Abstract

Introduction: Tuberculosis remains a public health problem despite all the efforts made to eradicate it. To strengthen the surveillance system for this condition, it is necessary to have a good data management system. Indeed, the use of electronic information systems in data management can improve the quality of data. The objective of this project was to set up a laboratory-specific electronic information system for Mycobacteria and Atypical Tuberculosis.

Methods: The design of this laboratory information system required a general understanding of the workflow and the implementation processes in order to generate a realistic model. For the implementation of the system, Java technology was used to develop a web application compatible with the intranet of the company. The impact and the acceptability of the use of the system on the running of the laboratory were evaluated using Likert scale.

Results: The system in place has been in operation for about 12 months, in conjunction with the paper registers. Since then, 4811 requests for examinations concerning 6083 samples have been registered. The results of analysis of 3892 patients were printed from the Laboratory information system. In order to produce tuberculosis drug resistance reports and laboratory performance reports, dashboards have been developed.

Conclusion: The system has been adopted by the staff because of the time and efficiency gained in managing laboratory data. However, obtaining an optimized tool will only be done in a cycle of sustained improvement.

Keywords: Clinical laboratory information systems, Public health, Tuberculosis

Introduction

Tuberculosis remains a public health problem despite all efforts to eradicate it. According to the World Health Organization (WHO), the number of tuberculosis cases in the world was estimated 9.6 million in 2014 (1). To strengthen the surveillance system for this disease, we need to have a good data management system.

The use of electronic information systems can improve the quality of clinical data (2) and thus the management of patients. Studies have shown that the implementation of computer tools is a performance factor for laboratory activities (3). The results of laboratory analyses provide important data for clinical decision-making and treatment. Effective management of this data is essential for strengthening the health care system as a whole.

Laboratory information systems have been developed and used for about half a century (3, 4). Like all laboratory information systems, the microbiology laboratory information system must be secure, user-friendly and able to interact with other information systems. However, there are several unique features of microbiology that are not used in other clinical laboratories, i.e. tracking multiple drifts, laboratory electronic notes, reporting results, and taking the preliminary and final results into account (3).

The strategic plan of development of e-health has been defined and is being implemented (5). All health facilities have to implement an electronic information system for better management of data generated by their activities.

The purpose of this project was to set up a Laboratory Information System (LIS) at Institute
Pasteur of Côte d’Ivoire to collect specific data for mycobacteria Tuberculous. This LIS will allow the recording of the data resulting from the activities of the laboratory. It should also allow for the generation of results that are ultimately given to the patient as well as the generation of reports on the activities of the laboratory. Finally, an analysis of the impact of this new system in the laboratory routine was carried out.

Methods

Design

Designing a laboratory information system requires an understanding of the workflow and the processes implemented. The data collection and recording sheet was the starting point for this work as the first objective, which was to build a system capable of recording the data and results from the laboratory’s activities. This data sheet is a key element in the activities of the laboratory since all patient information such as socio-demographic data, information on the samples, the preliminary and final results, and the notes of the various examinations are notified. This sheet was previously reorganized by the epidemiology unit. Then, from this new form and a series of interview with biologists, some improvements were made. It was noted that in the paper recording system used before, the biological monitoring of a patient throughout his/her treatment was not possible. This feature was thus integrated into the new system. After analysis of all data, the application with conceptual, logic and physical characteristics was designed, using Merise method in the open source tool MySQL Workbench (6, 7).

Architecture and System Features

We opted for a web-based application used in the company’s intranet. It should be noted that the project was entirely based on Java technology. The design of the application was based on the “Framework” Struts 2 (8) that defined a three-layer design that is the Controller-View-Template. The database connection layer uses Hibernate (9), which is an ORM open source solution that facilitates the development of the persistence layer; this database connection layer is also based on JDBC for some modules of the application. The production of PDF reports was possible by the use of Jasper Report framework (10). The reports in the Excel format required the libraries of the POI project from the apache Software Foundation (11). The Java Enterprise Edition, Glassfish 4.1 (12) deployment server in its free version was used to host the application and the MySQL 5.1 Database Management System (DBMS) which was used to manage the database. The MySQL DBMS and Glassfish Server were installed on an HP ProLiant server running on a UNIX CentOS 6.7 OS. All the client machines were PC-type computers. All web browsers could be used as web clients for the application with a preference for Google Chrome, Microsoft IE and Edge and Safari browsers, like Firefox, do not support the “date” and “time” tags. The data stored in the database benefited from automatic backups to an external hard drive, and replication of this external hard drive was done at the end of the week. The source code of the application as well as the different steps of the implementation was documented to allow future maintenance. The user interface was modeled to be fairly similar to the original paper form. System access management was also taken into account in the implementation. The system modules are accessible according to the rights assigned by the administrator.

