

The Evaluation of Quality Control and Laboratory Management in Microbiology Laboratories in Sudan Comparing to the International Standards

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Abstract:- A complex adaptive system of laboratories is required to pursue appropriate performance by using the quality management system model. This study was aimed to evaluate the microbiology laboratories quality control and laboratory management performance as well as to develop a systematic approach to ensure the validity, reliability and timeliness test results, and for continuous performance improvement. This study was carried out in Khartoum state in the period 2014-2022. governmental hospital based and private sector microbiology laboratories were thoroughly evaluated using structured questionnaires divided into 7 parts to assess the facility setup, personnel, laboratory facilities, environment and biosafety, equipment, quality system, identification methods, Antibiotic susceptibility testing methods, they were selected in an experimental manner, enabling the collection analysis and study of the data, using the statistical program SPSS to reach the results.

Keywords:- Quality management system, Quality control, Clinical microbiology laboratory, Quality improvement, complex adaptive system.

I. INTRODUCTION

A laboratory quality management system is a systematic process that monitors the effectiveness of laboratory work operations, complies with the national regulations and accreditation bodies requirements and encourages the functional anticipated laboratory resources. (Lucia, et al, 2011).

An extensive review of quality management in clinical microbiology laboratories by Bartlett and Colleagues provides a comprehensive overview of past and merging approaches to managing quality. (Peddecord, 1996) Dr. Bartlett's concepts about quality management in clinical microbiology laboratories contribute to increase the effectiveness of the management of microbiology laboratories, and are used today as (SOPs). (Onderdonk, 2015), 1965, had introduced a monitoring system of the structure of microbiology laboratories, one year later Barson dealt with solving mistakes in microbiology laboratories, 2 years later Harding release recommendation in the same field of microbiology laboratories quality control, during the same period Petersdorf and Sherris written about the quality control of Antibiotic sensitivity testing, between the same time and 6 years later many publications have talked about the quality control in microbiology laboratories. (Bartlett, et al, 1994)

The quality management in microbiology laboratories depends on four elements:

- Quality control and quality assurance plans.
- Quality control techniques.
- Quality assurance(planning and control).
- Opportunities to improve management processes. (Nanda, 2005)

Quality control and quality assurance Planning processes care about all decisions and actions and allocate resources required to meet quality objectives. (Admussen et al, 2015). Quality plan Must specify specific instructions to meet the microbiology laboratories goals, operational procedures inside the microbiology laboratory, assign responsibilities and authorities, yardstick to the instructions and procedures and practices applied inside the laboratories, monitoring and evaluating the process quality objectives achievements. (ASQ, 2022).

Quality Improvement An even wider concept of quality management is presented coming into vogue. (Reeuwijk and Houba, 1998), It's produced through the sustainability of the evaluation and monitoring of the quality system in the microbiology laboratories. (Gravells, 2016).

Quality Control techniques sustain the good laboratory practices and services inside the microbiology laboratories (Besterfield, 2013). It's the test results accomplishments and to find the Accuracy levey and jennings inside the microbiology laboratories.(Mondal, 2017).

Quality Assurance A simply stated, is a documented system of protocols to assure reliability of analytical results. (Drilling et al, 2010), is part of quality management and is an ongoing process that is implemented to monitor and evaluate every step of laboratory's testing operation (Tambwekar, 2014), refer to eliminate any deviations in time, specimen, results, interpretations, data and try to get it right the first time. (Rahman, 2011)

A correct diagnosis of infectious disease and putting it under the control, evaluation prognosis, identification of role of environmental factors of bringing health differences across the geographic areas and convenient treatment depends on reviewing any systematic process of determining whether a service in microbiology laboratories meets specified requirements. (Majid et al, 1996) these processes include standardized quality control strains, staining procedures, sterilization media, appropriate disposal of infectious materials. (Zaman, 2018).

To maintain standard microbiology laboratory practices the quality must be complete of all elements of the test procedure, rational in accordance with reason or logic, and in definite pattern. (Noble, 2004), the oversight of this practices must be to observable result of the successful achieve the process purpose and the equipments. (Brundtland, 2002).

Biosafety in microbiology laboratories consists of a combination of good laboratory practices and techniques, appropriate laboratory facilities. (CBSG, 2013), a periodically preventative maintenance program established safety equipment. (Koneman, et al, 2017). In addition to a realistic, well organized, and well documented program of scheduled preventive maintenance, it is essential that laboratory personnel know and document that all equipment is in good working order each day of use, function checks are used to accomplish this objective and include the activities often referred to as calibration and validation. (Miller, 1987).

A microbiology laboratory must prove its performance and enroll in one of the accreditation programs. (Light Foot and Maier, 1998), from these accreditation programs the ISO 15189 medical laboratories- requirements for quality and competence that have management requirements and technical requirements that focus on areas such as technical competency. (Turgeon, 2016)

Release by the world health organization's regional office for Africa (WHO AFRO) with partnership with the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Towards Accreditation (SLMTA) program to achieve the requirements of the ISO 15189, and teach how to implement practical quality management processes in African medical laboratories. (Bouchet, 2015).

