HIV Aid and Control: Telemonitoring System Oriented toward HIV Patients Undergoing Antiretroviral Therapy

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Abstract. The Human Immunodeficiency Virus (HIV) is a cytopathic retrovirus that mainly infects CD4+T lymphocytes. Antiretroviral therapy (ART) and particularly highly active antiretroviral therapy have allowed reducing the mortality caused by HIV so that it is currently considered a chronic disease susceptible to control. However, several factors decrease the therapy's success, such as the patient's lack of strict adherence to medications and timely therapy adjustments by the medical specialist in the face of abnormal changes in the symptoms. This paper presents the analysis, design, and development of a telemonitoring system oriented toward HIV patients on ART. Our system is characterized by offering multiple services that contribute to empowerment and patient education, facilitate adherence to therapy, provide assistance to medical consultation and compliance with preventive measures by the patient, allow timely therapy adjustments, detect early risk situations and adverse events, and remote therapy monitoring by the specialist doctor.

Keywords: Telemonitoring, antiretroviral therapy, HIV, mobile-health, design, and development.

1 Introduction

Although the natural evolution of HIV disease has changed dramatically since the introduction of antiretroviral therapy in 1987 and particularly since 1996 with combination therapy, HIV continues to be one of the biggest problems for global public health. The World Health Organization (WHO) reported in 2017 that the Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome

(AIDS) is still within the first ten causes of mortality, reaching 40.1 million deaths since the beginning of the epidemic and about 650,000 in 2021 [1]. As part of the efforts to end the epidemic [2-3], WHO has set the goal 95-95-95 by 2030, claims that 95% of people living with HIV are diagnosed, 95% in antiretroviral therapy and 95% achieve optimal virological control. By 2022, 29.8 million people gained access to antiretroviral therapy of the 39.0 million people living with HIV [3]. As soon as a person with HIV initiates antiretroviral therapy, they must proceed without interruptions, respecting doses, and schedules, to achieve optimal virological control, which is reflected with an undetectable viral load in peripheral blood, allowing the immune system regeneration and therefore enhancing the patient quality life. The therapy alteration or the lack of medical monitoring can lead to virological failure due to drug resistance, complications derived from therapy, HIV infection, or diseases not associated with the virus [2-3].

In recent years, there has been a growing interest in strategies derived from mobile media to promote medical monitoring and to enhance adherence to treatment in the HIV field, such as sending text messages, reminders to attend medical appointments, promotion of healthy behaviors, cessation of smoking, among others [4]. Some works [5–9] have proposed software tools that remotely monitor and control patients' antiretroviral therapy with HIV. However, these systems lack important services that contribute to achieving continuous monitoring, adherence to therapy by the patient, and timely therapy adjustment by health staff in the face of abnormal patient symptoms. In this work, we present the analysis, design, and development of a system for monitoring and controlling remote antiretroviral therapy in patients with HIV. Our system is integrated with two mobile applications: a native Android application, which provides patient-oriented services, and a mobile web application aimed at medical specialists. We selected the Android platform since this is free software, and it has 78% of the Smartphone world market [10]. The mobile web application, aimed at the specialist doctor, provides the following services: user administration, medical history, physical examination, viral load evolution, laboratory exams, vaccines, notifications, medical appointments, and medical notes. On the other hand, the patient's application provides the following services: viral load evolution, risk alerts, laboratory exams, notifications by the doctor, links of interest, and reminders. Based on the offered services, some benefits that our system could provide to the patient in ART and the specialist doctor are: contribute to the patient adherence to the therapy, educate the patient about HIV infection, simplify the medical record facilitating decision-making, improve the interrelation between patient and doctor, provide a daily and distance monitoring of the therapy, allow timely therapy adjustments, detect early risk situations and adverse events, as well as contribute to improving the positive perception of the beneficiary about the monitoring and therapy of their illness.

2 Related Work

Several works have proposed software tools for HIV patients in ART: Medisafe [5], TheBody [6], HIV AIDS Therapy [7], HIV-DHHS Guidelines [8], inPractice HIV

[9], VIH/SIDA Spanish Red Cross [11], AIDS Guidelines—AIDS Info [12], AIDS Digital [13], UNAIDS DATA DASHBOARD [14], and NACO [15]. These software tools can be classified into two categories: informative and monitoring. Following, each category is described in detail.

