Patient and personnel safety: a techno-vigilance review in Uruguay.

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Abstract: ***Introduction:*** **The medical field has had an exponential growth throughout the last decade, allowed by the development of new biomedical technologies. When facing these devices, the health personnel is challenged and bound to err. Therefore, the health institution has to modify their strategies in order to ensure patient and personnel safety.**

Methodology: **This paper presents a bibliographic review addressing risk management, techno-vigilance and adverse events.**

Results and discussion: **Standards as leadership, infrastructure, training and risk management must be fulfilled by the institution providing healthcare. Reporting is the main tool to ensure safety for the patient as well as the health personnel. Adverse events are preventable and better addressed if these elements are correctly and actively supervised by the institution and by techno-vigilance national programs.**

Conclusion: **Safety culture has to be a public health problem, and it is an issue gaining significance among Latin-America and Uruguay. Adverse events will always occur, but if the situation is tackled by several angles, the outcome is more effective. Therefore, putting into practice a national program of certification for medical devices would be of incalculable aid to assure patient and personnel safety.**

***Keywords*— Techno-vigilance, Latin-America, adverse event, safety, Uruguay.**

Resumen— *Introducción:* El campo de la medicina ha tenido un crecimiento exponencial a lo largo de la última década, permitido por el desarrollo de nuevas tecnologías biomédicas. Al enfrentarse a estos dispositivos, el personal de salud se ve desafiado y puede errar. Por lo tanto, la institución de salud debe modificar sus estrategias para garantizar la seguridad del paciente y del personal.

***Metodología:* Este artículo presenta una revisión bibliográfica que aborda la gestión de riesgos, la tecnovigilancia y los eventos adversos.**

***Resultados y discusión:* Estándares como liderazgo, infraestructura, capacitación y gestión de riesgos deben ser cumplidos por la institución que brinda atención médica. La notificación es la principal herramienta para garantizar la seguridad del paciente y del personal sanitario. Los eventos adversos se pueden prevenir y abordar mejor si la institución y los programas nacionales de tecnovigilancia supervisan estos elementos de manera correcta y activa.**

***Conclusión:* La cultura de la seguridad tiene que ser un problema de salud pública y es un tema que adquiere relevancia en América Latina y Uruguay. Los eventos adversos siempre ocurrirán, pero si la situación se aborda desde varios ángulos, el resultado es más efectivo. Por tanto, la puesta en práctica de un programa nacional de certificación de productos sanitarios sería de una ayuda incalculable para garantizar la seguridad del paciente y del personal.**

***Palabras clave*— Tecnovigilancia, América Latina, evento adverso, seguridad, Uruguay.**

INTRODUCTION

Throughout the years, the evolution of the medical field has had an exponential course. Thus, allowing an increasing life expectancy and better life quality for the global population [1]. Hence this rise in the demand explains what The World Health Organization (WHO) estimates: almost half of current therapeutic advances did not exist 10 years ago [2].

For this fact to take place, numerous biomedical inventions -for example, vascular catheters, vaccines, intra -medullary nails, electrocardiogram- had to be developed and tested to later be introduced to the daily practice of medicine. Furthermore, it is not surprising that when facing new equipment, the number of errors made by the health personnel could be increased due to several reasons such as lack of knowledge and a scarce adjustment of the facility for such devices [3]. In response to this situation, the health system itself was forced to modify and create new strategies in order to control and manage healthcare technology to prevent hazards, then improving patient and personnel safety [3].

In this paper I will focus first on portraying risk management and techno-vigilance in Latin-America, by analyzing the actual situation in Uruguay and including an approach to its adverse events, with the purpose of putting into practice a national program of certification for medical devices.

I. MATERIALS AND METHODOLOGY

The information presented in this paper was acquired by a bibliographic review of scientific studies. Mostly regarding risk management within the hospital environment, associated with the usage of biomedical devices, and therefore with techno-vigilance. They were obtained from platforms like PubMed, Portal Timbó and Elsevier, using as key words: Techno-vigilance, Latin-America, adverse event and Uruguay.

Around 120 papers were found. After reading title and abstract, the ones where the study was too specific for a particular medical device or problem were discarded as the main exclusion criteria. The selected papers converged into a total of 11 from Brazil, Colombia, Peru, Mexico, Spain and Uruguay portrayed in “Fig. 1”.

