, and creating workspaces amenable to the use of information technology. A myriad of proven methodologies will be required for the different types of institutions and contexts all over the world where medical informatics applications can be of use.

These methodologies should prevent organizations from making the same mistakes that many clinical organizations who have implemented information systems. Among the most common mistakes are: 1) simplifying the challenge of implementing medical information systems to installing computers and software, 2) not controlling the ownership of the systems they implement thereby becoming dependent on a company for any change, 3) using systems that do not inter-operate, not allowing for communication with other systems in their own institution and in other institutions. At a national level, countries should learn the importance of having a vision and plan to create inter-operable systems and having these systems reduce the workload on an already overloaded workforce by, for example, having clinical systems report consolidated data to district-wide information systems, rather than having the clinical staff manually create these reports. Also, these methodologies should outline the optimal order of implementation of systems depending on the situation and needs of a country, the requirements, costs, and times of such implementations, and factors external to the systems that need to be in place for success.

Finally, further evaluations and improved evaluation methodologies will be required to ensure that patients and countries are actually benefiting from the investment in medical informatics applications. At the time of this work, these were the only randomized controlled trials performed on laboratory information systems in resource-poor settings and they were among only a handful of randomized trials performed on any medical information system. More such trials are needed to determine if medical informatics can deliver its promised benefits.

Large investments are currently being made in medical informatics for resource poor settings. We believe that this work has provided a critical foundation for how this investment should be used and how information systems should be developed and implemented. First, they must be carefully designed with the end users in mind and taking all stakeholders into account, especially those on the ground. Many systems implemented are only for reporting purposes and, though perhaps useful for national statistics, are a burden on usually over-worked clinical and administrative staff. A better option is to implement a clinical system from which a reporting system could automatically consolidate required data. This benefits both the on the ground staff and the national offices. Second, there must be local interest and political support to implement the system. Systems should not be imposed by an external party. This is a difficult position since most funding sources have deadlines or policies that prevent long-term relationships where

such collaboration can happen. Finally, when possible, the information system should be implemented as part of larger structural improvement within the public health sector. The implementation of an information system will require a change in workflows. By being part of a larger project, this change in workflow will be easier to implement since other factors are changing as well and the system will not just be replicating a potentially poorly designed workflow. Also, there are many difficulties in working in resource-poor settings. When a more holistic approach is taken to the implementation, more possible failure points will be addressed. If only the information system was implemented other external factors could lead to its failure. It is also preferable to work within the public health sector to ensure the sustainability of the project by training local personnel and strengthening already existing infra-structure.

This work has shown that if a medical information system is implemented according to the principles described it may have a large impact on the care provided to patients. It has also shown that these systems can be evaluated in a resource-poor setting. This we hope will be a call to others that systems being implemented in settings of poverty must be validated and evaluated to ensure that the optimal care is being provided. Currently, most systems being implemented in the field have not been evaluated.

Finally, we believe that these are foundational studies for the emerging field of global health informatics. These initial randomized controlled trials show that these laboratory information systems are a worthwhile investement both in terms of the benefits they provide and the costs to implement. We hope that this work will inspire others to invest in this work in a communal and scientific way, as described here.

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Appendix A Palm Project User Survey

Encuesta de Usuarios del Proyecto Palm

Por favor, tome algunos minutos para completar la siguiente encuesta sobre su satisfacción con respecto al método de recolección de datos del Proyecto Palm.

Preguntas sobre el uso del sistema de papel

1. En promedio, ¿**Cuántos años** ha trabajado con el sistema de papel para recolectar datos bacteriológicos? _____

2. En general, ¿Qué tan **satisfecho/a** se encuentra usted usando el sistema de papel como método de recolección de datos? (**marque sólo una respuesta**):

❑ Muy satisfecho	❑ Algo satisfecho	❑ Ni satisfecho ni insatisfecho	❑ Algo insatisfecho	❑ Muy insatisfecho

3. En promedio, por cada dato ¿**Cuántos minutos** le toma en total desde recolectar un dato bacteriológico hasta ingresarlo al EMR?

   ❑ 0 - 2 minutos

   ❑ 2 – 4 minutos

   ❑ 6 – 8 minutos

   ❑ 8 minutos o más

4. **Por favor califique los siguientes enunciados referidos al sistema de papel:**	**Excelente**	**Muy bueno**	**Normal**	**Pobre**	**Muy Pobre**
A. Su aprendizaje en como usar el sistema de papel para recolectar datos bacteriológicos	❑	❑	❑	❑	❑
B. Facilidad para usar el sistema de papel solo para recolectar datos bacteriológicos	❑	❑	❑	❑	❑
C. Facilidad para usar el sistema de papel para todo el proceso de trabajar los datos bacteriológicos	❑	❑	❑	❑	❑
D. El entrenamiento recibido acerca de como usar el sistema papel para recolectar datos bacteriológicos	❑	❑	❑	❑	❑

5. ¿Cuál considera usted la **mayor ventaja** de usar el sistema de papel?

