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SIMENS-LIS4SC, a Laboratory Information System for Biological Tests of Sickle Cell Screening and Healthcare

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Abstract

Neonatal screening and ongoing follow-up of children with sickle cell disease are essential to reduce the mortality caused by this disease. To ensure care continuity, it is essential to include in the patient's record the history and details of biological tests. Thus, it is necessary to provide a Laboratory Information System for electronic management of biological test prescription and results, and the laboratory system must integrate well with Health Information Systems. In this paper, we propose a Laboratory Information System for the management of biological tests for the neonatal screening and healthcare of sickle cell disease in Senegal.

Keywords:

Clinical Laboratory Information Systems; Anemia, Sickle Cell; Neonatal Screening

Introduction

Large amounts of data pass regularly through Senegal's health system between medical services and biological laboratories. This data includes on one hand the tests issued by the physicians and on the other hand, the test results produced by the laboratories. In addition, there is data specific to laboratory activities such as sampling data, the test results, and the test reports, etc. This data is usually recorded in paper documents and is accessed manually. This situation also leads to recurrent back and forth by patients or their carers between medical services and laboratories. Thus, the labs face enormous problems related to (i) collection, storage and processing of test prescriptions and results, (ii) data security, and (iii) possible impaired data integrity because of the frequent use of archives. It then becomes necessary to implement a Laboratory Information System (LIS) integrated into existing Health Information Systems (HIS) to overcome all these difficulties.

The purpose of the LIS is to manage the laboratory's workflow, including processing, storing, and managing biological analysis data in order to provide accurate results for clinical decisions [1,2]. In Senegal, the integration of a LIS with an HIS represents a new scientific and organizational dimension in the local medical practice. Indeed, despite several initiatives including the National Medical Information System for Senegal (SIMENS) project [3], a modular HIS, initially designed for medical services in health facilities of level three in the sanitary pyramid of Senegal [4,5], a LIS has never been proposed.

In this article, we propose a laboratory information system for the management of screening tests for sickle cell disease and all other tests (hematology, biochemistry, parasitology, and bacteriology) necessary for proper monitoring and good management of

positively screened patients. The LIS is designed as a module of SIMENS and is called SIMENS-LIS4SC (SIMENS LIS for Sickle Cell) and is integrated with the HIS of the Center for Research and Ambulatory Care of Sickle Cell Disease (CERPAD) in the Saint-Louis region of Senegal. CERPAD aims at proposing a model for neonatal screening and early healthcare of sickle cell adapted to Senegal's public health system. Indeed, sickle cell disease is a major public health problem occurring in approximately 300,000 births annually worldwide [6]. According to a systematic review on sickle cell disease for children under five years old [7], both the highest prevalence and highest mortality of sickle cell is in Africa, and there is a need for national comprehensive newborn screening to identify patients, and to develop holistic care programs to provide therapeutics and education for families and children with the disease. In Senegal, there are no published studies on sickle cell prevalence. Few local and specific studies, such as one in Senegal, [8] reveal that sickle cell disease mainly concerns children and adolescents.

In the results, we cover the first phase of the project, which began in April 2017. The health services involved were the maternity wards of the Saint-Louis' Regional Hospital Center (CHRS) and the reference health center of the city of Saint-Louis. We present the different interfaces designed for managing the biological test data of the CERPAD laboratory. We illustrate the system contribution in terms of quick and easy access to statistical data for decision-makers through a reporting and dashboard module. A preliminary evaluation was also conducted to show the LIS assessment by the different CERPAD actors involved in the laboratory tests processes.

Methods

The neonatal screening program included every newborn with the consent of their parents. Specially trained midwives and gynecologists informed parents about the process. Materials collected included for each newborn, a blood drop sample and an information sheet regarding the baby's medical data, the parents' marital status, contacts, and socio-professional status. In addition, for newborns suspected of having sickle cell disease or homozygous C after the initial screening, a second venous blood sample was collected for detailed analysis.

