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# Patient Safety in a First-Level Hospital in Colombia, According to London Protocol

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## Abstract

The objective of this study is to identify the adherence of the health personnel of the state social enterprise Norte 2 institution, Caloto, Department of Cauca, Colombia, in the application of the London protocol, referring to patient safety policy, where a quantitative investigation was conducted; observational, descriptive through a census of 92 officials of the institution through a survey designed to measure adherence to protocol, all information was tabulated in the Epi-info 7.2 program and presented by descriptive statistics; the results of this study showed that the population is composed of 60% of female nursing assistants who are more than 1-year old and that the protocol is partially met, where it was found that only 52% of adverse events are reported, concluding that there is no defined patient safety culture, which means that adverse events are not documented.

**Keywords:** MeSH and DeCS, adverse event, preventable adverse event, Non-preventable adverse event, London protocol, patient safety policy

## 1. Introduction

Health care over time has become a complex and very careful act, which, in addition to providing users with adequate treatment for their health problems, represents a latent risk since it can cause involuntary damage. This, for obvious reasons, since 2002 the World Health Organization (WHO), requested in Resolution WHA55.18 the member states to pay as much attention as possible to the problem of patient safety [1]. This difficulty being an attenuator over time has become a public health problem that directly impacts the quality of care of users of health services and the fall in their indicators.

This World Alliance, which aims to coordinate, disseminate, and accelerate the improvement of patient safety worldwide, is a means that fosters international collaboration and the adoption of measures among member states, the WHO secretariat, the technical experts and consumers, professionals, and industrial groups [2]. Different studies conducted in our country at different levels of care, such as

the ENEAS study, the National Study on Adverse Effects linked to Hospitalization [3], and the Study on Patient Safety in Primary Health Care (APEAS) [4], have quantified the importance of these effects.

Different investigations have been found in relation to patient safety, where the one carried out by Villareal [5] is found, in Third World countries and in those with transition economy; there is evidence that the probability in the occurrence of adverse events is caused due to the poor state of the infrastructure and the equipment, the quality of the medicines, the irregularity in the supply, the deficiency in waste disposal and infection control, and the poor performance of the staff due to lack of motivation or knowledge is insufficient and due to the serious lack of resources to cover essential operating costs.

Also in 2011, Blandón, Gómez, Muñoz, and Zafra [6] carried out a patient safety audit process from the analysis of the adverse event report at the Francisco Luís Jiménez Martínez de Carepa hospital (Antioquia), where flaws were evident in the fulfillment of the processes related to the prevention of events and where improvement activities were proposed in order to minimize and prevent the recurrence of events highlighting the awareness of all personnel prioritizing those who work in the emergency department on adverse events, in addition to developing improvement plans regarding the control of dangerous conditions in the physical environment.

In 2013, an investigation was conducted on safety culture and adverse events in a first-level clinic [7]; this shows the prevalence of adverse events in nursing staff, where the main errors were the lack of communication and techniques of poor application of medications in nursing staff which affects patients in 29.9% producing an adverse event. In 2014 Meléndez Concepción, Garza, González, Castillo, González, and Hernández [8] conducted an investigation on the perception of nurses towards the culture of safety in a pediatric hospital in Mexico, where the average age of the respondents was 49 years old for men, 91% were women, and 70% were general nurses. Nurses believe that the strengths that are available in the hospital are few and that many things are missing to ensure patient safety.

Poma Vanessa [9] developed an investigation with the purpose of contributing to the improvement of quality and safety in the care of patients of the internal medicine service of the Eugenio mirror hospital in the city of Quito, in 2015, for which it was carried out a parallel between the reality evidenced in the service and the national and international quality standards of process and results structure where it could be established that the institution did not meet the specific criteria in terms of structure and results compared to international standards, so which emphasized the safety culture of internal users as well as of patients as a fundamental axis for continuous improvement, revealing not only the failures of the institution but also the responsibility of the collaborators of the institution.

In the IBEAS study, Colombia specifically showed a prevalence of adverse events of 13.1%, 27.3% of the events occurred in children under 15 years, and 27.7% occurred during the performance of a procedure [10] and where it has been estimated by WHO under its studies that one in 10 hospitalized patients suffers an incident that will cause damage during their stay. Studied in countries with medium and high economies, is not yet known in countries with emerging economies, but it is thought that in these, the magnitude of the problem may be even greater [11], which allows to demonstrate that in general terms, health in Colombia is going through a difficult stage in terms of quality.

