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Quantitative Assessment of the Benefits of Specific Information Technologies Applied to Clinical Studies in Developing Countries

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Abstract. Clinical studies and trials require accessibility of large amounts of high-quality information in a timely manner, often daily. The integrated application of information technologies can greatly improve quality control as well as facilitate compliance with established standards such as Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). We have customized and implemented a number of information technologies, such as personal data assistants (PDAs), geographic information system (GIS), and barcode and fingerprint scanning, to streamline a pediatric dengue cohort study in Managua, Nicaragua. Quantitative data was obtained to assess the actual contribution of each technology in relation to processing time, accuracy, real-time access to data, savings in consumable materials, and time to proficiency in training sessions. In addition to specific advantages, these information technologies benefited not only the study itself but numerous routine clinical and laboratory processes in the health center and laboratories of the Nicaraguan Ministry of Health.

INTRODUCTION

Dengue is the most important mosquito-borne viral disease affecting humans. Tens of millions of cases of dengue fever (DF) and 250,000 to 500,000 cases of dengue hemorrhagic fever/dengue shock syndrome (DHF/DSS) occur annually worldwide.[1] Dengue continues to be a major health and economic burden in Nicaragua, which is considered one of the Western hemisphere's poorest countries. Therefore, the availability of a safe dengue vaccine would greatly benefit Nicaragua's population. In 2004, a Pediatric Dengue Cohort Study (PDCS) was established in the capital city of Managua to characterize the natural history of dengue transmission, to collect biologic specimens for vaccine safety research, and to establish appropriate infrastructure and methodology in anticipation of a potential dengue vaccine trial. This was achieved through the collaboration of the Nicaraguan Ministry of Health, the Sustainable Sciences Institute, and the University of California at Berkeley. Currently in its third year, the PDCS follows a cohort of 3,800 children aged 2–11 years old at high risk for dengue in Managua's densely populated, low- to mid-socioeconomic status District II.

Over the past 3 years, the PDCS has successfully implemented low-cost, modern information technologies. These technologies include Geographic Information Systems (GIS) to map and easily locate study participants' homes, barcode scanner-enabled Personal Data Assistants (PDAs) for paperless data entry and control of specimen temperature and transport time, barcodes for tracking participant information and specimens, fingerprint scanning for streamlining patient identification, low-cost communication systems, electronic document back-up, and interdigitating databases for information access and control.[2] The use of these technologies greatly streamlines information flow and accessibility, improves the quality of data as well as quality control procedures, and reduces operational costs. To quantify the specific contribution of the technologies in daily PDCS operations, we conducted several studies as described below.

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MATERIALS AND METHODS

All hardware used in this study is available from various on-line vendors, and either software can be downloaded free-of-charge upon purchase of hardware or software licenses can be purchased and downloaded from the Internet. The PDAs used were the SPT1550 model with integrated barcode scanner and accompanying recharge cradle (Symbol, Oakland, CA) or the Palm Tungsten model (Palm, Sunnyvale, CA) with Plug-N-Scan Barcode Kit (Portable Technology Solutions, Calverton, NY), and NiMH and AAA rechargeable batteries and chargers. PDA software consisted of Palm OS 4.1 or higher (Palm), HanDBase Professional Edition PDA database manager (DDH Software, Wellington, FL), Pendragon Forms 5.0 (Pendragon Software Corporation, Libertyville, IL), and handheld user licenses. The fingerprint scanner selected was the U.are.U 4000 (Digital Personna, Redwood City, CA) with VeriFinger 4.2 SDK standard software (Neurotechnologija, Vilnius, Lithuania) with associated software licenses. Barcode materials consisted of Print Studio Professional 2.0 software (Jolly Technologies, San Carlos, CA), MS9520 Voyager handheld scanners (Metrologic, West Deptford, NJ), Opticon LG2 2D applications hardware (Opticon USA, Bellevue, WA), TLP 2844 thermal transfer printer and TR 220 portable printer adaptor, 5095 universal resin ribbons, Polypro 1000 labels, and Cryocool 3000 labels (Zebra, Vernon Hills, IL). The GIS devices used were Garmin GPS 60 and Garmin e-Trex (Garmin, Olathe, KS) with mapping software Mapsource (Garmin) and Arc View (ESRI, Redlands, CA). All devices ranged in price from approximately US$100–500.[2]