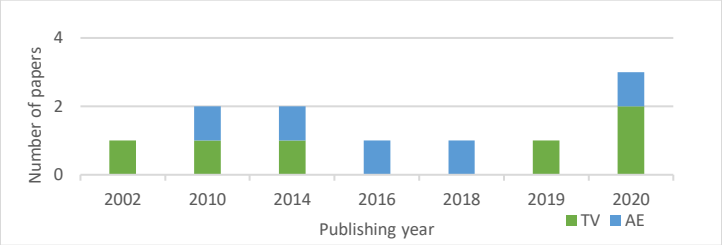

Fig. 1: Stacked bar graph that relates the number of papers found with the year of publication and the subject: Adverse events (AE) and techno-vigilance (TV).

For a better understanding of this paper, it is wise to start defining the foundations that compose it as a tool to later comprehend the results obtained.

A. Medical devices:

Firstly, a medical device is defined by the WHO as any instrument, machine, software or material to be used with specific medical purpose such as diagnosis and treatment [4].

B. Adverse event and Incident:

The usage of a medical device may end in a non-desired event that harms or endangers the life of the patient or health personnel which is known as an adverse event (AE). These AE are grouped in 3 levels: mild, moderate and severe. In which mild does not modify life quality, moderate does temporarily, and severe puts life in danger provoking longer hospitalizations, disability or even death[5]. In addition, when the damage does not occur, it is called a healthcare incident [6].

C. Techno-vigilance:

It is crucial to introduce the main term for this paper: techno-vigilance. Being primarily a group of measures aimed at prevention and evaluation of adverse effects, including potential ones, that could harm the patient, the operator or the facility concerning the use of medical devices [5].

D. Quality control:

One of the most imperative aspects to be evaluated when facing new equipment for a medical institution is quality control. A fundamental requirement that brings about the safety to ensure and fulfill the purpose for which it was made for. What’s more, it is known that the renowned hazards can occur at any circumstance even with known good quality

products. A methodology of evaluation for these medical devices gains importance not only once the error has already taken place but also in the preacquisition fase [2].

E. Risk management:

Risk management is a process that encompasses identifying the menace in order to attain the elimination of the root cause of the healthcare incident. Therefore, attaining the opportunity to communicate its likelihood in order to prevent it accordingly [3]. Risk management has to be integral in an organization, always involving structure and decision-making. Being then communication and consultation -with each of the parts involved- incredibly relevant to sustain it, as it promotes awareness and comprehension earning feedback, respectively [7].

F. Risk management methodologies:

There are several known procedures to apply as risk management strategies such as the Failure Modes and Effects Analysis (FMEA) and the London protocol to name a few [3].

Firstly, the FMEA aims to classify a potential failure concerning the severity of the damage produced by it, during any fase within the lifecycle of the biomedical device. Then it proceeds to analyze the possible consequences. An action plan to avoid failure is where this method starts, where risk priority is a concept that gains significance. To achieve it a calculation has to take place, in which three variables have to be multiplied (Severity, occurrence and detectability of the failure). Each variable takes a value from 1-5 being 1 the lowest risk [3].

Once the priority is calculated, the risk is classified in three categories: Significant (14-24) that can result in death, moderate (8-13) encompassing reversible or small injuries, and finally insignificant failures of the device (2-7) where the harm provoked is of no relevance to the life of the patient or health personnel [3].

On the other hand, the London protocol is a standardized tool mostly used in industries but that has developed experience in the health system throughout the years. It is focused on identifying not only the incident itself, but the series of events that led to it. Thus, it starts with an investigation to elucidate how it happened and why, without judging someone specifically [3]. This method states that for an adverse event to happen, a series of conditions have to be set first, starting with high management decisions that later affect the employees and patients when using the device. The protocol analyzes each part involved separately, looking for unsafe actions and failed barriers in any level of the organization [3].

II. RESULTS

As it was stated in the FNR manual (Uruguayan high-cost procedures state insurance body) referring to the evaluation of standards and tracking of highly specialized medicine centers (“IMAEs”), there are four standards to follow to ensure safety to the patient and health personnel: leadership, training, infrastructure and risk management[8].

