PRE-ANALYTICS IN A LABORATORY DIAGNOSTICS SETUP: ENHANCING QUALITY AND EFFICIENCY AT FORTIS ESCORT HOSPITAL JAIPUR

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By

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TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mr. Vikas Saini has successfully completed his dissertation in the Quality Assurance Department at Fortis Escort Hospital Jaipur.

The Dissertation period was from 18th March 2024 to 18th June 2024. During this period Mr. Vikas demonstrated exceptional dedication and commitment to his work , contributing valuable insights and advancements to our departments.

We Acknowledge and appreciate his his efforts and wish him all the best in his future endeavors.

Fortis Hospitals Limited JAIPUR

Authorized Signatory

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Pre-Analytics in a Laboratory Diagnostics setup: Enhancing Quality and Efficiency at Fortis Escort Hospital Jaipur** is the Bonafide record of my original researchwork. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished workof others has been duly acknowledged in the text.

Name of the student Vikas Saini

Date 12/07/2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that the dissertation titled **Pre-Analytics in a Laboratory Diagnostics setup: Enhancing Quality and Efficiency at Fortis Escort Hospital Jaipur** is a record of the research work undertaken by **Vikas Saini** in partial fulfilment of the requirement for the award of the degree of MBA (Hospital and health management) from the IIHMR university, Jaipur under my guidance and supervision, and his approach to the research study has been sincere, scientific, and analytical.

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS

HCP Health Care Personnel

JCI Joint Commission International

KOL Key Opinion Leader

NABL National Accreditation Board for Testing and Calibration Laboratories

NABH National Accreditation Board for Hospitals and Healthcare Providers

QCI Quality Council of India

SOP Standard Operating Procedures

SME Subject Matter Expert

Chapter 1

Background:

Laboratory Setup: The laboratory setup is the start of the total testing process. Quality, therefore, is the core issue for every laboratory. This calls for the implementation of total quality management within the entire process of the laboratory from the pre-analytics to the analytic and post-analytic phases.

In total quality management, the processing of a sample begins from test ordering and ends with the final interpretation of results by clinicians. It aims at the reduction or elimination of intrinsic errors in each sequential process in order to enhance the quality of the laboratory services. Total Testing Process The total testing process is the entire process of testing, from initial ordering of the tests to the result interpretation. It consists of three broader steps which are substantially divided into three separate steps: the pre-analytical step, analytical step, and post-analytical step; it starts and ends with the patient. Pre-analytics in any new setup laboratory occupies a significant space for accurate and reliable scientific research. Pre-analytics involves steps prior to the actual

testing, namely, collection, transportation, processing, and storage of samples. These procedures are very important and ditto careful as they have an effect on the quality of the results. Firstly, samples should be collected carefully and properly. There are even guidelines which a trained person has to follow just to make sure that samples do not get contaminated and truly signify what they are supposed to. The right containers and preservation methods must also be used in order to keep the samples in good condition through travel and storage. It is, therefore, very important to transport the samples safely from the collection site to the laboratory.

Such samples require most delicate handling to avoid any form of deterioration or changes in the sample. This would therefore require proper labeling, packaging, and temperature control measures—which logically involves specialized equipment such as dry ice or containers controlled at a certain temperature. Processing the samples gets them ready for testing upon arrival at the laboratory. Processing means classifying, organizing, and executing some procedures, which involve centrifugation or filtration steps enabling the separation of specific components of blood, such as plasma. It is also important to follow instructions meticulously and keeping everything clean because one would not want samples to go bad due to contamination.

Proper storage of samples is necessary to maintain their integrity over time. The laboratory accordingly needs to provide the right environment in view of the nature of samples—temperature, humidity, and lighting. The system applied for tracking the location, consumption, and disposal of samples should also be successful. The need for rigorous record-keeping and data management also becomes very important.

All activities pertaining to sample collection, transportation, processing, and storage should be tracked and monitored through documentation. This is not only to ensure adherence to the protocol but also to make the interpretation of results much easier and simpler. Setting up a secure and systematic data storage system in an institution where laboratories operate is therefore very important. Pre-analytical factors are thus very crucial for any new set-up of a laboratory to yield good results in both clinical and research aspects. This way, the laboratories will ensure accuracy in their results and

acquire some trust. Also, taking care of pre-analytics does not only help acquire good results but also assists the researcher to be efficient and productive.

