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Possible Impact Factors for Poor Quality Management of Clinical Laboratory Performance in Wad Medani City, Sudan

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Abstract

Background: The medical laboratory has a fundamental role in diagnosing diseases, following up and correcting treatment at the right time. The quality of laboratory result was affected by multiple factors through the stages of work. **Objective:** The study aimed to identify impact factors of poor quality management of clinical laboratories' performance in Wad Medani city, Sudan. **Methods:** A descriptive cross-sectional study was followed; enrolled medical laboratories were seven governmental hospital laboratories and nine private laboratories. Medical laboratory design assessment data, personnel management and sampling, and general concepts of quality control were collected through the questionnaire. **Results:** The overall observed rates for proper design and structure, personal management, sample management, and quality control requirements in medical laboratories were 22.5%, 39.25%, 23.45%, and 30.50%, respectively. **Conclusion:** Several impact factors in design, person management, sampling and overall quality led to poor performance in medical laboratories in Wad Medany city.

Keywords

Clinical Laboratories, Quality Management, Performance, Sudan

1. Introduction

Quality in clinical (medical) laboratories is defined as the accuracy, reliability, and timeliness of tests results obtained (Ivanov, 2011). The importance of clini-

cal laboratory activities represented in medical decisions, public health and the serious consequences of the growing challenge of non-communicable diseases in health-care settings (Wilson et al., 2010; Lippi et al., 2015). In addition, it has been observed that 80% - 90% of correct diagnostic decisions are based on the quality of laboratory results (Plebani, 2010; Wagar et al., 2008). One of the biggest obstacle to not being able to provide quality health-care is the lack of confidence in medical laboratory results, especially in countries with poor economic status. In the delivery of health care, a high quality laboratory facility is critical for a variety of diagnostic, treatment and control procedures (Dacombe et al., 2006; Koplan et al., 2005). However, many developing countries are still not aware of the importance of medical laboratory services (Ndongmo, 2005). Medical laboratory testing has long been recognized as the most sensitive aspect of the overall testing phase, with the bulk of mistakes occurring there, which can lead to misidentifications, transportation/storage errors, or misleading findings due to inadequate sample quality (hemolysis) or contamination, any of these could have adverse effects on patient care (Lippi et al., 2015; Lippi et al., 2013; Lippi, Bassi, Brocco, Montagnana, Salvagno, & Guidi, 2006).

Errors may appear after submitting the test request before the sample is available from the doctor for examination, while errors in sources account for up to 70% (Lippi et al., 2011). The latter is the stage of the purchasing, processing, checking and reporting process (Rynning et al., 2007), such as improper test request, order submission, wrong patient and specimen identification, hemolysis or coagulation, insufficient quantity, improper container, poor sample handling and transportation (Plebani, 2010). These mistakes may have a variety of effects, such as doing an invasive surgery on the wrong patient and reporting the results on the wrong patient (Wagar et al., 2008). One of the challenges that affect the achievement of quality in health services in Sub-Sahran Africa is the lack of reliability in laboratory services (Koplan et al., 2005). The patient management process is based on clinical laboratory results and this can influence final treatment decisions in up to 70% of medical cases (Lippi, Guidi, Mattiuzzi, & Plebani, 2006; Plebani, 2006). Sampling of poor quality and factors related to pre-analytical stage also contributed to the misdiagnosis of patients (Bonini et al., 2002; Carraro & Plebani, 2007). Regarding the instruments and reagents used in medical laboratories, evaluation tools are among the most important parts of total quality management, and with them, it is easy to evaluate the performance of medical laboratories. The innovation of such study in Sudan comes from several aspects related to the seriousness of the work of medical laboratories, the detection of deficiencies and their consequences.

2. Methods

2.1. Study Design and Settings

This was an analytical comparative, cross-sectional study based on medical laboratory participation. The study was evolved governmental and private labora-

tories in Wad Medani city; capital of Gezira State, Sudan in the periode from 2018 to 2021. Participated laboratories were sixteen; seven were governmental hospital laboratories and nine were private laboratories.

