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THE CONTRIBUTION OF ERGONOMICS IN ENABLING THE TRACEABILITY OF HOMEOPATHIC PRODUCTION IN THE CONTEXT OF UNIVERSITY PHARMACY

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Abstract

The university pharmacy is a healthcare facility that provides teaching, research and drug handling activities. In this sense, its contribution to society is extremely important, as it makes medications more accessible at a reduced cost. The objective of this study is to identify potential problems throughout the entire process of providing homeopathic and herbal medicines for the application of ergonomic solutions based on the principles of Ergonomic Work Analysis. The methodology used includes the selection and focal analysis of characteristic situations that identified the first impressions arising from interviews with local specialists, followed by pre-diagnosis and focused analysis. The results showed the need to investigate solutions for the traceability of medications, complying with the current legislation of the Ministry of Health and corroborating more efficient pharmaceutical care and a healthier work environment.

Keywords: Ergonomics, Homeopathic Medicines, University Pharmacy, Medicine Traceability.

1. INTRODUCTION

The University Pharmacy (FAU) aims, in addition to supplying medicines to the community ensuring therapeutic efficacy, to be a place conducive to the development of future professionals in this specialty. In this perspective, pharmacy students consolidate all theoretical learning by acquiring practical experience under the supervision of a pharmacist. It is a health establishment in which students have the opportunity to assist in the provision of pharmaceutical services, whether in the manipulation or dispensation of medicines, promoting the exchange between theory, social problems and learning (De Sousa Vieira et al., 2018).

The study presented was carried out at FAU, linked to the Fluminense Federal University - UFF. Inaugurated in March 1996 and located in the city of Niterói - RJ, it contributes significantly by offering services of manipulation and dispensation of allopathic

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and homeopathic medicines, for the access of the local population to these drugs at a reduced price. In addition, in the academic sphere, it develops teaching, research and extension activities. The University Pharmacy seeks to provide the student with the daily life of a professional as it adds practical knowledge, expanding learning beyond the University classrooms.

The production of drugs and their related activities have been the object of Ergonomics, as shown by some academic works that deal with the analysis of cases of work-related musculoskeletal disorders (Bordin, 2004), through the analysis of design, visual comfort and identification of misinterpretation in safety information of package inserts (Da Silva, 2008 and Blum, 2015) to the use of *fuzzy* set theory to establish a methodology for assessing resilience in organizations dealing with dangerous technologies (Grecco, 2012).

In this work, the methodological approach of Ergonomics, supported by the current legislation, allowed to improve the traceability of the production process of homeopathic and herbal medicines (tinctures). As a result, practical solutions were proposed that are applicable to the context of recording crucial production information for the proper traceability of these drugs, in compliance with RDC 67 of ANVISA[1] (Brasil, 2007), with an impact on the in the improvement of the process and reduction of stressors to the well-being of FAU workers.

2. METHODOLOGY

The methodology adopted in this study was built based on the foundations of the Ergonomic Analysis of Work, characterized by Vidal (2001) in five typical phases:

I. Choice of Characteristic Situations;

II. Focal Analyses in Characteristic Situations;

III. Pre-diagnosis;

IV. Focused Analysis;

V. Ergonomic Specifications.

The information presented below was obtained through situated observations and conversational action with the pharmacist of the Homeopathy Laboratory of FAU/UFF during field visits.

[1] National Health Surveillance Agency.

2.1. About FAU/UFF

The University Pharmacy (FAU) is linked to the Faculty of Pharmacy of the Fluminense Federal University - UFF. It was inaugurated in March 1996 and had its service to the public started in July of the same year. In this perspective, in addition to contributing to the training of pharmacists within the academic scenario, it plays a relevant role in the access to medicines by the population of the municipality of Niterói - RJ and surroundings, as it provides compounded (allopathic and homeopathic) and industrialized medicines at a reduced price.