On-Site System Installation and User Training

The server housing the executable files of the information system and the database were installed in a room which was secure and protected from the weather. A high capacity UPS was connected to this server to prevent the system from shutting down in the event of a power outage. The client computers comprised the ordinary service computers. The application was available on the corporate intranet from a web browser.

The training of six members of the laboratory staff was conducted in half a day. The assimilation took place quite quickly because the members of the laboratory all had good notions of the computer tool. Consultations were often sought when certain aspects had been forgotten when using the system. After each update, a short information session was organized to share the new features after which the software use continued without interruption. Using LIS by biologists often found bugs that were corrected; suggestions and comments were often made by users to improve this information system.

Qualitative Assessment

The management of patients with tuberculosis involves regular biological tests. Monitoring of the analyses over time for a patient becomes problematic, which is also the case with the search for information on a sample, as well as the completion of activity reports and the delivery of results. The information system put in place should be able to improve the realization of these tasks on a daily basis.

After 12 months of usage, we evaluated the
acceptability of this information system and the impact of implementation on the functioning of the laboratory by different users of the system, namely a data manager, two technicians, two engineers and a biologist who had to use the software continuously. This evaluation was based on the Likert scale (14). To do this, we administered a questionnaire to selected staff members. The interviewees were to choose one response from the five possible responses given for each of the questions which included: Strongly Agree (5), Agree (4), Neither Agree or Disagree (3), Disagree (2), and Strongly Disagree (1). Summary statistics were generated from the responses obtained.

Results
Results of the System Launch

The system in place has been in use since the 1st of January, 2017. Until the 31st of December 2017, 3892 patients were registered in the LIS with a 4811 visits and 6083 collected samples recorded. Of the registered patients, 805 made at least 2 visits to the laboratory. In this information system, 93.9% (185/197) of the entry fields from patient card and the visit card are field with drop-down lists of those pre-recorded at the level of the administration module. These mechanisms were put in place to avoid the errors inherent in free text field filling. LIS allowed the patient folder creation as well as the creation of visit cards related to requests for examinations. These visit sheets were linked to the same record for a patient, which helps to monitor his/her condition (Figures 1, 2, 3).

The printing of the results intended for the patients requires the preliminary validation by biologist responsible for test results; otherwise, the request for printing is not executed. Six laboratory-delivered results could be printed, including microscopy, Genexpert, solid and / or fluid culture, genotypic test, standard antibiogram, and extended antibiogram. In the interests of quality assurance of the laboratory, the second impression for the same result carries the duplicate mark, so during this period, 6075 printed results were obtained which included 3415 microscopy examinations, 1591 Genexpert and LPA, 35 culture samples, 90 classical antibiogram, and 5 expanded.

A dashboard system allows the calculation of indicators for the monitoring of laboratory activities and also provides indicators on the state of the health of the patients. These dashboards generate indicators for activities include microscopy, Genexpert, culture in liquids and solids media, LPA, and antibiotic sensitivity (antibiogram) for a period defined by a time interval to complete. It also allows you to generate an Excel spreadsheet, the list of samples with associated information such as sample number, methods and test results, (Figures 4, 5).

Perception and Usability of the System

The questionnaire was administered to the laboratory staff. Table 1 details the results obtained for these five questions. Regarding the assertions,
they’re saying “the user feels comfortable with the LIS”, “LIS allows security and quick access to information”, “the LIS improves the quality of the work in the laboratory”, and “the user considers to switch to exclusive use of the electronics for managing the laboratory data”; 100% (6/6) responded favorably. One in six found that LIS did not save time in performing data management tasks.

Discussion
We have developed an electronic laboratory information system that takes the specificities of a microbiology laboratory focused on mycobacteria into account. This LIS based on the existing paper collection form has been implemented to manage the data resulting from the activities of this laboratory except for the management of laboratory inputs.