RESULTS

Fingerprint scanning. When a study patient presents to the Health Center Socrates Flores Vivas (HCSFV) that serves as the base for the PDCS without his/her ID card, a fingerprint scan is performed to identify the child's study code needed to locate his/her medical records. To compare the efficiency of using fingerprint scanning instead of the traditional card catalog inventory system, the medical charts of 54 patients were located using either the traditional method with cards based on last name and date of birth ($N = 27$) or the new method based on fingerprint scans ($N = 27$). The time elapsed in locating the pertinent medical chart was monitored by stopwatch. Fingerprint scans allowed for more efficient location of records, with a mean time to complete the task of 7.0 (SD 3.5) seconds, versus 27.3 (SD 7.1) seconds using the traditional method (Figure 1). When fingerprint or barcode scans are implemented in everyday use, these time savings represent considerable cost savings and improved efficiency.

Barcode scanning. On occasion, patients present to the admissions office and their medical chart is not found because it is in another locale in the Health Center (e.g., data entry, clinical laboratory, consult, etc.). Barcode-based patient ID cards were implemented to retrieve medical records from various locations in the Health Center, replacing the traditional registry book system. To compare the efficiency of the barcode-based system for medical chart retrieval with the traditional system, 33 non-study patient chart numbers were located via the traditional registry system based on patients' date of birth and initials, while 33 study participant chart numbers were identified using barcodes on ID cards. The time elapsed during search and localization of each medical chart was recorded with a stopwatch. The average time it took to locate a patient's chart using traditional methods was 2.9 (SD 2.1) minutes, whereas using barcode-based methods the average was 0.09 minutes, or 5.5 (SD 1.2) seconds (Figure 2). This illustrates how the use of barcode-based applications facilitates medical chart and patient flow in the clinic.

Geographic Information Systems. The use of GIS has facilitated numerous strategies involving home visits. Maps have been produced with the geographic location of the vast majority (> 95%) of cohort participants, useful in a city with unplanned urbanization and lack of street addresses or house numbers. GPS devices are used to facilitate localization of subject homes during collection of convalescent samples from children suspected of dengue, during the annual sample collection, and during home visit surveys, as well as to track the progress of teams during large field operations (Figure 3A). The latter is particularly important because real-time knowledge of the geographical coverage of field visits allows efficient planning of the next day's visits and recapture strategy. In addition, accurate maps permit efficient selection of houses, thus streamlining logistics and planning even in the absence of addresses. Finally, the ability to visualize patient location coordinately with health status allows spatiotemporal analysis of dengue cases (Figure 3B).

When the time it took study personnel using a GPS device versus study personnel using the address alone to locate the same 51 study participants houses in five neighborhoods was measured using a stopwatch, results indicated that the use of GIS did not significantly decrease the time necessary to locate a home (data not shown). However, GPS is useful in the following situations: (i) to locate the reference point from which directions are given in a particular neighborhood (e.g., "where the movie theater was" [before the earthquake in 1972]); (ii) to locate houses one-at-a-time during convalescent visits to suspected dengue cases, as opposed to locating a large number of homes in the same area during the annual sample collection; and (iii) when the terrain is such that knowledge of vertical direction is useful (e.g., following the road that goes up or the one that goes down) because GPS provides orientation in the XY plane. This information has allowed the study to make appropriate use of information technologies in the field and apply them when most beneficial for study personnel.

Personal Data Assistants. The efficiency and accuracy of manual data collection were compared with that of PDA data collection methods in surveys conducted both in the field and in the Health Center. The survey interviews were tape-recorded to obtain a record against which any discrepancies could be checked. IRB approval was obtained for this study from the University of California, Berkeley, and the Centro Nacional Diagnóstico y Referencia (Nicaraguan Ministry of Health), and only participants who provided informed consent were included. In the Health Center, during the annual sample collection in July of 2005, one group of nurses obtained participant information using manual paper-based col-