CHAPTER 2

REVIEW OF LITERATURE:

SNo Author Year Title/Objectives Study design Results/Conclusion

1 Jivita Cattleya Badarjahan Andantino Tjahjo 2011 Perceived accreditation benefits, participation and organizational commitment in hospital accreditation performance observational and descriptive The study results that the perceived benefits of the accreditation, employee participation and organizational commitment have an impact on performance simultaneously. The perceptions of Accreditation benefits, participation and commitment have a significant impact on Accreditation performance. This study identified that the perceived benefits of accreditation did not directly influence the performance of employees with regard to the accreditation process. Improving the performance of accreditation could occur only if there were support and dedication that mediated the views of health workers about the usefulness of accreditation. This research has implications for the hospital management in optimizing the performance of the accreditation process. This can be achieved by increasing the perception of the benefits of accreditation through training, sharing, assessment, award, and monitoring and evaluation involving all employees.

2 Kirsten Brubeck, Gunn E. Vest, Geir Backholm, Paul Barach & Ole Toseland 2015 A systematic review of hospital accreditation: the challenges of measuring complex intervention effects observational and descriptive The literature review yielded three previous systematic reviews and one randomized controlled trial. The only one of these studies that examined the effectiveness of the intervention measured the impact of accreditation on the outcomes of care in hospitals and reported mixed effects. Studies that could not be included are summarized along with their findings.

3. Chandrasekar, S., 2022 Comparative Analysis of NABH and JCI Guidelines: Impacts on Hospital Quality Assurance

The research aims and objectives are to assess the efficiency of the NABH and JCI guidelines in bringing improvement in Hospital Quality Assurance. Approach: Observational and Descriptive The finding was that JCI guidelines showed more stringent compliance with patient safety and clinical care standards. In contrast, NABH guidelines were found to be more responsive locally to health care settings. 4. Author: Singh, R., 2023 Implementation Problems of NABH and JCI Standards in Hospitals of India

Objective: The main objective of the paper is to identify the difficulties confronted by Indian hospitals in implementing NABH and JCI standards. Observational and descriptive. Common challenges related to lack of trained personnel, financial constraints, and resistance for change; however, JCI standards were more challenging in view of their international requirements.

CHAPTER 3

METHODOLOGY

The methodology adopted for the present study was a mixed one: descriptive analysis along with retrospective study, aided by data extracted from Laboratories' internal system. The study also included observational study in its scheme of things.

The aims were to conduct detailed study and analysis of various aspects associated with the research topic. The LIMS system, also referred to as Laboratory Information Management System, was utilized for conducting a retrospective study along with the descriptive analysis of various research articles.

Coupled with this observational study was also implemented to get a more comprehensive idea regarding real-time management in the pre-analytics aspect. Gathering this data in one place and analyzing it—the full concept of what actually pertained to pre-analytics was acknowledged. By this combination, visualization of what, why, and how questions were answered.

For this to happen, it had to be measured that the points regarded during our study were universal in all laboratory pre-analytical aspects. Hence, extensive and exhaustive literature review was done to identify key variables and defining these variables precisely.

Quantitative data for the retrospective analysis were majorly contributed by the laboratory information management system, which had valuable data regarding elements like accessioning delays, test TAT, and sample requirements. The data gathered was safely stored in a database for further examination. Excel was used to perform the analysis. The LIMS acted as the primary source of data since it contained a lot of valuable information that is helpful in the given research study.

The Misreported provided test names, types of samples required for these tests, the concerned department, TAT of tests, personnel assigned, etc. In order to ensure the system was working correctly it was cross checked once in a while with the physical registers

maintained by the accessioning team and the respective department. Apart from this, strict confidentiality was maintained and not compromised in terms of the patient's data.

Everything was anonymized. A mixed method approach was used for the study so as to collude important facts and data points together. This helped in establishing a solid structure to initiate further proceedings and to analyze the past discrepancies.

The use of a combination of descriptive, observational and LIMS study helped in putting together a comprehensive review.

CHAPTER 4

RESULTS

After the review, it established a fact that there are considerable issues in process flows and training of the personnel. Issues were also found regarding sample management, like no standard ways for sample collection, handling and transportation, were present. Due to different rules in different labs the quality and condition of the samples can be different and that might make the test result wrong.