For its part, the state social enterprise Norte 2 located in the municipality of Caloto, department of Cauca, is a social enterprise of the state that provides health care of low complexity for around 7000 people living in the municipality. This institution as a company that currently provides health services has found that the patient safety protocol established by the Ministry of Health and Social Protection is not being applied

under the guidelines of the patient safety policy in Resolution 0112 of 2012. In addition to this, health professionals for unknown reasons do not apply the London protocol and generally do not exercise the functions of inspection, surveillance, and control in order to provide reports in a timely manner, to take corrective actions and relevant improvement to mitigate adverse events that are becoming increasingly evident.

The objective of the present investigation is to identify the adherence of the health personnel of the state social enterprise Norte 2 health institution, Caloto, Cauca, during the first quarter of 2019, in the application of the London protocol, referring to the security policy of the patient, to propose an improvement plan according to the results obtained. In this sense, the application of the London protocol in patient safety policy in the state social enterprise Norte 2 health institution is of vital importance, in order to impact on the improvement of the quality of health care as a systematic tool for a continuous improvement defined in the mandatory quality assurance system, increasing its quality of service making it a competitive entity.

In Colombia, the Ministry of Health and Social Protection [12] defines patient safety as the set of structural elements, processes, instruments, and methodologies based on scientifically proven evidence that tend to minimize the risk of suffering, an adverse event in the process of health care or mitigate its consequences. Under the obligatory system of quality assurance of health care, the country, through its components, seeks and promotes a patient safety policy whose objective is to prevent the occurrence of situations that affect patient safety and reduce and if possible eliminate the occurrence of adverse events to have safe and competitive institutions internationally [13].

In addition to this, Resolution 2003 of 2014 [14] dictates the design of processes and procedures focused on the promotion of safe health care, the identification of the risks in health care provided to patients in different services and its prioritization and intervention, the definition of safe care processes, the education of patients and their families in the knowledge and approach of the factors that can influence in improving the safety of the care processes of which they are subjected, and the application of mandatory safe practices, reporting, measurement, analysis, and management of adverse events.

More than a concept, it is a movement that emerges worldwide as a rethinking of the effectiveness of health systems in different countries. Health systems and especially the professionals that integrate it, without a doubt, aim at the well-being of patients; however, despite their good intentions, they can also cause harm [15]. The effectiveness of health systems then depends not only on the impact caused by the improvement of the health of the users but also on the safety conditions in which care is given, which is the *raison d'être* of the patient's safety policy: provide safe and effective care.

According to the Ministry of Social Action [16], the guidelines of the London protocol are taken under the guiding principles of the policy in order to achieve the purpose of establishing safe attention; it goes beyond the establishment of standards; these are only the frame of reference. The commitment and cooperation of the different actors is necessary to raise awareness and promote, arrange, and coordinate actions that really achieve effective achievements. Patient safety problems are inherent in health care. For this purpose it is relevant to establish transversal principles that guide all the actions to be implemented.

Patient safety is presented as a fundamental pillar within the patient safety protocol, which is defined as the set of organizational structures or processes that reduce the probability of adverse events resulting from exposure to the care system. Have medical attention throughout the procedures or diseases [17]. In this way, patient safety is part of a whole set of legal requirements, which must be fully complied with by health professionals, which guarantee that the patient is prevented from any risk present in medical services.



In this regard and under the London protocol in patient safety policy, according to the Ministry of Social Action [18], the guidelines of the London protocol are taken. The guiding principles of the policy are that achieving the purpose of establishing safe attention goes beyond the establishment of standards; these are only the frame of reference. The commitment and cooperation of the different actors is necessary to raise awareness and promote, arrange, and coordinate actions that really achieve effective achievements. Patient safety problems are inherent in health care. For this purpose, it is relevant to establish transversal principles that guide all the actions to be implemented [19]. These principles are as follows:

1. User-centered focus of attention. It means that the important thing is the results obtained in it and its safety, which is the axis around which all the patient's safety actions revolve.
2. Security culture. The environment for the deployment of patient safety actions must take place in an environment of confidentiality and trust between patients, professionals, insurers, and the community. It is the duty of the different actors of the system to facilitate the conditions that allow the said environment.
3. Integration with the mandatory quality assurance system of health care. The patient safety policy is an integral part of the mandatory quality assurance system of health care and is transversal to all its components.
4. Multicausality. The problem of patient safety is a systemic and multicausal problem in which different organizational areas and different actors must be involved [20].