_____

_____

6. ¿Cuál considera usted la **mayor desventaja** de usar el sistema de papel?

_____

Preguntas sobre el uso del sistema Palm

Estas preguntas son sobre el sistema Palm **DESPUES de que comenzó el estudio** el 20 de Marzo, 2006. Por favor, responda estas preguntas teniendo solo ese periodo en mente.

1. En promedio, ¿**Cuántos años** de experiencia tiene usando el Internet? _____

2. En promedio, ¿**Cuántos años** ha trabajado con el PIH-EMR? _____

3. En general, ¿Cuán **satisfecho/a** se encuentra usted usando el sistema Palm como método de recolección de datos? (**marque sólo una respuesta**):

❑ Muy satisfecho	❑ Algo satisfecho	❑ Ni satisfecho ni insatisfecho	❑ Algo insatisfecho	❑ Muy insatisfecho

4. En promedio, por cada dato ¿**Cuántos minutos** le toma en total desde recolectar un dato bacteriológico hasta ingresarlo al EMR?

   ❑ 0 - 2 minutos

   ❑ 2 – 4 minutos

   ❑ 6 – 8 minutos

   ❑ 8 minutos o más

3. **Por favor califique los siguientes enunciados referentes al sistema Palm:**	**Excelente**	**Muy bueno**	**Bueno**	**Regular**	**Pobre**
A. Su aprendizaje en como usar el sistema Palm para recolectar datos bacteriológicos	❑	❑	❑	❑	❑
B. Facilidad de usar el computadora de mano palm solo para recolectar datos bacteriológicos	❑	❑	❑	❑	❑
C. Facilidad para usar todo el sistema palm para todo el proceso de trabajar los datos bacteriológicos	❑	❑	❑	❑	❑
D. El entrenamiento recibido acerca de como usar el sistema Palm para recolectar datos bacteriológicos	❑	❑	❑	❑	❑

4. **Por favor califique su satisfacción para los siguientes enunciados:**	**Muy satisfecho**	**Algo satisfecho**	**Ni satisfecho ni insatisfecho**	**Algo insatisfecho**	**Muy insatisfecho**
A. Beneficio de tener la lista de pacientes activos en la palm	❑	❑	❑	❑	❑
B. Asistencia técnica para resolver problemas por los coordinadores de estudio	❑	❑	❑	❑	❑

C. Uso del puntero y los botones de la palm para el ingreso de datos	❑	❑	❑	❑	❑
D. Ayuda de página de Tabla de Errores para procesar datos bacteriológicos	❑	❑	❑	❑	❑

5. ¿Cuál considera usted la **mayor ventaja** de usar el sistema Palm?

_____

_____

6. ¿Cuál considera usted la **mayor desventaja** de usar el sistema Palm?

_____

_____

7. ¿Cómo cree que el uso de la Palm fue percibido por el personal de salud con quien usted interactúa?

❑ **Muy Positivo**	❑ **Positivo**	❑ **Normal**	❑ **Negativo**	❑ **Muy Negativo**

8. ¿Cómo cambio su relación con el personal de salud por el uso de la Palm?

_____

_____

9. En promedio, ¿**Cuántas veces** al mes tuvo problemas con la Palm?
   - ❑ 0 veces
   - ❑ 1-2 veces
   - ❑ 3-4 veces
   - ❑ 5-6 veces
   - ❑ 7 veces o más

10. En promedio, ¿**De que severidad** eran estos problemas que tuvo con la Palm?
    - ❑ Lo podía arreglar en ese instante y continuar mi trabajo
    - ❑ Tenía que continuar en papel ese día y lo podía arreglar en la oficina solo/a o con el equipo de BK
    - ❑ Tenía que continuar en papel ese día y lo podía arreglar en la oficina con ayuda técnica
    - ❑ No lo podía arreglar

11. ¿Tiene alguna sugerencia de cómo mejorar el sistema Palm?

_____

12. ¿Cuál de los dos métodos prefiere usted prefiere? (Elija sólo una alternativa):

- ❑ Prefiero recolectar datos con el sistema Palm
- ❑ Prefiero recolectar datos con el sistema de papel
- ❑ No tengo preferencia por uno u otro método.

Comentarios adicionales: Por favor utilice este espacio y la siguiente hoja de ser necesaria para comentarios adicionales que usted desee hacer con respecto al método y/o al proceso de colección de datos o sobre la presente encuesta. Su opinión es muy valiosa.