The study further established that staff in the laboratories were not well-trained and conversant with proper procedures to ensure that handling was done in good order for the samples. This continued to problemize the situation in maintaining samples in good condition. Amongst all the problems associated with sample management, it was found out from research that there were numerous shortcomings on the part of the personnel concerned when it came to processing items before analyzing them.

The results showed that it was not well outlined within the laboratory as to who was to do what in terms of sample collection and processing. Inefficiency of the process was evidenced by the presence of disorder and errors in task allocation. From the research, the study has concluded that there is a need for increased levels of communication and collaboration between workers at the laboratory and other health professionals tasked with sample collection. This mostly brought about delays, misunderstandings, and probable mistakes on the identification and recording of the samples when they did not coordinate well.

These are the few gaps that were fanned out during the corresponding study. However, these few gaps created the most part of the reason for the pre-analytic errors :. That said, some of the measures that could be put in place are: first, coming up with standardized protocols on sample collection, handling, and transportation to guarantee integrity and uniformity in the samples across the lab units. There should be training programs set up for staff in the laboratories on standardized procedures, with emphasis on good techniques in

handling samples. Regarding this the following draft for Standard Operating Procedure for Sample Acceptance and Rejection was made:

Purpose: This is about making sure of the proper receipt and processing of samples originating from patients.

Objective: This procedure describes how the rules for acceptance and rejection criteria of a sample are formulated.

Responsibilities: -The Quality Manager supervises the documentation of policies for sample rejection and acceptance criteria.

These policies need to be passed by the Laboratory Director. - The onus of the following policies for sample rejection and acceptance needs to be taken seriously by the laboratory staff. Specimens: - Histopathology Specimens (FFPE blocks, Slides, Tissues in Formalin) - Molecular Specimens (Blood in Pox Gene Tubes, Plasma, FFPE) Material: - Hand Glove - Mask - Lab Coat -Closed shoes/Shoe covers Mode of operation: Initial activities on the receipt of a sample of the patient:

1. Date and time of receipt of the sample

2. See that the information about the patient on the TRF is consistent with the information on the sample. 3. Check that the test requested is appropriate to the type of sample collected.

4. Prepare an entry in the LIMS system from the accession room on the received sample.

5. Blood specimen in PAX gene light blue coloured cap, EDTA Purple coloured cap shall be received with Gel Packs at a temperature of less than >4 degrees Celsius. Plasma shall be received in dry ice. FFPE blocks should be properly embedded in the paraffin wax, slides & Tissues in Formalin shall be received at room temperature packed in proper containers.

All received samples should be labelled with the same number as on the histopathology reports.

Note: Sample accessioning team should receive the samples. Samples should not be opened at the front desk. Information to be provided on the test request form(TRF):Following details should appear on the test request form:- Complete patient identification, i.e., full name, age, sex, contact information- Clear description of the type of sample. - Date and, where relevant, time of sample collection. - Tests requested. - Diagnosis or description of the clinical investigation. - Name and contact details of the requesting doctor & hospital. Criteria for rejecting a sample/putting a sample on hold due to Non-Compliance to the following criteria : 1. Samples without labels or with incorrect labels.

2. Leaky containers: If the container exterior is contaminated with the specimen, or if the container is leaking, a fresh sample be obtained.

3. Inappropriate source of specimen: Specimens, other than those indicated, are unacceptable for the assay. For example, receiving a specimen for a test that we do not do, or receipt of a different specimen than is noted in the reports.

4. Delayed Transportation Time and Processing of the Sample: The blood samples, under ideal situations, should be less than 2 days old when received in the PAX Gene tube light blue cap, & less than 3 hours old when received in EDTA tube purple colored cap.

A new sample is to be requested when the time between sample collection and receipt at the laboratory is too long for a valid test to be performed.

If adequate is received after a long delay but not rejected, document with the time elapsed from collection.5. Wrong papers along with the sample. Sample and TRF mismatch. What to do when samples are rejected: - If the unsatisfactory sample can be replaced, the requesting hospital/doctor is informed, reason for rejection is documented, and another sample is requested.

