PLASU Law Journal (PLASULJ) Vol. 1, No. 2, 2024
A Publication of Faculty of Law, Plateau State University, Bokkos –Nigeria
EISSN 1596-0625 (Online) https://journals.plasu.edu.ng ISSN: 2695-2661 (Print)

MEDICAL LABORATORY SCIENCE IN NIGERIA: NAVIGATING MEDICOLEGAL AND ETHICAL DILEMMAS

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Abstract

The practice of medical science in Nigeria is fraught with numerous medicolegal and ethical challenges that impact healthcare delivery and patients outcomes. The laboratory testing process, including the preanalytic, analytic, and postanalytic phases, is an area where errors frequently occur. These errors may impair the diagnostic process and compromise patient safety. Delay in diagnosis and failure to diagnose are common reasons for a medico-legal action. The research methodology employed in writing this research is the doctrinal methodology. The primary and secondary sources were employed. This paper interrogated that the laboratory and hospital need to design systems that reduce the possibility of error and to rapidly identify and resolve the errors that do occur. Because the pre- and postanalytic processes extend into the clinical operations of the hospital, the laboratory can play an important role in promoting patient safety by assisting clinicians with test ordering, communicating test results appropriately, and aiding in the interpretation of results. The study recommended the development of comprehensive guidelines on medicolegal and ethical issues, regular training and education for medical practitioners advisory unit to provide support and guidance. It's further recommended that there is a need for increased awareness and enforcement of patients' rights and the adoption of electronic health records to improve documentation and reduce errors.

Keywords: Medico-Legal, Ethical, Issue, Medical, Laboratory, Science Practice

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Introduction

Medical laboratory science has been defined by the Medical Laboratory Science Council of Nigeria (MLCN) Act 11 of 2003, as the practice involving the analysis of human or animal tissues, body fluids, excretions, production of biological design and fabrication of equipment for the purpose of medical laboratory diagnosis, treatment and research[1]. Quality practices in medical laboratory services are of paramount importance in health care delivery.

Healthcare ethics is not routinely taught to the health professionals, and there are reports that even the word “ethics” has been completely ignored in the undergraduate curriculum of some health professionals. Thus, it is not surprising that the theory and application of healthcare ethics in day-today practice is still not well known to many healthcare providers; medical laboratory professionals inclusive. Therefore, practice of ethics in healthcare, may be very much influenced by the cultural background and beliefs of the people in every region. Ethical behavior means doing the "right" thing. Frequently, the ethical approach is not the most cost effective way to solve a problem nor does the ethical solution always result in greater short term profits. However, the moral structure and legal framework encourage us to walk the ethical high road. Failure to do so can lead to public humiliation and legally enforced penalties.

The last decade has seen a rapid expansion of the various branches of health care services in Nigeria. This has seen a corresponding increase in consumer knowledge, which has resulted in (a) increased demand for high quality services and (b) these services to be provided in a timely manner. Medical laboratory plays a central role in the delivery of these services as over 70% of clinical decisions are taken based on laboratory reports.

An important component in the whole process is laboratory error and an expectation to get error free services. With growing awareness amongst customers, in this case, largely patients and increasing cost, medico- legal litigations are on the rise. Court cases are often filed against doctors by patients for real or perceived reasons of dissatisfaction. Medical malpractice law suits against medical laboratories are also on the rise. This has placed a significant onus and urgency on clinical laboratories to ensure that quality and error free work practices are maintained[2].

There has been a steady improvement in the quality of tests due to improved technology. Laboratory automation, has also taken on a new level of importance in improving quality. We have the ability now to get instruments interfaced to various laboratory information systems. Information technology, has consequently taken a giant leap in the field of biomedical equipment to drastically reduce manual intervention during the analytical procedure without compromising on established levels of care.

Despite the above developments, errors due to pre-analytical factors, continue to occur and we have to focus on these issues to reduce the errors. The high frequency of errors, still attributable to processes external to the laboratory, requires special attention and efforts to prevent such errors. This will ultimately contribute to prevention of direct or indirect involvement of the laboratory in medical liability cases.