Under the conceptual model and basic definitions of patient safety policy, the following figure shows in a pictorial way the conceptual model on which the terminology used in this document is based, and then the definitions related to the different items raised and used are included in the patient safety policy of the compulsory quality assurance system of health care. It is necessary to integrate international terminology with specificities of the terminology requirements identified in the country [21].

The methods used were designed with the aim of promoting an open environment that contrasts with the traditional ones based on personal accusations and fault allocation. This protocol covers the process of research, analysis, and recommendations. There is no need to insist that the proposed methodology has to be separated, as far as possible, from disciplinary procedures and those designed to address permanent individual poor performance. In health, very often when something goes wrong, bosses tend to overestimate the contribution of one or two individuals and assign them to blame for what happened [22].

This does not mean that the indictment cannot exist, what it means is that this should not be the starting point, among other things, because the immediate allocation of guilt distorts and hinders subsequent serious and thoughtful investigation. Effectively reducing the risks implies taking into account all the factors, changing the environment and dealing with the failures by action or omission of the people. This is never possible in an organization whose culture puts disciplinary considerations first. In order for incident investigation to be fruitful, it must be carried out in an open and fair environment [22].

For its part, the organizational model of causality of clinical incidents is supported under the theory of the protocol, and its applications are based on research conducted outside the field of health. In aviation and in the oil and nuclear industries, accident investigation is an established routine. Safety specialists have

developed a wide variety of methods of analysis, some of which have been adapted for use in clinical care contexts [23].

In this way, they raise the need to conduct the investigation and analysis of incidents (errors or adverse events), which refer to the basic process of investigation and analysis is quite standardized. It was designed with the idea that it is useful and can be used both in minor incidents and in serious adverse events. It does not change if it is executed by a person or a large team of experts. In the same way, the investigator (person or team) can decide how fast he goes through it, from a short session to a full investigation that can take several weeks, including a thorough examination of the chronology of the facts, of the unsafe actions, and of the contributory factors. The decision about the length and depth of the investigation depends on the severity of the incident, the resources available, and the potential institutional learning [24].

And where under the Reason model of causality (Swiss cheese model), belonging to the problem solving and identification models, it works to identify what aspects or decisions of the organization may have been a conditioning factor in an accident and how the organization can learn from an accident, perfecting the defenses in a cycle of continuous improvement [25, 26]. Also called Swiss cheese model, which was raised in order to analyze the possible causes that develop potential risks, the model compares the causes of risk with layers of Swiss cheese, where for an action to be generated, several failures are required to reach this, since, if there is a barrier, that potential cause will undoubtedly not allow it to become damage. It speaks of four factors that contribute to the extent of the damage: insufficient training, poor communication, lack of supervision, and inadequate apparatus [27].

On the issue of safety, the causes identified have been grouped in different ways (organizational causes, equipment, supplies, people, etc.) and specifically on the issue of patient safety. In the United Kingdom, an organizational model for the causality of errors and adverse events (organizational accident causation model) was developed in the context of the so-called London protocol or “systems analysis of clinical incidents—the London protocol” [28, 29]. Among the possible solutions is the fishbone formulated by Ishikawa who was an industrial chemist and a business administrator, in response to the need to implement quality in business processes and services. Through its proposal it is easy to observe the relationship between cause and effect. Mention six components that lead to the problem which are labor, material, method, machine, measuring, and environment [30].

## **2. Materials and methods**

This research is quantitative, observational, and descriptive, and a census was carried out on the 92 officials of the state social enterprise Norte 2, Caloto, Cauca (Colombia, Sur America) institution, under the inclusion criteria: be a worker linked to the institution by employment contract, have the institutional consent of the company, and have informed and understood consent with each of the units of analysis and where exclusion criteria are not contemplated. Study variables such as sociodemographic characteristics, knowledge variables, and improvement variables were taken into account.

The analysis plan of the present investigation had the collection of information through a survey created by the researchers and reviewed by four experts in the field; for the tabulation of the data, the researchers created an instrument to obtain a database in the Epiinfo 7.2 program; this program is a free epidemiological analysis software supplied by the World Health Organization and in which the analysis of results with descriptive statistics was performed. The bioethical component was

aligned in accordance with Resolution 008430 of 1993 and Resolution 0314 of 2018 which regulates ethical responsibilities in research in humans and health institutions, taking into account that the research has a lower risk than the minimum. Complying with Colombian regulations, institutional consent and informed consent were obtained by each participant. The credits of the institution in which the research is carried out are included, according to copyright.