2.1 Informative Software Tools

Systems and mobile applications within this category of tools are VIH/SIDA Spanish Red Cross [11], AIDS Guidelines — AIDS Info [12], AIDS Digital [13], UNAIDS DATA DASHBOARD [14], and NACO [15]. The main objective of these software tools is to provide the user with readings, reports, databases, institutions' addresses, information related to infection, therapy, laboratory tests, and service providers. Some of them allow adding notes and reminders about medications, and most of them, such as AIDS info, provide updated content.

2.2 Monitoring Software Tools

In this category are the following works reported in the specialized literature: Medisafe [5], TheBody [6], HIV AIDS Therapy [7], HIV-DHHS Guidelines [8], and inPractice HIV [9]. These software tools facilitate the monitoring of patients with HIV in ART and provide modules where patients can consult the medical history, the management of medications, and telepharmacy. In some cases, systems offer virtual assistance, which is an effective tool in controlling patients infected with HIV. On the other hand, attention via chat, webcam connection, and telephone assistance reduces the consultation time, optimizing the medical control, see Table 1.

2.3 Analysis and Comparison of Software Tools focused on the Monitoring and Control of ART.

Table 1 presents an analysis of software tools focused on monitoring and controlling of ART. Based on the health standards [16], [17]. Table 1 shows the main services that software tools should provide to achieve adequate monitoring and remote control of antiretroviral therapy:

- Record Clinical History (CH): The CH must be composed of four sections: medical history, non-pathological history, family history, and sexual health. Sexual health (SX) should present information about sexual, STI/STD, and family planning.
- Record/Update physical examination (PE): In this service, information related to the clinical signs of the patient is registered, such as frequencies, blood pressure, and BMI, among others.

- Viral Evolution (VE): This service should report the patient's antiretroviral therapy and its initiation date, the viral load in HIV copies per milliliter of blood, also described in logarithm-based 10 and the concentration of CD4+ lymphocytes per cubic millimeter of blood.
- Medical Appointments (MA): service to schedule patient appointments.
- Laboratory Tests (LT): This functionality includes specific measures from requested exams, previous laboratory test results searching, and a form to register new results.
- Vaccines (Vac): Service that must present the recommended vaccination schedule for the patient's ART, specifying the date of application of each dose.
- Notifications (Not): The specialist can generate a notification, message, reminder, or recommendation to the patient. It should also be considered whether the patient reports an abnormal symptom (alarm categorized by the specialist doctor); the doctor can respond through this service, optimizing the control against these adverse reactions.
- Risk Alerts (RA): The pharmacoresistant, adverse reactions or symptomatology outside the ART reflected through alarming signs, categorized by the infectious disease specialist, should be communicated by the patient to their specialist through this service immediately.
- ART Visualization (ARTV): Review the patient's viral evolution history and the therapy control history.
- Private Laboratory Tests (PLT): Laboratory tests performed by the patient in a private health institution should report to the specialist doctor.
- Reminders: In order to encourage adherence to therapy by the patient, a service of appointments reminder (AR), exam reminder (ER), medication reminder (MR), and vaccine reminder (VR) should be considered. Each of these reminders is important for the therapy's success and helps the patient not to forget the medication times, the vaccines control, the appointment, or laboratory test schedules.
- Doctor-Patient Data Synchronization (DPS): This system feature allows maintaining communication between doctor and patient through services that synchronize information generated by both users.

Table 1. Software Tools Analysis.

Apps/ Systems	Requirements															
	CH	SX	PE	VE	MA	LT	Vac	Not	RA	ARTV	PLT	AR	ER	MR	VR	DPS
[5]	.	.	.	.	.	.	.	.	.	.	.	✓	.	✓	.	.
[6]	.	✓	.	.	✓	.	.	.	.	.	.	.	.	.	.	.
[7]	.	.	.	✓	.	.	.	.	.	.	.	.	.	.	.	.
[8]	.	.	.	✓	✓	.	.	.	.	.	.	.	.	.	.	.
[9]	.	.	.	✓	✓	.	.	✓	.	.	.	.	.	.	.	.

