

Functional Requirements and Conceptual Design for a Computerized System of Traceability of Medical Equipment for Nursing

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Abstract

Currently, healthcare uses very complex medical equipment, particularly for life-support. Although medical equipment helps to improve care, it is not without risks; events can occur as a result of failures, malfunction or user error. The Department of Biomedical Engineering is responsible for the management of medical equipment in Hospitals to guarantee safety and quality in patient care; nursing is not involved in this process. This paper proposes a methodology to identify the functional requirements to design a computer system, called Nursing Medical Equipment System (NMES) to support the traceability of maintenance, training and monitoring of medical equipment; to comply with one of the four-pronged approach policy concerned to medical equipment use, issued by the World Health Organization.

A survey was conducted among 24 nurses from Intensive Care Units of three hospitals, from this survey and additional information provided by the Department Biomedical Engineering, the software components were designed. The conceptual design was based on the unified modeling language methodology and a three-tier architecture (client-server model) was proposed for its implementation. NMES consists of the following modules: inventory, track work order, maintenance logbook, quick

reference, and technovigilance. NMES supports nursing staff to get involved in the functioning status of medical equipment, raise awareness in the nursing staff regarding the importance of having technical support from the DBE in their daily work process, in order to contribute to the continuous improvement of care delivered to patients.

Index terms: health informatics system, medical equipment, traceability, nursing, biomedical engineer.

Resumen

(Requerimientos funcionales para el diseño conceptual del sistema automatizado para la trazabilidad del mantenimiento equipos médicos)

Actualmente, la atención médica utiliza equipos médicos complejos, particularmente para el soporte de vida. Aunque son una ayuda para mejorar la atención médica, no están exentos de riesgos; los cuales pueden ocurrir como resultado de fallas, mal funcionamiento o errores de usuario. El Departamento de Ingeniería Biomédica (DBE, por sus siglas en inglés) es responsable de la gestión del equipo médico en los hospitales para garantizar la seguridad y la calidad en la atención al paciente, sin embargo, enfermería no está involucrada en el proceso. Este artículo propone una metodología para identificar los requisitos funcionales para diseñar un sistema informático denominado "*Nursing Medical Equipment System*" (NMES, por sus siglas en inglés) para que enfermería lleve a cabo la trazabilidad del mantenimiento, capacitación y monitoreo del estado funcional de equipos médicos; con el objetivo de cumplir con una de las cuatro políticas relacionadas al uso de equipos médicos, emitida por la Organización Mundial de la Salud.

Se realizó una encuesta a 24 enfermeras de las unidades de cuidados intensivos de tres hospitales, a partir de la cual se obtuvo los requerimientos funcionales para el diseño conceptual del sistema basándose en la metodología del lenguaje de modelado unificado proponiendo una arquitectura de tres niveles (modelo cliente-servidor) para su implementación. El NMES consta de los siguientes módulos: inventario, seguimiento de orden de servicio, bitácora, guías de referencia rápida y tecnovigilancia. El NMES permite a enfermería involucrarse con el estado de funcionamiento del equipo médico.

Palabras clave: sistema médico informático, equipo médico, trazabilidad, enfermería, ingeniería biomédica.

1. Introduction

According to the World Health Organization (WHO), Health Technology is defined as "The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives." [1]. On the other hand, medical equipment for human beings, is any instrument, apparatus, implementation, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination [2].

These devices range from a simple technology (i.e. catheters and syringes) to more complex machines (i.e. cardiac output monitor, ventilators or defibrillator) that guide nursing care to patients [3]. Medical equipment is indispensable for diagnosis, prevention, monitoring and treatment of the diseases, in fact, it is more relevant in critical areas, such as the Intensive Care Unit (ICU) or Operating room.

Decision-making in nursing practice should not only be based on experience and knowledge, but also on the understanding of healthcare technology, which helps to detect physiological changes even before clinical symptoms appear.