For research the guidelines of the London protocol are taken. The guiding principles of the policy with which, to achieve the purpose of establishing safe attention, goes beyond setting standards; these are only the frame of reference. The commitment and cooperation of the different actors is necessary to raise awareness, promote, arrange, and coordinate actions that really achieve effective achievements. Patient safety problems are inherent in health care. The transversal principles that guide the actions to be implemented are:

1. User-centered focus of attention. It means that the important thing is the results obtained in it and its safety, which is the axis around which all the patient's safety actions revolve.
2. Security culture. The environment for the deployment of patient safety actions must take place in an environment of confidentiality and trust between patients, professionals, insurers, and the community. It is the duty of the different actors of the system to facilitate the conditions that allow the said environment.
3. Integration with the mandatory quality assurance system of health care. The patient safety policy is an integral part of the mandatory quality assurance system of health care and is transversal to all its components.
4. Multicausality. The problem of patient safety is a systemic and multicausal problem in which different organizational areas and different actors must be involved.

An instrument with 12 specific questions about patient safety and questions about demographic aspects was implemented. The specific questions, with multiple answer options, and yes or no, were:

1. What is the definition of adverse event?
2. Do you know the protocol model for the report of adverse events?
3. Have you received trainings from the institution in protocols that guarantee patient safety?
4. Does the institution have the patient safety program to obtain safer care processes? Do you know?
5. In case of an adverse event, would you ask for support for report?
6. Who is the official in charge of performing the report of the adverse event?
7. What is the main cause why you do not report the adverse events?
8. Do you notify all reports of adverse events, clinical incidents, and complications related to health care?

- 9. What do you consider is the main cause for not reporting adverse events related to health care?
- 10. What is the definition of clinical incident?
- 11. What is the definition of clinical complication?
- 12. Does the institution perform the feedback of adverse events?

3. Results

It was found that demographically the female gender represents more than half of the population, being mostly people with a technical academic level, who have been in ESE for more than a year, and of which three out of four are auxiliary of nursing, which represents a population trained in technical tasks linked to day-to-day work in the ESE, with an experience of more than 1 year within the said institution in three out of four officials; on the other hand, it is observed that only 1 of every 11 people in the population are nurses, who are in charge of coordinating these assistants and are the guarantors of the proper performance of all protocols within the institution (**Table 1**).

For the frequency of response according to the definition of adverse events according to the London protocol, it is possible to justify that the entire population surveyed is clear about the concept of the definition of adverse events under current regulations, which demonstrates that the ESE performs an adequate accompaniment regarding the acquisition of knowledge regarding the definitions of the terminology used within its facilities, which allows all its collaborators to be in the same tuning, avoiding communication problems in terms of technical terminology and knowledge of the laws and resolutions of the ministry of health that define under presidential ruling the conception of these.

For the knowledge of the London protocol model for the reporting of adverse events, officials have one out of five present ignorance of the protocol, which can lead

Variable	Answer	Frequency	Percentage
Sex	Female	61	66
	Male	31	34
Education level	Technical	67	73
	Professional	14	15
	Support	6	7
	Others	5	5
Antiquity	Under one year	29	32
	Older than one year	63	68
Job that performs	Doctor	4	4
	Nurse	6	7
	Dentist	3	3
	Nursing assistant	64	70
	Other	15	16

**Table 1.**  
*Frequency of demographic variables of health personnel of state social enterprise Norte 2, Caloto, Cauca, Colombia, in the first half of 2019.*

