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Analysis of the Performance Level of Pre-analytical Indicators in the Areas of Clinical Chemistry and Hematology at the Laboratory of the Inmaculada Concepción District Hospital in Caaguazú, Paraguay Inmaculada Concepción

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Abstract: Introduction: The pre-analytical phase is an essential component in the clinical analysis algorithm, which entails a series of steps and procedures. Objective: To describe the level of compliance with pre-analytical indicators in the chemistry and hematology areas of the clinical laboratory of the Inmaculada Concepción District Hospital. Materials and methods: A non-experimental design was applied with a mixed cross-sectional approach and descriptive scope. Three biochemists and one hundred patients were included through convenience sampling. Data were obtained through structured patient observation and semi-structured interviews with hospital staff. Results: The level of performance of biochemists in relation to pre-analytical indicators presents both positive and negative aspects, of which the positive aspect stands out at 61% and 39% corresponds to aspects considered deficient. The existing difficulties are the correct identification of the patient and the communication between the attending physician and/or technician with them, most of whom are unaware of the conditions under which they should present themselves for a medical examination. Conclusion: The proper implementation of the correct actions, as well as their quality, in the pre-analytical phase is directly related to the results obtained, which will then be used by the requesting professionals for decision-making. Therefore, it is an initial link that affects the entire subsequent process.

Key words: health care quality; laboratory; pre-analytical phase

1. Introduction

The medical request for a patient's clinical examination involves several phases, including correct identification,

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collection of the samples to be used, and transportation to the subsequent examination site, among others. This entire process determines the implications of the pre-analytical stage, which ends just as the analytical stage begins, always following a chronological order as indicated by the Draft Standard in Application PNA-NM ISO 15189. [1] These steps, which comprise the procedures prior to the laboratory test, are called the pre-analytical phase, according to Hernández. [2] This phase plays a fundamental role since it is part of the diagnostic phase and, for the most part, is where errors are made that can affect the entire process prior to the final phase, as Espinoza and colleagues comment. [3]

Within the clinical laboratory, the general steps are performed in a fairly complex manner, and although they are strictly safe, in some cases, this is apparently not sufficient. They can be divided into major stages, depending on the literature used and the authors who introduce new steps to minimize each process before reaching the final stage. These are the pre-analytical, analytical, and post-analytical stages, respectively. [4]

Since their inception, clinical laboratories have focused on implementing effective intervention techniques and implementing quality assurance measures, especially those related to analytical procedures at laboratory stages, due to the traditional and laborious nature of manual measurement and control operations. In her research, Luisina indicates that each procedure, resulting from the implementation of new technologies and the modular arrangement of sophisticated automated equipment, required significant adjustments and new ideas for the design and execution of controls, thus ensuring both internal and external quality. [4]

In the healthcare sector, knowledge and proper compliance with the pre-analytical phase in clinical laboratories are crucial to achieving an accurate and unequivocal diagnosis. The progress and effectiveness of the treatment administered by the physician are closely related to and dependent on the results issued by the biochemist. Any mistake or error committed in any of the phases, no matter how insignificant, would significantly affect the patient's health. [5]

Authors such as Guevara and Tangarife suggest that all phases involved in the analysis process are important, however, the pre-analytical phase is considered the most vulnerable because "the control of all aspects related to the pre-analytical phase must be a priority in all clinical laboratories". [5]

This study presents pre-analytical aspects of the most common tests used in clinical diagnosis in order to provide important results regarding the level of performance in meeting clinical indicators in the laboratory of the Inmaculada Concepción District Hospital in Caaguazú City.

Based on the above, the following question is posed: What is the level of performance of pre-analytical indicators in the clinical chemistry and hematology areas of the clinical laboratory of the Inmaculada Concepción District Hospital in Caaguazú City?

2. Materials and Methods

Design: This research approach is a mixed, descriptive, and cross-sectional approach. Qualitative data (through observation and interviews) and quantitative data (records of pre-analytical error rates) are collected. The variables were studied at a given time point without any follow-up. [6] This research approach is non-experimental, as it was conducted without altering any variables.

Population and sample: This study used a non-probability convenience sample. The sample was taken from the Inmaculada Concepción District Hospital, where approximately 1,000 patient specimens are processed monthly, 100 of which constituted the sample for this study. Additionally, three biochemists were interviewed; they provide services at the hospital studied.