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[1] Medical Laboratory Science Council of Nigeria Act 2003

[2] *Indian Journal of Clinical Biochemistry*, „Effective Laboratory Quality Management Towards Preventing Medical Liability Cases*’*, , 2010|25 (1) 1-3

In the laboratory, mistakes are liable to occur in each possible step starting from preparation and sample collection down to actual dispatch of the report. For example, consider the following scenarios:

(a) A blood sample was drawn from a patient for electrolyte estimation but was wrongly collected into a tube containing anticoagulant with K+ (EDTA). On realizing his error the technician tips the sample into the correct tube. As a result of this the measured K+ value in this sample is falsely high due to the added K+ in the EDTA while the Ca is falsely low due as the available Ca in the sample got chelated by the EDTA. All of this is due to a simple mistake of collecting the sample in the wrong container![3]

(b) A hospitalized diabetic patient whose blood glucose had been brought down to and maintained at euglycaemic levels, was on a particular day found to be quite abnormal. A thorough enquiry revealed that the duty doctor forgot to enter the order for insulin injection for the next morning, which was consequently not administered by the nurse. Hence, the abnormal blood glucose value[4].

(c) Medico legal litigations involving Fine Needle Aspiration Cytology (FNAC), are a result of a poorly prepared sample. This fact is neither mentioned in the report, nor reflected in the diagnostic conclusion[5].As a result, the clinician assumes that conditions for a reliable diagnosis were met and on this basis plans a therapeutic procedure[6]

d) Cytological diagnosis has its own fallacies. For example, the sensitivity of FNAC in breast lesions is 90 - 95%. Failure to communicate the limitations of FNAC, in various lesions can result in surgeries, which may be unwarranted. These form a bulk of medico legal litigations involving practice of cytology[6].

There are innumerable examples such as these that can be quoted, which are certainly a timely reminder to clinical laboratories to make sure that pre-analytical steps are very important in the provision of valid results and clinical management. As consumers raise the bar on their expectation of provider quality, laboratories must respond by using management methods of continuous improvement to reduce and eliminate any and all sources of errors and defects in their work flow, analytical activities and customer service execution.

Yet another factor to consider is how the senior laboratory personnel, can provide value adding to the results generated by giving interpretative comments on laboratory reports. In this regard, several legal steps have been taken by the Government of
Nigeria to help the public get maximum compensation for errors made by doctors and laboratories, one of which is the Medical and Dental Practitioners Act 2004.

Legal Relationship Between Laboratory Manager And Patient

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[3] Ibid

[4] Ibid

[5] Ibid [6]

Kocjan G, Fine needle aspiration cytology, "Diagnostic principles and Dilemmas" 1st edition, 2006 (Chapter 2); 11-13).

[6] Orell SR and others, *Manual and Atlas of Fine Needle Aspiration Cytology*, 3rd edition, 2006 (Chapter 7); 150-51)

Laboratory manager performs the medical analysis on account of his/her contractual relationship with the addressee4. Said contract can be considered to have been formed upon patient's request for the analysis (offer) and laboratory manager's acceptance to perform the analysis (acceptance)[7]. The party of the contract who undertakes the transaction is usually the laboratory manager. Although there may be various employees in the laboratory who perform the necessary transactions, the contract is nevertheless formed with the manager of the establishment.

Although the contract regarding medical analysis is established usually with the laboratory manager, in some instances, it is also possible to obtain the said service directly from the laboratory manager without any contract whatsoever. In some circumstances, however, it is not the patient, but the physician selects the laboratory manager. Accordingly, the party to the contract is usually the patient, although this may not always be so. In certain cases, even though the medical analysis relates to a patient, the contract may be formed with another person[8]. For instance, where the sample is collected from the patient in a different place and delivered to the laboratory, the contract is established with the person who sends the sample. An example to such a situation is the circumstances where a physician himself/herself collects the blood sample of the patient for therapy and he/she sends it to the laboratory with which he/she has a agreement with. Again, the circumstance where an employer sends the samples of his/her employees to a certain laboratory constitutes a similar situation.

Another example is in cases where the employer sends his/her employee to a certain laboratory so that a sample may be collected, the contract is established between the employer and the laboratory manager. Even though collection of a certain sample from an individual's body constitutes an invasion to his/her absolute right which is strictly linked to the personality of the involved party, since the person involved will have

personal consent to the test, this will not be an obstacle against his/her absolute right being subject to the contract[9]. Particularly, for instance in cases where the owner of the workplace undertakes the costs of the analysis, this should be accepted as not only a contract for costs but also a contract of analysis which also involves the costs between said owner and the laboratory manager. Besides, this acceptance is a consequence of the intent of the parties because especially the intent of the laboratory manager for establishing a contract is addressed to the employer.

The obligation of the patient concerning the contract is generally the payment of costs. Payment of costs constitutes the remuneration for the work performed therefore the cost, as such, is not an action which defines the nature of the contract. It is the counter obligation, i.e. act of work or service that mostly defines the nature of the contract[10].