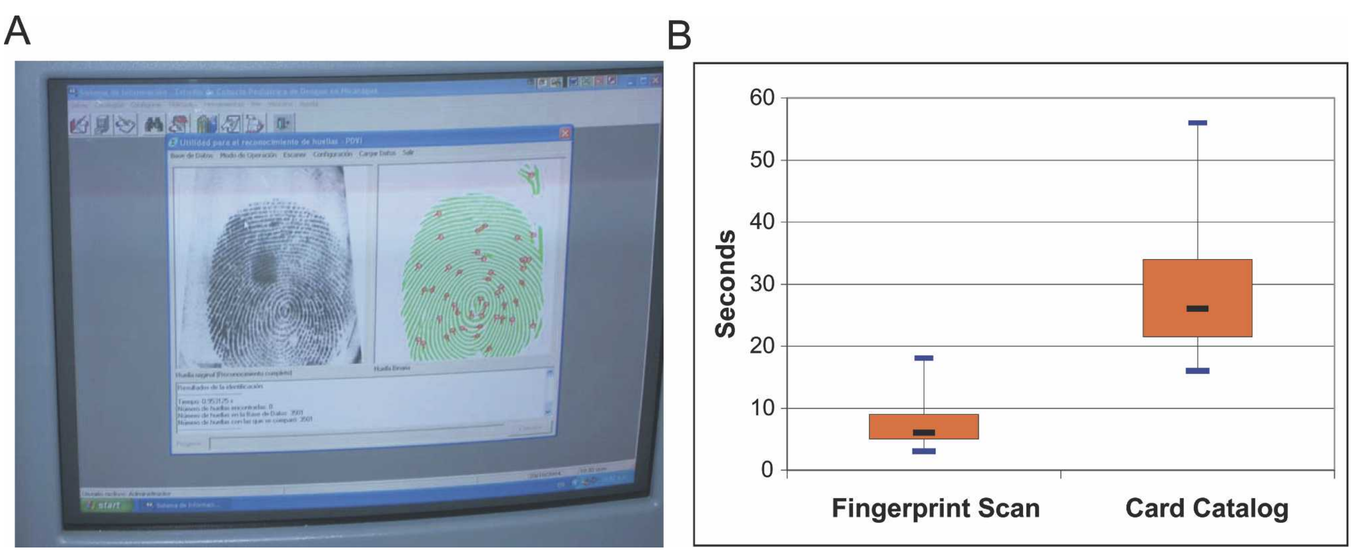

FIGURE 1. Fingerprint scan for rapid retrieval of medical charts. **A**, Fingerprint scan at admission matched to computerized scan linked to chart number. **B**, Time elapsed during search for medical charts in the Admissions Office using fingerprint scan to identify chart number ($N = 27$) vs. traditional card catalog system ($N = 27$) to find chart. -, median; box, Q1–Q3; horizontal bars, minimum and maximum values. This figure appears in color at www.ajtmh.org.