(Por favor use la siguiente hoja de ser necesario)
GRACIAS POR COMPLETAR LA PRESENTE ENCUESTA!!!

Appendix B e-Chasqui and Control User Survey

B.1 e-Chasqui User Survey

Encuesta de Usuarios

Por favor, tome algunos minutos para completar la siguiente encuesta sobre su satisfacción con el sistema e-Chasqui.

Información Demográfica

4. Sexo:
   - ❑ Femenino
   - ❑ Masculino

5. Indique su cargo:
   - ❑ Administrador
   - ❑ Doctor
   - ❑ Enfermera
   - ❑ Técnica/Auxiliar de Enfermería
   - ❑ Laboratorista
   - ❑ Otro (por favor especificar):

   _____

6. ¿En cual DISA trabaja? _____

7. En promedio, ¿**Cuántos años** tiene usando el Internet? (Si no usa el Internet, ponga 0)

   _____

8. ¿Donde **usa el Internet** usted actualmente? (Elija todas las alternativas que sean correctas)
   - ❑ Programa de PCT/Laboratorio
   - ❑ Otra oficina de un Establecimiento de Salud
   - ❑ Mi casa
   - ❑ Cabina de Internet
   - ❑ Oficina
   - ❑ Otro (por favor especificar):

   _____

Preguntas sobre el sistema e-Chasqui

9. En promedio, ¿**Cuántas veces** ingresa usted al e-Chasqui?
   - ❑ Varias veces al día
   - ❑ Una vez al día
   - ❑ Una vez a la semana
   - ❑ Una vez al mes
   - ❑ Casi nunca

10. En general, ¿Cuán **satisfecho/a** se encuentra usted usando el sistema e-Chasqui para comunicar los resultados de pruebas de TBC? (**marque sólo una respuesta**):

❑ Muy satisfecho	❑ Algo satisfecho	❑ Ni satisfecho ni insatisfecho	❑ Algo insatisfecho	❑ Muy insatisfecho

11. ¿Usted usa el e-Chasqui durante la visita de un paciente? (Elija sólo una alternativa)

❑ Más de la mitad de mis pacientes ❑ Menos que la mitad

❑ Menos de un cuarto ❑ Muy pocos

❑ Ninguno

12. Si respondió afirmativo a la previa pregunta, ¿Qué cantidad de pacientes han expresado que encuentran el e-Chasqui beneficioso?

❑ 1 de cada 2 pacientes ❑ 1 de cada 4 pacientes

❑ 1 de cada 10 pacientes ❑ 1 de cada 50 pacientes

❑ 1 de cada 100 pacientes ❑ Ninguno

13. ¿Pudo encontrar información en el e-Chasqui que no hubiera tenido sin el sistema?

❑ Sí ❑ No

14. ¿En que forma influyo esta información en sus decisiones para el paciente?

_____

_____

15. **Por favor califique el beneficio de los siguientes enunciados:**	**Mucho beneficio**	**Algún beneficio**	**Ni mucho ni poco beneficio**	**Poco beneficio**	**Ningún beneficio**
A. Recibir un correo electrónico diario con mis resultados recientes	❑	❑	❑	❑	❑
B. Poder ver la lista de pruebas pendientes	❑	❑	❑	❑	❑
C. Poder ver resultados de mis pacientes en otros establecimientos	❑	❑	❑	❑	❑
D. Tener acceso al sistema fácilmente y en cualquier lugar	❑	❑	❑	❑	❑

16. ¿Cuál considera usted la **mayor ventaja** de usar el e-Chasqui?

_____

_____

17. ¿Cuál considera usted la **mayor desventaja** de usar el e-Chasqui?

_____

Preguntas sobre el sistema de papel

18. En el sistema actual de papel, ¿Con que frecuencia usted no encuentra un resultado de cultivo o prueba de sensibilidad que existe?

❑ 1 de cada 2 pacientes ❑ 1 de cada 4 pacientes

❑ 1 de cada 10 pacientes ❑ 1 de cada 50 pacientes

❑ 1 de cada 100 pacientes ❑ Nunca

19. En referencia a la previa pregunta, ¿Usted cree que esto disminuye la oportunidad del tratamiento dado al paciente?

❑ Sí ❑ No

20. Si respondió Sí, ¿Cómo cree que esto disminuye la oportunidad?

21. En general, ¿Qué tan **satisfecho/a** se encuentra usted usando el sistema de papel para comunicar los resultados de pruebas de TBC? (**marque sólo una respuesta**):

❑ Muy satisfecho	❑ Algo satisfecho	❑ Ni satisfecho ni insatisfecho	❑ Algo insatisfecho	❑ Muy insatisfecho

