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

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Abstract:

Background: The microbiology laboratory plays an important role in isolation, characteristic of microorganisms, clinical function {infection control}, epidemiological, surveillance, prevention, finding the route of transmission of infective microbe, and participate in the antimicrobial stewardship programs (1). Hence the basic rights of laboratory test reports are the reliability, accuracy, timeliness, and in form that can be sense (2), so, the quality management system model is remarkable to attaining excellence in laboratories practices and improving quality (3).

Objectives: The main objective of this study was to evaluate the quality control and laboratory management of microbiology laboratories in Sudan comparing to the international standards.

Materials and Methods: The type of this study is non interventional study, observational research method, cross sectional study was carried out between 2014 to 2023 structured questionnaire distributed to the seven microbiology laboratories in Khartoum state and Aljazeera state in Sudan to evaluate the quality control and the laboratory management checking and assessing the facility setup, personnel, laboratory facilities, environment and biosafety, equipment, quality system, identification methods, Antibiotic susceptibility testing methods of these microbiology laboratories. SPSS statistical system and Microsoft excel were utilized for data analysis.

Results: The results proposed in Tables and demonstrated that most of the questionnaires respondents about the procedures for the tests and methods done in the laboratory standardized in accordance with the ISO 15189:2012 their number was 81 with percentage (64.3%) there were 45 with percentage (35.7%) was not complying the standards.

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Conclusion: The study revealed that all these microbiology laboratories have moderate performance quality control and laboratory management standards and their needs to continuous improvement programs to provide better patient care.

Keywords: ISO 15189:2012; Reliability; Accuracy; Equipment; Antibiotic Susceptibility Testing

1. Introduction:

In microbiology a quality service can be defined as (the right result, right test, right specimen from the right patient on the right time and properly interpreted (4), these procedures give the services more credibility (5). Quality management system in microbiology laboratories is managed by introduction the quality system which is managed all activities from preanalytical through postanalytical stages of the tests (6), Pre laboratory phase, laboratory phase, and post laboratory phase activities influence the quality of the laboratory outcomes and must be defeated to structured quality control protocol the two an internal one, in addition an external one (7) there is important regulations to ensure implement quality standards in microbiology laboratories during the three phases of the testing procedures, that is includes:

1.1 Pre **analytical stage:**

 is important stage of the laboratory quality management system it includes ordering the test from the provider, patient identification, handling and transportation of the samples, samples acceptance and rejection criteria, sorting out.

1.2 Analytical phase (Laboratory phase)

 it includes regulation of the testing method in agreement with the standards of medical knowledge, ensure the laboratory instrument have been measured what it was designed to measure, ready list of the available tests, follow the standard operation procedures, after completion of the test methods storage the microorganisms and ideal strains too.

1.3 **Post analytical phase** (**post laboratory phase**):

This stage encompasses the process of releasing, issuing, evaluation, and interpretation of the laboratory test results (8).

The quality management system in microbiology laboratories depend on four elements:

A. Quality control and quality assurance plans.

B. Quality control techniques

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    C. Quality assurance (planning and control)

    D. Opportunities to improve management processes (9)

The quality system essentials are critical to maintaining quality management system in microbiology laboratories tool up a framework to ensure that all laboratory processes are completed correctly and within established standard.

    A. Organization.

    B. Customer focus.

    C. Personnel.

    D. Purchasing and Inventory.

    E. Equipment.

    F. Documents and records.

    G. Information management.

    H. Non-conforming event management.

    I. Assessment.

    J. Continual improvement.

    K. Process management.

    G. Facilities and safety (10)

1.4   Types of Quality Control:

There are two types of quality control:

1.4.1 External Quality Control:

The evaluation of the accuracy of the testing procedure at regularly occurring intervals and retrospectively to enhance the laboratory performance and monitoring the tests on identical or similar test materials by two or more laboratories (11), types of the external system are the proficiency testing or other types of interlaboratory comparison testing (12), which implies microbiology laboratories to compare the laboratory performance with other reference internal and/ or external laboratories, cooperative in the same disciplines (13).

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1.4.1.1 Proficiency testing (PT):

A proficiency test (PT) is a method used to determine the performance of laboratory workers to validate a particular measurement process, the artifacts send to the laboratory's, measurement values are not known by the participating laboratory to checks the laboratory workers competency (14).

