Original Article

Adherence To The Clinical Laboratory Quality Standard In Public Primary Healthcare Facilities

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Abstract

The improvement of clinical laboratory procedures has become a priority for the Regional Department of Health in Andalusia (Spain) due to their clinical and economic significance. A single laboratory protocol was put into place, which included standardizing criteria for handling, processing, and reporting samples.

This study aims to characterize the level of adherence to the clinical laboratory protocol during the preanalytical phase, encompassing the analytical request through the laboratory delivery, along with the factors that contribute to this compliance. 214 medical professionals who work in primary care settings during the preanalytical stage of laboratory procedures were included in the cross-sectional descriptive study. Data were gathered using an 11-item self-report questionnaire. Every item was evaluated independently using a 0–10 scale. A score of five points served as the threshold. The Mann-Whitney U test was employed in conjunction with descriptive analysis to ascertain differences between subgroups. The questionnaire's internal consistency was taken into account.

There were found to be statistically significant distinctions between accredited and non-accredited centers. There were no appreciable differences between the centers with and without a teaching activity. Every item was measured independently. Primary healthcare workers followed the protocol appropriately; they play a crucial role in the collection and transportation of samples during the preanalytical stage. Standardization should therefore be given top priority in order to lower errors and enhance clinical safety and outcomes.

Keywords: Error Prevention, Healthcare Management, Preanalytical Errors, Primary Care, Quality Control.

Introduction

Over the past thirty years, clinical laboratories have experienced a radical transformation brought about, among other things, by significant technological advancement and staff involvement (Sikaris, 2017). Laboratory personnel can now provide a wider range of services, including a greater number of tests and more work, without compromising the caliber of the results because of newly available resources. This has resulted in a centralized management approach where all healthcare system departments receive services from large laboratories (Plebani, 2015).

The clinical laboratory PAI protocol establishes the tasks that must be completed beginning with the requested laboratory test and continuing until the applicant receives the results report (Carraro, 2007). It also coordinates the interaction between professionals and levels of care. In order to ensure that every task is completed as effectively and as efficiently as possible—the process's ultimate goal is to produce high- quality outcomes that meet user demands and needs—minimum criteria are also included for each phase (Junta , 2004).

The clinical laboratory PAI protocol was created with this goal in mind and is now in use across the Andalusian healthcare system. The actions required to standardize clinical laboratory procedures are outlined in this protocol, along with the roles of the various healthcare professionals and quality indicators (Stankovic, 2006). The improvement of these processes is particularly tied to the preanalytical phase quality control, since PCs account for

the majority of sample errors in our setting (Gomis , 2017).

This study's objective is to characterize the preanalytical phase's level of adherence to the Clinical Laboratory PAI protocol and the factors
that influence it.

Methods:

- Using an online survey that was created on the fly, a cross-sectional descriptive study was carried out.
- Changeables: The dependent variable under analysis in this study was adherence to the clinical laboratory PAI protocol. Sociodemographic factors like age, sex, and occupation (nurse, general practitioner, doctor, or other healthcare professional) are examples of independent variables.

Questionnaire:

A questionnaire dubbed "ad hoc" was created with both independent and dependent variables. A group of experts was gathered to discuss the PAI protocol's compliance. The experts included a PC nurse, a general practitioner, a PAI protocol evaluation specialist, and a specialist in clinical quality and safety. They created 11 items that, by consensus, represented the degree of compliance, starting with the goals and quality standards outlined in the clinical laboratory PAI during the preanalytical phase. An expert panel evaluated the first version in an effort to determine its validity. Following the triangulation, expert panel consensus, and content analysis, a pilot study involving 48 healthcare professionals was carried out. The completed form was a self-reported survey comprising 11.

Study and sample:

The preanalytical phase, which includes actions from the test request to sample delivery to the laboratory, piqued the interest of the authors of this paper because it has been found to be the period with the highest frequency of errors. Therefore, it was thought that nonlaboratory professionals' participation was more significant.

Nonprobability sampling was used to choose the sample, and Question Pro, an online sample calculator, was used to estimate the ideal sample size of 231 participants with a 95% confidence level, 7% precision, and 15% loss adjustment. Following filtering, the sample size was 214, representing a 7.36% loss.

Results:

The study's findings demonstrated that there is generally good adherence to the clinical laboratory PAI protocol. The participants said they did a very good job of confirming the patient's identity and the request's correspondence. They did, however, note that there was very little guidance available regarding sample extraction, sampling, and transportation. A comparison of the results based on the type of health center revealed that accredited centers outperformed non-accredited centers in terms of adherence to the clinical laboratory PAI protocol. No discernible variations between teaching and non-teaching centers were discovered. Consequently, our findings demonstrate the clinical laboratory protocol's utility and degree of professional acceptance.

Knowledge about the process has been enhanced by adding the viewpoint of the experts engaged in the laboratory procedure. We conducted a number of analyses in the past that had an impact on this. The analysis of opportunities, weaknesses, threats, and strengths has been added to the trustworthy and valuable information that the qualitative approach has produced (Jurado , 2012).

Recommendations:

- Since primary healthcare facilities serve as integrated parts of the regional health system, standardization ought to be a top priority. The clinical laboratory PAI protocol has been in use in our healthcare system for more than ten years; initially, it was distributed erratically, but more recently, it has been made available to all regional public health centers.
- This study evaluated the implementation and was created with input from all the professionals involved, including PC healthcare professionals who provide the majority of the samples in addition to laboratory personnel. The number and caliber of data pertaining to the steps that need to be taken to improve the process could be greatly

increased by using this more comprehensive approach.

- Regarding the level of protocol compliance, PC healthcare professionals had very positive opinions.This demonstrates a sufficient understanding of the protocol, which is extremely important. They have already been covered in previous reports along with their strategic role in sample collection and transportation and how it relates to preanalytical errors.
- **The current study has several limitations.** Firstly, we did not obtain the minimum sample size, even though we believe we have sufficient information to process the data analysis. Furthermore, it is imperative to acknowledge the restricted geographic scope of data collection, as this constrains the applicability of the findings. Furthermore, the sample's uneven distribution—which consisted primarily of nursing professionals—may have an impact on how the results are interpreted.

Conclusion:

The findings demonstrate that among PC health professionals, the level of adherence to the clinical laboratory PAI protocol is both high and sufficient. There were distinctions between health centers that were accredited and those that were not, but not between teaching and nonteaching facilities. Standardization has to be a top priority in order to lower errors and enhance clinical safety and outcomes, even though the degree of implementation among PC professionals—whose role is crucial in the sample collection and transport steps of the preanalytical phase—was demonstrated to be excellent. The health professionals' commitment to the upcoming interventions for improvement would be strengthened if they were involved in evaluating their degree of compliance.

We could not locate any prior research on adherence to our clinical laboratory PAI protocol. Being the first could be our study's primary finding. Because of this, the suggested methodology starts a significant new research project on reliable methods for assessing laboratory protocols. These results reinforced the need to continue this line of inquiry by allowing for a more thorough examination of the data and the inclusion of the patients' point of view. They also supplied pertinent information and knowledge about the protocol, its application, flaws, and areas for improvement.

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