It is important to determine between whom the contractual relationship is formed because demands based on contract, as a rule, may only be claimed by the contracting parties those between whom the contract is formed.

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[7] Zekeriya Kursat, *Legal Liability of Medical Analysis Laboratory Managers due to Laboratory Errors*, 2010

[8] Zekeriya Kursat, *Legal Liability of Medical Analysis Laboratory Managers due to Laboratory Errors,* 2010

[9] Ibid

[10] Ibid

The main obligation of the laboratory manager is to perform the necessary analysis and report the results thereof. In addition, other obligations may arise based on the content of the existing contract. Accordingly although changes may occur depending on the characteristics of every individual situation, the obligations of the laboratory manager may be listed as follows: i. Collecting sample from the individual. ii. Examination of the sample.
iii. Reporting the results of examination. iv. Interpretation of the result.

The laboratory manager should demonstrate all care required in his/her profession. For instance, he/she should duly be aware whether the sample subject, is ready for this action in terms of food intake, hunger, exercise, smoking, alcohol intake, drug intake, high fever, age, sex or pregnancy, etc., thus ascertaining that the sample reflecting the real situation can be collected.

The laboratory manager should consider different issues depending on the type of the sample and should handle the sample with necessary care. It is instructive that, he/she should see to it that the tourniquet applied to the arm during blood collection does not stay longer than a certain time period. Similarly, he/she should pay due care to matters such as selection of vein or body part or collection of urine in the right timing.

Determination as to whether due care was shown for such matters, is the subject of the field of medical science and as such, should be evaluated by relevant specialists within the framework of professional requirements.

Results caused by inadequate care can cause liability of the laboratory manager. For example, if the parameters in blood are affected due to keeping of tourniquet in the arm for too long causing identification of incorrect blood values, unwanted consequences may occur. In particular, it is a high probability that incorrect test results influence the therapy method to be chosen by the physician. In such a probability, the error in the preferred therapy and the harm that this causes may bring forth the liabilities of the laboratory manager under discussion.

The laboratory employee’s task is not limited to the collection of the sample. Naturally in cases where the patient brings his/her sample or the sample is delivered to the laboratory the liability of the laboratory manager emerges as of the stage that follows the collection of the sample. However, even in this case, the laboratory manager is responsible for re-collection of sample or is expected to recommend and inform the patient accordingly if any need or especially, if any suspicion arises. Should the patient nevertheless reject submission of a new sample, the liability of the laboratory manager, ceases for that stage.

The liabilities of the laboratory manager at this stage, consist of subjecting the samples to the necessary tests in a timely manner, correct execution of tests and taking due care for preserving a sterile environment. In addition, if additionally required or if the circumstances necessitate, the resulting test should be interpreted correctly in the framework of his/her professional knowledge, otherwise it is possible that he/she, may be held responsible for the damages caused by incorrect assessment.

Main Obligations Arising from the Relationship between Contracting Parties

The content of the contract established between the parties, is the primary determinant source for the obligations of the parties.

Therefore, obligations are identified by evaluation and interpretation of the contract in the concrete situation.

The Concept of Laboratory Errors

There are two important aspects of the process of medical analysis in order to consider whether the laboratory manager has performed the act or task properly. These are: i. Providing the analysis results in a timely manner ii. Providing reliable or correct analysis results.

Acts contradicting these two aspects may be considered as "*laboratory errors*". In this regard, laboratory errors pertain to matters which may be laid at a person and which prevent the analysis to provide the true results.

Although the delay in providing the analysis, does not as such mean that the analysis is erroneous, the delay itself may hinder the benefit expected from an analysis. Therefore, it is possible to consider the liability of the laboratory manager for compensating damages resulting from delays. This is why, the concept of "*laboratory errors*" as used here, includes both delays and erroneous results.

Laboratory errors may occur in various forms which differ in each individual case depending on the type of the analysis, type of the sample and personal condition of the patient[11].

The equipment utilized during collection of samples or execution of tests, the laboratory environment, manner of working, deficiency in personal skills or know-how or the methods used, may lead to laboratory errors.

An erroneous analysis result may be caused by incorrect evaluation of the result as well as incorrect selection of samples, ill preparations or incorrect application of tests. In this regard, it is crucial that a result achieved through utilization of various equipments is evaluated with the necessary know-how in compliance with scientific criteria and professional standards.

The Legal Effect Of Laboratory Errors: Liability

In private law, *liability* usually means to constitute the remuneration of the debt of *compensation*. Accordingly *liability* is closely linked to the concept of *damage*. In this regard, liability is a concept that is referred to in order to acquire the compensation for damages suffered by a certain person[12].