1.4.1.2 Alternative performance Assessment (APA): (Alternative Proficiency testing)

Is an alternative system for influence the reliability of tests for which proficiency testing (PT) is not readily accessible, is occurring twice yearly (biannually) (15).

1.4.2   Internal Quality Control:

Internal quality control is done through self-assessment (16). Set of procedures undertaken by laboratory staff for continuous monitoring of day-to-day processes and to determine the reliability of patients results before released (17) The main purpose of an internal quality control is to confirm that results remain compatible overtime (18).

Quality system in clinical microbiology must thoroughly covering every point in the diagnostic stage from the collection the samples to the result interpretation, mistakes at any point in the diagnostic stages can lead to erroneous outcome (19).

1.5 Guideline of Microbiology Laboratories Quality Parameters:

The quality parameters in microbiology laboratories are outlined as follows:

   A. Process of collection and transportation of the specimens.

        1. Give instruction for collection and transport process.

        2. Well established criteria for acceptance and rejection of the specimens.

   B. A policy and laboratory Procedure manual

        1. Characterize test performance, toleration limits, specimen appropriateness, chemical reagent preparation quality calculation and reporting.

        2. Assessment yearly.

        3. Afford it in the workplace.

   C. Laboratory Personnel (staff)

        1. Utilize qualified enough personnel based on the workload

        2. Provide continuous educational programs.

        3. Issue written performance point of reference and clear standards.

        3. Assess every year.

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D.   Laboratory Quality control reports

    1. Report only to authorized persons only.

    2. Inform the test requester of significant values instantly.

    3. Give reference ranges where applicable.

    4. Correct mistakes in the patient's laboratory report on time.

    4. Record retention no less than two years.

E.   Referral laboratories

    1. Operate just approved reference laboratories.

    2. Add name of approved reference laboratory on patient's laboratory reports.

F.   External quality assessment

    1. Engage in appropriate external quality assessment scheme (EQAAS).

    2. Hold internal proficiency testing programs.

G.   Equipment performance

    1. Records equipment function checks test.

    2. Achieves as regularly as established by the manufacturer.

    3. Records regular and routine preventive maintenance.

    4. Maintenance records retention for the equipment lifespan.

 H. Laboratory Culture media

    1. Commercial microbial prepared medium.

     a. checks all lot for damaged media or petri dish, hemolysis, unequable.

      filling, redundant bubbles and contamination.

     b. Record deficiency, take appropriate corrective action, notify manufacturer.

    2. User prepared microbial medium

    a. Documents quantity prepared, source, shipment numbers, methods of sterilization, date preparation, PH, date of expiration.

    b. Inspect media for pigment, uniformity, deepness, or slant, smoothness, hemolysis from blood contamination, air bubbles. attempt media with known microbiologic quality control microorganisms

    c. Stains, chemical reagent, and serum

    d. Categorize containers as to contents, concentration, regulations for storage, preparation date, received/availability for use and service life.

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      e. Store as per manufacturer guidance.

      f. Check with positive and negative controls before use.

      g. Ditch out of date materials and reagents.

      h. Check all lot as per of the manufacturer guidance (20).

The evaluation of microbiology laboratories quality control and management system is covered by numbers of research and scientific published papers all over the world because of the importance of the topic and the critical role of the microbiology laboratory. the evaluation of external quality control and laboratory management for clinical microbiology is carried out in Tokyo metropolitan, they implement external quality assessment scheme they concluded that there is poor and deficient in the performance in the microbiology laboratories external quality assessment scheme, they put a recommendation to fix the poor laboratory managements by the continuous training, skilled medical technologists, administrative capacity of the adviser physicians in separate medical microbiology laboratories, adopt the quality system style from industrial carrier may give us with powerful guide to build good system models for the good microbiology laboratories, there some barriers to implement the program like community factors includes deficient in the infrastructure of the training programs specially in the small private medical microbiology laboratories, confined number of skilled clinical pathologists in the Japan society of clinical pathology (21). Arabic study carried out in 2007 in microbiology laboratories in Tehran and districts to analyze the external quality assessment report out of business and public-sector hospital-based microbiology laboratories in Tehran and districts, the external quality assessment scheme-proficiency testing carried out by distributed two unknown samples for bacterial identification of couples unrevealed samples Burkhederia cepacia and checked out the sensitivity testing of Staphylococcus epidermis only, to total of121 microbiology laboratories 79 of them in public-sector 42 of them in business-sector, the results obtained from 106 laboratories approximately all microbiology laboratories obtained right answer for recognition and sensitivity testing of Staphylococcus epidermidis there is a problem with Burkhederia cepacia identification specially in the business-sector, they concluded that Tehran and districts microbiology laboratories struggling with identification of some microbial strains particularly in business-sector, appropriate guidance to the manufacturers to make essential culture media and chemical reagents to diagnosis of Burkhederia cepacia build on continuous training program, guidance on good scientific practices (22). One of the little research done in Sudan to review the microbiology laboratories it carried out at 2010 to observe,