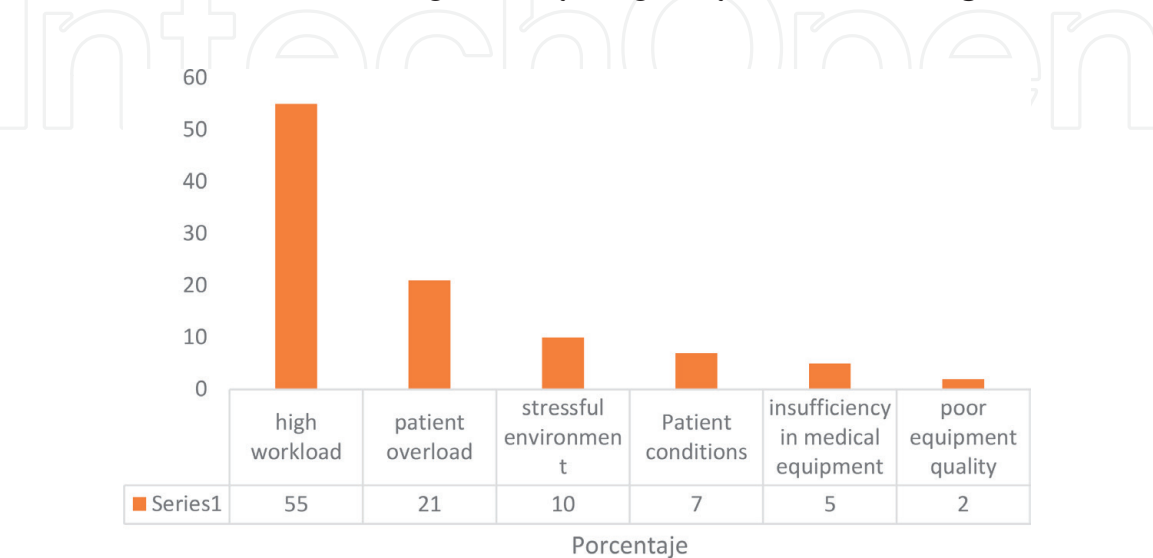


to failures in the practice of this, either due to lack of training and induction or recognition and omission which generates a latent risk both in terms of the quality of the service provided and in the care provided to the patient, putting his integrity at risk. In addition to the frequency in terms of training carried out by staff in the institution in protocols that guarantee patient safety, there is a group of people who have not received training in the patient safety protocol, which is presented as an administrative failure on the part of the institution, and the area in charge of carrying out the training of the collaborators, 1 of every remaining 11 has omitted the training provided by the ESE, generating problems that directly compromise patients and their safety.

The institution has the patient safety program to obtain safer care processes. Less than half of the respondents acknowledge that the institution has the patient safety program in terms of obtaining safer care processes, this amount being less than half of the officials surveyed, which describes a total lack of awareness for more than half of these, which generates a critical picture given that ignorance is counterproductive, given the nature of the ESE, demonstrating that more socialization of the documentation that the institution possesses, as well as training and documentation, is needed of the programs.

When an adverse event occurs, who is the person in charge of supporting the report of an adverse event? According to the established protocol, it was found that the person in charge of supporting the report of an adverse event is intended to guarantee quality of health care and serve as a bridge to generate a solution to the event presented; in this sense there is no consensus, given the ignorance of the protocol and the poor socialization of this both by the administrative area and by the same care staff, where more than half of the officials have full knowledge of who is the person in charge of carrying out the accompaniment and providing support if necessary when an adverse event occurs.

Likewise, within the knowledge of the official responsible for making the report of the adverse event according to the established protocol, it is described that within the report of the adverse event, the immediacy in the realization of this has its incidence within the quality system and of the patient safety protocol; for this reason the person who detects the adverse event must perform it in a short period of time when it is detected; in this sense more than half of the respondents know who should do it, with which you can affirm that some of these seek to separate themselves from their functions or they are not aware of the protocol and the step by step to follow when an event of these occurs, looking for a way to lighten your workload, **Figure 1**.



**Figure 1.**  
*Main cause for not reporting adverse events related to health care.*

The frequency of response regarding the most frequent cause of not reporting adverse events, it was found that the main causes of failure to report adverse events are divided perceptions, since on average 3 of every 11 believe that the mistakes made within their daily work will be a cause for dismissal, which shows the lack of knowledge of the internal regulations of the institution regarding the grounds for withdrawal, and a similar average thinks that they have used it during their rest or active breaks, which is linked to another portion, which states that the workload does not allow their report, which must be reported immediately after its occurrence, as evidenced by the ignorance of both its functions and the patient safety protocol.

Within the culture of patient safety, the reporting of adverse events, clinical incidents, and related complications in health care allows the generation of corrective and improvement actions within the health system, which by not reporting or reporting spontaneously, like 4 out of 11 of the officials surveyed, it does not allow for the maturation or improvement of this, since the causes for which adverse events are being generated are unknown and opportunities for the quality team to solve underlying problems are lost. In this sense, a percentage close to half of the respondents duly report the adverse events and other incidents and complications, this being a lack of empowerment by the collaborator who does not have a safety culture present in their work.