Based on the presented analysis in Table 1, the informational and monitoring software tools of the reviewed works, lack important services such as risk alerts, patient evaluation history and therapy control, medication reminders, appointments, examinations, viral evolution, and monitoring of the vaccination scheme. These services contribute to achieving continuous monitoring, adherence to therapy by the patient, timely therapy adjustment by medical staff in abnormal patient symptoms, permanent telemonitoring of treatment by the specialist physician, and early detection of risk situations, including adverse events.

3 Analysis and Design Model

The complete development of the telemonitoring system was divided into two stages, which were developed based on the ICONIX methodology [18] as a formal development methodology. In this methodology, analysis and design models are applied. These include use case diagrams and component diagrams. Each diagram is detailed in the following sections.

3.1 Use Case Diagrams

Use case diagrams presents the main system services (use case), as well as users (actors) and their interactions with system services. Use case diagrams (UC) of both applications are detailed below. Fig. 1 shows the mobile web application use cases oriented toward the doctor. In this diagram, 26 UC are identified; the most important are:

- UC04 to UC08 represent the clinical history module, which records, updates, and visualize the services information about the sexual history and HIV infection, medical history, non-pathological history, family history, and clinical history visualization.
- UC09 to UC10 represent the record/update and visualization of the antiretroviral therapy, i.e., the viral copies control.
- UC11 to UC16 represent the record/update and visualization of the blood biometry and glucose services. Lipid, renal, and hepatic profiles, as well as serological studies, are part of this UC regarding the laboratory exams module.
- UC17 and UC18 represent the record/update and visualization of the vaccines that should be applied to the patient.
- UC19 and UC20 regard to notifications service, in UC19 the alerts for patients, are recorded or updated. In UC20, every registered notification can be visualized.
- UC21 and UC22 record/update and visualize the medical appointments granted to the patient by the specialist doctor.
- UC23 to UC27 indicate how the record/update and visualization process should be for the laboratory exams module, which covers vital signs and symptoms, sexual health, physical exam, and diagnosis.

- UC28 represents the medical note visualization. This UC displays information from the other modules, i.e., it is free of records and update processes.