The staff of FAU/UFF is made up of public servants – administrative technicians and pharmacists – and, like the institution, serves as a reference for practical classes by professors and scholarship students of the Pharmacy course at UFF in disciplines such as pharmacotechnics and homeopathy. The opening hours for the public are from 09:00 am to 05:00 pm (Monday to Friday, except holidays). According to data for the year 2019, FAU obtained a number of 6,038 people served and 10,161 medicines (allopathic and homeopathic) sold.

2.2. Focal Analysis

After the first visits, it was possible to list a set of situations with potential for unfolding in a more in-depth analysis as described below:

I. Considering the context of the process of manipulation of homeopathic patients in the workstation called the pharmacist's room, where the registration of information contained in the prescription and the printing of the production forms occur, the absence of entry of the batch number and expiration date of the drug inputs was verified as the main adversity found.

II. The cleaning and sterilization of the materials after use in the handling procedures, both of the materials of the homeopathy laboratory and of allopathy, is carried out in the same washing sector, increasing the risk of contamination of the materials. This working condition requires increased attention to care at the time of handling materials beyond that necessary, if there were a dedicated washing place for both types of medicines.

III. The gels used in manipulation in the semi-solids laboratory were not differentiated in the production form. According to the report of the specialist pharmaceutical professional, the lack of differentiation, in addition to making it difficult to predict the quantity to be supplied of the most demanded typologies, requires pharmacists

and students in training to perform manual work that demands an effort beyond what is necessary in the routine, generating work overload.

IV. In the dispensing sector, inadequate exercise allocations were verified. The limited contingent of employees resulting from the restriction in the opening of public tenders at UFF resulted in the customer being served by the administrative technician. Thus, it was found that the pharmaceutical assistance was provided by an unqualified individual.

2.3. Pre-Diagnosis

Initially, it was chosen, among the characteristic situations collected, to deepen the analysis of the occurrence of non-compliance with an adequate protocol for the separation of materials from homeopathy and allopathy to avoid contamination with substances – a protocol provided for in legislation. However, after a more comprehensive investigation and validation with the specialist in charge, we concentrated our efforts to meet the demand of the homeopathy laboratory.

In the demand of the homeopathy laboratory, it was possible to identify three significant problems through the observations made during the process of instruction of the demand. These are: (i) the production form of the medicine with the absence of the batch number of the raw materials (tinctures and gels), (ii) the registration of the packaging of the tinctures and, in the case of the homeopathic medicine, (iii) manual filling of the batch and the expiration date in the production form.

With these observations, we found that the reported problems can be observed in the light of organizational and cognitive ergonomics, due to their immediate consequences to people and the process, in the following aspects:

V. the pharmacist has considerable time of his working day manually filling in and verifying the data that is not contained in the production form, being liable to make a mistake in the control of these inputs in production and impacting productivity in strictly manual functions;

VI. the function requires a high degree of concentration and can generate fatigue and prolonged stress;

VII. A negative effect can be found in reverse logistics, when the patient returns to the pharmacy with the product and the pharmacist must be able to readily identify all the information that identifies each ingredient contained in the drug;

VIII. compliance with ANVISA's RDC No. 67, which deals with good practices for handling magistral and officinal preparations for human use in pharmacies. This resolution indicates, in sub-item 5.19, that "the entire compounding process must be documented, with written procedures that define the specificity of the operations and allow the tracking of the products" and in sub-item 3 it states that "the pharmacy must have a Prescription Book, computerized or not, and record the information regarding the prescription of each compounded drug".

2.4. Focused Analysis

Regarding the focused analysis, we deal with a set of micro processes that characterize a set of operational actions. Thus, the cut of the situation comprises the customer, the buyer of the medicine, the product (drugs) and the pharmacist in the production chain. Fig. 1 presents a flowchart elaborated from systematic observations and conversations with different employees, from the service sector, administration to the drug handling sectors.