In addition, medical equipment can prevent errors and adverse events but it can also cause them, therefore, it is necessary to ensure the patient's safety when medical equipment is used. For this you should comply with the guide called "8 correct items for patient": 1) correct patient, 2) correct location, 3) correct time, 4) correct condition, 5) correct procedure, 6) correct anatomical site, 7) correct patient, and 8) correct user [4].

Today, nursing staff must comply the next Four-Pronged Approach (FPA) developed by WHO Medical Equipment and Equipment Team[3], [2], described here after.

- Policy: Nursing must be involved in establishing and evaluating public policy related to technologies.
- Quality and Safety: Nursing must confirm that the technologies they use meet international quality and safety standards and technical specifications needed to perform in the clinical environment in which they are used.
- Access: The institutional decisions are made with Nursing input and from the input of other critical stakeholders.
- Use: Nursing should be involved in the processes regarding related to maintenance, training, monitoring, and reporting adverse events related to technology.

It must be taken into account that not only effective nurse-patient, nurse-physician or nurse-technician communication is important, [5] but also nursing-biomedical engineer interaction

should be close. A poor communication between nursing and the Department of Biomedical Engineering (DBE) staff can contribute to adverse events or other harms when medical equipment is used during nursing care. Usually, there is a communication failure due mainly to the lack of standardization to understand the medical and technical terms, for example, each area names the medical equipment differently, makes its own inventory, as well as, training is inefficient or non-existent, and nursing staff does not know the maintenance process performed by DBE. Insufficient communication, nurse-biomedical engineer, added to poor training can also create problems when nurses are inadequately prepared to fulfill their responsibilities concerning the use or track of device status, maintenance program, and problem identification. These activities are extremely stressful for nursing staff. Communication gaps may also reflect on an engineer's lack of awareness of a problem nursing face to safely use the medical equipment. According to McConnell [6] "the use of medical devices causes more than 75 % of staff nurses to feel stressed; because 11 % had used a medical device that had harmed a patient".

In hospitals where there is a large number of medical equipment, it is a challenge to control (inventory), maintain, and train for optimal, adequate and safely use of that healthcare technology. The DBE has the responsibility to management all the medical equipment in hospital; they are of different brands, risk classes and categories. The most DBEs use a Computerized Medical Equipment Management System (CMEMS), that allows to manage the medical technology and assure efficiency, efficacy and security. Although medical equipment help to improve care, it is not without risks and it can introduce unintentional side effects and failures, if it is not used according to regulatory requirements, manufacturer guidance and security measures [7]. Injury may be attributed to a medical equipment when events occur as a result of failures, malfunction, improper or inadequate design, manufacture and labeling, or user error [8]. The DBE uses a CMEMS to document the history of activities related to the medical equipment -deployment/installation, acceptance, scheduled maintenance: parts & labor expenditures, recalls and other events such as technovigilance documentation [9], [10].

As already stated, nurses must have extensive knowledge and training in the use of medical equipment, its scope, how to detect troubleshooting timely, and even more, they have to know when supplies and/or parts are replaced. In most hospitals, nursing control record of medical equipment, if it exists, is carried out manually, which prevents adequate monitoring of the functional status of the medical equipment by nursing staff [11].

This paper presents a methodology to identify the functional requirements for the conceptual design of a computerized

system of traceability called Nursing Medical Equipment System (NMES) that allows the nursing staff to know the functional status of the medical equipment at any time.

2. Methodology

The first step was to form an expert committee made up of developers, nurses and biomedical engineers. This committee proposed how to design and develop the NMES.

The conceptual design consisted of three stages: The first stage focused on the identification of the Functional Requirements (FR) and the Non-Functional Requirements (NFR) of the system. This task is fundamental because FR define who the users (nurses and biomedical engineers) are, what users require, and thus, generates in a consistent and compact manner the specifications that describe what the system will do. NFR determine the quality attributes of system, such as security, availability, storage and efficiency.