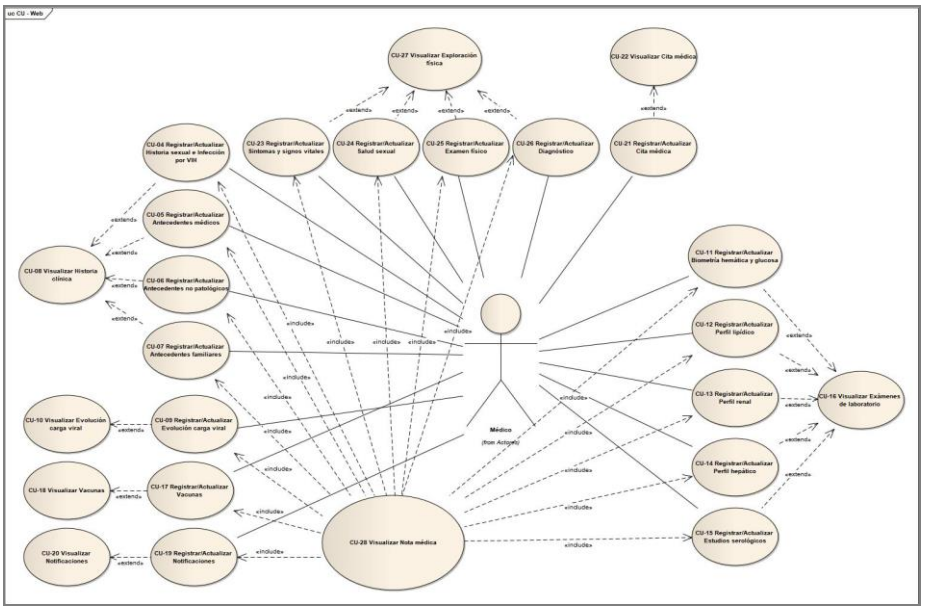


Fig. 1. Web application use cases

The use case UC09 represents the viral evolution service, one of the most important in the system. This use case stores the viral copies of records registered by the doctor in each medical appointment. The stored records are presented on the patient's side as a detailed list and a graph representing the viral copies. As in most UCs of the native application, the viral evolution UC interacts only with the doctor, whereas the patient only holds visualization options. On the other hand, Fig. 2 shows the use cases diagram of the native Android application oriented toward patient actor/user. In this diagram, 8 UC are identified as follows:

- UC29 regards viral evolution visualization to display the viral copied list and more therapy components; this UC consumes web application services.
- UC30 is responsible for recording the risk alert information that the patient may have.
- UC31 and UC32 represent the record and the visualization of the patient's exams outside the hospital locations.
- UC33 is the notifications UC; this visualization module consumes web services to present the information recorded by the doctor in the notification module or by the patient in the risk alert module.
- UC34 to UC37 present the record and visualization of vaccine reminders, medical appointments, exams, and medications; these reminders are synchronized with the Google calendar.

- UC38 presents the links of interest visualization, i.e., redirects to websites that offer information related to antiretroviral therapy.

The services offer real-time information from the server if the device has an internet connection. Otherwise, only the data saved during the last connection will be presented.

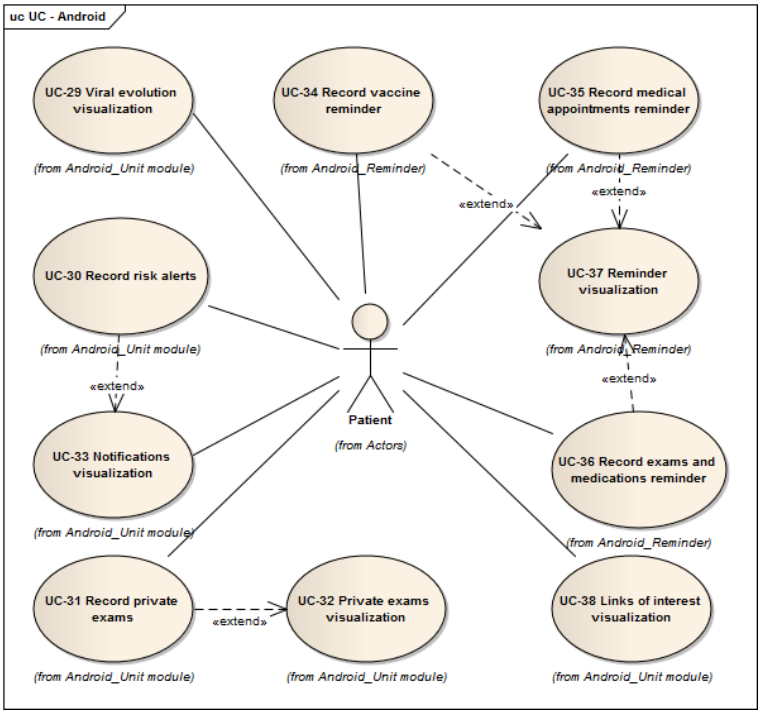
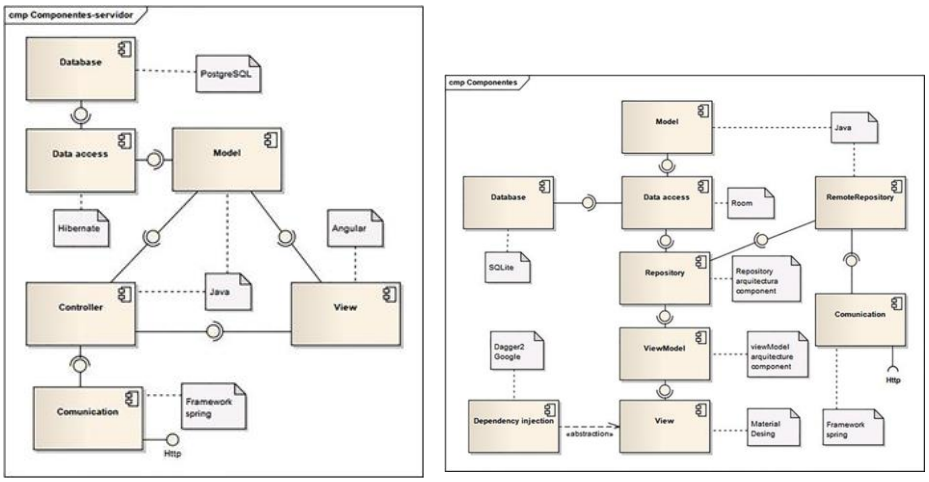


