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Implementation of the document management system for a mixing center for the pharmaceutical service of an IPS

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ABSTRACT: *The pharmaceutical industry is characterized by having institutions with a high level of complexity, which must be kept in compliance with a series of guidelines and requirements prescribed by national regulatory entities and international standards. This study describes the main results of the research on document management for the optimal operation of a central mixing plant oncological located in Bogotá, which begins with the diagnosis, compilation and review of existing archives, according to the information obtained and taking into account the internal quality process of the IPS, it proceeds with the updating and preparation of the respective records. This is carried out through the application of technical standards that are characterized by their practicality at the time of file management, resulting in the management and updating of 100% of the necessary and required documentation. Subsequently a study was carried out to record the work times of the stages that make up the production process in the oncological drug preparation activity, demonstrating a reduction in times of up to 60% with respect to the previous preparation unit, thus establishing an improvement in the efficiency of the process. Finally, a social impact evaluation was carried out, which allowed identifying the benefits that the Institution and the surrounding population would obtain, such as facilities for patients, response times, compliance, recognition and participation.*

KEYWORDS – *Oncology mixing center, standards, time study, document management, social impact.*

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I. INTRODUCTION

The nature of hazardous and non-hazardous drugs produced in the central mixing plant of the pharmaceutical service has evolved over the last decades. [1]. Taking into account this need and the evolution of good practices in the elaboration of magistral preparations, the respective documentation of the processes and basic activities of the pharmaceutical service that may affect or have influence on the quality of the appropriate drugs in the central drug preparation of the IPS has been performed in order to comply with current regulations and obtain the corresponding certifications issued by the regulatory entities, and thus establish the necessary quality controls in the processes [2][3].

Document management in the pharmaceutical sector is one of the tasks to which most attention should be paid, as it is one of the most important elements that are compulsorily reviewed during inspections by any regulatory entity, and statistically between 15 and 30 percent of the nonconformities detected are directly related to the archival part of the quality system [4].

The fact is that practically all national and international regulations on good processing practices (GMP) establish as a principle that adequate documentation is an essential part of the quality assurance system and, as such, must be present in all aspects [5][6]. No GMP regulation will specify in detail what the archival system should look like, however, it should at least meet the following objectives.

- Define specifications and procedures for all materials and production and control methods
- Ensure that all production related personnel know what they have to do and when they have to do it
- Ensure that there is documented evidence, traceability and records that allow an inspection to be carried out and determine whether compliance is being achieved [7]

Ensuring quality is important in all sectors, but for pharmaceutical companies the consequences of improper handling can be disatrous [8]. Incorrect mixtures of drug compositions or outdated instructions for use

can lead to health risks [9]. The fundamental idea of each of these studies is that there should be homogeneity in the practices and procedures that these activities entail, through the development of manuals and procedure guides, with the main objective of implementing a document management system for the process of preparation and control of drugs [10] For this reason, archival management may be the key to optimal quality control and safety in the sector [11].

Within the process of improving and updating the documentation for the central mixing plant, the time study is of great importance where its main objective is to determine the working times corresponding to the elements of a defined activity, carried ourt under certain conditions [12].

Oncology IPS in Bogota

IPS private non-profit, which has a high complexity pharmaceutical service led by pharmaceutical chemists, as specified by the regulations, follows the guidelines of the pharmacopoeia, complies with the processes and procedures of pharmacovigilance - technovigilance, in order to detect, evaluate and report the undesirable effects of drugs, which is reflected in a positive impact on the quality of life of the patient and in compliance with current regulations [13].

Reference framework

Currently, Colombian legislation requires that any drug preparation be carried out in special areas (medicines preparation centers) that guarantee specific conditions of hygiene and quality to minimize the risks to the patient, the treating staff, the environment and the medicines. One of the options of preparations is known as parental nutrition, which has a high social impact because it is aimed at critical health patients; it can be considered as a contribution to hospital centers, both public and private, by providing an undoubted benefit to their patients and having good medical practices accompanied by ISO Quality Management Standards [14].

For magistral preparations, the term quality is a set of controlled, maintained and verified actions, which can be defined as compliance with manufacturing protocols that represent how to do, how to plan, how to execute and control pre-established work processes, over which control can be exercised, and which become an important foundation for the definition of quality, whose purpose is to ensure the potency, safety and effectiveness of magistral preparations [15].