Data collection techniques and instruments: The method used for data collection was structured observation and interviews with laboratory personnel at the Inmaculada Concepción District Hospital. A voice recorder and an observation

sheet were used to record the data obtained.

Data collection procedure: Data collection began with the creation of pre-analytical indicators based on the research questions and objectives. Prior to the field study, the pre-analytical indicators underwent a validation process using the Delphi Method (a process by which a group of people, considered experts, come together to reach an agreement on a common theme or topic. A person with experience in the field is generally consulted).

Data processing and analysis: The quantitative paradigm is characterized by coding, tabulation, sampling, and the application of statistical methods. This way of presenting the results visually expresses numerical values and facilitates their analysis and interpretation. In the qualitative paradigm, information is processed and presented in narrative or descriptive form.

The interview data were analyzed using Framework Analysis based on the study's objectives. This method consists of a systematic process that allows for the analysis of the collected data through interconnected stages. [7] This method is appropriate because its approach involves a well-defined step in the selection, recording, and classification of data according to key questions and themes, while the analytical method adopted was inductive.

Because the research follows a mixed approach, data processing uses both modalities (qualitative and quantitative), and the data are presented using statistical graphs and descriptive tables.

Pilot test of the data collection instrument: For the pilot test, five biochemists were involved in reviewing and subsequently correcting the pre-analytical indicators to be used to evaluate the performance level of biochemical personnel in the laboratory of the Inmaculada Concepción District Hospital. The method used is known as the Delphi Method.

Ethical considerations: This research was conducted taking into account basic ethical principles such as beneficence, respect, autonomy, justice, etc. Written informed consent was provided to each professional in the area under investigation, ensuring the protection of their identity. Participant responses were anonymized.

3. Results

Section 1. Structured observation results

The biochemists' performance level in relation to the pre-analytical indicators presented both positive and negative aspects. 61% of these indicators were considered positive, while 39% were considered negative in the aforementioned areas. Among the difficulties in this first stage of the pre-analytical phase were illegible requests (21%), incomplete patient names (72%), and the date of issue and patient address (70% to 71%). 100% of patients do not receive guidance on the pre-analytical conditions they must meet beforehand. (see Figure 1)

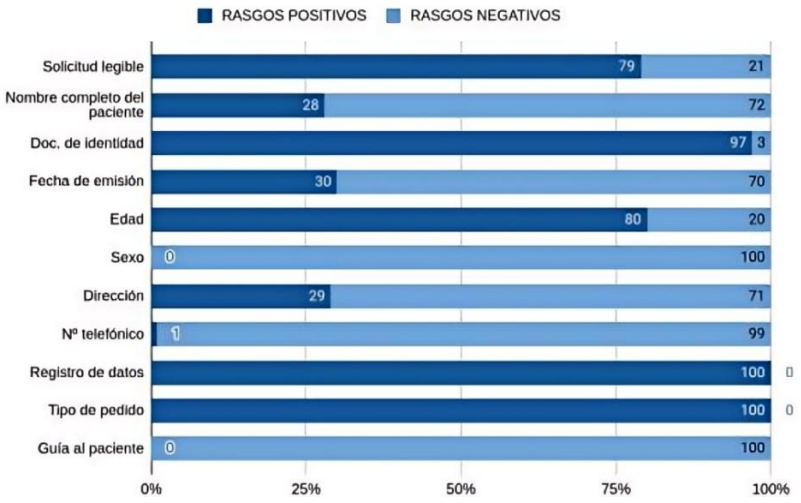

Figure 1. Related to the request.

From the medical request, laboratory personnel receive the information necessary to perform their work. All data that can be included in the pre-analytical phase is important, but some are essential so much, so that if the sample, the request, or the patient themselves do not meet the appropriate conditions, it is not recommended to begin the analytical procedure. It was found that between 95% and 100% of physicians or laboratory technicians do not provide data that would aid in a better interpretation of the patient's clinical condition, such as: the presumptive diagnosis, the record of modifiable/non-modifiable factors, and the hours of fasting prior to sample collection. (see Figure 2)