Comparación del e-Chasqui con el sistema de papel

22. ¿En cual sistema cree que la información estaría **más completa (las solicitudes están llenadas mejor)**? (Elija sólo una alternativa):
    - ❑ El sistema e-Chasqui
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

23. ¿En cual sistema cree que la información sería **más confidencial (accesible solo al personal adecuado)**? (Elija sólo una alternativa):
    - ❑ El sistema e-Chasqui
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

24. ¿En cual sistema cree usted que la información estaría **más segura (no se perderá)**?:
    - ❑ El sistema e-Chasqui
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

25. ¿Cuál de los dos sistemas **prefiere usted** para ver sus resultados? (Elija sólo una alternativa):
    - ❑ El sistema e-Chasqui
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

Expansión del e-Chasqui

26. ¿Lo ve adecuado expandir el sistema a otras Direcciones de Salud?

    ❑ Sí ❑ No

27. ¿Cómo cree usted que usando el e-Chasqui en otras Direcciones de Salud impactaría **la calidad del tratamiento** al paciente?

❑ Mejoraría mucho	*❑ Mejoría un poco*	*❑ No mejoraría ni empeoraria*	*❑ Empeoraría un poco*	*❑ Empeoraría mucho*

B.2 Control User Survey

Encuesta de personal de TBC

Por favor, tome algunos minutos para completar la siguiente encuesta sobre su satisfacción con el método actual de comunicar los resultados de pruebas de TBC y la posibilidad de usar un sistema electrónico basado en el Internet.

Información Demográfica

1. Sexo:
   ❑ Femenino ❑ Masculino

2. Indique su cargo:
   ❑ Administrador ❑ Doctor
   ❑ Enfermera ❑ Técnica/Auxiliar de Enfermería
   ❑ Laboratorista ❑ Otro (por favor especificar):
   _____

3. ¿En cual DISA trabaja? _____

4. En promedio, ¿**Cuántos años** tiene usando el Internet? (Si no usa el Internet, ponga 0)
   _____

5. ¿Donde **usa el Internet** usted actualmente? (Elija todas las alternativas que sean correctas)
   ❑ Programa de PCT/Laboratorio ❑ Otra oficina de un Establecimiento de Salud
   ❑ Mi casa ❑ Cabina de Internet
   ❑ Oficina ❑ Otro (por favor especificar):
   _____

Comunicación de de resultados bacteriológicos

6. En el sistema actual de papel, ¿Con que frecuencia a usted le falta un resultado de cultivo o prueba de sensibilidad que existe para un paciente? (**marque sólo una respuesta**)
   ❑ 1 de cada 2 pacientes ❑ 1 de cada 4 pacientes
   ❑ 1 de cada 10 pacientes ❑ 1 de cada 50 pacientes
   ❑ 1 de cada 100 pacientes ❑ Nunca

7. En referencia a la previa pregunta, ¿Usted cree que esto disminuye la oportunidad del tratamiento dado al paciente?
   ❑ Sí ❑ No

8. Si respondió Sí, ¿Cómo cree que esto disminuye la oportunidad?

9. En general, ¿Qué tan **satisfecho/a** se encuentra usted usando el sistema de papel para comunicar los resultados de pruebas de TBC? (**marque sólo una respuesta**):

❑ Muy satisfecho	❑ Algo satisfecho	❑ Ni satisfecho ni insatisfecho	❑ Algo insatisfecho	❑ Muy insatisfecho

10. ¿En cual sistema cree que la información estaría **más completa**? (Elija sólo una alternativa):
    - ❑ Un sistema electrónico basado en el Internet
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

11. ¿En cual sistema cree que la información sería **más confidencial (accesible solo al personal adecuado)**? (Elija sólo una alternativa):
    - ❑ Un sistema electrónico basado en el Internet
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

12. ¿En cual sistema cree usted que la información estaría **más segura (no se perderá)**?:
    - ❑ Un sistema electrónico basado en el Internet
    - ❑ El sistema actual de papel
    - ❑ Los dos sistemas son iguales

Uso de Sistemas Electrónicos a Nivel Nacional

13. ¿Cree usted que se puede **mejorar la calidad del tratamiento** al paciente usando un sistema basado en el Internet para comunicación de pruebas de TBC a nivel nacional?
    ❑ Sí ❑ No

14. ¿Cree usted que es **factible/posible implementar** tal sistema a nivel nacional?
    ❑ Sí ❑ No

Comentarios adicionales: Por favor utilice este espacio y la siguiente hoja de ser necesaria para comentarios adicionales que usted desee hacer con respecto al método y/o al proceso de comunicación de resultados o sobre la presente encuesta. Su opinión es muy valiosa.

(Por favor use la siguiente hoja de ser necesario)
¡GRACIAS POR COMPLETAR LA PRESENTE ENCUESTA!