The workflow begins with the sample arrival in the laboratory for examination of the bulletins coupled to billing. The invoicing forms attest to the agreement of the office of entries to the processing of the application by the laboratory. From the information on the request for examination, a search is made on the last name and name of the patient in the LIS at the search field of the page “Create new patient record “. If there is ambiguity for a name, it is to say that we find several identical names and surnames; other parameters such as date of birth, date of registration, telephone number, or residential city can be used to discriminate the patients and find the one that corresponds to the patient on the examination form. In case there is no match, a new folder is created, and the identification number used for this electronic file is generated manually from the laboratory register. This step of the process is often a bottleneck, because persons can have the same names and first names; the search can then become long. A unique identification number generated from the laboratory’s office of entries would solve this problem, but it requires a re-engineering of the procedures of the office of entries.

After sample processing, the corresponding patient record previously created is searched from the sample number or name, and opened. Visit form is created and all the results obtained are recorded. Thus, for the same patient, the LIS makes it possible to follow the evolution of its biological parameters from its visit forms.

The LIS has saved time in the process of generating results before the patients results were enrolled manually on a pre-print form made in Microsoft Word. This process required at least 5 minutes per result; the generation time was less than a minute with the LIS (4).

To this day, all the results of LMTA came from the
Development of an electronic information system for the management of laboratory data of tuberculosis and atypical mycobacteria

LIS; this has the spirit of improving the completeness of the data recorded. Pre-recorded drop-down lists, formatted fields such as the date field and controls set up on free fields such as sample number fields reduce the recording of erroneous data and consequently improve their quality, but there are errors inherent in the user that the system cannot control such as the registration error on a patient’s name or age.

Dashboards play an important role in monitoring laboratory activities and checking the evolution of the population health status. They also help monitor the laboratory's performance indicator and the drug resistance shown by the MDR-TB and XDR-TB.

Overall, the LIS was very well accepted, and all the staff of the laboratory found it comfortable since it is commonly used in the laboratory’s data management activities. The figures of the survey carried out is in the same line with those of the study carried out in South Africa which showed the good perception of computer systems in the management of health structures (15). A lab technician disagreed with the statement that the system saves time in performing data management tasks. After investigation, some bugs were found during the generation of the smear distribution table depending on the result, type of the sample, origin of the biological product, and the profile of the sample, thus motivating this response. This particular malfunction has been corrected. Unlike the study conducted by Barbara Castelnuovo et al. (2) who showed unwilling users adopted the electronic information systems, our study demonstrated the total approval of the laboratory staff as to upgrading to the LIS, as shown by the results of the LIS evaluation by users.

Conclusion
The introduction of the information system for the microbiology laboratory has necessitated the understanding and modeling of various processes used from the arrival of the examination requests to the printing of the results. The system in the current use has been adopted by the laboratory staff who see in them a tool facilitating their work for laboratory technicians. LIS reduces the workload by automating a generation of the results and reports. For the biologists in charge of the laboratory, the LIS through the dashboards allows them to have in real time the indicators on the follow-up of the samples, the activity carried out in the laboratory, and the state of resistance to antituberculosis treatments. The LIS has a positive impact on the laboratory activities, but obtaining a perfect tool is only done in a cycle of sustained improvement.

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Contributions of the authors
CJK made the modeling and design, coding the application and writing the manuscript, TA made the conception and modeling of the Fact Sheet, MKD reading and validation of the manuscript, NR made the conception and validation of graphical interfaces and dashboard, SMK conception and modelisation epidemiological record reading and validation of the manuscript. All authors read and approved the final manuscript.

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Conflict of Interest: None declared.

References

J Health Man & Info, January 2019, 6(1) 5

Appendix A: Questionnaire Instrument (Likert Scale Structured Questions)
Please answer the following questions by indicating which answer most accurately represents the extent to which you agree or disagree with the statement on the left. There can only be one answer per statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  I am completely comfortable with LIS</td>
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<tr>
<td>2  LIS saves time in completing tasks</td>
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<tr>
<td>3  The LIS allows access to information quickly and securely</td>
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<td>4  LIS improves the overall quality of work</td>
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<tr>
<td>5  I plan to move to the exclusive use of the LIS for laboratory data management</td>
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