The initial blood sample was used to perform hemoglobin typing by the isoelectrofocusing method. The second sample was used for performing capillary electrophoresis of hemoglobin, to identify and confirm the sickle cell status. The center followed monthly newborns with a major sickle cell syndrome profile (SS, SC, SE, SD Punjab, SO Arab, SLepore, S β^0 thalassemia, S β^+ thalassemia) or a CC status during systematic visits. They also received emergency care during acute attacks or other complications related to the disease.

Recommended during the follow-up for diseased patients, mandatory biological and radiological examinations evaluated systematically and periodically the patients' health state. These examinations' objective was to detect complications in early stages in order to propose preventive treatment before any organ deterioration or the appearance of functional repercussions. A doctor from the HIS could also prescribe these examinations during the patient consult and could send patients directly to the nurse for sampling. Samples were then passed to the lab technician to trigger the biological test process of sample sorting. The biological examinations were proteinuria (after 24h), blood count and reticulocyte level (every month from birth), serum iron, ferritin, lactate dehydrogenase, and irregular agglutinins (every year since birth), and micro-albuminuria and creatinine (every year from 5 years old). The radiological examinations were transcranial ultrasound (every year from 2 years old), abdominal ultrasound (every year from 5 years old), retinal angiography, and cardiac ultrasound (every year from 10 years old). Radiological examinations were performed in an external department to CERPAD and were not yet taken into account in the SIMENS-LIS4SC.

An application dedicated for data management of laboratory tests for sickle cell disease screening and healthcare was implemented. It became a part of a module integrated in SIMENS, acting as a laboratory information system and connected to the HIS module of SIMENS dedicated to sickle cell neonatal screening and healthcare. The SIMENS-LIS4SC had two main inputs (neonatal screening test request from maternity wards and biological test request for the diseased patient follow-up and healthcare from the physician) and one output, which were the test results integrated in the patient record. The application was implemented using an Agile development process [9]. We used PHP and the ZEND 2 framework to develop the LIS, as these technologies were already a part of SIMENS. For data management, we used the MySQL relational database management system. We worked with a medical and medico-technical team of doctors, nurses, laboratory technicians, biologists, and administrative secretaries who were very involved in the software design. Regular meetings made it possible to clearly identify needs, discuss the various user profile requirements, present intermediate results to gather opinions and suggestions, and define the following work, etc. To guide the design of new features and interfaces, workflow schemes and other essential information were regularly shared.

As a preliminary evaluation, we gathered the opinion of 9 users using a qualitative form including 18 questions. These users included a secretary, nurse, technician, biologist, and physician using the LIS for almost 2 years. For each question, users had to answer using a 4-value scale (fully agree, partially agree, partially disagree, fully disagree) and were allowed to give no opinion.

Results

Workflow

Figure 1 shows the proposed workflow for laboratory tests management of sickle cell neonatal screening, follow-up, and healthcare. The maternity wards intervened in the sampling phase for the newborn screening, the secretary while creating the patient's record, and the nurse for filling the sample data from the maternity wards. The nurse could have taken samples at the CERPAD center if necessary, for instance when the physician prescribed additional biological tests for the diseased patients follow-up and healthcare. When the samples were transmitted to the laboratory, the technician performed some checks before completing the tests and filling the results. Then, the biologist

interpreted, validated and sent the results to the secretary for printing.

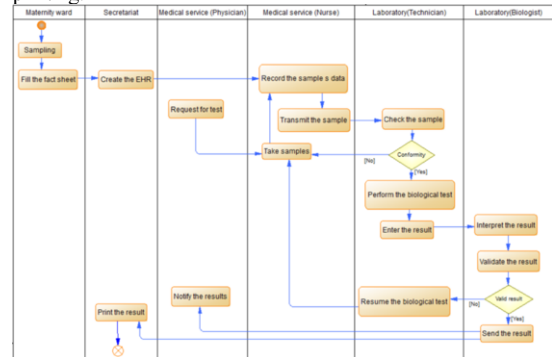


Figure 1– Workflow of Laboratory Tests Realization

The SIMENS-LIS4SC

In this section, we focus on the LIS interfaces that highlight the management of the sickle cell biological test data within the CERPAD for the neonatal screening and healthcare. Any of the identity data in screenshots does not refer to any real patient.

