The Development and Use of an Automated Laboratory Information Management System (ALIMS) to Reduce Processing Time in a Microbiology Laboratory

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DOI: 10.1309/GRLPEY3EM3MUK5V1

Abstract

Background: The objective was to describe the development and use of an Automated Laboratory Information Management System (ALIMS) designed to reduce time from sample collection to results reporting for a large HIV Prevention trial in Peru.

Methods: Three HIV STD prevalence studies were performed in 3 Peruvian cities. In study 1, samples were received by the laboratory and manually entered into a database. For the other 2 studies, the ALIMS was implemented, using barcode labeling.

Results: In study 1, 3,258 samples were collected with an average of 39.1 days (range: 3.9 - 126.0) from collection to results reporting. After ALIMS implementation, average processing time was 23.1 days (range: 22.7 - 36.5) for study 2 (2,746 samples) and 12.4 days (range: 10.5 - 19.2) for study 3 (6,593 samples).

Conclusions: The ALIMS substantially reduced the time from sample collection to results reporting. Automated systems such as ALIMS could help laboratory data management for large studies and provide rapid results.

The automation of laboratory systems is of increasing importance and is critical in research settings because the laboratory not only needs to produce accurate results but must do so in a timely fashion since there are often clinical implications for the research subjects. Automation of laboratory systems helps assure that the correct results reach the corresponding participant. This is important for any biological result; however, with incurable diseases with sensitive reporting issues like HIV, this is of particular importance. For large-scale laboratories or clinical trials, automated laboratory systems help reduce total processing time and increase quality control, thereby freeing laboratory staff to dedicate its time to more laboratory related and fewer clerical activities.1-3

In this paper, we describe the implementation of an automated laboratory system in the Peru Site of the NIMH Collaborative STD and HIV Prevention Trial funded by the United States National Institute of Mental Health. This is a randomized community level trial that is being conducted in 5 countries: China, Peru, India, Russia, and Zimbabwe. This is the first international trial using Community Public Opinion Leaders as agents of change to evaluate HIV/STD prevention at a community level.

We initially determined the need to code samples at the time of their collection to avoid human errors. Later, we applied this improvement to the laboratory testing, quality control, and results reporting.1,4 During the pre-baseline 1 study, we had a prolonged time from sample collection until results reporting to the participants because all processing was performed manually. However, for the subsequent trial studies, we developed a custom software solution, "ALIMS," which worked with human, technical, and logistic support to automate the laboratory systems.

Methods

The Microbiology Laboratory at the Naval Medical Research Center Detachment (NMRCD), based in Peru, processed and tested samples from the NIMH Collaborative HIV/STD Prevention Trial's Peru site. The study was conducted by Cayetano Heredia University and the Universities of California at San Francisco and Los Angeles and included 2 pre-baseline studies, and a baseline study.

During the 3 studies, 14,094 samples were collected (Table 1). The laboratory work was divided into 4 processes4,5: (1) sample reception and registration; (2) sample aliquoting and initial processings; (3) testing; and (4) printing results for each study participant.

Three studies were performed (pre-baseline 1, pre-baseline 2, and baseline) to determine the prevalence of HIV-1 and STDs (Herpes simplex 2, Chlamydia trachomatis, Neisseria gonorrhoeae, and Treponema pallidum in 3 Peruvian cities. In the pre-baseline 1, the samples were received at NMRCD and manually entered into a database (Figure 1). For the subsequent studies,
The ALIMS was implemented with the following procedures: (1) urine, vaginal swabs, and blood samples were codified by barcode labels at collection; (2) samples received at NMRCDD were entered into the ALIMS using a digital barcode reader; (3) ALIMS created a worksheet for each test to be performed; (4) results from the automated tests, EIAs, and PCR were sent electronically to the ALIMS, which verified the validity of the tests using the manufacturers’ criteria and also identified those samples that needed repeat or confirmation testing; and (5) the ALIMS generated a complete table of results using the initial barcode entry for each participant (Figure 2).

For the implementation of this automated system, 3 desktop computers were installed in the laboratory and networked with a main computer outside the laboratory. The ALIMS was installed on all 4 computers and each computer had a barcode reader connected. The desktop computer at the sample reception unit had a barcode label printer, which generated the barcode labels to identify each of the samples and their corresponding aliquots.

The ALIMS system was connected to Freezerworks 5 (Dateworks Development), a program built in Microsoft Access and structured according to the needs of the laboratory users to assure accessibility, security, ease of use, and to provide an intuitive interface. This system permits data importation from the Freezerworks sample database. Once imported into the ALIMS, worksheets are generated for each test according to sample type. For this study, we used worksheets for the HIV-1 and HSV-2 immunoassays, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/NG) PCR, and the detection of antibodies for syphilis. Once the worksheets were generated, testing was performed using the corresponding manufacturer-recommended technique (HSV-2, Focus Technologies; HIV-1, Biomerieux and BioRad; PCR CT/NG, Roche Diagnostics). For tests using microplate readers (Molecular Devices with Soft-max software), HIV-1 EIA, HSV-2 EIA and CT/NG PCR, the machines were connected directly to the ALIMS computers. Thus, once the test was completed, all of the optical densities from the readers

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**Table 1. Number and Type of Samples Collected and Processed in the Different Parts of the Study**