In 2004 the FNR together with UDELAR (“Universidad de la República”) accorded that the NIB (“Núcleo de Ingeniería Biomédica”) would take part in techno-vigilance program of evaluation and tracing of IMAEs, reviewing the fulfillment of the standards mentioned above [9].

A. Leadership:

Leadership must have as main role the communication between all parts of the organization. Always aiming to encourage a culture of trust and respect, ensuring a harmonic environment where the personnel can contribute efficiently. The leader must state long-term and short-term objectives and have the ability to change them according to the results obtained in the process. To achieve a successful leadership, the whole team responsible of the area has to include a professional related to it [8]. This was demonstrated by a Colombian study that evaluated 21 health institutions, it showed that in most hospitals the person in charge of techno-vigilance had a professional background related to the field, such as biomedical engineering or pharmaceutical chemistry [3].

B. Training:

Training of the personnel, including non-clinical, is another standard to fulfill and it must be constant to ensure a correct development in the task[8].

This was portrayed in a Brazilian study made in a hospital university in Rio de Janeiro that evaluated health incident voluntary notifications from October 2015 to May 2018. It was shown that an increase in reporting healthcare incidents was influenced by the implementation of periodical educational activities and the creation of a patient safety center in charge of risk management [6].

From another point of view, not only training in patient safety is important, but also in team work between nurses and doctors that come from a different undergraduate formation[10].

C. *Infrastructure:*

The building has to be designed accordingly to the complexity of the procedures and the type of medical assistance provided. It is fundamental to employ architects qualified specifically in hospital environments, always taking into consideration the incorporation of new health technology [8]. The NIB found that among the years (2004-2017) of supervising and detecting defects in the electrical setting, the hazardous equipment and environmental risk decreased, whereas problems regarding risk management emerged [9].

Interviewed nurses stated that a poor place to perform their task has an influence in AE incidence, such as tiny work tables that have to be shared between other nurses at the same time, enabling mistakes due to lack of concentration provided by the discomfort[11].

D. *Risk management:*

To manage risk a series of elements have to be constantly evaluated: not only environmental risks provided by the building itself and equipment, but also the healthcare protocol [8].

A study made in the southwestern region of Colombia in 2017 that evaluated the practices of techno-vigilance and risk management in 21 health institutions, showed that 17 of them used the London protocol whereas 7 used the FMEA. Even when in 2012 the INVIMA ("Instituto nacional de vigilancia de medicamentos y alimentos" of Colombia) set that the FMEA is the most recommended strategy to follow [3]. This was explained by the fact that some institutions were in the process of changing their risk management methodology at the time, so as to be in line with the recommendations. Bringing about one of the cardinal variables regarding risk management: being up to date with the national and international alarms for certain medical devices and methodologies [3].

E. *Reporting:*

In order to prevent risks, adequate reporting of AE becomes the skeleton to support healthcare safety. For a notification system to be useful, all incidents have to be reckoned with, healthcare incidents as well as adverse events [6]. It is known that underreporting is the biggest problem when managing risk in organizations, therefore it has been proved that a culture of voluntary reporting is the best weapon to overcome it [6] [12].

As depicted in a Brazilian study from 2013 that compared voluntary handwritten and computerized reports, fear of punishment and lack of knowledge were aspects that contributed to underreporting, as well as the difficulty in the access to handwritten forms when this method is used [12].

It was concluded that computerized reporting showed certain characteristics that made it a greater tool than handwritten forms, for example, it has 24 hours availability through internet to fill it in, mandatory data fields to complete, it eliminates illegible handwriting and intermediates such as supervisors before the submission [12].

Moreover, a study from Uruguay on 2020 regarding AE reporting in intensive care units (ICUs), compared clinical audit of patient records with handwritten forms, finding 74,7% against 43,9% respectively [13].

It was seen in a Uruguayan qualitative study from 2014 that most nurses did not know how and when to report an AE purely out of lack of knowledge on how to proceed [11].

The Uruguayan health ministry ("MSP") contemplates the notification of AE when they are produced by therapeutic devices[14].

F. *Safety:*

In 2007 a national commission for patient safety and medical error prevention was created under the Uruguayan health ministry wing, making it mandatory for public and private health institutions in 2008[10].

