SIMONE - Neonatal Monitoring System. An Open Source Solution in Health Care from R+D+i

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Abstract. In Neonatal Intensive Care Units, the proclivity to error and the occurrence of adverse events is even greater, given the greater vulnerability of newborns. From the General Dr. José Penna Interzonal Hospital, a combined strategy was developed to reduce the incidence of safety problems in neonatal care. One component in the strategy is the safety checklist (LVS). The LVS constitutes a tool that facilitates the review of critical processes in patients and facilitates the detection of safety problems. The LVS developed for the Neonatal Intensive Care Unit of Hospital Penna was complemented with the implementation of a neonatal monitoring system called SIMONE. It has the safety checklist, a system of alerts and patient management. This application provides speed and simplicity to the task of daily check-up and storage of information for future analysis and is available an open source solution in health care from R+D+i. Although the use of safety lists is not new, its implementation through an open source and free-use software system, developed by an inter-disciplinary team, positions this proposal as one of a kind.

Keywords: innovation, health care, free and open source solution

1 Introduction

In Neonatal Intensive Care Units (NICU), the proclivity to error and the occurrence of adverse events is even greater, given the greater vulnerability of newborns who require admission and the complexity of the care they require. From the General Dr. José Penna Interzonal Hospital (Penna Hospital), a combined strategy of dissemination and integration of a comprehensive package of safety interventions was developed to improve the climate, acceptability and willingness of the team to participate in its implementation and reduce the incidence of safety problems in neonatal care. One of the pillars of this strategy is the development of a safety checklist (LVS for its spanish meaning *Lista de Verificación de Seguridad*). The LVS constitutes a tool that facilitates the review of critical processes in patients and facilitates the detection of safety problems. They have been widely used in surgery and obstetrics and recently, in the NICU. So far, all LVS usage was done through paper and pen. This method proved to be inefficient and demotivating for the staff. The NICU staff from Penna Hospital approach the Department of Computer Science and Engineering at University of the South (DCIC-UNS) to see if it was possible to develop a software solution to help the LVS application. The objective was to have an application that not only allowed to use the LSV but also that was motivating for the work of the staff . This project was accepted by the DCIC-UNS as part of its work on software innovation and community services. As a result, an open source system called SIMONE (*SIstema de MOnitoreo NEonatal*) was design and develop. SIMONE has the safety checklist, a system of alerts and patient management. The application provides speed and simplicity to the task of daily check-up and storage of information for future analysis. The definition, design and implementation of the application interactions with the user were done under a User Centred Design strategy ([4]) and with consideration of the work done by Johnson et. al in [10]. This solution was created as the thesis of two student under the direction of two research professors and the collaboration from the Penna Hospital's staff and a researcher for the Economy Department.

This article details and describes the experience and the design and development process of SINOME, as a research, development and innovation project in collaboration with a heterogeneous team. The remainder of the article is organized as follows. Next section, "Motivation", presents the research done and the solutions currently available for LVS implementation. Then, in section "Proposal & Implementation" our solution is presented and details are given on how it was developed. The set of interaction available is also described. In section "Validation" we present the test cases done to probe the effectiveness of the application. Finally, in the last section, we draw some conclusions and outline future work.

2 Motivation

Based on the dissemination of the results of several studies that show the magnitude and impact on health of adverse events (AE) attributable to medical care, several international organizations have focused their agenda on the topic of patient safety ([7], [13], [1]. [14]). One of the first studies on the frequency and type of AE in hospitalized patients was the Harvard Medical Practice Study, conducted in the United States and published in 1991 ([3]). In this study, the incidence of AE, defined as injuries directly attributable to medical practice, was investigated. The AE identified within this group were those preventable errors occurred due to inadequate care or negligence. Out of a total of 30,122 clinical records selected at random, 3.7% AE were found; of these (1133 adverse events), 58% were considered preventable errors. Considering the total population sampled (2,700,000 hospitalizations), it was estimated that the number of AE in hospitals would amount to approximately 98,000 cases. The Harvard study had an important political and scientific impact. Based on their results and the study conducted at UTA-Colorado ([16]), researchers from the US Institute of Medicine estimated the number of US citizens who would die in hospitals because of errors in care. These projections were published in the book "Err is human" ([7]), published in 1999, which had a very large impact on politicians, officials, health sector professionals, and even the general public, and put Patient Safety as one of the priorities of health policies.