<table>
<thead>
<tr>
<th></th>
<th>Pre-baseline 1 (April - August 2001)</th>
<th>Pre-baseline 2 (September – October 2002)</th>
<th>Baseline (January – March 2003)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood samples</td>
<td>1,629</td>
<td>1,373</td>
<td>3,291</td>
<td>7,434</td>
</tr>
<tr>
<td>Urine samples</td>
<td>668</td>
<td>1,251</td>
<td>2,964</td>
<td>5,996</td>
</tr>
<tr>
<td>Vaginal swabs samples</td>
<td>981</td>
<td>122</td>
<td>320</td>
<td>1,474</td>
</tr>
<tr>
<td>Total</td>
<td>3,328</td>
<td>2,746</td>
<td>6,595</td>
<td>14,904</td>
</tr>
</tbody>
</table>

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**Figure 1.** General flowchart for the processing of samples processing prior to the implementation and utilization of the ALIMS. The manual processes include the entering of identification codes for the samples, and the entering of the aliquots to the Freezerworks system for sample storage.
were automatically transferred into the ALIMS, which then assigned results to each of the samples. Discordant results or results in the previously established grey zone were automatically assigned a new worksheet repetition according to the study protocol. As the Syphilis RPR test (RPRnosticon, Bio- merieux) was manually performed, these results were entered manually. Positive results were then titrated and entered to a new worksheet for the TPPA (Treponema pallidum particle agglutination) confirmatory test (Fujirebio); results from TPPA were also entered manually into the ALIMS. For positive HIV test results, once the ELISA was repeated, the system automatically assigned a new worksheet for the confirmatory Western Blot test as per study protocol. The data from the Western Blot tests were also entered manually into the ALIMS, as this is a manually performed test.

The creation of the ALIMS' automated interface necessitated the implementation of a new system for registering samples using barcodes, and integration with the Freezerworks system for aliquot storage. All laboratory activities, including sample registration, worksheet generation, and results reporting, were interconnected.

The study was approved by the Committee of Human Research of the University of California, San Francisco; University of California, Los Angeles; Cayetano Heredia University, Peru, and the Naval Medical Research Center Institutional Review Board, in compliance with all federal regulations regarding the protection of human subjects. The barcodes used in the ALIMS corresponded to the participant's 10-digit study ID, allowing anonymity and confidentiality in the laboratory process.

Results

The laboratory processing time diminished substantially when the ALIMS was implemented (Table 2) from 39.1 days in the pre-baseline 1 to 23.1 days in the pre-baseline 2 to 12.4 days in the baseline study. The automated processes included sample collection (Figure 1), sample registration, sample storage, worksheet generation (including repetition and confirmation worksheets), and results reporting (Figure 2).

The overall integration of all of the systems within the laboratory allowed the ALIMS to automatically determine the cutoff value and quality control validation data each time a test was performed. The automation of these procedures diminished the possibility of clerical errors and allowed more time for results validation and quality control.

Discussion

The ALIMS substantially reduced the overall processing time for samples from collection to results reporting. The incorporation of the barcode system for samples identification was the

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Figure 2. General flowchart for sample processing after the implementation and utilization of the ALIMS. The processes that remained manual are in blue. The processes in yellow were automated; these include sample entering, sample storage using the Freezerworks, the generation of worksheets and transference of data and results reporting.
Table 2. Comparative Table of the Time of Processing of Samples in the Different Parts of the Study

<table>
<thead>
<tr>
<th>Study*</th>
<th>Mean time for processing samples (days)</th>
<th>Range (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-baseline 1</td>
<td>39.1</td>
<td>3.9 – 126.0</td>
</tr>
<tr>
<td>Pre-baseline 2</td>
<td>23.1</td>
<td>22.7 – 36.5</td>
</tr>
<tr>
<td>Baseline</td>
<td>12.4</td>
<td>10.5 – 19.2</td>
</tr>
</tbody>
</table>

* Each part of the study had different sample sizes:
  Pre-baseline 1 = 1,767, Pre-baseline 2 = 1,367, Baseline = 3,304

initial point of the automation; this system permitted the movement of the samples through the laboratory avoiding errors in identification and location. Automated mechanisms for sample identification are critical in research studies that involve fieldwork and collection and processing of biological samples due to the large amount of information that is generated and that must correspond to the true data. Additionally, in studies that include HIV testing, the impact that this result could have on the participant demands certainty of the result and that the correct result is given to the correct person. The use of this automated system could be of great utility for data management in research laboratories that receive large quantities of samples and require rapid results reporting for the study participants. Additionally, rapid results reporting allows statistical analysis of such studies to occur faster.

The shortened processing time was mostly likely principally due to the system of automatic alerts for the samples that required repeat and confirmatory testing. This allowed the laboratory staff to perform the additional tests for these samples as part of the normal testing process. Another advantage of the system is its ability to generate 2 types of file output: one file is encrypted and used only for the statistical analysis (and does not connect the identities with the results) while the other file, prepared in Microsoft Excel, is created for results reporting to the participants.

This system also proved to be an important time-saving mechanism for laboratory staff, allowing them to devote more attention to the quality of the laboratory procedures and less attention to more trivial administrative details such as paperwork. The staff improved the capacity of discrepancy resolution and eliminated all possibilities for pending testing because the system controlled generation of these worksheets.

For large clinical studies, integrated laboratory management systems substantially reduce sample processing time, thereby increasing the laboratory’s efficiency in a cost-effective manner. Cost effectiveness was reflected in the decrease in repetitions of positive results, the decreased time invested in review of reports, and the increased dedication of the personnel to the testing itself.

Finding: This study was supported by the grant U10 MH61536 del NIH/NIMH. This is a Multisite Collaborative Trial that is developed in 5 countries: China, India, Peru, Russia, and Zimbabwe. This study was partially supported by L.P CRADA NM-04-1787 and Work Unit Number 847705 82000 25GB B0016.

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