Fig. 2. Use cases diagram of the native Android application for the patient.

3.2 Component Diagrams

The architecture patterns and technologies used in our system are presented in the component diagrams from Fig. 3. For web application components, see Fig. 3a, the communication is performed through the Spring framework, the model and controllers are developed in Java; controllers make requests through web services (RESTful) connected to entities by the Data Access Object (DAO); the database is in PostgreSQL, and it is accessed through the Java Persistence API (JPA). On the other hand, Fig. 3b shows the component diagram of the native application developed based on the Model-View-View- Model (MVVM) structure [19]. This architecture focuses on abstracting models and codes to simplify programming and easily achieve code reuse. In our case, the native application requests the web server services; depending on the service consulted, the information is stored in the cell phone, and the data is stored in SQLite and accessed through the Room Persistence library. Regarding the

injection of dependencies, the Dagger framework version 2 is adopted, supported by Google and Square.



a) b)

Fig. 3. Components diagram of the web application (a) and native application (b)

4 Developed Services of the HIV Aid and Control System

This section describes the services grouped into modules that allow the medical specialist and the patient to carry out a systematized telemonitoring of antiretroviral therapy. It also describes the performed tests for each application and the integration tests, which correctly reflect the sending and receiving of data between applications. It should be noted that the mobile web application, oriented towards the doctor, and the mobile application, oriented towards the patient, are communicated with each other, enabling both users to access the control of viral evolution and other services offered by our system.

4.1 Medical Specialist Services

The web application provides ten services, including user authentication. Services such as viral load evolution, vaccines, notifications, and medical appointments are partly used by the native application; the rest are exclusive to the monitoring that the doctor should perform to control the viral load and clinical history. After correctly logging in, the patient selection option is displayed. The patient must first be selected to access other web application services such as user administration, clinical history, viral load evolution, laboratory exams, immunizations, notifications, medical

appointments, physical exams, and medical notes. The main services of the web application are described below:

a) Clinical history module: In this module, different medical histories of the patient are recorded:

- Sexual history and infection by HIV: In this sub-module, the doctor records data about HIV infection, sexual couples the patient has had, the therapy the couple has taken if the person is HIV positive, and the STDs — STIs patient has had.
- Medical history: In this section, the doctor records the surgeries, transfusions, traumatic, and allergies, among other aspects that contribute to the therapy control. For example, allergies are relevant for the doctor when choosing an antiretroviral therapy for the patient.
- Non-pathological history: In this sub-module, the doctor records information about community bacillus exposure (COMBE), smoking, alcoholism, and other drugs.
- Family history: The doctor records in this sub-module the diseases of each family member. The relatives stored in the family history are the mother, father, uncles, and grandparents.

b) Viral evolution (Response to therapy monitoring): This section reflects the viral load control of the patient, see Fig. 4, the antiretroviral therapy (ART) name, the ART initiation date, and the results presented through copies per milliliter, logarithm-base 10, the number and percentage of CD4, for each of these records the exams' date is required. This service is one of the most important for the doctor and patient in our system.