After the Harvard study, several investigations were conducted with the objective of describing the epidemiology of AE in hospitalized patients. When analyzing their results, it is observed that the frequency of adverse events varies between 2.9 and 16%. In Argentina, one of the first studies of these characteristics was conducted in the city of Bahía Blanca, in a private hospital ([13]) in 2004. In total, out of 459 clinical records 133 (29%) were found with potentially AE. In 61 hospitalizations, at least 1 AE was observed, representing a rate of 13.3%. In 2006, in this same city, another study ([1]) was carried out that applied the same methodology in the Intensive Care Unit of Penna Hospital in Bahía Blanca. In this case, 484 clinical histories were included, finding 146 AE in 82 hospitalizations (16.9%). More than 90% were considered preventable. The most frequent adverse events were intrahospital infections, events related to catheter management and extubations. The probability of adverse events was inversely associated with birth weight and gestational age; directly with the hospital stay (was greater to longer stay) and with the type of hospitalization (major in intensive care).

The LVS constitutes a tool that facilitates the review of critical processes in patients and facilitates, and in consequence the detection and prevention of AE. They have been widely used in surgery ([12]) and obstetrics ([17]) and recently, in the NICU. In 2016, a group of professionals from Spain ([15]) developed and implemented an LVS for the review of care processes for hospitalized newborns. The compliance rate of application of the LVS was 57%, detecting 4 incidents for each patient admitted. The most frequent incidents were those related to medication, followed by inadequate settings of monitor alarms and infusion pumps. 75% of the staff considered the LVS useful or very useful; seven out of ten professionals from the NICU thought that the LVS had managed to avoid some EA, showing, in 83%, satisfied or very satisfied with the use of the tool.

Current implementations of LVS ([6], [5], [11], [8]) are limited to the use of paper and pencil for information gathering. This generates a discomfort in the staff due to the large amount of information that must be revealed and its presentation on paper. In addition, the use of paper also generates an extra workload when dumping information into a database for further analysis.

The use of software, intuitive and easy to use, for the implementation of the LVS is an extremely attractive idea. If we combine this with the use of mobile devices, such as tablet it is possible to achieve a satisfactory solution. This state of the art on LVS implementation and the requirements established by the Hospital Penna staff to the DCIC-UNS were the motivation for the development of SIMONE. From the survey carried out, we did not find a history of similar implementations to SIMONE in the context of medicine.

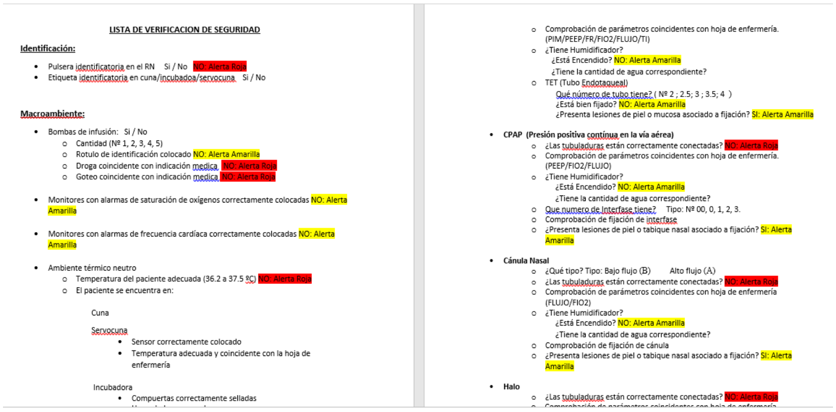
3 Proposal & Implementation

When talking about Human Computer Interaction ([9]), we can say that it is a discipline that relates to designing, implementing and evaluating interactive systems for human beings. It is responsible for studying the hardware, software and the impact on interaction. The ability of users against the system with which they interact, the tasks performed by the system and its adaptation to needs towards the recipients. Also the design directed and focused on users, as well as the organizational impact. The graphical user interface makes the system tangible to the user and allows him/her to communicate what he/she wants to do to with the system. Understanding how people work and make use of the systems and transfer this understanding to the software design and development results in a more efficient, effective and safe interactive system ([2]).

The LVS defined by Penna Hospital staff is a 4-page document (Figure 1) that contains 25 questions, many of which generate new questions based on the answer given. The team's job was to transform this document into a series of intuitive and easy-to-use screens, in addition to incorporating functionality that would increase the utility of the system. From interviews with hospital staff it was determined that the extra functionality that should be offered in the system was an alarm system and a single patient registry. A priority objective of this development was to maintain this development as freely available for those who require it and open source.

We chose a simple design, keeping the screens simple and easy to understand (Figure 3). The questions of the LVS were migrated to the application. Many questions should be answered only when specific answers to other questions have been given. If the nurses had been working with paper and pencil all the questions should have been displayed at the same time. However, having a dynamic environment such as software on a mobile device, it was possible to hide these questions and simplifying the design of the screens. Only when it is necessary to show them is that they appear on the screen. Any new question that appears, does it with a transition and animation easy to see but that does not take long.