(K. Kumasake and Rinsho, 1993), proposed a external quality control program by using an open and blind surveys and simulated samples, the surveys report on the identification of some kinds of pathogenic organism were inaccurate, discrepancies in media used for isolation were detected, the continuous education of laboratory personnel is essential, previous nationwide external quality control programs have been valuable in promoting general improvement in clinical microbiology. (Ezekiel, 2013), proposed an internal quality control program for diagnostic microbiology by using small scale international quality control program, Ciprofloxacin vs Moxifloxacin calibrated dichotomous susceptibility by using disc diffusion vs antibiotic susceptibility testing performed directly on the patient's specimens, the program show up source of disagreement in the results of the laboratory. Also a quality of microbiology laboratories presented by (Luciano. B, et al, 2013), twelve laboratories lack Ziehl Neelsen staining, 271 free of safety cabinets, >30% with no automated safety cabinets by prevalence survey. And (Ismail, 2013) conducted a microbiology laboratories evaluation by using structural questionnaire, site visit, and simulated samples. An overall poor performance and deteriorated quality control measures at different levels including laboratory

design, equipment and technicians in result. And (Jean, et al, 2014) conducted a country wide domestic laboratories EQA, the performance of bacteriology laboratories leveraged from 75% to 81% to the superior performance 87% from 2006 to 2008, the main challenges spotted were the funds and transmission of quality panels to all laboratories. Also (Othman, 2016) conducted an Arabic studies record for microbiology laboratories by using non interventional observational descriptive cross sectional design. The assessment shows that the microbiology laboratories are necessary to check their integrated set of activities, incorporate procedures and monitor the work processes in all phases, manage resources, behavior assessments and create improvements processes to guarantee appropriate quality results . The system can periodically extend to be able to assess the performance. External quality assessment scheme presented by (Salla, 2020). The commitment to external quality assessment was good, the laboratory attended 4 rounds per year and the submitted results for samples varied from 95% to 99.5%.

Moreover, limited research has evaluated the quality control and laboratory management standards for the microbiology laboratories in Sudan referenced with the previous studies. This study conducted to evaluate current situation of quality control and the laboratory management performance in compare with the international standards by assessing quality control and laboratory management implementation level and practices of technical staff, equipment provided for microbiology laboratory workers and assess the culture of safety to ensure the accuracy, reliability and timeliness of patient test results as well as to develop a quality management system for continuous performance improvement.

II. MATERIAL AND METHOD

A. Sampling plan

Technical staff from different private and governmental-sector microbiology laboratories were selected for data collection.

B. Study design

This research is quantitative study, prevalence study in the survey structured to analyze quality control and laboratory management performance through a structured questionnaire. It made use of both quantitative and qualitative tools in analyzing the data collected through questionnaire and personal observations. The analysis of data collected will be done at the end of the data collection. To interpret frequency, graphical presentation was used through Excel, while qualitative analysis of the personal observations for standard microbiological practices will be made and the results will be described.

The questionnaire are covering the following:

C. Facility setup

Available tests, examination procedures, assuring the quality of examinations

D. Personnel

Organization chart availability, staff availability, professional direction, Job descriptions and contract, staff training, staff education, staff qualifications, staff experience, staff records.

E. Laboratory Facilities, environmental and biosafety

Extend of diagnostic service, Referral to other laboratories, examination processes, authority to enter the laboratory, availability of electric power and backup, ventilation system, air conditioning system, lightning system, laboratory design (enough space, separation between the sections), fire extinguisher, separate area for eating and drinking, biosafety cabinet, disposal container for infectious material, UV light, centrifuge with safety lid and canisters, autoclave, disinfected workbench, personal protective apparel, masks, SOPs, specimens handling, appropriate practices, staff monitoring, new staff training, staff competency testing, laboratory safety.

F. Equipment

Equipment machine, functionality of machine, test that can be performed by the machine, capacity, backup, quality control checks/record.

G. Quality system

Quality manual mission, organization chart, staff responsibilities, job descriptions. Standard operating procedures Identification methods. Colonial morphology, Gram's stain, biochemical reactions, serological tests.

H. Antibiotic susceptibility testing methods

Antibiotic disc availability, antibiotic susceptibility testing methods

I. Sample size

The sample size for this study was 138 technical staff working in microbiology laboratories of ()different private and governmental-sector laboratories in Khartoum state-Sudan according to the formula: $n_0 = z^2 \cdot p(1-p) / e^2$

All technical staff who voluntarily participated in this survey were interviewed using a structural questionnaire, after collection of data, analysis will be performed depending on data from the survey questionnaire, analyzed, suggestions and recommendations.

III. CONCLUSION

The main aim of this research was to evaluate the microbiology laboratories quality control and Laboratory management in Sudan in comparison with international standards.

Research hypotheses have been made for this research some of which have been taken out made axes, including the creation of a questionnaire distributed to the private and governmental-sector medical microbiology laboratories in Sudan to evaluate the quality control and Laboratory management through assess the available tests in these laboratories and the methodology of identification and antibiotic sensitivity testing, staff qualification and training program, laboratory design, facilities, environmental and

biosafety, equipment quality control and maintenance program, quality management system (quality manual, standard operating procedure, external and internal quality control program). It's expected to obtain positive results after analyzing the results.

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