For the development of this project, a variety of engineering tools were taken into account, but always under the national and international regulatory framework related to this sector in order to follow the same quality standard [16][17].

II. METHODOLOGY

In order to obtain sufficient information, a clear and concise methodology is defined for the documentation, standardization and implementation of the central mixer in the pharmaceutical service.

System characterization

The characterization is a tool that facilitates the description, management and control of the processes through its essential elements, which allows an understanding of the objective and key aspects of how it should be executed. The main objective of the characterization of this IPS is to plan in a coordinated, controlled and timely manner the activities, procedures and interventions of a technical, scientific and administrative nature, related to the pharmaceutical products used in the promotion, prevention, diagnosis, treatment and rehabilitation of patients who require them, in order to contribute in a harmonious and comprehensive way to improve the quality of individual and collective life [18].

Document review

First, an evaluation was carried out to establish the initial archival status of the central mixing plant, in order to compare it with the requirements of the law, for which a format (Monitoring Matrix) was structured and used with the support of the head of the pharmaceutical service, with which it was determined in each of the numerals established therein as a check list of how the central mixing plant was complying with them. The physical and digital documentation was verified item by item, identifying dates, versions and archiving in an orderly manner for a future update or change of version, based on the standards established by the IPS.

The documentation was classified by large groups that make up the entire archival structure of the pharmaceutical service, focusing on the process of adaptation of the central mixing plant, which are:

- Selection
- Procurement
- Technical reception
- Storage
- Adequacy

- Distribution
- Dispensing
- Pharmaceutical care

The documents that were reviewed and that belong to the archival structure of the Central Mixing Plant are:

- Procedures
- Instruction
- Formats
- Annexes
- Manuals

Updating documentation

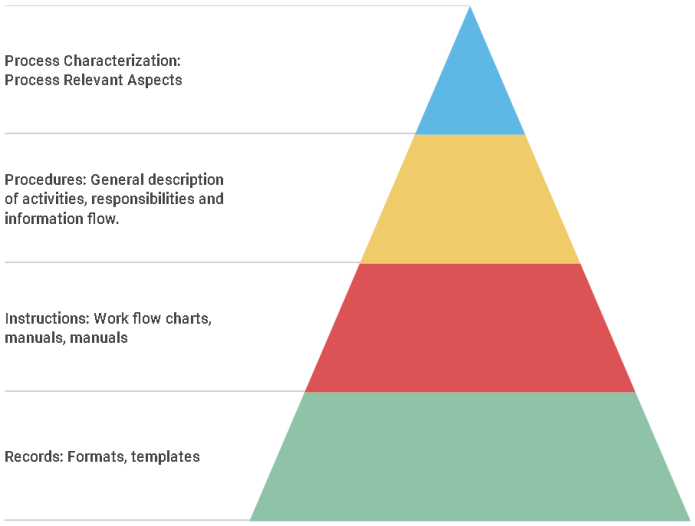
In order for the creation and updating processes to be established and governed under standardized regulations and quality assurance, they must be supported by national and international standards, because the documents that will be generated will define parameters of credibility, reliability, authority and recognition, and internally will guarantee the optimization of procedures and lead to the accuracy of the results.

The archival management carried out in an IPS can be related to the activities and tasks it performs, as long as the content of the documentation of the quality management system is oriented to the standards it intends to comply with [19].

The pyramid reflects the importance and organization of documents in the IPS [20]. (See figure 1).

The archival system of the central mixing plant, in addition to the aforementioned, has registered procedures. These contain a structure and format, which are defined by: a text, flow charts, tables, or a combination of these or any other suitable method according to what is needed [21]. These procedures contain the necessary information and each of them has a unique identification.

Figure 1. Pyramid



Source: Own elaboration, 2020

Documentation archive

Finally, files were created and sections were established for obsolete documents and documents in force, in addition to their organization according to code and version [22].

Compilation of times of internal processes of the mixing plant.

Study time was carried out in order to standardize the production process within the drug preparation center, for which direct observations were made on the professional in charge (production pharmaceutical chemist) throughout the entire operation, repeatedly measuring with a stopwatch the different activities (medical order validation, adequacy and quality control, dispensing, return) and considering every detail to discard non-productive times and establish the effective time. The timing method used was the back to zero method for each activity [23].