The SIMONE application was developed specifically for tablets with Android operating system. It was decided to develop it only for Android devices since the hospital had tablets with this system, and has no plans in the future to obtain a tablet with a different system. All the code of the application was written in Kotlin language. The main advantages of this language over others like Java is that it requires fewer lines of code and is more secure. Any portion of code



LISTA DE VERIFICACION DE SEGURIDAD

Identificación:

- Pulsera identificatoria en el RN Si / No NO: Alerta Roja
- Etiqueta identificatoria en cuna/incubadoa/servocuna Si / No

Macroambiente:

- Bombas de infusión: Si / No
  - Cantidad (Nº 1, 2, 3, 4, 5)
  - Rotulo de identificación colocado NO: Alerta Amarilla
  - Droga coincidente con indicación medica NO: Alerta Roja
  - Goteo coincidente con indicación medica NO: Alerta Roja
- Monitores con alarmas de saturación de oxígenos correctamente colocadas NO: Alerta Amarilla
- Monitores con alarmas de frecuencia cardíaca correctamente colocadas NO: Alerta Amarilla
- Ambiente térmico neutro
  - Temperatura del paciente adecuada (36.2 a 37.5 ºC) NO: Alerta Roja
  - El paciente se encuentra en:

    Cuna

    Servocuna
    - Sensor correctamente colocado
    - Temperatura adecuada y coincidente con la hoja de enfermería

    Incubadora
    - Compuertas correctamente selladas

- Comprobación de parámetros coincidentes con hoja de enfermería. (PIM/PEEP/FR/FIO2/FLUJO/TI)
- ¿Tiene Humidificador?
  ¿Está Encendido? NO: Alerta Amarilla
  ¿Tiene la cantidad de agua correspondiente?
- TET (Tubo Endotaqueal)
  Qué número de tubo tiene? (Nº 2 ; 2.5; 3 ; 3.5; 4)
  ¿Está bien fijado? NO: Alerta Amarilla
  ¿Presenta lesiones de piel o mucosa asociado a fijación? SI: Alerta Amarilla

- **CPAP (Presión positiva contínua en la vía aérea)**
  - ¿Las tubuladuras están correctamente conectadas? NO: Alerta Roja
  - Comprobación de parámetros coincidentes con hoja de enfermería. (PEEP/FIO2/FLUJO)
  - ¿Tiene Humidificador?
    ¿Está Encendido? NO: Alerta Amarilla
    ¿Tiene la cantidad de agua correspondiente?
  - Que numero de Interfase tiene? Tipo: Nº 00, 0, 1, 2, 3.
  - Comprobación de fijación de interfase
  - ¿Presenta lesiones de piel o tabique nasal asociado a fijación? SI: Alerta Amarilla
- **Cánula Nasal**
  - ¿Qué tipo? Tipo: Bajo flujo (B) Alto flujo (A)
  - ¿Las tubuladuras están correctamente conectadas? NO: Alerta Roja
  - Comprobación de parámetros coincidentes con hoja de enfermería (FLUJO/FIO2)
  - ¿Tiene Humidificador?
    ¿Está Encendido? NO: Alerta Amarilla
    ¿Tiene la cantidad de agua correspondiente?
  - Comprobación de fijación de cánula
  - ¿Presenta lesiones de piel o tabique nasal asociado a fijación? SI: Alerta Amarilla
- **Halo**
  - ¿Las tubuladuras están correctamente conectadas? NO: Alerta Roja

Fig. 1. .The original LVS created by the Hospital Penna staff. It contains 25 questions, many of which open new questions based on the answers.

written in Kotlin is much smaller than that written in Java, since it is less verbose. And as we all know: "less code means fewer bugs." Therefore, less time spent on programming and savings in development and testing time.

Kotlin is safe against NullPointerException. All null situations in the code are warned at compile time. The developer must explicitly specify to the language that an object can be null, and then check its nullity before using it. The null references are controlled by the type system, and will verify if the code contains a null instantiation, avoiding the dreaded NullPointerException.

For the storage of the data, it was decided to use "Firebase Realtime Database". Firebase Realtime Database is a NoSQL database hosted in the cloud that allows users to store and synchronize data in real time. This database works in real time so the changes will be displayed instantly. These are stored in JSON format and rules can be added to allow requests with token or only from a URL for example. When using Firebase Realtime Database, it is no longer necessary to use web services, REST APIs, etc., which greatly reduces the development time.