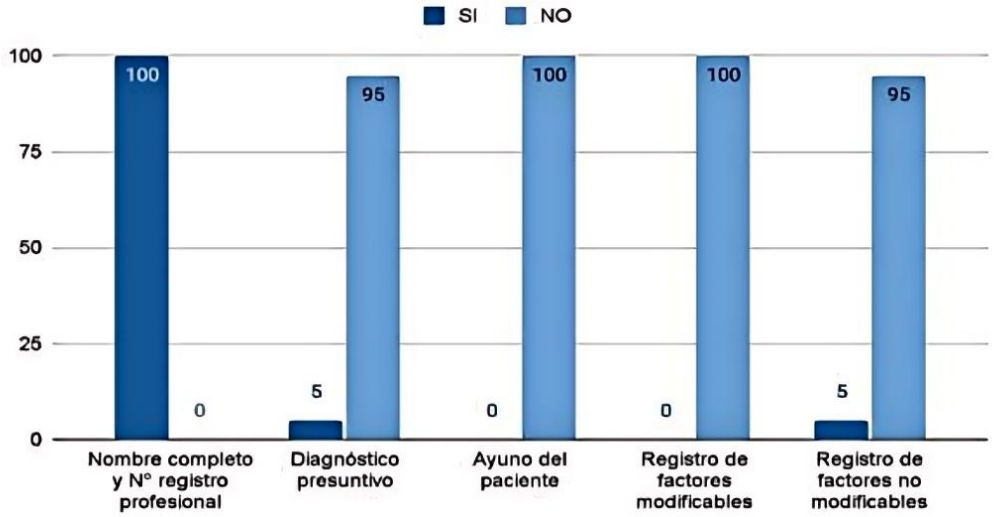

Figure 2. Data provided by the requesting physician or phlebotomist.

Participants mention that, due to lack of time, they are unable to adequately guide patients regarding the tests and the conditions under which they should be tested. Furthermore, patients are reluctant to provide their data, making it difficult to obtain a presumptive diagnosis. Regarding sample collection, the process was generally good, but areas for improvement were also identified during sample handling, such as the correct aseptic technique and mixing of the sample (52-85%) with the anticoagulants required for each test. Setbacks were observed during sample collection, such as venous stasis or traumatic puncture, but these situations were minimal and were attributed to the patients' conditions due to their medical conditions. (see Figure 3)

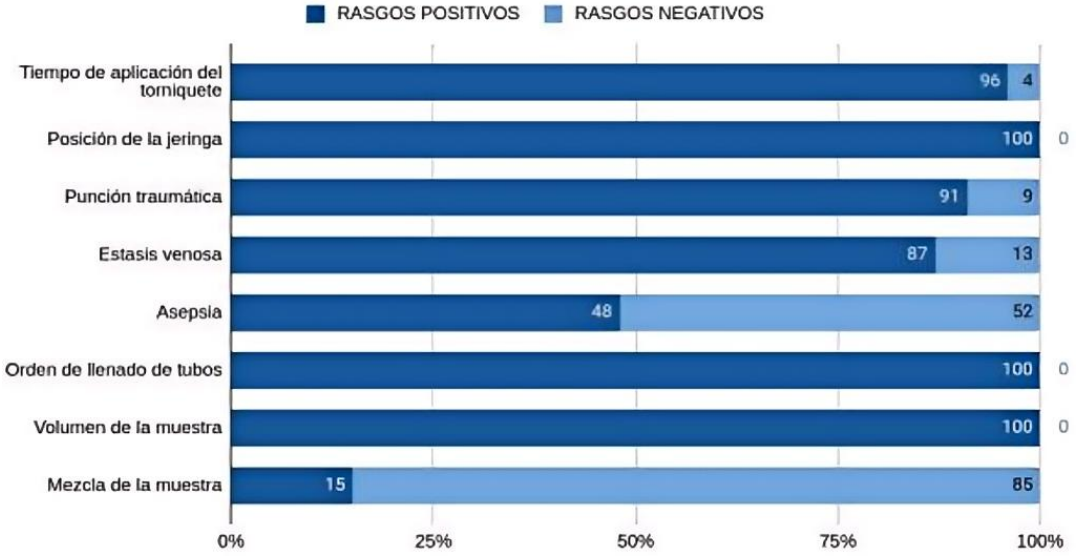

Figure 3. Related to sampling.