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monitor, and manage the infectious transmissible disease like meningitis, cholera, shigella, and also water quality by public health microbiology laboratories and analysis the barriers to microbiology laboratories development, they choose to applied routine microbiology diagnostics methods, open access networks applications stated the results gain from microbiology laboratory into actual time district geographical, case surveillance system and reporting system for transmissible disease, they noticed poor and defective laboratory infrastructure and shortage of microbiology public health laboratories (23). In Asia between 2009-2015, they outlined and checkout the microbiology laboratories proficiency testing, external quality assessment program (EQA) survey and performance report of Philippines microbiology laboratories by recognizing three microorganisms and fulfilled antimicrobial susceptibility testing on one of the identified organisms, from 468 participating microbiology laboratories during the period from 2009 to 2015 high rate of microbiology laboratory attained the performance improvement during several years 33.3% were good performers, 6.6% were fair performers, 60.0% were poor performers, the concluded that the reason of poor performing deficiency of unskilled laboratory staff, microbiology laboratory resources, and fulfillment quality management system standards in microbial diagnostic testing, the corrective action required to handle the circumstances of poor operating microbiology laboratories (24).

Throughout the worlds, the pursued the assessment of external quality assurance scheme at 2019, by evaluate the external quality assessments program attendance and cooperation status in Salmonella and Shigella species has been treated for 6 years undergoing WHO-AFROGSS EQAs program, the bacterial identification and typing of 7 Salmonella , Shigella spp, Campylobacter and other unknown enteric pathogens the culture media carried out on adequate and selective media, bacterial typing were described using expression in accordance with Kauffmann-white Le Minor techniques, for sensitivity testing disc diffusion techniques and CLSI explanation, results of the samples from 2008-2013 typing reports were accurately noted as 87% zero deviations was documented for Shigella spp, 2 Campylobacter spp in 6 years in 2009-2010 the reports is compromise with the predicted rate 50% and 100% subsequently, the antimicrobial sensitivity testing was accurately documented as 89.9% , the agreement and application of external quality assessment programs in developing countries are limited reported and practiced, they recommended to assign sufficient resources to improve the external quality assessment program (25).

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Moreover, the importance to evaluating the quality control and laboratory management in the microbiology laboratories in Sudan is important because of its privileged location in Africa, some big hospitals are based there, and patients come for treatment, therefore providing reliable and accurate diagnostics services is essential. Knowing the evaluation of the quality management system in microbiology laboratories is a stone corner for adopting a system based on quality and looking forward to continuous quality improvement and accreditation. The aim of this research is to evaluate the quality control and laboratory management of microbiology laboratories in Sudan comparing to the international standard since little evidence for that and highlight the importance of applying quality standards in microbiology laboratories.

2. Materials and Methods

This research is a Quantitative non interventional descriptive study, was carried out in Khartoum State and Al Jazeera State at governmental and private laboratories during the period from 2014 to 2023. One hundred and twenty-six questionnaires according to the formula

$$n_0 = z^2.p(1-p)/e^2$$

were distributed to seven governmental and private-sector microbiology laboratories talking the responds that meet Inclusion and Exclusion Criteria from laboratories of governmental and Private sector with microbiology department, data Processing and Statistical Analysis uses SPSS (Statistical Package for the Social Science16.0) and Microsoft Excel and is presented in the form of frequency distribution tables.