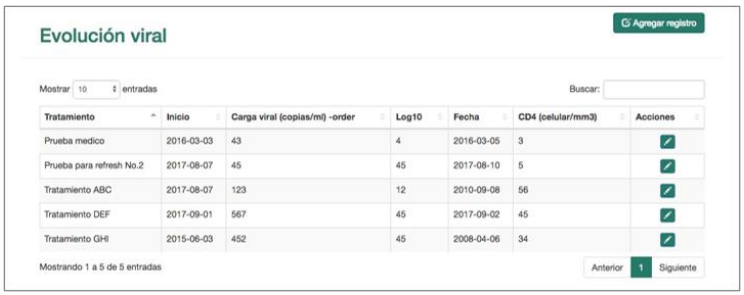


Fig. 4. Web application view: viral evolution

c) Laboratory tests: The five sub-modules presented in the laboratory test service correspond to the exams indicated by health standards [16] and [17] or that are sent directly by the specialist doctor. Some results can be presented in different units, depending on the laboratory in which they were performed. However, the system stores the results according to the unit assigned in the modal for each entry. The visualization of each sub-module offers, among other fields, observations where it can store any important information derived from each exam or profile. The sub-modules are listed below:

- Blood count and glucose: This sub-module presents values corresponding to the blood count performed in biometrics, allowing the specialist doctor to evaluate the amount, proportion, and variation of each test.
- Lipid profile: This service shows the lipid profile test results.
- Renal profile: This sub-module presents the results of the renal profile exams.
- Liver profile: This sub-module shows the results of the bilirubin, transaminases, total proteins, and the observations field.
- Serological studies: This service shows the results of serological studies such as Hepatitis B, hepatitis C, syphilis (VDRL), and HIV.

d) Vaccines: This module shows the required vaccines for antiretroviral therapy and those the patient must have before the therapy begins. Each vaccine possesses a recommended application date and an indication. This information is also visualized by the patient in the native application. The patient must notify the doctor every time a vaccine is applied and the application date to register in the system.

e) Notifications: In this module, the patient can generate an alert when an abnormal symptomatology is detected. After sending the alert, the doctor can visualize it and respond with an appropriate indication to the patient, see Fig. 5. The notifications list is available for both users.

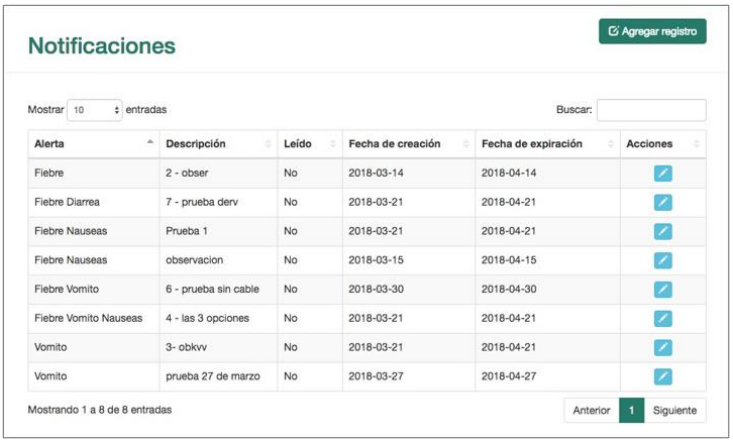


Fig. 5. Web application view: notification list

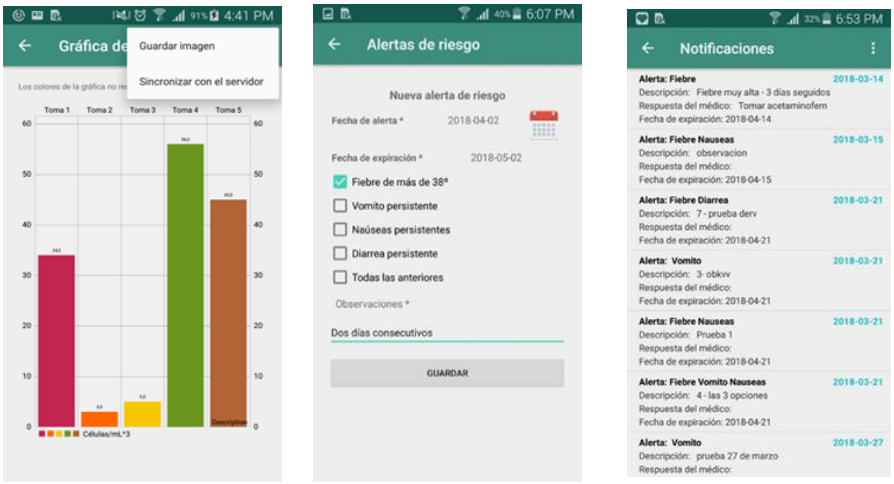
4.2 Patient Services

The native application oriented toward the patient provides nine services. In order to access all services, the device must have an internet connection, and the server must be active; otherwise, the application will display a message notifying that the server is not available. The native application's main services are detailed below:

a) Viral load evolution: This service first shows the patient the control of his viral load through a list. Furthermore, the application displays a graph with this information, which can be stored in the phone gallery for future reference, see Fig. 6a.

b) Risk alerts: In this service, the application generates risk alerts based on the data recorded by the patient, which are sent to the doctor's notification module, see Fig. 6b. The alert options were set according to the kind of warnings that could cause the antiretroviral therapy [16], [21]. After the alarm is generated, the doctor can answer it from their web application, generating direct and real-time communication with the patient. The patient also has an observations field in which the adverse symptoms can be described, with the option of requesting an emergency appointment according to symptoms.

c) Notifications: This service presents the doctor's responses to the patient's alerts, according to the order in which the notifications were recorded, see Fig. 6c. In this module, the patient receives the necessary feedback from the doctor in case of a risk situation.



a) b) c)

Fig. 6. Android view: viral evolution graph (a), record risk alerts (b), and notifications list (c)

d) Private test: This module allows the patient to manage the tests performed independently at a public health institution. This module records the main measurements performed in a blood test. These exams can only be viewed in the patient's application. To visualize exam details, the patient should choose the option to display previous exams within the options menu.

The services developed in both applications were reviewed and validated by a specialist in charge of the care of HIV patients at a General Zone Hospital of the IMSS of Veracruz North region, who also contributed to the analysis and the list of

requirements initially requested. In the analysis phase, we considered specialized documents and guides from the World Health Organization (WHO), the Joint United Nations Program on HIV/AIDS (UNAIDS), hence, our system is aligned with international standards.

5 Test Model

To ensure the correct functioning of the proposed system, we performed unit tests on modules for each application, as well as integration tests with both applications of the system. The unit tests and system integration represent a quality filter either to decide its acceptance, for the analysis of global defects or to study specific aspects of its behavior, such as security or performance [18]. The verification result of each service is described individually and comprehensively; in each, the functioning and the correct data exchange are demonstrated. The format used to control the performed tests contains the following data: 1.- Purpose, description of the service goal; 2.- Requirements, previous steps for the service action; 3.- Entry, information occupied to perform the test; 4.- Action, description of the service action; and 5.- Result, indicates if the service works correctly.

5.1 Web Application Unit Test

All tests were simulated using two doctors and four patients for the different modules and scenarios. For each iteration, a doctor and two patients were registered, the information was sequentially appended for every module. Finally, the database was cleaned, a doctor was registered, and a patient was chosen, who registered information in all application modules and fields. In some modules, we performed two additional iterations due to the information synchronization with the native application. Table 2 shows the performed tests summary on the application aimed at the specialist doctor.

Table 2. Web application test.

Module	Sub-Module	Errors found	Errors solved	Errors pending	Iterations
User authentication	Log in	1	1	0	3
	Log out	0	0	0	3
Viral load evolution	Viral control detail	2	2	0	3
	Viral control graph	1	1	0	3
Risk alerts	Record risk alerts	1	1	0	3
Private exams	Record private exams	1	1	0	3
	Private exams visualization	0	0	0	3
Notifications	Notifications visualization	0	0	0	3
Reminders	Vaccine reminder	1	1	0	3

	Medical appointments reminder	0	0	0	3
	Exams and medications reminder	1	1	0	3
	Reminder visualization	0	0	0	3
Links of interest	Links of interest visualization	0	0	0	3

This table shows the found, resolved, and pending errors. In addition, the number of iterations performed on the application was with different scenarios. Based on the tests performed and errors corrected, it can be guaranteed that the web application is completely functional.