Regarding transportation and distribution, it was observed that the packaging and temperatures were appropriate, and the samples were distributed to the corresponding locations in an appropriate manner. (see Figure 4)

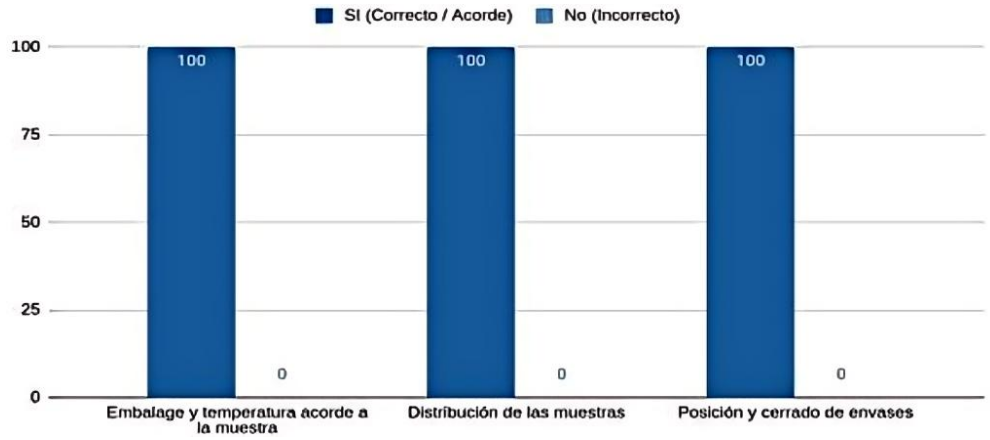

Figure 4. Related to transportation and distribution.

The bibliographies consulted for this research work mention that working with hemolyzed samples is not appropriate, a case that occurred in 11% of cases. [4-6] The use of sample separators (sticks, tips) and repeated centrifugation cycles were also observed in 100% of cases; this is not recommended for certain determinations due to possible hemolysis or contamination. Regarding conservation, 100% took care to keep samples and/or reagents well refrigerated and away from any environment exposed to significant amounts of light (sunlight/electrical). (see Figure 5)

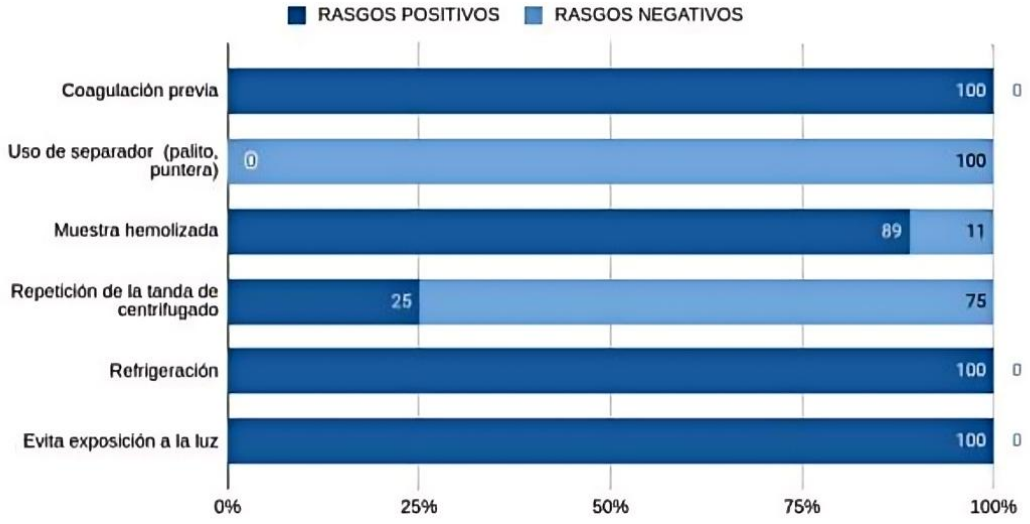

Figure 5. Preprocessing and preservation (samples and/or reagents).

Section 2. Results of the semi-structured interviews

The emerging patterns of the interview are presented using the Framework Analysis technique. This section specifically analyzes the most salient aspects of each of the work dimensions, along with excerpts from the responses of three interview participants.

Overall, the results indicate that all three participants agreed that the most common errors in the pre-analytical phase can occur in the identification of the patient and the sample bottles/tubes, in their verification, and in the lack of patient guidance regarding the conditions under which they should be present for sample collection. The impact and importance of careful sample handling are highlighted below.