Damage, on the other hand, may occur when a person is subject to a material or moral infringement against his/her existence; moreover, it may occur as a loss or damage against assets and even as a matter of economic activities[13].

In the light of these, the liability for the laboratory manager may come up due to damages incurred by the contracting party or the owner of the sample that was subjected to analysis.

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[11] Zekeriya Kursat, *Legal Liability of Medical Analysis Laboratory Managers due to Laboratory Errors*, 2010.

[12] Ibid

[13] Ibid

Moreover, liability may rise with regard to any person who justifiably trusted the information established by the laboratory manager due to its credibility.

How to avoid Laboratory Errors / Preventing the involvement of the Laboratory in Medical Liability Cases

1. The laboratory and hospital, need to design systems that reduce the possibility of errors and to rapidly identify and resolve the errors that do occur. Because the pre- and post-analytical processes extend into the clinical operations of the hospital, the laboratory can play an important role in promoting patient safety by assisting clinicians with test ordering, communicating test results appropriately and aiding in the interpretation of results.

2. For patients, some of the most devastating medical mistakes, can start in the laboratory, where studies show that 3 percent to 5 percent of the billions of specimens taken each year are defective, be it a biopsy that does not extract the tumor cells, blood that is not drawn correctly or a mix-up with another patient's sample[14]. Therefore, sampling must be made with proper care.

3. The laboratories should incorporate effective specimen rejection criteria towards preventing the process of defective/doubtful samples.

4. Specimen integrity has definitely increased with the introduction of bar- coded Technology. When the system is used properly, we know with certainty the patient to whom a specimen belongs. The laboratory should avoid critical specimen errors such as incorrect patient ID, incorrectly labeled specimen, incorrect time on label, delayed transportation to laboratory, computer-related error, insufficient quantity, hemolysis, etc1516

5. Bidirectional interface and on-line data transfer:

Interface of machines will help in increasing turn-around times, less error in patient samples through positive identification, easily carrying out management stats, ease of transmitting results to digital medical records thus increasing paperless environment, less error in transmitting results to reports, better maintenance of results quality through error reduction.

6. Reporting of patient's test results at the earliest possible time, is of paramount importance. Laboratories have been penalized by the courts in our country for the exorbitant delays in giving crucial test reports.

7. Total compliance with the rules on documentation.

It is the foremost responsibility of the laboratory to make sure that patients always receive the service they deserve – a good quality result be ensures our referring clinicians can practice good medicine. Patients deserve quality. As for any other type of medical errors, the most effective path to improvement in laboratory performance is the implementation of a total quality management system, encompassing a multifaceted strategy for process and risk

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[14] "Landro L, „Hospitals move to cut dangerous lab errors", *'The Wall Street Journal'*, 2006; June 14.

[15] Bologna LJ, Motter M. Life after phlebotomy development: Reducing major patient and specimen identification errors. J Healthcare Information Management 2002; 16(1): [16] -70)

analysis, based on error detection, prevention and management. Let us remember that a solid base for quality, is to establish a strong foundation of quality assurance and the watchwords are **"SAY WHAT YOU DO, DO WHAT YOU SAY & PROVE IT"**.

Ethics Of Medical Laboratory Practice In Nigeria

There are 'do's and 'don't's, which constitute ethical values in this environment and in compliance with provisions of rules of the regulatory body-Medical Laboratory Science Council of Nigeria. The list is inexhaustible but some of the specific guidelines are listed below:

1. Adhere to Standard Operating Procedure (SOP), for all analysis in the laboratory even if it means a longer turn-around time and costs more resources[15].

2. Do not discriminate in observing safety precautions at the point of contact with patients for example during phlebotomy and in handling samples. Observe universal precautions by wearing personal protective equipment (PPE) and designating dirty and neat regions in the laboratory for the safety of laboratory staff, the patients and the environment[16].

3. Guard the privacy of the clients as provided for by the Laboratory guidelines. Do not compromise patient confidentiality. Therefore, resist all temptations to divulge laboratory results to unauthorized individuals.

4. Ensure that internal proficiency testing is conducted at intervals, depending on work load and enroll for an External Quality Assurance (EQA) Program.

5. Practice waste disintegration and dispose of all biohazard wastes generated in your laboratory as provided for by the law.

6. Engage trained, certificated and licensed individuals in your laboratory and do not promote quackery. Subject these employees to retraining at intervals by enrolling them for continuous professional development (CPD) of Medical Laboratory Science Council of Nigeria (MLSCN) to enable them perform their tasks well.