When an AE takes place, the first victim is the patient, the second one is the person in charge of the healthcare assistance for that patient. A Mexican study from 2018 revealed that burnout syndrome within the health personnel had a major influence in AE occurrence, with emotional consequences such as having difficulty to focus on the tasks, anxiety and insomnia [15].

That is to say, a Uruguayan qualitative study from 2014 already addressed this connection by interviewing 12 nurses and 4 nurse supervisors that were involved in an AE, being the lack of adequate rest between shifts and work overload two of the reasons behind the occurrence of the event [11].

G. *Adverse Events:*

A 2016 cross-sectional study involving 58 secondary and tertiary hospitals from five Latin-American countries (Argentina, Colombia, Peru, Mexico and Costa Rica) found that at least 10,5% of the 11379 patients suffered an AE. Around 59% were considered preventable, being the most prevalent AE nosocomial infections by 40%. In addition, it was seen that 6% resulted in death [16].

The more specific and complex the healthcare area is, the easier is for AE to happen[16]. That is to say in Uruguayan ICUs 35% of 174 patients presented at least one AE. The accidental exit of urinary and vascular

catheters, as well as drainage tubes where around 42% of the adverse events, followed by a 40% of unprogrammed extubating and events related to medication by 12,8%[13].

III. Discussion

Healthcare has become more complex by the day due to the numerous medical processes and technological advances within the biomedical field. They support and allow this complexity to grow accordingly to the demand. Latin-America has had a growing interest in patient and health personnel safety addressed by a rising number of papers published throughout the last decade about techno-vigilance and adverse events.

To provide a good service to the patients a safe healthcare environment is crucial. The first step to attempt to achieve this has to come from the institution itself by handling standards as infrastructure, leadership, personnel training and risk management.

It is mandatory that the building fulfills the needs of the patients and staff, especially when a new technology wants to be introduced in the institution as a standard procedure. That is to say, the constant regulation of the electrical settings and comfortable workplace areas have to be a priority, being of great significance to avoid errors easy to commit but of immense magnitude. A suitable professional has to be in charge of the area at hand to ensure a profound understanding of the daily problems that the staff has to undergo during their work shifts regarding medical devices. This leader not only has to have biomedical knowledge, but also be capable of comprehend and guide the personnel when AE takes place, promoting a constant training and reporting in order to improve the culture of patient safety.

Training the health personnel, even non-clinical staff, has to be active and educational. This way it would be guaranteed that if and when an adverse event takes place, the employee directly involved in it knows exactly what to do and where to submit the report. By doing this, the institution would ensure that they have a complete control and can see the bigger picture to then identify and attack the root cause of the adverse event, strengthening their risk management range, making it a more fruitful tool. On the other hand, it could decrease the emotional consequences that the staff suffers after an AE occurred promoting a good work environment and a safe place where mistakes can be made and be fixed without fear of punishment.

Safety culture has to stand over a strong reporting system, where handwritten forms are only one of the roads to report, not the primary one, as it was demonstrated that computerized reports were superior in achieving this goal. It would be advisable to add the audit of medical records too, as it was seen that compared to handwritten forms, they were also a superior tool.

But is it enough with the fulfillment of these standards to ensure patient safety? As it was portrayed in this paper it is of enormous importance to count on a greater organization that provides the guidelines for it, and supervises this hazardous equipment by an active techno-vigilance program. In Uruguay, the program of evaluation and tracing of IMAEs carried out by the NIB is the living proof that a constant surveillance is required to ensure changes in the health institutions.

The MSP has several ordinances regarding notification[17], and supervised the techno-vigilance task portrayed by the NIB, but that is the extent of it. The UTEC (“Universidad tecnológica”) of Fray Bentos, Uruguay, has a project in hands regarding a laboratory specialized in reviewing the medical devices. Thus, to ensure a safely handling by the health personnel when the device get to their hands, and also to analyze it when a problem has been detected while its being used by the operator.

IV. Conclusion

In conclusion, it is indisputably that safety culture has to be a public health problem, and that a road in improvement has been drawn along the years in Latin-America and Uruguay that has to continue to grow. Adverse events are bound to happen, because to err is human, but when a multifaceted situation is attacked by several angles, the results are bound to be more prosperous. Therefore, putting into practice a national program of certification for medical devices would be of incalculable aid to assure patient and personnel safety.

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