The most frequent cause of not reporting adverse events related to health care, evidence within the different research questions, that the workload prevails, in this sense in more than half being the main cause for not reporting an adverse event, this situation being an attenuating one, since it is possible to relate directly to the lack of human resources within the institution, or the charges within it are not level with the staff, which is supported by two out of ten who affirm that the overload of patients also does not allow an adverse event to be reported, missing opportunities for improvement within the institution that manage to generate a positive effect within the care of patients.

For the frequency of response for the definition of clinical incident according to the London protocol, it can be affirmed that within the theoretical knowledge of ESE officials, it is found that more than half of the respondents know the definition of clinical incident, and a small part present difficulties in answering correctly, this being a serious failure, when making the report of an adverse event, since the misrepresentation of the terms can cause misunderstandings and that at the time of generating a report, the indicators are erroneous regarding the nature of adverse events. However, for the definition of clinical complication, approximately four out of every five officials know its concept, which shows that only a considerable minority represents confusion, which, in a real plane, can generate confusion and ignorance of the steps to follow or perform incorrect procedures, since the nature of each event is different and must be known from the theoretical basis in order to be clear about the concepts.

Within the administrative failures found, the socialization of adverse events in the institution, only half of these are carried out, which demonstrates that the commitment that exists within the protocol is not adequate within the nature of this; there is also one in five people who do not know if they do it or not, which allows us to affirm that there is a problem of latent communication within the ESE and the collaborators; they do not know everything, given the different shifts they have and the changes in the staff schedules, as well as their lack of commitment to the quality system of the institution, being a very marked problem within the institution, seeking to improve this perception within the collaborators.

## **4. Discussion**

After the analysis of the results, investigations found that, under the same study theme, they manage to show similar results regarding the patient's safety policy and what was found in state social enterprise Norte 2 of Caloto, Cauca. It was found in the study carried out by Villareal [15] that the results obtained show that the institutions of Third World countries such as Colombia do not fully meet certain requirements for the reduction of adverse events, taking into account variables such as infrastructure, the state of the equipment, the quality and adequate supply of medicines, and the motivation of the staff, which confirms what was found in state social enterprise Norte 2, where professional and care personnel do not have full knowledge of the policies, in addition there was little motivation given the high workload they maintain and the low culture of patient safety that exists.

In 2014, Meléndez, Concepción, Garza, González, Castillo, González, and Hernández [19] found that within the demographic variables, the care staff has an age greater than 6 months, and where the average age of the respondents was 49 years, 91% were women and 70% are general nurses, who presented adherence to the patient safety protocol, which differs from what was found in the state social enterprise in Caloto, Cauca, since although the majority of the population were 69% women and nurses, older than 1 year, they did not show adherence to the humanization protocol of the patient due to different causes such as ignorance of the general concepts and the low report of adverse events.

Blandón, Gómez, Muñoz, and Zafra [16] carried out a security audit process that showed flaws in the fulfillment of the processes related to the prevention of events, where improvement activities were proposed in order to minimize and prevent the recurrence of events highlighting the awareness of all personnel, which corroborates what was found in the present investigation, since the staff does not comply with the safety culture regarding the reporting of adverse events, being necessary to propose actions which improves proposals, a plan prepared for them in order to reduce this problem.

In general, the research presented a difficulty which was access to primary information, and some of the professionals were reluctant to conduct the survey, as well as access to these for their work shifts was complicated, but nevertheless within the achievements, the latent problem was found in terms of both administrative and assistance failures of professionals, which do not present a culture of patient safety, and therefore, opportunities for improvement were found by creating a plan for improvement.

Converting the organizational culture for the improvement of the processes is one of the main objectives since adopting it as a culture will be immersed in the daily life of the institution, thus leading to continuous improvement reaching the expected quality. The contribution of reading about this program executed in the aforementioned institution serves as a guide and guidance that contributes to the enrichment of knowledge that allows the implementation of the audit plan to improve the quality of health care in the institution providing health services.

## **5. Conclusion**

With the completion of the previous investigation, it is concluded that state social enterprise Norte 2, CALOTO CAUCA does not comply with the adherence to the London protocol in patient safety policy, taking into account that only 70% of officials It has adherence to this protocol, in addition, only 52% of adverse events

are reported, the main cause of not being carried out, the workload and the little time they have for administrative work.

## Conflicts of interest

The investigators do not declare conflicts of interest.

## Thanks


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