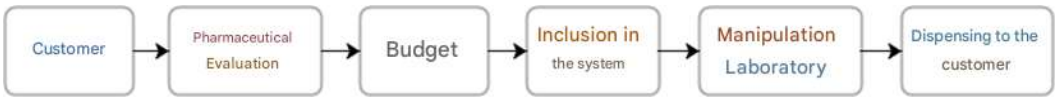

Figure 1. General Process Flowchart.

As shown in Fig. 1, the customer informs the administrative employee of the necessary data to check the availability of inputs and thus determine the budget. At this point, the registration of the product code, patient's name, price and delivery date is carried out on paper and attached to the prescription for the customer to present at the cashier for payment. Then, the production sheet is included in the system and its identification is related to the insertion of the generated code in the operating system. After handling the drug, the pharmacist notes the batch and expiration date on the production sheet and then performs the labeling, sending it to the dispenser, the sector where the drug is stored for the patient's withdrawal.

The process described is similar for herbal medicines, the administrative technician must fill in the same way the code of the tincture on paper attached to the recipe. However, all of them belong, in this context, to a single identification number.

In practice, to know the quantity sold of this input, it is necessary to manually count and verify the quantity registered by hand on each paper. Internal control, in this perspective, is carried out twice, both in the production form and in the registration of the packaging of the dyes.

The absence of the batch number in the production form and the presence of a unique code for all tinctures of homeopathic medicines became the object of study. This is justified by the fact that it considers the minimum requirements set in RDC No. 67, which deals with activities of manipulation of magistral propositions. Together with on-site observations and conversational analysis with the specialist, it is understood that the traceability of medicines is essential to ensure not only compliance with legislation, but also the adequate care provided to patients.

In addition, the persistence of these problems impacts, to a certain extent, the demand forecast for these inputs and the identification of crucial information for the drug handled in a more productive and efficient way. And this situation even causes a stressful work environment and overwork for the pharmacist, compromising not only their health, but also the productivity of the pharmacy.

In order to raise the root causes of the unpredictability of homeopathic medicine traceability, the Ishikawa Diagram (also known as the Fishbone Diagram) was used, the result of which is as follows:

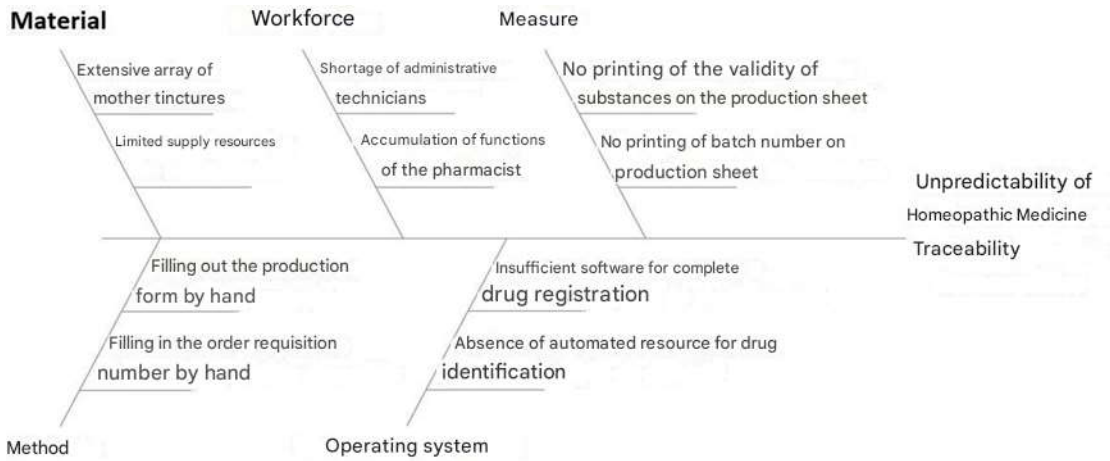

Figure 2. Survey of the causes of the traceability problem of the homeopathic medicine.

This diagram made it possible to identify the causes related to non-compliance with RDC No. 67, which refer to the categories of measurement and method shown in Fig. 2.

Therefore, to correct the traceability problem, a solution proposal should focus on modifying the procedure for preparing the production sheet.