A Medical Equipment Management Questionnaire (MEMQ) of 150 items was designed to identify the FR. The questionnaire is divided into five modules: 1) demographic data (DD) of 7 items;

gender (female or male), age, education (undergraduate, postgraduate or specialty), hospital name, position (Chief Nurse Officer, Nurse Practitioner, Bedside Nurse), experience in ICU (years), and work shift (standard, afternoon, night). 2) Information on the type of training concerning medical equipment (TME) of 12 items. 3) Level of Knowledge of medical equipment (KME) of 114 Items. 3) Management method for nursing planning (NP) of 6 Items, regarding the use and control of medical equipment. 4) Level of communication between nursing and biomedical engineering (NCBE) of 15 Items, and, 5) knowledge about technovigilance (T) process implemented in México integrated of 3 items, includes questions about the Mexican norm NOM-240-SSA1-2012 and the role of the COFEPRIS (acronym Spanish Comisión Federal para la Protección contra Riesgos Sanitarios means Federal Commission for the Protection against Sanitary Risk). Table 1 shows the purpose of the five sections of the MEMQ.

The second stage consisted of the identification of FR, for which, literature research, brainstorming and interviews & application of the MEMQ surveys were carried out.

For to know the survey sample size, the formula used was the equation 1:

Table 1. Medical Equipment Management Questionnaire (MEMQ).

TRAINING
The training for Nursing has as purpose to present the operation, care and safety for both patient and user (Nursing, physicians, technicians), and also, supplies needed to the operation. This section collects information about how nurses learn about medical devices.
LEVEL OF KNOWLEDGE ABOUT MEDICAL DEVICES
Knowledge about medical devices operation allows the Nursing staff to act on the management of medical devices. This section asks about the knowledge of five devices that are used in the ICU.
MANAGEMENT METHOD
Nursing planning (NP) in the ICU for both medical devices and their supplies is important, because it affects in the care quality provided to the patient. In this section, Nursing indicates the management method.
LEVEL OF COMMUNICATION WITH BIOMEDICAL ENGINEERING
The goal of the DBE is to maintain the optimal functioning of medical equipment, so that Nursing staff can provide quality care to patient in the ICU. This section asks to Nursing staff about the communication with the DBE.
LEVEL OF KNOWLEDGE ABOUT TECHNOVIGILANCE
The purpose of doing technovigilance is to ensure that medical devices operate in accordance with the manufacturer's intended use. Three questions are formulated to inquire about this subject:
1) Do you know the NOM-240-SSA1-2012 standard?
2) What is an adverse event?
3) How is COFEPRIS notified of adverse event caused by medical equipment?

Source: Quiroz, Gutiérrez and Bernal.

$$n = \frac{NZ^2p(1-p)}{NZ^2p(N-1)\varepsilon^2 + Z^2p(1-p)} \quad (1)$$

where

$$N=66$$

$$Z=1.65$$

$$p=0.8$$

$$\varepsilon=0.10$$

thus $n = 24$.

The sample size was 24, where N is the universe of nurses. The survey was applied in the Intensive Care Unit of the 3 Hospitals. The survey was validated by a committee of experts, in order to identify relevant FR elements. The nominal scale was used as method to validate the measurement.

At the third stage, the expert committee proposed the conceptual model of the system based on the information & analysis of the surveys. The static structure and the dynamic behavior define the conceptual design by means of use cases, classes, and sequence diagrams. To ensure effectiveness, usability and avoid fail of the entire system, the development was based on the iterative method and incremental build.

A three-tier architecture (client-server model) was proposed to implement the NMES, in which, the graphical user interface (GUI) is the presentation layer, the functional process logic (application logic rules layer), and data management (data access layer) are developed and maintained as independent modules [12]. Through the GUI, multimedia content is accessed, such as text descriptions, illustrations and interactive pages of the system, as well as functional elements of navigability. The GUI was implemented in hypertext preprocessor (PHP) programming language for web application.

Data exchange such as name, serial number, control ID and equipment model is essential for the CMEMS to authorize NMES to share data. They must be interoperable, that is, their communication interface must use the same standard communication protocol and specific data. Once the NMES sends the device ID to CMEMS, the authorized nursing staff can access to system.