First, the screening process consisted for the secretary, to create a record in the Electronic Health Record (HER) for the patient based on his information sheet data from the maternity ward. The secretary was also responsible for recording biological test requests, such as hemoglobin screening as shown in Figure 2.

Figure 2– Screening Test Request from the Secretary Interface

Then, the nurse filled the data related to the samples (Figure 3) taken on the patient before sending them to the laboratory technician who performed the verification.

Figure 3– Sample Data Entry by the Nurse

Verification step shown in Figure 4 consisted of checking the state of the samples, the conformity of the material used, etc. In the event of a problem, the technician could request through SIMENS the resumption of the samples concerned.

The screenshot displays a patient record for 'bébé DIAKHOUMPA' (1 00767 2019 E). It includes fields for patient name, sex (Masculin), date of birth (30/03/2019), and age (2 jours). Below this, there are sections for 'Bilan des prélèvements' (Sample Analysis) and 'Liste des analyses à trier' (List of analyses to sort). The 'Bilan des prélèvements' section shows 'Nombre de prélèvements' (1), 'Date & heure' (01/04/2019 - 16:12), and 'A jeun' (Oui). The 'Liste des analyses à trier' section shows a table with columns: Type, Analyse, Tube, Autre, Conformité, and Note. The table contains one row for 'TYPOLOGIE DE L'HEMOGLOBINE'.

Figure 4– Samples Checking by the Technician

The technician was also responsible for recording the results of the biological tests as shown in Figure 5.

The screenshot shows the 'Entrez les résultats des analyses' form. It includes a dropdown for 'DEPISTAGE' and a dropdown for 'TYPAGE DE L'HEMOGLOBINE'. Below these, there are sections for entering results for three patients: 'bébé DIAKHOUMPA (1 00767 2019 E)', 'bébé BASSENE (1 00770 2019 E)', and 'bébé BANGOURA (2 00769 2019 E)'. Each section has a 'Matériel utilisé' field and a 'typage de l'hémoglobine' dropdown. At the bottom, there are 'Enregistrer' and 'Fermer' buttons.

Figure 5– Test results entry by the technician

Finally, the biologist interpreted and validated the results for printing. The results were integrated into the patient's EHR. The secretary could access the results and print them as shown in Figure 6 for transmission to physician and newborn's parents.

The screenshot shows a printed result for 'bébé DIAKHOUMPA' (1 00767 2019 E). It includes the patient's name, sex (Masculin), age (2 jours), and date of birth (30/03/2019). The 'RESULTATS D'ANALYSES' section shows 'TYPOLOGIE DE L'HEMOGLOBINE' as 'ISOFOC'. The 'PROFIL DU PATIENT' section shows 'SS'.

Figure 6– Example sickle cell screening result print

In addition to accessing the laboratory test results directly in the patient record, the physician could prescribe complementary tests directly during the consultation. The Figure 7 shows how the SIH

alerted the physician about the mandatory exams to prescribe for the follow-up of the diseased patient.

The screenshot shows the 'Examen complémentaire' section. It includes a dropdown for 'Examen à faire' and a table of tests. The table has columns for 'Examen à faire', 'Résultat', and 'Statut'. The tests listed are: 'HEMOGRAMME', 'TAUX DE RETICULOCYTES (TR)', 'CREATININEMIE', 'FER SERIQUE', 'FERITINE', 'ELECTROPHORESE DE HEMOGLOBINE', 'PROTEINURIE DES 24H (PU 24H)', 'MICRO-ALBUMINURIE', and 'LDR'. The 'Statut' column shows 'X' for all tests.