Social analysis

The initial objective of this study was to evaluate the social impact that the central mixing plant had on its patients. Taking into account that a study of these characteristics requires time to acquire certain rigor, it was adjusted to the conditions and situation of the moment, deciding to work towards the reality of the social impact that this type of activities could be generating in the communities [24].

To measure the impact that the central mixer has had on society, an ECLAC methodology was selected based on the measurement parameters that allow determining the social benefits it has had since its implementation.

III. RESULTS

It should be noted that the documentation developed to start the activities of the central preparation of mixtures was implemented 100% after being approved by the pharmaceutical service management, quality of the pharmaceutical service and the institutional quality area, such documentation is in document management software used by the IPS, this contains in a methodical and orderly manner each of the documents in order to facilitate their search, location and consultation.

When the central mixing plant starts operating, a time study is carried out, taking into account the technical characteristics of the processes involved in the preparation of magistral preparations. In the production activities studied, the average number of patients arriving per day was taken into account, thus establishing estimated times, since the number of patients varies. Therefore, the only times that vary from one patient to another are those specifically related to the chemotherapy protocol and infusion times. Additionally, the times were compared with another central mixing plant in order to look for improvements within the internal processes.

Tables 1 to 3 show the time study by activities for a single patient.

Table 1. Time of adequacy and quality control process

MEDICAL ORDER VALIDATION			
Number of activities	Name of the activity	Time (min/day)	RESPONSIBLE
1	Prescription	1.33	Pharmaceutical Chemist
2	Prescription validation		Pharmaceutical Chemist
3	Chemotherapy scheduling	N/A	Pharmaceutical Chemist
4	Prescription validation	1.04	Pharmaceutical Chemist
5	Adequacy required		Pharmaceutical Chemist
6	Generate production order		Pharmaceutical Chemist
7	Standard dose preparation		Pharmaceutical Chemist
Total		2.87	

Source: Own elaboration, 2020

Table 2. Medical order validation process times

ADEQUACY AND QUALITY CONTROL			
Number of activities	Name of the activity	Time (min/day)	RESPONSIBLE
1	Patient confirmation	1	Pharmaceutical Chemist
2	Confirmation of adjustments		Pharmaceutical Chemist
3	Generate labels	7.03	Pharmaceutical Chemist
4	Revision of labels		Pharmaceutical Chemist
5	Preparation of supplies	2.05	Pharmaceutical Chemist
6	Enlistment review		Pharmaceutical Chemist
7	Review and analyze finished product attributes		Pharmaceutical Chemist
Total		10.08	

Source: Own elaboration, 2020

Table 3. Dispensing times

DISPENSING			
Number of activities	**Name of the activity**	**Time (min/day)**	**RESPONSIBLE**
1	Preparation of medicines or mixtures of medicines for delivery according to medical orders.	1.20	Pharmaceutical Chemist
2	¿Is the revision approved?		Pharmaceutical Chemist
3	Hand over to the infirmary		Pharmaceutical Chemist
4	Reception		Pharmaceutical Chemist
Total		1.20	

Source: Own elaboration, 2020

TOTAL TIME FOR 1 PATIENT	**14.15 minutes**

The method developed by means of engineering tools determined the standard time of the patient care process, starting from the moment the professional (production pharmaceutical chemist) receives the medical order to the delivery of the medicine to the respective patient. Through the application of time study techniques, the following was evaluated: the established tolerances, the professional's work rhythm, fatigue and the standard time for each activity. This process results in a very acceptable time and considering that it can be improved as the professional acquires more expertise.

Finally, a Social Impact Assessment was carried out to establish the social benefits that were obtained with the implementation of the blending plant and what it can produce in the surrounding environment, as well as to prevent the consequences of the actions generated by the plant.

Table 4 below shows the main benefits obtained after the study was carried out.

Table 4. Social benefits

SOCIAL BENEFITS OF HAVING AN IN-HOUSE, NON-TERMINALIZED MIXING CENTER	- Patient response time - Benefit in patient compliance with pharmacotherapy due to highly specialized technology - Education and information to all the personnel of the services related to the central mixing center (CM) - Improved safety in the use of medications, reducing the risks related to contamination in handling or adaptation in unsuitable environments - Facilities and benefits for the institution's patients

Source: Own elaboration, 2020

For a more complete analysis of the criteria to be taken into account when implementing a project with social objectives, the multi-criteria index method was analyzed as shown in Table 5.