In addition, techniques as firewalls, encryption, data encapsulation and role assignments were considered to guarantee quality attributes such as security, confidentiality, integrity, availability, reliability and performance. Three user profiles were considered; the administrator, the manager (Chief Nurse Officer) and the general user (Nursing and Biomedical Engineering staff).

The data obtained from the MDMQ were analyzed using descriptive statistics (average and standard deviation, percentage of cases) through SPSS v. 17 software.

3. Results

MEMQ was applied to 24 nurses of ICU of three Hospitals, two public and one private (Instituto Nacional de Rehabilitación, Instituto Nacional de Neurología y Neurocirugía, Hospital Ángeles de México). 75% of respondents were women and 25% were men with an average age of 36.24+/-11.41 years, and an average experience of 9.04 +/-7.99 years working in the ICU. 33.33 % are technicians in nursing, 29.17% have a graduate degree, 20.83 % have a specialty, 12.50% have a PhD, and 4.17% did not specify their schooling; 25% work in the morning shift, 37.5% in the evening shift, and 37.5% in night shift.

Figure 1a shows the means by which nurses learn to use the medical equipment. Training provided by the product specialist (83%) is what contributes most to the knowledge of the device, and self-learning (8%) the least used. NP activities related to the control and supervision of medical equipment, demonstrated that, 88 % of ICUs have an inventory, 79 % used a logbook, 83 % of communication between shifts was verbal and only 8 % used a computerized program to record, analyze and graph data (e.g. Microsoft® Excel), as can be seen in figure 1b.

Regarding being aware of preventive maintenance programs of medical equipment, NCBE outcomes show that nursing staff participated few in its programming (only 29 %), the DBE support was 71 % for the workday, but no biomedical engineer was on the night shift. 9 of 24 nurses (37.5 %) work at night, therefore they do not have the support of the DBE. To investigate the level of nursing knowledge about medical equipment, it was proposed to examine six devices used in the ICU, focusing on seven critical issues; operational principles, precautions, safety, regulation, operational failures, care & cleaning procedures and technovigilance process. Table 2 shows the questions for each section and the results for each device (vital sign monitor, electrocardiograph, defibrillator, capnography, ventilator, cardiac output).

Regarding the principle of operation, knowledge ranges between 54 % and 63 %. We observed that vital sign monitoring was the device that nurses most commonly use and know, however, as the medical equipment is more specialized and complex, the level of knowledge decreases up to 71 %, since it demands a high degree of knowledge both for its operation and range of measurement. For questions about precautions, we made a subdivision, classifying the devices into monitoring and life-support equipment: the