3. ERGONOMIC SPECIFICATIONS

As a result of the analyses, it is suggested, as a proposal for practical application, the creation of a matrix of unique codes for each dye and gel, associating them with their scientific and common name so that they can be identified through the use of a barcode label. In practice, the data would be consolidated in an Excel spreadsheet. A model label is also indicated for printing for the purpose of identifying the vials of these inputs (see figure below).

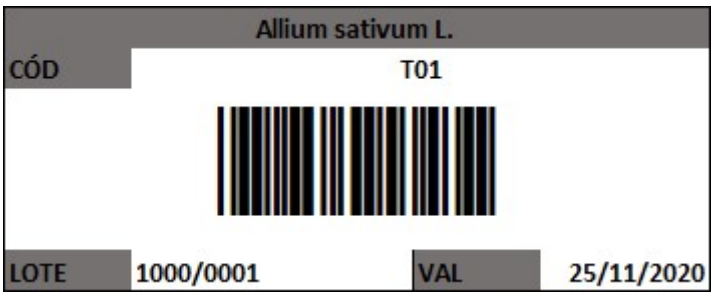

Figure 3. Label of the proposed model.

The spreadsheet is structured in two tabs, each with its own objective as follows:

I. gathering of all the labels (in the model in Fig. 3) for the purpose of organization for later printing;

II. tables to control all the information contained (name, code, lot and expiration) of each label, allowing changes such as exclusion and addition of references.

This model includes the recording of missing data, as indicated by the Measure category in Fig. 2. It also conditions this record for tracking in an automated way, replacing manual control that is subject to a higher degree of human error, eliminating the causes presented by the Method category in Fig. 2. Therefore, in addition to the gain in quality, it contributes to productivity by reducing the time for the pharmaceutical professional to prepare and review the data of the production sheet. And, for the human factor, it provides better working conditions, reducing stress in the daily life of the pharmaceutical employee.

The change in the process with the application of the proposed solution can be found in the flowchart below (Fig. 4) in which it is possible, graphically, to identify that the consolidation of data reduces the presence of manual activities.

The inclusion of the prescription in the operating system already present in the pharmacy will be interconnected with the tool proposed for use (graphically in yellow), as the dye matrices will be registered and constantly updated according to the need for use in production and the control data (name, expiration date and batch number) will be linked to the compounded drug. The Excel spreadsheet, as it contains all the information mentioned above, will also serve for the internal control record.