Table 5. Rating scale

Rating Scale	
1	Very Low
2	Low
3	Middle
4	High
5	Very High

Source: Own elaboration, 2020. Based on ECLAC 2005 methodology

Table 6 below presents the evaluation criteria.

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Evaluation criteria	Evaluation variable	Description
Social	Relevance	Criteria seeks to measure the level of importance of the Central de Mixes
Social Economic	Vulnerability reduction	With this criterion, the level of vulnerability obtained after the start-up of the Mixing Plant can be evaluated.
	Project coverage	With this criterion, the impact generated by the start-up of the Mixing Plant is analyzed.
	Efficiency	Measures if the project adequately meets the standards according to the regulations
Economic Institucional	Profits	Patient satisfaction with the IPS for the quality of its pharmaceutical products

Source: Own elaboration, 2020, basada en metodología CEPAL 2005

Table 7 below shows the weighting of the method.

Table 7. Justification and weighting of the assessment

Evaluation criteria	Evaluation variable	Consieration	Score	Total	justification
Social	Relevance	15%	5	0,75	The implementation of a CM has a high degree of importance for the development of the IPS, a development that will be evidenced in infrastructure, technology, quality and greater recognition among the institutions that provide pharmaceutical services.
	Vulnerability reduction	15%	5	0,75	After a time of not having your own CMS, the level of vulnerability increases, since you do not have the expertise on many current issues of great relevance
	Project coverage	20%	4	0,8	With the implementation of the CM within the IPS, the aim is to optimize and improve processes, always seeking the benefit and well-being of the patient
Economic	Efficiency	10%	5	0,5	The implementation of the CM is governed by multiple national and international standards and regulations
	Profits	20%	4	0,8	The main objective of the IPS when implementing a CM is to provide its patients with security, trust and quality with the service provided, thus making itself known in the middle for being a prestigious mixing center
Institutional	Participation	20%	3	0,6	The IPS has shown a high interest in the implementation of its own CM
Total		100%		4.2	

Source: Own elaboration, 2020

The rating of 4.2 was obtained, which indicates that the implementation of the central mixer in the IPS has been very favorable and has been well received and welcomed by the surrounding society, which has increased the level of confidence of the patients who are treated there.

IV. DISCUSSION OF THE DOCUMENT MANAGEMENT METHOD

Document management is based on a set of techniques and good practices whose administrative model is based on the application of a correct methodology without neglecting the fundamental objective, which focuses on controlling the workflow related to the administration and management of archival information. This is to ensure traceability and compliance with the processes, resulting in the monitoring and validation of indicators, as well as guaranteeing the integrity of the information contained and the corresponding records [25]. The improvement of processes implies a continuous and systematic work that can be achieved through the integration of document management tools with the organization's quality management system.

In the article "Documentation, standardization and implementation of the pharmaceutical service processes at the FVC Bucaramanga Heart Institute", a methodological guideline is followed, designed to comply with the requirements and requests of the institution in its archival management, based on a diagnosis, planning and sensitization, highlighting the training provided to pharmacy personnel to ensure continuous improvement and comprehensive development of skills and abilities for the benefit of the processes carried out within the central mixing plant.

With the experience in the research, it is observed that in the medium term a time study can be carried out to determine the possible shortcomings and what solutions improve the efficiency in each production process of the preparation plant. In addition to this, it is advisable to update the impact assessment since today's society is constantly changing.

It should be noted that the pharmacy personnel were involved throughout the process carried out in the central blending plant, which allowed each worker to acquire knowledge and take ownership of all the issues involved in good manufacturing practices.

Finally, the importance of compliance with regulations related to the preservation of documents, both physical and digital, and the establishment of policies and regulations in accordance with the guidelines of the institutional quality management system can be evidenced in the institution.

V. CONCLUSIONS

The document management system implemented in the IPS has contributed efficiently to the control and administration of documents received and issued by the institution, with the support and participation of the pharmacy and quality personnel of the IPS, who directly influenced its development and implementation.

Time recording has contributed effectively to the identification of strengths and weaknesses of each activity involved in the mix preparation process, allowing the most efficient work method to be established.

The social impact assessment made it possible to determine both the benefits for the institution and for the patients, as well as to identify the possible consequences of the implementation of the preparation center.

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