A small script for Google Sheets was generated to export the data. The script is responsible for loading the data and inserting it into a spreadsheet. The script generates a menu on the spreadsheet with 3 options (Figure 2), each one to load the patient list, check-ups or alerts.

For the management of the users, another Firebase service was used: Firebase Authentication. Firebase Authentication provides easy-to-use backend services, SDKs, and ready-made UI libraries to authenticate users in the application. It supports authentication using passwords, phone numbers, popular federated identity providers, such as Google, Facebook and Twitter. The firebase panel provides an easy way to administer to the users, where the hierarchical staff of the hospital can add users, change their password, or unsubscribe them.

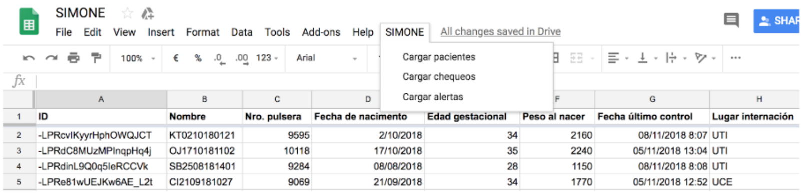


Fig. 2. .To facilitate and simplify access to the information surveyed a small script for Google Sheets was generated to export the data. The script is responsible for loading the data and inserting it into a spreadsheet. The script generates a menu on the spreadsheet with 3 options each one to load the patient list, check-ups or alerts.

3.1 Alert System

Taking into account the occurrence, severity and possibility of detection of faults (with a scale of 1 to 10), the alert system was designed. For each failure mode (response indicating a risk), an RPN (risk priority number) was calculated and, from this, the following types of alerts were defined:

- Red Alerts: those with an RPN greater than 100.
- Yellow Alerts: those with an RPN between 75 and 100.
- White Alerts: those with an RPN less than 75. These are not displayed until the moment of saving the check.

When the user save the check, a message is displayed with the alerts generated. In the patients view, a summary of the recorded alerts is provided (Figure 4).

3.2 Unique record system per patient

A patient registration system was implemented within SIMONE, which allows registering a patient based on the following data:

- Name: for greater privacy, it was decided that in this field only the initials of the patients will be entered.
- Bracelet number: the wristband identification number of the patient.
- Birth date
- Gestational age
- Birth weight
- Place of hospitalization: it can be ICU (intensive care unit) or SCU (special care unit)

In turn, within the application the user can access a screen with patient information (Figure 4). In this the user will see the data and a summary of the last 5 controls that were made. It should be clarified that the patient's data can be edited at any time.

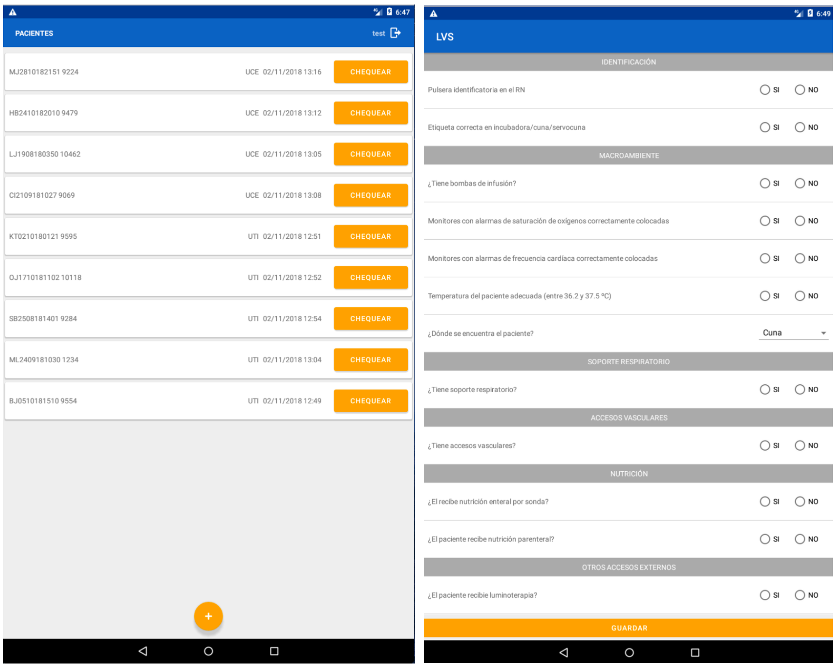


Fig. 3. .On the left we can see the SIMONE home screen where you can see all patients currently hospitalized. By touching on each patient you can access a summary of the checks made with the LVS. Touching the button starts a new check. On the right we can see the screen of a check by LVS.