5.2 Native Application Unit Test

In this application, we performed tests on the following services: viral evolution, private laboratory tests, risk alerts, notifications, links of interest, medication reminders, vaccine reminders, medical appointment reminders, and laboratory exam reminders, see Table 3. All tests were simulated with three patients who entered and visualized information in the different mobile application services. The application was also tested with different internet networks, verifying the correct and timely response of the server or web application. After three iterations, the system did not present any errors.

Table 3. Native application test summary.

Module	Sub-Module	Errors found	Errors solved	Errors pending	Iterations
User management	Record Doctor	1	1	0	3
	Record/Update Patients	0	0	0	3
Clinical history	Record/Update Sexual history and infection by HIV	2	2	0	3
	Record/Update Medical history	1	1	0	3
	Record/Update Non-pathological history	1	1	0	3
	Record Family history	1	1	0	5
	Clinical history visualization	0	0	0	3
Viral load evolution	Record/Update Viral load evolution	0	0	0	3
	Viral load evolution visualization	0	0	0	3
Laboratory exams	Record/Update Blood count and glucose	1	1	0	3
	Record/Update Blood count and glucose	1	1	0	3
	Record/Update Lipidic profile	1	1	0	3

	Record/Update Renal profile	1	1	0	3
	Record/Update Liver profile	1	1	0	3
	Record/Update Serological studies	1	1	0	3
Vaccines	Record/Update Vaccines	0	0	0	3
Notifications	Record/Update Notifications	2	2	0	5
	Notifications visualization	2	2	0	5
Medical appointments	Record/Update Medical appointment	0	0	0	3
	Medical appointment visualization	0	0	0	3
	Record/Update Symptoms and vital signs	1	1	0	3
	Record/Update Sexual health	1	1	0	3
Physical examination	Record/Update Physical exam	1	1	0	3
	Record/Update Diagnosis	1	1	0	3
	Physical exploration visualization	1	1	0	3
Medical note	Medical note visualization	2	2	0	5

5.3 System Integration Test

The integration tests were conducted to verify the correct flow between the mobile web application, corresponding to the specialist doctor, and the native Android application, corresponding to the patient, see Table 4. For these tests, three iterations were performed by a doctor and two patients, testing each module with different data in different scenarios of connection to the server and internet access by the Android application. In the first iteration, compatibility, and data synchronization errors were found between the two applications, which were corrected. Later in the second iteration, errors were identified in synchronization between the modules that consumed REST services and were corrected. Finally, in the third iteration, no errors were detected.

Table 4. System tests summary

Rol	Errors found	Errors Solved	Errors Pending	Iterations
Web application	25	25	0	3
Native application	8	8	0	3
Complete system	3	3	0	2

6 Conclusions and Future Work

This work presented the analysis, design, and implementation of a telemonitoring system focused on the supervision, control, and treatment of patients with HIV. Our

system is integrated with two mobile applications: a native Android application that provides diverse patient-oriented services and a mobile web application aimed at medical specialists. Our system is characterized by offering patients and doctors services such as viral evolution, risk alerts, patient examination history, medication reminders, appointments, exams, and monitoring of the vaccination scheme, among others. These services contribute to achieving continuous monitoring and motivating therapy adherence by the patient. They also allow a suitable therapy adjustment by the medical staff before abnormal symptomatology of the patient, a permanent telemonitoring of the treatment by the specialist doctor, and the early detection of risk situations and adverse events. The services developed in both applications were reviewed and validated by a specialist in charge of the care of HIV patients at a General Zone Hospital of the IMSS of Veracruz North region, who also contributed to the analysis and the list of requirements initially requested. In the analysis phase, we considered specialized documents and guides from the World Health Organization (WHO) and the Joint United Nations Program on HIV/AIDS (UNAIDS); hence, our system is aligned with international standards. It is also noted that the analysis and design models composed of the use case diagrams, and component diagrams could be used as a basis to extend the services and technologies of both applications. As future work, we propose a field study to assess the application by users (doctors and patients) and identify the application's utility in the therapy adherence rate, medical monitoring, and the incidence of adverse events.

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