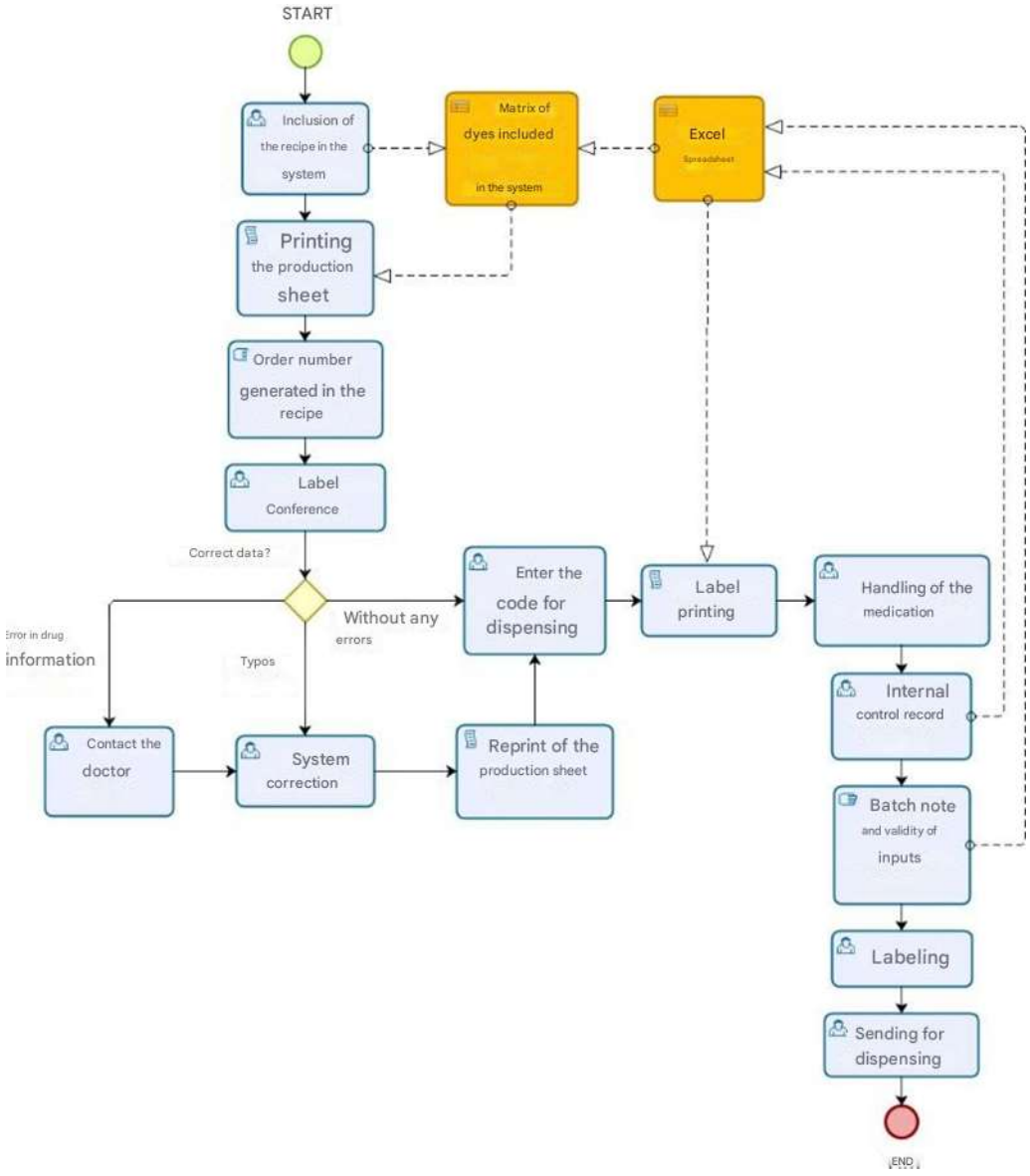

Figure 4. Homeopathic Medicine Flowchart

4. DISCUSSION

The implementation of barcode labels contributes to reducing the time spent by the pharmacist in controlling the inputs used for each master preparation. From this perspective,

the proposed solution presented to the specialist mitigates the problems related to the methods used to fill in the production data of the medicines.

Automated filling allows the user to be less exposed to the variabilities inherent to the production process, as it allows the prior formatting of constraints for filling fields with the possibility of invalidating the data. In addition, in the context of dimensioning the workload for the pharmaceutical professional, this tool allows, through optimization, a lower time expenditure in the activity of controlling data information.

Finally, for patients, providing traceability of the medication provides assistance for the period after dispensing in cases of return due to dosage complaints or side effects.

The study presented has future prospects for improvement in implementation. In this sense, it is intended that the information consolidated on the labels be incorporated into a QR *Code* system. Given the extensive amount of data regarding the drugs and necessary to perform a more complete tracking, it is proposed that the labels have this artifice printed and read by a cell phone application by the pharmacist at the place of dispensation and eventually during production.

It is important to highlight that within the scope of the project, however, there are some relevant premises such as: the maintenance of authorization for entry into the pharmacy by the institution's management; the pharmacist must be committed to applying the measures to make the solution applicable; Training times must be agreed upon in advance so that it does not disturb the work routine and the material necessary for printing the labels must be available for use.

Regarding the possible risks identified are: non-executable tool due to hardware problems; non-adherence to the users' practical routine and the threat to the continuity of the use of the tool proposed in the homeopathy laboratory when there is a change of direction.

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