2.2. Data Collection Techniques and Tools

The questionnaire used designed to be completed by all medical laboratory respondents. The questionnaire was designed based on the general requirements of the total quality management system and questions were categorized in four major parts; assessment of medical laboratory design, personnel management, sampling management and general concepts of quality control. Specified questions for design covered medical laboratory structural parts, instrumentation and safety considerations, while personnel management question dealt with knowledge-attitude-practice of medical laboratory staff. Questions directed to management of sampling included checking of request forms, physical examination and transportation status. Questions regarding quality control in medical laboratories turn around internal and external quality control. Firstly, for reliability the questions were directed to more than one person in the laboratory. Secondly, for validity the laboratories that were studied represent most of the service laboratories in the study area, and thus are a representative sample.

2.3. Data Analysis

The data were analyzed using SPSS version 19.0, and descriptive statistical analysis was used by frequency and tabulation.

2.4. Ethical Clearance

The study was complied with the guidelines of the ethical consideration of the researches and ethical clearance was taken from the Faculty of Medical Laboratory Sciences, University of Gezira and Ministry of Health, Gezira State. It received permission from each medical laboratory manager.

3. Results

Recruited bodies in the study constituted all governmental medical laboratories of central hospital in Gezira State; it's provided routine and special laboratory investigation as well as blood banking services. In addition, participated private medical laboratories represented laboratories with highest daily work and frequency of samples. Regarding the design and structure requirements, only 6.3% (1/16) from governmental and private laboratories showed availability of eye-wash station, emergency shower and quality officer (**Table 1**). Availability and usage of personal protective equipment's was recorded positively in 12.5% (2/16), frequency of 18.5% (3/16) of studied medical laboratories designed with washing room, separated stored room and organizational chart that describes the internal management and supervisory arrangements in the laboratory (**Table 1**). Regarding personnel management, the written policies dealing with trauma

Table 1. Design and structural status of studied governmental and private medical laboratories in Wad Medani city. No 16.

Task	Percentage %
The presence of separate rooms designated for laboratory departments, sample collection and blood donor activities	56.5%
Availability of washing room	18.5%
Availability of manager office	31%
Presence of separated stored room	18.5%
Presence of staff rest room	37.5%
Laboratory organizational chart that describes the internal management and supervisory arrangements	18.5%
The availability and usage of personal protective equipment's	12.5%
Presence of emergency exit door	25%
Presence of fire distinguisher	37.5%
Availability of first aid box	31%
Appropriate wastes disposal containers	75%
Presence of extraction fan	31%
Availability of eye wash station	6.3%
Presence of emergency shower	6.3%
Laboratory have the organizational and management structure	43.75%
Availability and sufficient wastes disposal facilities; is wastes separated into infectious and non-infectious, is infectious wastes autoclaved, incinerated or buried	25%
Availability of wastes disposal guidance	31%
Presence of quality officer	6.3%
Total average	**22.5%**

during work were reported positively in 12.5% (2/16), while training of medical laboratory staff was followed in 25% (4/16) (Table 2). For management of samples, policies for laboratory specimens storage/disposal found in 6.3% (1/16). While 25% (4/16) of observed medical laboratories had and follow SOPs for safe handling of samples (Table 3). Observation of quality control resulted in 6.3% (1/16) of governmental and private medical laboratories participating in external quality assessment scheme whereas, 12.5 (2/16) were implemented an internal quality control program (Table 4).

4. Discussion

It noted that studies related to performance evaluation in medical laboratories in poor countries are limited (Petti et al., 2006). Such bad consequences in medical laboratories in Africa have been discussed in many circumstances (Alifrangis et al., 2009; Carter, 2017). In Sudan, weakness in many components of quality management practices in Khartoum's public medical laboratories had been observed

Table 2. Availability of personnel managements tasks in governmental and private medical laboratories in Wad Medani city.

Task	Percentage %
The regularly immunized of laboratory personnel	37.5%
Members of the laboratory staff appointed as Safety Officer and quality officer	43.5%
Awareness of staff to WHO Laboratory biosafety manual and have they received training in its procedures	37.5%
Personnel training in Lab safety and waste management	56.25%
Personnel training in instrumentation and its maintenance	25%
The operational procedures systematically review by laboratory management at regular intervals	62.5%
Availability of written policy to dealing with occurrence or trauma during your work	12.5%
Total average	**39.25%**

Table 3. Availability of sample management guidelines in governmental and private medical laboratories in Wad Medani city.