Unless the request is cancelled by the clinician, do not discard a sample until the patient's doctor has confirmed that a repeat sample can be taken. If the patient has already been treated or a repeat sample, for any reason cannot be taken, this should be clearly documented. If a repeat specimen is not available, document the problem and perform the test if possible. If a sample is accessioned but rejected upon investigation of the tumor content, contact with the doctor/hospital is needed to obtain re-sampling. Moreover, it is very important to outline the roles and responsibilities of each laboratory person involved

in the pre-analytical phase so as to avoid confusion at work, which eventually leads to reduced errors. This can be achieved by forming paper protocols and following them up by holding training sessions on a regular basis so that all staff members are well aware of their duties and responsibilities. It is through the improvement of communication channels and building up of good collaboration between the laboratory staff and other healthcare professionals that the whole efficiency of the pre-analytical phase can be enhanced. The following process flow was established: a. Sample Collection: This is done by the respective hospitals. Recently, the organization has started taking help from third-party phlebotomists for inaccessible regions. b.Sample Transportation: The verbal responses indicated that tube was the correct practice in sample receiving followed by most of the other laboratory staff.

However, some laboratory technicians reported difficulties in identifying correctly the collection site; such challenge made them to halt these activities. In such instances, they would wait for confirmation from the hospital from which the sample was received.

Processing of Samples: The secondary research done showed variations in sample processing practices across different laboratories. Some laboratories reported the implementation of automated systems for sample processing, improving efficiency and reducing errors. We have an internal system in our lab for easy processing.

Standardization Needed: Participants expressed the need to have standardized guidelines and protocols for constant work in the laboratory.

This included emphasizing the role of regulatory bodies and professional organizations in terms of providing clear guidelines on best practices and requisite compliance oversight that should be instituted to enhance pre-analytics.

In other words, the main discovery of this research is the presence of vast lacunae in the present pre-analytical system regarding sample management and personnel practices. Standardized protocols and training programs could be introduced, along with enhanced communication that can enable a more reliable pre-analytical phase for better accuracy and quality in test results from laboratories.

CHAPTER 5

DISCUSSION

The aim of the discussion chapter is to carefully give analysis and interpretation of the implications of the results that the study on pre-analytics within laboratories has cited. It explores the findings 'implications, identifies key trends, and ascertains their significance concerning pre-analytical process improvement .

It covers the areas on:

1. The value of standardization: The current study demonstrated that the standardization of pre-analytical procedures in laboratories was valuable. Standardization introduces consistency in practice, reduces mistakes, and increases the reliability of results. In view of the problems detected in this study and the quality of laboratory testing in general, it is worthwhile introducing standardized procedures of sample collection, transportation, processing, and storage.

2. Education and Training: The results point out the need for complete training programs regarding laboratory employees about pre-analytics. One of the major problems that has been leading to errors and variability in practices is due to a lack of training. Steps like the creation of systematic training programs and continuous education can enable the laboratory staff with the necessary skills and knowledge to accomplish pre-analytical tasks.

3. Good Quality Control Procedures: The practice of pre-analytics has to be preceded with emphasis on strong quality control procedures. Maintenance of equipment regularly, calibration tests, and compliance with requirements are done to ensure that accurate and reliable results will be obtained. Quality control should become the intrinsic part of laboratory procedures for the detection and prevention of errors at various phases of the pre-analytical stages.

4. Technological Developments: Integration of pre-analytics technology holds immense potential to change laboratory procedures. Robotics, automated technologies, barcode tracking—such error-free techniques—can facilitate sample identification more accurately while reducing human error and human effort, increasing productivity. Labs should

consider adopting such technological advancements to simplify procedures in the pre-analytical area.

5. Resource Constraints: One of the major challenges that cropped up in pre-analytics is resource constraints. Best practices can be quite difficult to implement in laboratories with fewer resources and facilities. The best pre-analytics can be ensured if only the policymakers and healthcare organizations can allocate proper funds to sustain and develop laboratories, infrastructure, equipment, and training needs.

6. Sharing Knowledge and Collaboration: The outcome of the study is an excellent pointer toward the need for laboratory collaboration and knowledge sharing. It is if the best practices, life lessons, and experiences are shared in pre-analytics in unison. Network building, preparation of workshops, and the creation of platforms for communication and information exchange are some of the joint efforts.

7. Patient Safety and Result Accuracy: It clearly is depicted that there might be a direct effect of pre-analytics on the safety of patients and result accuracy. Pre-analytical processes that have errors or are inconsistent may lead to misdiagnosis, delayed therapy, and poor care to the patient. Improvements are therefore needed in pre-analytics practices to give an accurate and reliable laboratory result that can help in better patient outcomes.