A. Internal quality control should be based primarily on risk recognition, constant error detection, and the determination of indicators.

The pre-analytical phase is an important part of the processes carried out in the laboratory, given that there are certain variables that could affect clinical trials. From the request to the collection and the other steps to follow, they must be considered relevant because any oversight can have a negative impact.

"The pre-analytical process is of vital importance because it involves various procedures, and any of these phases can negatively affect the final result of the analysis" (LB). "This stage begins with sample collection; to obtain quality results, we must focus primarily on extraction" (X).

B. The main errors that are made in this phase are taking samples from the wrong patient.

The pre-analytical phase consists of several stages in which one or more errors can occur. In this case, the most common error is taking a sample from the wrong patient. This would have a very negative impact on the final result because the procedure would not be based on the patient's real needs (timely and appropriate treatment).

"There are always errors such as taking a sample from the wrong person" (OO). "Another equally common error is incorrect patient identification" (LB).

C. The pre-analytical phase primarily requires care and attention when performing each procedure.

Being attentive and careful is the primary requirement for carrying out all the steps involved in the pre-analytical phase in order to avoid or minimize any errors that could affect the sample, results, and/or treatment. In other words, the patient's life largely depends on the diagnosis issued by the laboratory.

"Anyone who handles samples must be very attentive to any procedure they are about to perform" (X). "We always try to be careful when checking materials before beginning sample collection. We check the tubes, the measurements, the anticoagulants, whether the sample is clotting or not, whether it took too long to extract the sample and whether it was extracted from the appropriate area, etc." (OO).

D. It is important to ask the patient for their ID to avoid any confusion.

In places where a clinical examination request form is not available, situations may arise in which the doctors' handwriting is difficult to interpret. Therefore, it is imperative to correctly record the patient's information and verify it with their ID before proceeding to the next phase.

"Usually, the analysis request is made by box (printed), meaning it is not written, it is just checked. If we have cases where the ID number does not match the patient's, our system recognizes the ID number. Upon entering it, the patient's identity appears and we compare it. If it matches the name on the order, the sample can be processed" (OO). "It is a priority to ask the patient for their ID; if they do not have one, their ID number and full name are recorded" (X).

E. One of the strengths of the pre-analytical phase, apart from the correct sample collection, is the guidance given to the patient prior to the clinical analysis.

It is more than evident that guidance on the conditions under which the patient should present for sample collection is essential and indispensable. In this regard, the direct or indirect participation of physicians is very significant; unfortunately, the physicians, biochemists, or technicians who are in direct contact with patients do not fully appreciate the influence they can exert with their actions or inactions. Failure to do so could significantly alter the final result.

"We cannot talk to or guide the patient about prior preparation due to the time we have; that task falls to the doctor or nurse" (OO). "Taking the necessary precautions prevents sample contamination. So yes, it can significantly influence the results" (LB).

F. Regular maintenance and equipment calibration guarantee the quality and reliability of the analysis.

Although it may not seem like it, laboratory equipment maintenance, calibration, and measurement standards are directly related to the pre-analytical phase, as the final results depend on them. Various factors, such as humidity, temperature, and even the length of time they are used and the workload to which they are exposed, can cause deterioration in their functions, and consequently, tests and measurements inevitably become questionable, and the results are evident. A periodic preventive review ensures proper functioning and guarantees the reliability and traceability of the measurements.

The job of biochemists is to calibrate the equipment in the clinical chemistry and hematology areas; this must be done for the results to be reliable (X). "The maintenance and calibration of equipment is important because this is the way we can verify its proper functioning and reliability; it gives us confidence in the results obtained" (LB).

4. Discussion

The objective of this research was to analyze the performance level of pre-analytical indicators in the areas of clinical chemistry and hematology at the clinical laboratory of the Inmaculada Concepción District Hospital in Caaguazú City. In the pre-analytical phase, mostly positive aspects have been recorded, ranging from the test order to the sample preparation, the conditions at the time of extraction, and some factors related to the sample. In this regard, Panuzio et al. in 2022 confirmed that these aspects significantly influence the results, given that, in their research, they found values close to 50% of processing errors at different stages [6]. Among the findings of the pre-analytical indicators, they presented both positive and negative aspects in the performance of their work as professionals in the area, of which the positive aspect stands out at 61%, while 39% correspond to aspects considered negative.