Figure 7– Complementary Tests Prescribed by the Physician

Example of Statistical Data on the Screening Tests

The neonatal screening program started in April 2017 with a two-month experimental phase. This phase also made it possible to test and maintain the SIMENS HIS and LIS modules for sickle cell disease screening.

Table 1– Summary of the screening from 06-2017 to 08-2018

Period	AA	AC	AD	AS	CC	SC	SS	Total
2017-06	226	10	0	23	0	0	0	259
2017-07	236	5	1	22	0	0	2	266
2017-08	48	1	0	6	0	0	0	55
2017-09	146	4	0	13	0	0	0	163
2017-10	286	5	0	29	0	0	1	321
2017-11	245	2	0	29	0	0	0	276
2017-12	261	7	0	21	1	0	0	290
2018-01	308	6	0	26	0	0	0	340
2018-02	251	7	0	30	0	0	0	288
2018-03	216	6	0	31	0	0	1	254
2018-04	208	2	0	19	0	1	0	230
2018-05	174	6	0	16	0	0	0	196
2018-06	219	3	0	19	1	0	0	242
2018-07	241	5	0	23	0	1	2	272
2018-08	43	0	0	1	0	0	0	44
Total	3108 (88.90%)	69 (1.97%)	1 (0.03%)	308 (8.81%)	2 (0.06%)	2 (0.06%)	6 (0.17%)	3496

Table 1 shows the evolution of the data over time and their distribution according to the various screened sickle cell profiles, covering a period of 15 months from June 2017 to August 2018. 3496 newborns were screened during this period. 3180 (green columns) of them were healthy and non-carriers. 316 (orange and red columns) were carriers of the gene Hemoglobin S. Among carriers, we had healthy carriers (AS) and diseased patients (SS, SC, SE, SDPunjab, SOArabe, SLeopore, S β thalassemia, S β thalassemia). In this first phase, we found 8 (red columns) diseased patients of SS profile.

The figure 8 shows a dashboard of the distribution of (1) the overall screened newborns between internal and external status, (2) the diseased patients between gender and (3) the diseased patients according to SS, SC and CC profiles.

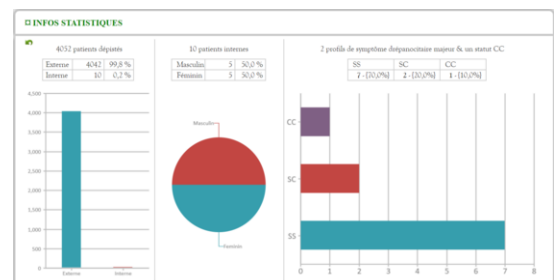


Figure 8– Patients Distribution According Internal and External Status, Gender and Sickle Cell Diseased Profiles

Table 2– Evaluation results and analysis

[illegible]

The figure 9 shows a dashboard of the distribution of only validated results by the biologist of the overall screened newborns between (1) gender, (2) sickle cell all profiles and (3) ethnic groups.

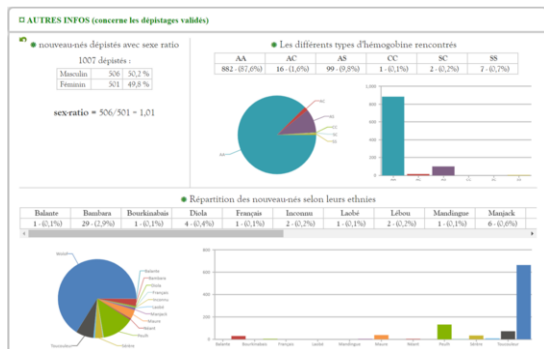


Figure 9— Patients' Distribution of Validated Results, According to Gender, Sickel Cell All Profiles, and Ethnic Groups

Evaluation of SIH SIMENS-LAB

The qualitative evaluation yielded very good results (see table 2). All users found that the system was easy to use, reliable, secure, and that it facilitated their work. Moreover, most of them considered that it was able to improve the quality and the continuity of care, and, to a lesser extent, the decision-making process. Decision-making seemed to be the weakest point of the system, though, with two users finding that the system did not improve decision making, and 3 expressing no opinion.