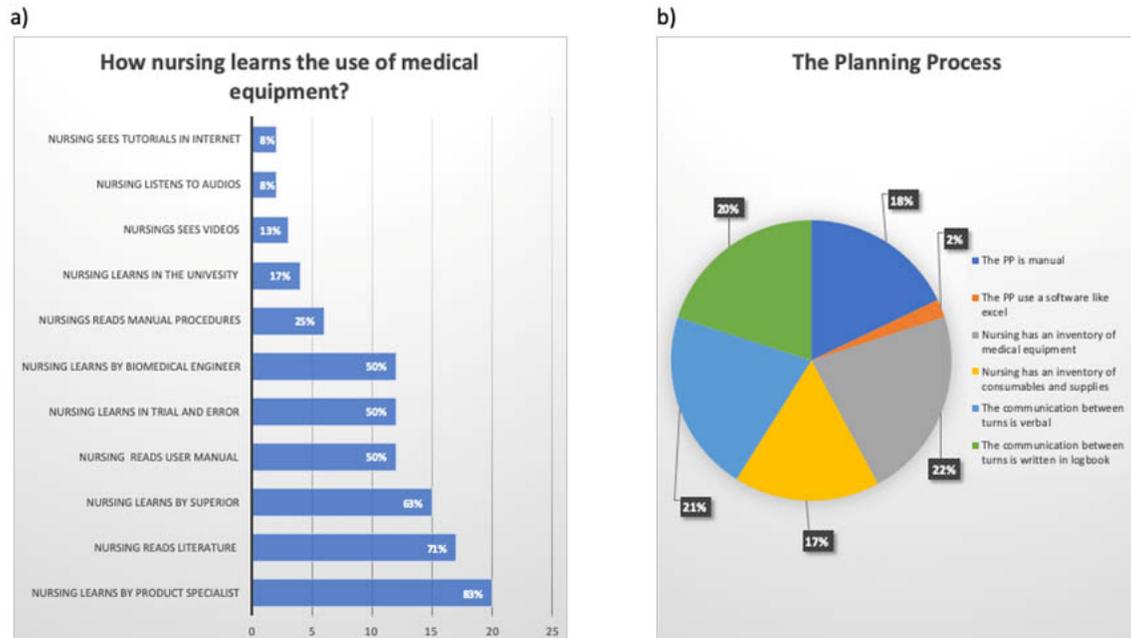


Fig. 1. a) Graph shows how nursing learns about the use medical equipment, b) The Planning Process respect to track of medical equipment by nursing staff is depicted in the pie chart. Source: Quiroz, Gutiérrez and Bernal

defibrillator and the ventilator belong to the latter. We observed low percentage of knowledge of use for the defibrillator, although it must be considered that this is not critical because the nursing staff is not responsible for using it. In terms of care & cleaning, we observed that it is necessary to reinforce this task to avoid cross infections due to poorly disinfected transducers and other parts of the equipment used between clinical procedures.

Finally, with regard to technovigilance, three open questions were asked. 7 of 24 surveyed answered that they knew about the NOM-240-SSA1-2012 but only 2 understood it. Only one nurse knew that it is an adverse event two how to notify COFEPRIS and 54 % of nurses did not know how to document them. In summary, there is low level of knowledge about quality, security and normativity in technovigilance.

4. Proposed functional requirements

Based on the analysis of the results of the MEMQ survey, the NMES's FR were established, giving rise to the following five modules:

- 1) The Inventory Module (IM) is a complete list of the medical equipment data, such as name, brand, model and functional status. Only the nurse assigned to a specific clinical area can access to the medical equipment information of that area.
- 2) The Tracking Work Order Module (TWOM), nurses can monitor the functional status of the device and send a report and service request to DBE.
- 3) The Maintenance Logbook Module (MLM) is composed of fields data about the service history of the medical equipment.
- 4) The Quick Reference Module (QRM) allows access to manuals and user guides of medical equipment assigned to a specific medical area.
- 5) Technovigilance Module (TM) is implemented to assist nursing activities identifying potential risks, take effective measures to protect the health of patients and user, send notifications, perform registration and systematic

Table 2. Level of nursing knowledge about Medical Equipment of ICU.

	Vital Sign Monitor (n/N%)	Electrocardiograph (n/N%)	Defibrillator (n/N%)	Capnography (n/N%)	Ventilator (n/N%)	Cardiac Output (n/N%)
OPERATING PRINCIPLES						
Do you know how to use it?	100	96	92	83	83	71
What is its purpose?	100	83	92	92	92	83
Do you know the operating principles upon which the device is based?	58	58	63	54	54	58
Do you know the measurement range?	96	83	75	71	71	67
Do you know the factors that affect the measurements?	96	83	100	79	79	79
Do you know the function?	100	88	88	88	92	83
Do you know the indications to use it?	96	67	79	54	54	63
PRECAUTIONS						
Do you know the factors that affect the measurement?	96	75	100	71	71	67
Do you know the limitations?	75	58	63	58	58	63
Do you know what you should check to verify it works as expected?	79	63	79	58	58	54
Do you know the contraindications to use it?	58	63	75	50	50	54
Do you know the anatomico-physiological effects when it is used?	92	79	83	75	75	71
SECURITY AND REGULATIONS						
Do you know about functionality issues concerning patient and operator safety?	88	67	79	58	58	58
Do you know about potential risks of using the equipment towards the user and the operator?	71	75	79	50	50	58
Do you know the national regulations for its use?	33	38	42	29	29	33
Do you know about safety standards?	63	54	58	50	50	50
TECHNOVIGILANCE						
Do you know how to report the functioning issues to Department Biomedical Engineer?	75	63	75	54	54	58
Do you know how to document the adverse events caused by the malfunction?	71	54	54	46	46	46
MEDICAL DEVICE CARE & CLEANING						
Do you know what the care is, including cleaning requirements before using it with the patient?	88	67	75	63	63	63