Task	Percentage %
Availability to insure that all the specimens arrived to the laboratory with correct and sufficient clinical data	50%
Written policy to deal with incorrectly identified or incorrect specimens received in the laboratory	12.5%
Availability of SOPs available at all workstations for safe handling of all samples	25%
Presence of developing policy for sample storage and sample disposal	6.3%
Total average	**23.45%**

Table 4. Quality control requirements in governmental and private medical laboratories in Wad Medani city.

Task	Percentage %
Calibration of automatic pipette	12.5%
An internal quality control system in place that controls every batch of examinations	50%
Laboratory implement an internal quality control program	37.5%
Laboratory involved in an external quality assessment program	12.5%
The laboratory participate in an external quality assessment scheme	6.3%
Procedure whereby all results are reviewed and signed out by an authorized person	56.3%
Availability of customer's satisfaction feedback	25%
The presence of a monthly report system in your laboratory	50%
Results including date, time, procedure and receiver	25%
Total average	**30.50%**

(Adam, 2019). There are no findings in the current study area that reveal defects in medical laboratory work from aspects related to the parts of total quality; such as the non-conforming design, the lack of safety procedures (Alam, 2022), the management of clinical samples, the poor training and continuous education of laboratory personnel, and the absence of internal and external quality concepts.

In current results, the overall overage of studied medical laboratories regarding the proper design and safety was 22.5%, which is a strong indicator of poorness. Abdallah (Ali, 2010) and Siddig (Mohamed et al., 2016) recorded proportion of studied medical laboratories that designed with separate sample collection rooms equal 56.3% (9/16), near rates in Sudan (48.5%) and Ethiopia (43.75%) respectively. Possible problems related to design shortage in this situation are defects in sampling tracking methods, inadequate area for processing and personnel confusion during practicing (Plebani, 2015). Moreover, certain components of design and safety consideration showed severe deficiency with percentage of only 6.3% (1/16) and this included places of emergency shower, eye wash station and quality office.

This study found the overall average for personnel management parameters of 39.25%, which is lower when compared with other studies in Khartoum; 51% (Adam, 2019) and 55.5% which may reflect the observable variation in performance of medical laboratory personnel in different part of Sudan, some factors may attribute such as availability of training institutions and resources (Harb et al., 2021). In contrast, our results for staff performance over times gave 62.5% a positive rating, while in Khartoum the percentage of 33% was reported by Mahmoud (Adam, 2019), which may be due to factors such as workload, and instruments limitation.

Occurrence of disease e.g. HBV infection among medical staff had been documented to be 6.7 % in African countries and 4.9 % in Sudan (Atlaw et al., 2021), (Elduma & Saeed, 2011) despite of that in the current study only 37.5% of observed medical laboratories personnel were vaccinated. In line, during 2009, the rate of vaccination against hepatitis B among workers in medical laboratories in Khartoum was 16% (Elsir et al., 2018). On the other hand, vaccines against infectious diseases such as typhoid, cholera and herpes zoster which commonly occur in Sudan (El-Amin et al., 2013) still are not introduced.

The obtained results expressed serious defects regarding the sample management of studied medical laboratories; proper disposal of wastes was recorded only in 6.3% (1/16) of study subject, which means inevitability of environmental pollution adjacent to these laboratories. In addition, optimum specimen's identification and rejection followed in 12.5% (2/16), and this may lead to invalidity of wanted test and subsequently incorrect result.

From obtained findings, external quality controls for medical laboratory assessment showed 6.3% (1/16), the reasons that may contribute are lack of governmental directives and the high cost (Krleza et al., 2017). In spite of that, the internal quality control implementation must be taken into an account during all

stages of work from sample collection to report, the study recorded implemented internal quality control among 37.5% (6/16) of medical laboratories, and also this appears as discrepancy in the results obtained in the same laboratory. In conclusion, the study revealed the absence of many indicators of good performance in medical laboratories in the second inhabited city in Sudan, which necessitates more studies that are relevant in order to make suitable intervention decisions. Also, the absence of these important factors from laboratory work affects accuracy, speed, and integrity, and consequently incorrect diagnosis and wrong treatment.

Limitations of Study

There were no data from the medical laboratories that could be used to evaluate instruments or reagents.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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