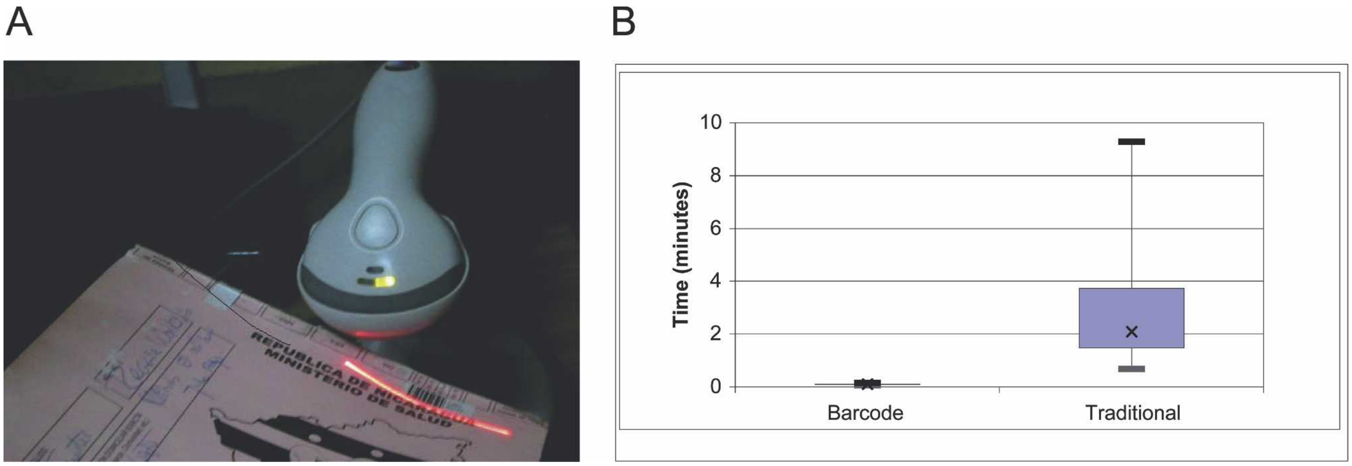

FIGURE 2. Use of barcodes to locate medical charts in the Health Center. **A**, Scanning barcode of medical chart. **B**, Time elapsed in search for location of medical charts using barcodes (N = 33) vs. traditional methods (N = 33). X, median; box, Q1–Q3; horizontal bars, minimum and maximum values. This figure appears in color at www.ajtmh.org.

lection methods, while a second group of nurses recorded the information during the same 558 interviews using PDAs. For field assessment, teams of study nurses conducted 1,543 home visit surveys. In each team, one nurse recorded all information on paper, while the other nurse collected data directly into a handheld PDA. In both studies, data collected via PDA was automatically uploaded into databases, while data entry personnel performed double data entry of paper-collected information into the databases. EpiInfo was used to generate a comparison report to check for errors between the data entered via double entry, as well as to identify discrepancies between answers recorded by the two distinct methods. When discrepancies were detected, the recorded patient interview was consulted to determine the correct answer and quantify errors.

Different data types (e.g., numerical, categorical, and open variables) were analyzed separately. The results of the two comparison tests of the use of PDAs versus traditional pen-and-paper methods for questionnaire completion demonstrated that the two systems were essentially equivalent in accuracy (Figure 4). In some instances the difference was statistically significant in favor of the paper method, likely due to the large sample size and low error rate using both methods. In the 558 patient interviews that were conducted within the Health Center, the overall accuracy rate for PDA data collection was 97.1% whereas that of pen-and-paper methods was 97.6%. For the 1,543 field visits, PDA data collection yielded an overall accuracy rate of 98.9%, and pen-and-paper methods resulted in a 99.3% accuracy rate. However, the use of PDAs offers a number of advantages, such as substantial savings in time, personnel, and paper; additional database backup; and real-time access to information. Importantly, training of computer-illiterate personnel in the use of PDAs was accomplished rapidly. For example, over the