n = Number of Positive Answer; N = Number of Samples. Source: Quiroz, Gutiérrez and Bernal

evaluation of adverse events to determine their frequency, severity and impact as well as to prevent its occurrence and minimize its risks.

In Table 3, it is shown the information contained by every module.

5. NMES design

The actors of the NMES are: Chief Nurse, (Practitioner and Bedside) Nurse, Administrator and CMEMS. Each actor had a specific role to play in the system (e.g., CMEMS exchange data with NMES), with different hierarchical levels of access. Chief Nurse Officer and Nurses are identified through a user ID, and authentication or authorization is accomplished when the user provides a valid password. When Chief Nurse Officer authorizes a user profile, an account is created for a nurse.

Personal, academic and adscription data such as name, age, degree of academic studies, professional experience and work shift must be registered.

Through the communication interface, NMES sends to CMEMS a request to access to the medical equipment information, such as inventory, operation status, maintenance program, service order, and procurement & disposal date. To retrieve the information, the user selects equipment and automatically it appears: ID, brand, model and serial number, and then the selection is confirmed.

In Figure 2 four screens of the NMES's GUI are shown: 2a) the login screen allows a particular user (Chief Nurse Officer, Practitioner and Bedside Nurse, Administrator) to request access to the system, 2b) the IM retrieves information, such as name, brand, or model of the device, 2c) TWOM, is where you can access options such as service type, service priority,

Table 3. Fields contained by the modules of the NMES.

FIELD	TWQM	IM	MLM	QRM	TM
Service	✓	✓	✓	Na	✓
No. Order	✓	Na	✓	Na	Na
Medical device name	✓	✓	✓	Na	✓
Control number	✓	✓	✓	Na	✓
Localization	✓	✓	✓	Na	✓
Request person	✓	Na	✓	Na	Na
Request date	✓	Na	✓	Na	Na
Service priority	✓	Na	Na	Na	Na
Service Type	✓	Na	Na	Na	Na
Delivery time	✓	Na	Na	Na	Na
Fault description	✓	Na	Na	Na	Na
Model	Na	✓	✓	Na	✓
Serie	Na	✓	✓	Na	✓
Date	Na	✓	Na	Na	Na
ID Report	Na	Na	Na	✓	Na
Alerts	Na	Na	Na	✓	✓
Status	Na	Na	Na	✓	✓
Reporter name	Na	Na	Na	✓	Na
User guide	Na	Na	Na	Na	Na
User manual	Na	Na	Na	Na	Na