In the 2021 study, Ballesteros and Trunzo found that the results were highly diverse and had very wide margins of error, ranging from 17% to 84% (even). Therefore, the margins of satisfaction with the findings of this study are satisfactory in light of the research related to the case. [9] In the 2011 study of seven clinical analysis centers in Valencia (Spain), too many variants of problems were found across centers due to a lack of standardized sample collection and transfer protocols, with coagulation and urine being the most common. [10] Therefore, it is necessary to develop an action plan, based on good laboratory practice appropriate to the workplace, to improve weaknesses and minimize situations that prevent quality service.

It is also important to highlight the importance of designing indicators to be taken into account when measuring the level of performance in the pre-analytical phase in order to identify errors in the areas of chemistry and hematology, thus facilitating the observational assessment of the performance level of laboratory personnel.

This topic is also of interest to training units, as in the thesis by Lorenzo and Campos (2021), where they identified the percentage of knowledge on various aspects, finding a level between 50% and 60% of knowledge regarding the different pre-analytical indicators. [11] When evaluating the level of compliance with the pre-analytical indicators by the clinical laboratory staff at the Inmaculada Concepción District Hospital, it was observed that there are difficulties in this institution regarding the identification and communication between the attending physician and/or technician and patients, the vast majority of whom are unaware of the conditions under which they should present for a medical examination.

In 2018, a group of researchers analyzed the application of the updated ISO 15.189 standard, which had been replaced by the current ISO 15.190 standard. In that study, they found a 48% compliance gap, which led to the standardization of five processes: sample collection, sample code assignment, sample transport, sample centrifugation, and sample distribution. This led to the identification of problems, the development of workflows, and more standardized handling protocols. [13]

An estimation of the percentage of pre-analytical errors in the chemistry and hematology departments of the clinical laboratory of the Inmaculada Concepción District Hospital shows that, in contrast to the pre-analytical indicators, errors in

patient identification occurred in 72%; also, a lack of guidance on the conditions to be met for sample collection in 100%, and in the practice of asepsis in 52%. Among the data required for clinical interpretation are the presumptive diagnosis and the record of modifiable/non-modifiable factors; such data were absent in the request in 95%. Likewise, errors in the preprocessing and preservation of samples were observed between 75% and 100% with respect to the repetition of the centrifugation batch, poor mixing of the sample and use of an inadequate separator.

Some of these errors were recorded in a 2022 study in Argentina, where one of the main reasons pre-analytical errors were not recorded was the belief that they are not that important. The same study cited that 70% of these errors are attributed to this phase. [14]

When analyzing the perspective of biochemists working in the hospital's clinical laboratory on the pre-analytical phase, they commented that the areas where errors can occur are in patient identification and in the steps prior to sample collection. This is where the greatest care must be taken because everything done in the stages corresponding to the pre-analytical phase will define the quality and reliability of the clinical assays that will later be used as a diagnostic method for various pathologies. [15]

The results of this research are consistent with those of other authors such as Duque. [4] More similarities were found regarding the possible errors present during the pre-analytical phase. According to the author, the most frequently reported indicators were requests with incomplete patient identification and hemolyzed samples. He also noted that this situation indicates a pre-analytical process that requires intervention and corrective actions to address the causes leading to the detected errors. [4]

It is important to implement corrective or palliative guidelines for biochemical professionals, technicians, and all involved personnel in order to improve the processes of the pre-analytical phase. It is recommended that all processes be designed with high quality standards and that control mechanisms be established in the pre-analytical stage to minimize errors that could compromise the detection or quantification of analytes and, in turn, the clinical management of patients. Furthermore, a training program should be developed for all stages of the clinical laboratory process, tailored to patient safety, and for all healthcare personnel working at the center who are in some way related to the pre-analytical phase in the clinical laboratory. It is necessary to implement pre-analytical error management from a patient safety perspective, recording the preliminary steps, improving and harmonizing procedures as a strategy to reduce the potential risk of errors based on the application of professional standards and guidelines. Finally, the results of this research should be disseminated to staff and decision-makers to obtain feedback on reducing administrative and technical errors prior to analysis.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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