3. Results

Data about Facility setup, Personnel, Laboratory facilities, Environmental and Biosafety, Equipment, Quality system, Identification Methods, Antibiotic Susceptibility Testing Methods were collected using structured questionnaires.

A total of 126 structured questionnaires were collected from two Sudanese States were selected randomly to participate in this research study, through seven participating clinical microbiology laboratories.

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there are (125) answers with percentage (28.9%) were Urine about the question that "What tests are available at your laboratory?" , (80) answers with percentage (18.5%) were Different swabs, (75) answers with percentage (17.3%) were stool, while (45) answers with percentage (10.4%) were Blood, (42) answers with percentage (9.7%) were C.S.F, (35) answers with Percentage (8.1%) were sputum, 31 answers with percentage (7.2%) were other body fluid.

Table 1. Available cultures test at the laboratories.

What tests are available at your laboratory?	Responses		Percent of Cases
	N	Percent	
Urine	125	28.9%	99.2%
Stool	75	17.3%	59.5%
Different swabs	80	18.5%	63.5%
C.S. F	42	9.7%	33.3%
Blood	45	10.4%	35.7%
Sputum	35	8.1%	27.8%
Other body fluids	31	7.2%	24.6%
Total	433	100.0%	343.7%

Table 1. Shows what is the most available cultures test at the laboratories.

Table 2. A procedure for the tests/ methods standardized in accordance with the ISO 15189:2012

Are the procedures for these tests/methods standardized in accordance with the ISO 15189:2012	Frequency	Percent
Yes	81	64.3
No	45	35.7
Total	126	100.0

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Table 2. Shows are these procedures for the tests/ methods standardized in accordance with the ISO 15189:2012

4. Discussion

The most specimens for culture were done by the microbiology laboratories that were urine culture 125(28.9%) These results and finding were agreed with a study which was done by Bartlett et al. they found that urine culture was represent the urine culture is the high-volume type of culture specimens encountered in most microbiology laboratories because it is easily to obtain it without needing to invasive process (26)

the present results and findings indicated that the quality management system in Sudanese microbiology laboratories need to improve due to the sensitivity of the diagnostic area in the patient care process, these results and findings were agreed with a study which was done by Ibrahem found that the poor adoption percentage of ISO 15189 requirements was between 34% to 64% (27)

the most respondents answer that the biochemical reactions used for identification of gram-negative bacilli because the nature of gram-negative bacteria that produce large volumes of enzymes that allow for their identification.

Kirby-Bauer disk diffusion method considers the standard method for the antimicrobial sensitivity testing of bacterial isolates, these findings were agrees with study which was done by Mohamed et al. because of some barriers and financial matters this medium is not feasible option in many developing countries and instead nutrient agar is used for antimicrobial sensitivity testing (28). The laboratory personnel need to be more aware of laboratory regulatory and policies, received regular continuous education programs, and assign with qualified professional in the carrier (29), these findings and results agreed with a study which was done by Barbé et al.

Is the most available equipment the microscopy (30) may be due to recognize different kinds of bacteria also may be due to its not expensive, then incubator 61(48.4%) may be because its essential part of the culture process via maintains a constant temperature suitable for the growth of a specific microbes, and the least is the hot air oven 47(37.3%) may be due to the limited used just for sterilization of glassware's, these findings and results agreed with a study which was done by Ibrahim.

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Laboratory quality management systems (LQMS) can provide a framework for document and process controls, These results and finding were agreed with a study which was done by Kecklera et al., as well as risk assessment and monitoring procedures to improve laboratory safety (31). The results and findings show that the need of improvement in varies ways according to evaluation of these quality system measures between Sudanese microbiology laboratories and similar microbiology results in other countries, however the performance of the laboratories was proved when they implement and sustain quality management system.

5. Conclusion

There are no constant overall policies for identification and Antibiotic sensitivity testing in Sudan. Microbiology laboratories in Sudan were not fully equipped and weak corrective actions for quality issues and response to equipment failures. Moderate performance of ISO 15189:2012 standards for procedures of testing methods were observed. Personnel need more awareness and recognition about the quality management system in the microbiology laboratories. limited microbiology laboratories facilities, environmental, and biosafety infrastructure. Low level of implementation of quality control and laboratory management were evident in the participated microbiology laboratories.

Acknowledgments

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