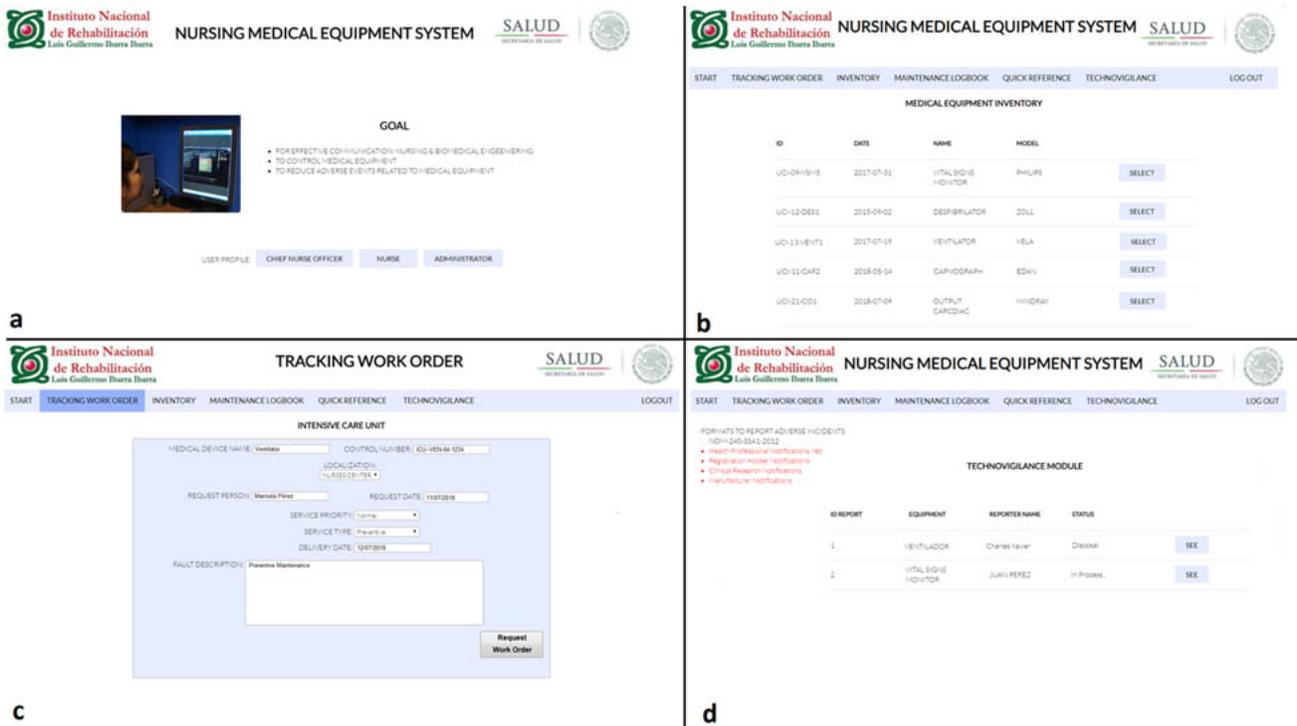


Fig. 2. Four views of NMES are shown. a) Log in NMES, b) Medical Equipment Inventory, c) Tracking Work Order and d) Technovigilance Module.

fault description, inventory, maintenance logbook, quick reference and reports, and 2d) the Technovigilance module allow send notifications.

6. Conclusions

NMES is a computerized system whose objective is to support the tracking of the functional status of the medical equipment, so that, the nursing staff can be involved more efficiently in the processes related to maintenance, training, monitoring, and vigilance, as it is established in the fourth item of FPA policies issued by WHO when using medical equipment in patient care.

Despite this policy, at present some nurses are not yet aware of the importance of knowing and understanding the implications of the use of medical equipment in medical care.

In the literature, we can find computerized systems for standardize nursing practice guidelines, care protocols, and interdisciplinary care plans [13]. The main functions offered by a nursing information systems (NIS) are: patient care, workload assessment, budget management, care assessment, clinical

nursing record; [14] and management of nursing care indicators[15]. The common nursing registers include evaluation of the nursing process, activities and outcomes [16]. None of those systems includes functions to comply with FPA policies regarding the maintenance of medical equipment.

The functionality of NMES supports decision-making related to activities that are directly affected by correct functioning of the medical equipment such as surgeries programming, plan in intensive care or schedule of imaging studies. The communication interface CMEMS to NMES provides information available at the moment that the nursing staff needs it, ensuring the reliability and accuracy of the data. This is crucial, mainly on the night shift when biomedical engineering support is not always available.

The incremental development approach for NMES is based on the functional requirements provide by the nurses, thereby to match their needs and supporting their tasks related to the operation and care of the medical equipment. Determine the baseline requirements before starting the development of the system, it is essential to build a solution, which is improved in each iteration. The proper design of the graphical user interfa-

ce is one of the vital elements that affect the user interactions for any NIS [17].

Further studies are needed to evaluate and verify the efficiency of NMES, to analyze its use and sensitize to nursing staff in relation to the importance of technical support by DBE in their daily work process in order to contribute to the continuous improvement of care delivered to patients.

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