Discussion

In this section, we discuss the related works on Laboratory Information Systems which have various features :

- The automatic validation of analysis results, which consists in checking the plausibility of the results by confronting them all with a certain number of previously defined parameters in the system. In some laboratories in Europe, it is necessary to validate more than ten thousand results per day. The system ensures the same quality of validation throughout the day. For

example, Valab software is a reference application in biological validation [10].

- The management of electronic medical records, sampling, data capture, validation, printing of results, and rapid communication of test results to connected health centers are executable tasks with e-Chasqui. This system is designed to support the national network of anti-tuberculosis laboratories in Peru. It improves the quality of care and ensures effective follow-up of TB patients [11,12].
- The management of HIV testing, treatment of HIV-positive patients, and patient data security is achievable through the NETLAB system. It is a software developed to improve the treatment of HIV in Peru. It manages 100 different diseases for which the National Institute of Public Health and the network of health laboratories in Peru provide test prescriptions and results. It ensures, among other things, the communication of laboratory results, in complete confidentiality to laboratory staff, health providers, and patients living with HIV [13].

In addition, there are other large-scale solutions for performing more complex tasks than in the examples mentioned above. For example, Delphic is a SIL for end-to-end information management for hospital and community labs. It covers all phases of the laboratory work process. It is adaptable to various laboratory environments and fully customizable, making it ideal for multi-laboratory organizations [14]. The BK-LIS is a LIS for patient data management of laboratories in health facilities in Vietnam. It is designed for the management of Hematology, Biochemistry, Immunology, Microbiology, Urine, Endocrine, and Cell Analysis.[15].

As far as we are concerned, information systems are being implemented especially for sickle cell disease, the most common genetic disease in the world. It is generally found in all continents but, the highest prevalence rates are observed in Africa. Thus, the Laboratory LARTIC (Support Laboratory Research and ICT) of the Faculty of Medicine of Antsakaviro of Madagascar in collaboration with the NGO Fight against Sickle Cell Disease in Madagascar, France and the Faculty of Medicine of Antananarivo have set up the openMRS-Sickle-Cell, an application based on OpenMRS for the network fighting against sickle cell disease in Madagascar. In Madagascar, where the prevalence of hemoglobin S trait carriers is estimated at

approximately 2,000,000 distributed in highly endemic areas that are often remote and almost inaccessible, the system allows the centralization of clinical data of patients screened and followed up [16].

In the context of CERPAD where we developed our LIS, we could design a system from scratch for systematic neonatal screening and ongoing follow-up of patients. We integrated social specificities of the West African region, such as the genetic roles played by ethnic groups, in a long-term multidimensional database for research purposes. This research should allow a better characterization of the disease taking into account the socio-demographic and environmental parameters in Saint-Louis of Senegal.

Conclusion

SIMENS-LIS4SC fulfills several functions allowing the realization of the different laboratory tasks for biological tests related to the management of sickle cell disease. It allows the laboratory to take advantage of the automation of tasks. The SIMENS-LIS4SC also makes data entry, reporting and archiving much easier within the CERPAD. Physicians can quickly access results and analysis reports interpreted and validated by the biologists, which greatly speeds up diagnosis and improves treatment. This system also provides efficiencies and decreases patient expenses by reducing the number of redundant tests. Researchers can use the data collected to carry out clinical, epidemiological, and social studies.

The SIMENS-LIS4SC is reusable in other sickle cell screening programs. It is also adaptable for any other disease screening and could extend to hospital level, by adding relevant tests.

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