7. Discuss all potential conflicts of interest with your supervisors so that you can be exempted from the procedures in which your interest may be a source of bias. For example, it is not ethical for you to handle parental dispute case in which a putative father is a relative or friend to you. You must not conceal your relationship with the client from your supervisor. This is to avoid the slightest hint of prejudice.

8. Do not pay kickbacks or any other improper incentives to clients and clinicians, with a view to induce them to request laboratory tests on patients who do not need them.

9. Do not lie about laboratory services of which you lack facility. Do not falsify any result for any reason whatsoever. Remember, there is no placebo in the laboratory.

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[15] Musa Abidemi Muhibi, „Adherence To Professional Ethics Among Medical Laboratory Personnel: A Prerequisite For Quality Health Care Delivery In Nigeria",2010

[16] Musa Abidemi Muhibi, „Adherence To Professional Ethics Among Medical Laboratory Personnel: A Prerequisite For Quality Health Care Delivery In Nigeria",2010.

10. Do not perform yet to be validated assays in medical laboratory for diagnostic purposes. Remember that medical laboratory techniques are standardized experiments that have been assessed for analytical reproducibility and analytical accuracy, and found suitable.

11. When the need arises, be comfortable to place a call back on an erroneous result that has left the laboratory. You will be doing the patient harm, if you do not call the result back.

12. Do not compromise quality for financial gain. Treat each specimen as if it were your own. Do not use an inferior method just because it saves you money. Do not hire technical support staff for the lowest salary if they are not qualified to fulfill the job requirements.

13. Regularly audit your ethics/compliance program 14. Do not violate relevant laws under any circumstances.

15. Perform only those tests requested.

16. Do not discriminate on any basis. Never discriminate on the basis of age, sex, gender, ethnic background, race, or any other factor unrelated to job performance. This applies to hiring, disciplining, promoting, or dismissing employees.

17. Do not punish employees who criticize. Be open to criticism from employees. In no case should you punish the worker who speaks his piece, especially if it disagrees with management policies or procedures. Of course, the employee in question, should present such criticism in the appropriate manner and forum.

18. Discipline employees who violate the laboratory's ethical guidelines. Don't accept unethical behavior from any employee. Send the clear message that your organization will not tolerate such action. If necessary, discipline and even dismiss those individuals who act in an unethical manner. The rest of the staff will get the message[17].

Conclusion

It is very clear that we have a lot of progress to make as a nation in providing an enabling environment with modern and innovative equipments to aid laboratory practitioners in carrying out their duties effectively and efficiently. However, Medicolegal and ethical issues are significant concerns in medical science practice in Nigeria, requiring attention to ensure quality healthcare delivery and protect the rights of patients and medical practitioners. By addressing these challenges, we can promote a culture of accountability, respect, and excellence in healthcare practice.

Notwithstanding, patients should remember that they have rights; the right to ask questions, the right to get second opinions, and a voice to complain.

We may not be able to solve all our challenges arising from medical negligence; however, we can collectively make efforts to make it bearable.

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[17] Musa Abidemi Muhibi, „Adherence To Professional Ethics Among Medical Laboratory Personnel: A Prerequisite For Quality Health Care Delivery In Nigeria“,2010.

The Medicolegal and ethical issues in medical laboratory science in Nigeria are complex and multifaceted. The conclusion drawn from various studies and reports highlight the need for improved regulations, standards, and guidelines to ensure the quality and reliability of laboratory results. Additionally, there is a need for enhanced training and education of laboratory professional on ethical and legal issues to promote a culture of professionalism and accountability.

Furthermore, the conclusion emphasizes the importance of addressing the challenges posed by inadequate infrastructure, equipment, and resources, which can compromise the accuracy and integrity of laboratory results. Strengthening the legal framework and enforcement mechanism is also crucial to prevent and address medicolegal issues, such as negligence, malpractice, and quackery. Ultimately, prioritizing medicolegal science, is essential to ensure patient safety, public trust, and the overall quality of healthcare services in Nigeria. However, the following recommendations are also very important:

1. Establish clear policies and procedures for handling medicolegal issues.
2. Provide regular training on ethical issues, such as confidentiality and informed consent.
3. Implement robust quality control and quality assurance measures
4. Ensure accurate and reliable test results to prevent legal liability.
5. Foster a culture of transparency and accountability in medical laboratory science
6. Encourage open communication among laboratory professionals, clinicians, and patients.
7. Stay updated on changing laws and regulations affecting medical laboratory science
8. Develop strategies for managing conflicts of interest and bias.