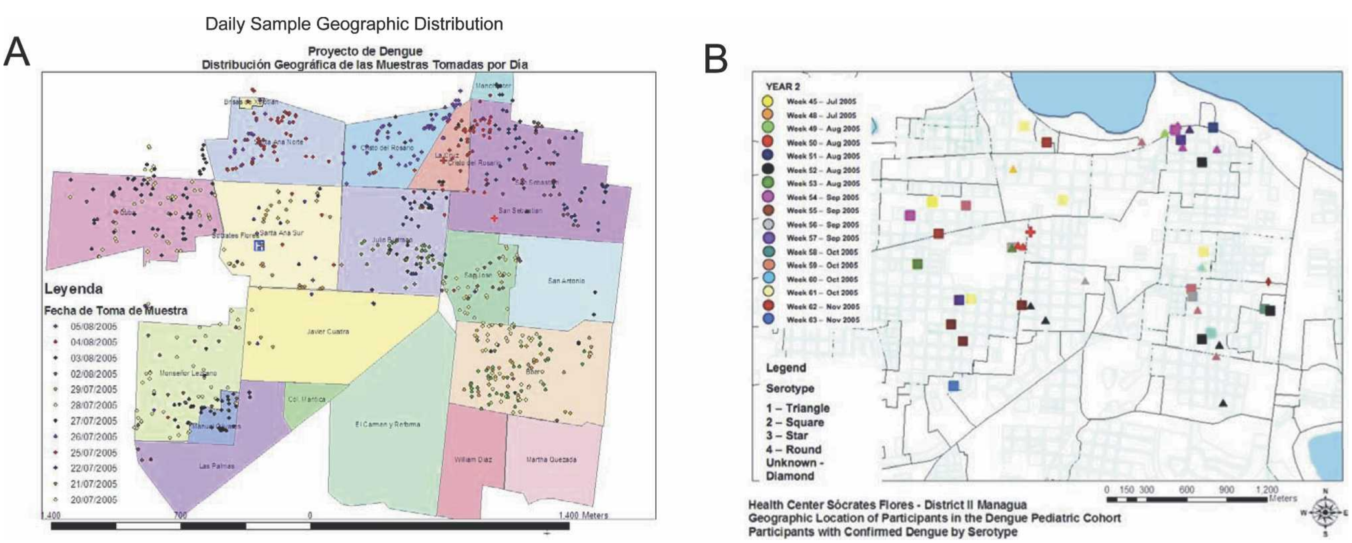

FIGURE 3. Use of Geographic Information System. **A**, Tracking home visits using GIS during annual sample collection. Each dot represents a study household visited by field nurse teams, and successive days are coded using different colors. **B**, Spatio-temporal analysis of dengue cases. Triangle, dengue virus type 1; square, dengue virus type 2. Different colors represent successive weeks during the 2005–2006 dengue season. This figure appears in color at www.ajtmh.org.