Each row of the list shows the date and time the control was performed, the name of the user who carried out the control, and the number of alerts of each type. When the user touch a control, a detail of the generated alerts is displayed along with the control comment if there is one.

4 Validation

For the evaluation of the application, a live test was performed at the Penna Hospital (Figure 5). In it, a tablet was delivered to hospital staff with the application already installed and they were told to use SIMONE without any prior explanation. This allowed us to evaluate not only the functionality of the system but also its usability.

The hospital staff created a test patient in the system and carry out a LVS check with SIMONE. For this, a baby doll specially used for nurse training was used. After this, a real patient control of the hospital was performed using our solution. At the end of the test, nurses and hospital staff were satisfied. They expressed that the application had been easy to use and intuitive. At the same

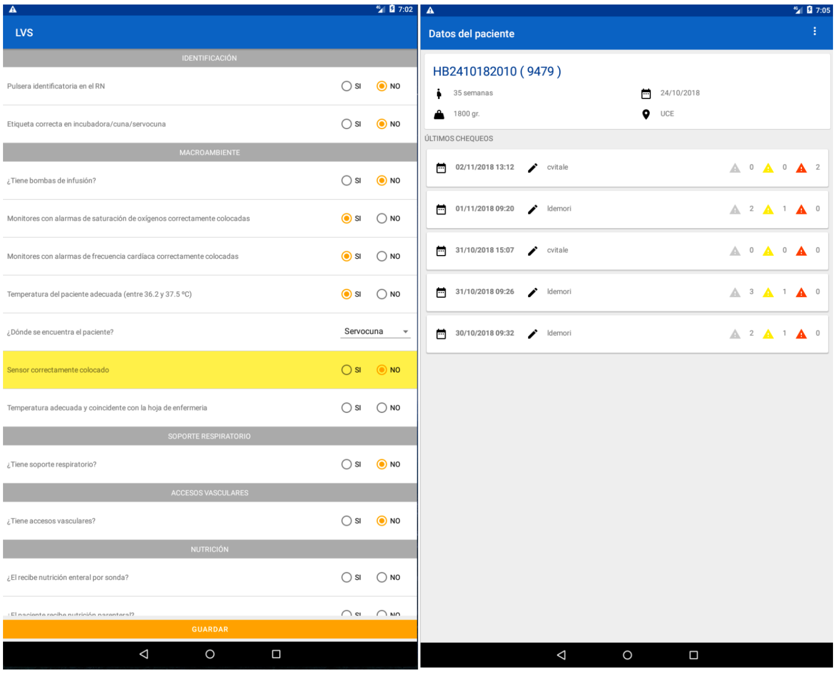


Fig. 4. .On the left we can see a yellow alert, which is visualized when answering the question that generates the alert. On the right we can see the summary of checks made to a patient.

time, they highlighted improvements that could be made to the application, which were implemented in the final version of it.

5 Conclusions & Future Work

It is expected, from this research, to favor the installation of a culture of safety in the Neonatal Intensive Care Unit (NICU) of Hospital Penna and implement a package of interventions, which together, we believe will have a positive impact on the processes of attention and will contribute to reducing the incidence of security-related incidents. This would be the first initiative, promoted by those responsible for the management of the service and with the active participation of several of its members, as well as by members of the academy, who would seek to implement a set of strategies aimed at improving the security of care provided to newborns who are they intern in the Unit. In addition, the research would generate and test different tools for improving safety that could be used by other NICUs. In the case of the detection of security incidents, the LVS have been used by Spanish researchers in NICU of that country, but we do not know similar experiences in Argentina.

Fig. 5. Nurses from the neonatal service of Hospital Penna performing a live test of the SIMONE system, without any prior explanation. At the end of the test, nurses and hospital staff were satisfied.

The integration of SIMONE to the care practice would contribute to standardize the attention processes and increase the motivation of people to participate. In turn, the interesting thing about this initiative is that SIMONE would not be remain in isolation, but within the framework of a set of security interventions that would link the results of one intervention with another. In this regard, we hope to be able to integrate SIMONE with new procedures that allow its application in different areas of the hospital.

The lessons learned from this experience can undoubtedly benefit other NICUs interested in improving safety, which could replicate the experience and implement the tools developed throughout the investigation. Ultimately, what is intended from this experience, is to implement an intervention that benefits newborns who are assisted in the NICU, with the possibility of benefiting, in the future, other newborns interned in other hospitals to from the replication of the experience carried out in this hospital. With this objective in mind, SIMONE is freely available and open source. It is only necessary to contact the authors of this work to obtain a copy of it.

Finally, we are currently working on an extension of SIMONE that allows a visualization of the registered information as a dashboard.

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