8. Regulation Oversight: It is in this context that regulatory agencies or professional organizations assume immense importance in demanding regulatory norms and ensuring adherence to pre-analytics standards. Results emphasize how regulatory agencies and professional organizations can actually play a very key role in legislation making and its enforcement toward addressing preanalytical issues, ensuring best practices, and promoting quality within laboratory setup.

The study on pre-analytics in the laboratory setting offers valuable information on the challenges, desirable practice, and process-frontier advancement possibilities. Priorities in the enhancement process for pre-analytic practice should be standardization, training, quality control, technical advancement, resource supply, cooperation, and regulative control. Such efforts will go a long way to ensure an enhanced level of patient safety and security, accuracy of test results, and overall health care delivery.

CHAPTER 6

CONCLUSION

Pre-analytics in the laboratory setting has been the subject of study that gave out the practices, difficulties, and prospective areas for its improvement in this very important part of the total testing process. Given that, the study has offered a number of helpful insights into the many preanalytical processes like sample collection, transportation, processing, and storage, using admixed-methods approach combining descriptive and observational retrospective analysis.

These results underline the requirement for standardization of pre-analytical procedures. Standardized procedures and rules support reliability and low error rates, as well as consistency, which is maintained. Labs should strive to adopt and apply standardized procedures in a bid to enhance the quality of their pre-analytical procedures.

The last critical point in the solution of the identified problems in pre-analytics is training and education. Inadequate training generates mistakes and engenders practices that are inconsistent. Pre-analytical processes can be optimized by continuous trainings and reinforcement of standardized practices.

Other promising prospects are in the development for technical improvement of pre-analytics through integration of automation, robotics, and barcode tracking, increasing

productivity and decreasing human error, facilitating pre-analytical procedures. Laboratories may want to study the possibility of implementing such technology advances as openers for improving their operations. Some participants mentioned that lack of resources was a challenge about pre-analytics.

Best practice implementation can, however, be quite challenging to labs with limited resources and facilities. Resources should be allocated adequately in terms of the infrastructure of the laboratory, equipment, and training. In personnel, since overworked employees result in human error.

The laboratory has improved pre-analytics through collaboration and knowledge sharing. Through sharing best practice, experiences, and lessons learnt, collective progress can be enabled. Setting up networks, organizing workshops, or developing venues for communication and information exchange facilitates collaboration and knowledge sharing.

The study pointed out how pre-analytics relate directly to patient safety and the accuracy of many test results: analytical processes with errors or inconsistencies at a high risk of incorrect diagnoses and poor treatment of patients.

Pre-analytical practices have to be better served if accurate and reliable laboratory results contributing to improvement in patient outcomes are to be provided. Regulation is then necessary to ensure that pre-analytics norms continue to improve and further advance.

The faults in pre-analytics are something that upper management has to pay attention to by doing audits annually or semiannually. In the final analysis, the research into pre-analytics in a laboratory setting has shed much-needed light on current practices, challenges, and areas of potential growth.

Only through strict standardization, training, technical quality improvement, resource supply, collaboration, and constant monitoring regarding changes in regulations can laboratories maximize pre-analytics. The implementation of all these measures will result in more accurate laboratory results, enhance patient safety, and produce better health outcomes.

Pre-analytical procedures can only be perfected for the highest levels of testing quality when there is vigorous collaboration among laboratories, health institutions, or policymakers.

REFERENCES

Hussein, M., Pavlova, M., Ghalyah, M. e. al. The impact of hospital accreditation on the quality of healthcare: a systematic literature review. BMC Health Serv Res 21, 1057 (2021). https://doi.org/10.1 186/s12913-021-07097-6

Al-Ahmadi H, Roland M. The role of accreditation in reducing the medical errors in some healthcare services in Saudi Arabia. Qual Assur 2012;14(1):10-20. https://

Brubeck, K., Vest, G. E., Backholm, G., Barach, P., &Toseland, O. (2015). A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. BMC health services research, 15, 280. https://doi.org/10.1186/s1 2913-015-0933-X

JCI Structure

Alchemizing A, Shaw C Impact of Accreditation on the Quality of Healthcare Services: a Systematic Review of the Literature. PubMed Central (PMC). https://doi.org/10.4103/0256-4947.83204

JCI Structure [Internet]. JCI Barbados. [cited 2023 May