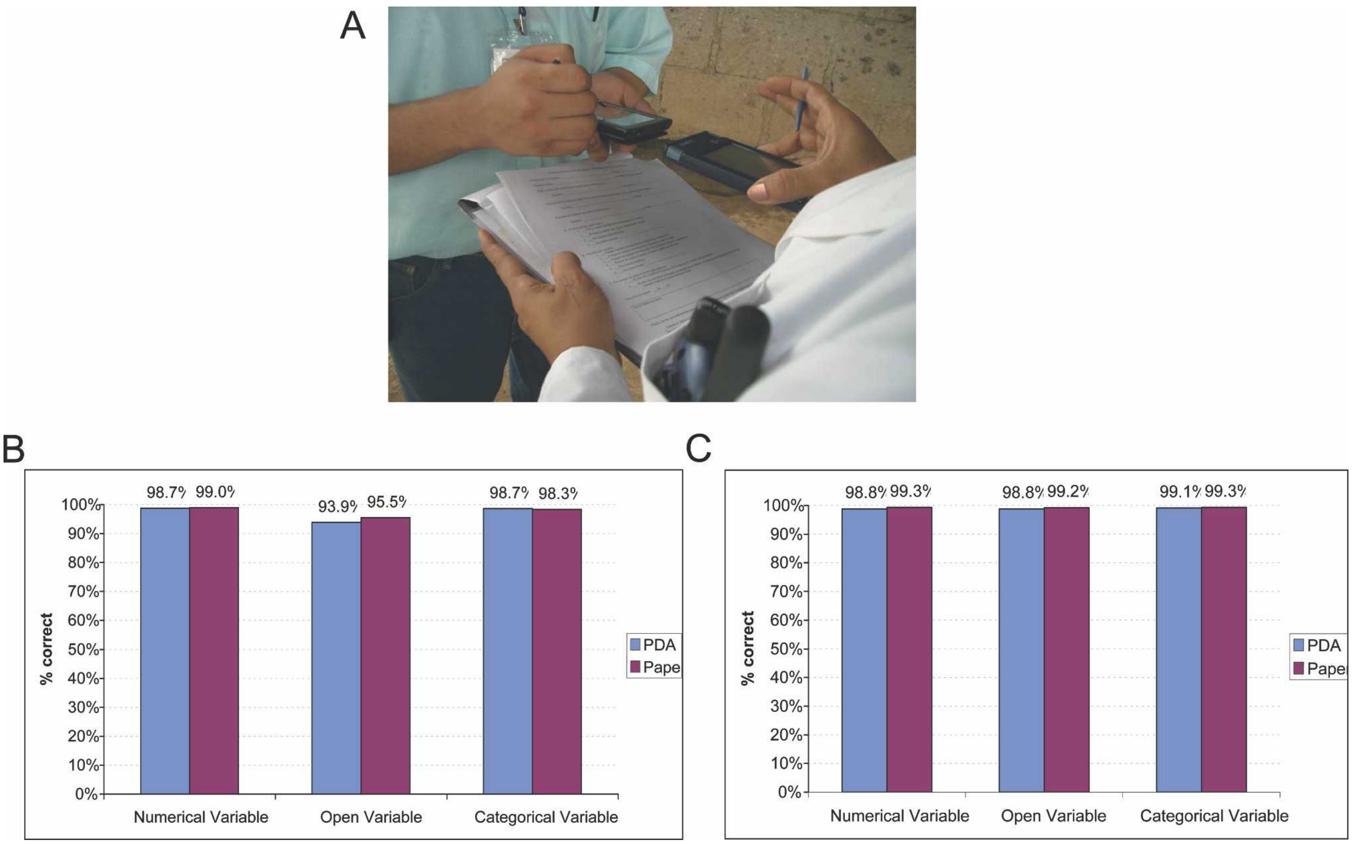

FIGURE 4. Use of PDAs. **A**, Beaming information from house visit questionnaires collected on PDAs to the supervisor's PDA. **B**, Comparison of the accuracy of PDA or pen-and-paper methods for different types of variables collected by questionnaires during 558 annual interviews at the Health Center. **C**, Same as B, except information was collected using 1,543 home visit questionnaires. This figure appears in color at www.ajtmh.org.

course of three 1-hour training sessions, nurses (who had no previous experience in the use of PDAs or in many cases even computers) improved in accuracy of data entry via PDA from an average of 77% to 97%.

DISCUSSION

We quantitatively evaluated several information technologies used to streamline a pediatric dengue cohort study in Managua, Nicaragua, to determine the specific advantage(s) provided by each. Barcode and fingerprint scanning enable more rapid localization of medical charts than traditional methods, decreasing the time necessary by 4- to 32-fold. GIS is helpful in locating participants' houses, greatly facilitates control and planning of field operations, and allows spatiotemporal analysis of dengue cases. When PDAs were compared with pen-and-paper data collection methods, no increase in accuracy was observed; however, PDAs provide major advantages such as real-time access to data, increased data backup, reduced use of paper products, elimination of the need for manual double data entry, and direct coupling with internal barcode scanners. When applied on a larger scale, these benefits translate to significant savings in time, personnel, materials, and increased productivity and quality control.

For example, GCP and patient care have benefited from PDAs that streamline documentation of clinical histories and consults and barcodes that allow tracking of medical files, consent documents, and patient flow through the Health Center. As a result, patients now enjoy better quality of treatment and less wait time. Fingerprint scans and ID cards with barcodes have facilitated identification of study children and location of medical charts. The application of GIS has been useful for informed logistical planning, directing field visit strategies, tracking of dengue cases in time and space, and location of study children's homes. Sample reception and handling at all levels has been greatly improved through the use of PDAs with embedded barcode scanners to control specimen temperature, quality, and transport and processing time, as well as to monitor equipment temperature (e.g., freezers, refrigerators, thermoses, and incubators). Real-time analysis of data is now possible on all levels, which contributes to improved quality control, data reliability, logistics, planning, and report generation. As an example of the combined benefits, the integration of the various technologies in the PDCS annual blood sample collection resulted in reduction in personnel from 23 employees to 12, a decrease from a 15-hour to an 8-hour workday, fewer data entry personnel (1 instead of 5); stricter control of supplies; and daily data analysis with graphical and geographic output, which allows for better planning and improved quality control. Importantly, the introduction and implementation of these information technologies have led not only to great improvements in quality control of information and biologic specimens, but to training and capacity building of local personnel.

Recently, the use of PDAs for data collection and wireless access to information has become more common for field and clinical work of health-related projects in the developing world[3,4] (www.Bridges.org). GIS use is also widespread and is emerging as a powerful tool in health applications; for instance, Dwolatzky and others[5] found that use of GPS devices reduced the time taken to locate households in a tuberculosis control study in South Africa. Although ID technologies such as fingerprint scans are not as prevalent yet, barcodes have been successfully integrated in a number of health applications in resource-limited settings.[6] Although information technologies are reported to facilitate diverse activities in the health arena, little data is available that quantitatively addresses their actual contribution.[7] Our analysis provides evidence-based information on the specific added value of integrating information technologies in health applications in the developing world that we hope will be helpful to investigators planning clinical studies and trials.

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