# MEDICAL LAW: EXPLORING DOCTORS' KNOWLEDGE ON THE LAWS REGULATING CLINICAL AND MEDICAL LABORATORIES IN NIGERIA.

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### **ABSTRACT**

#### BACKGROUNE

The Nigerian healthcare system has experienced repeated disharmony between the Medical Laboratory Scientist and the Pathologist. This may be seemingly due to lack of understanding of the Medical Laboratory Science Council of Nigeria (MLSCN) Act and the Medical and Dental Practitioners Act of Nigeria (MPAct) by those in the sector. These laws have clearly defined the two professions, their specific job role and the laboratories designated to them. The clinical laboratory is not the same as medical laboratory based on the Acts of the law that established these two laboratories.

The understanding of these Acts of the law will help to mitigate this disharmony in the healthcare sector.

#### **OBJECTIVE**

This study explored the knowledge of doctors on the laws regulating clinical laboratory and medical laboratory in the Nigerian healthcare sector in order to minimise disharmony in the health sector.

#### MATERIALS AND METHOD

The study was across-sectional descriptive survey. A sample size calculated was 216 using the Lesley Kish formula. (\*Simple random sampling was used to select participants at the University of Calabar Teaching Hospital, Calabar, Nigeria. The data forth is study was collected using semi-structured, self-administered questionnaire and it was analysed using SPSS version 21.

#### RESULT

The ratio of female to male participants was 1: 3.6, majority {132 (61.1%)} were less than 40 years of age and 41 (19%) had worked for more than 10 years. More participants {164 (75.9%)} were aware of the MP Act when compared to awareness of MLSCN Act {98 (45.4%)}. However, fewer number of participants had actually read the MP Act {56 (25.9%)} and the MLSCN Act {32 (14.8%)}. There was a statistically significant difference (p=0 . (b) (a) we have a wareness, reading of both Acts and understanding the job specifications of these two laboratories in the Nigerian health

#### CONCLUSION

The knowledge of the Acts regulating these two laboratories is poor among doctors. There is need to create more awareness through seminars, workshops and scientific conferences.

KEY WORDS: Medical and Dental Practitioners Act, Medical Laboratory Science Council of Nigeria Act, Clinical laboratory, Medical laboratory and Law

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### INTRODUCTION

he Nigerian medical law is the embodiment of laws concerning the rights and responsibilities of medical professionals and their patients. It focuses on confidentiality, negligence, medical malpractice, ethics and criminal law. All medical professions (both core medical professions and

Correspondence to: Archibong Felix Department of Family Medicine, University of Calabar Teaching Hospital, Calabar, Cross River, Nigeria. Email address: dr.felixarchibong@yahoo.com allied health professions) in Nigeria are established by the Acts of parliament. Examples of such Acts are: Community Health Practitioners Act, Dangerous Drug Act, Medical Rehabilitation Act, Medical Laboratory Science Council of Nigerian (MLSCN) Act, Medical and Dental Practitioners Act (MPA), Nursing and Midwifery Act, Pharmacist Council of Nigerian Act and Radiographers Act. For the purpose of this research our focus would be limited to MLSCN and MP Acts.

The Acts of law in Nigeria is enshrined in her constitution which is a binding force on the

authorities and people throughout the country to ensure peace, order and good operational governance. It gives an institution or profession a legal right to be established and operate in Nigeria. The Acts also serve as guidelines for the job roles of every profession, institution and establishment to prevent inter-professional conflicts.

According to MLSCN Act, the laboratory where the Medical Laboratory Scientist carries out their specified analysis is known as Medical Laboratory. The Medical Laboratory is under the regulation of the Medical Laboratory Council of Nigeria. The job specification of the medical laboratory as clearly spelt out on section 29 of the MLSCN Act, is for production, sales, importation and storage of medical laboratory reagents and production of diagnostic devices.

The Medical and Dental Practitioner Act identifies and defines the laboratory for diagnosis of diseases as Clinical laboratory. This means that the hospital laboratories where testing of patients' sample is carried out is the clinical laboratory. The laboratory physicians (pathologists) are responsible for all tests carried out in the clinical laboratory. The Medical and Dental Council of Nigeria has the sole responsibility for the regulation of the clinical laboratory.

The laws that established these two different professions had spelt out the scope of practice and created regulatory agencies for each of them. These Acts are without conflicts of Law.

Healthcare professions in Nigeria have recently faced industrial crisis and the court of law has been consulted concerning the job roles in the clinical laboratories in the tertiary hospitals. The authors were concerned about the repeated disharmony in the hospital (clinical) laboratories hence they were prompted to ask a research question: Do doctors in University of Calabar Teaching Hospital know the differences between the scope of practice of medical laboratory and clinical laboratory, based on Nigerian laws?

This study aimed at exploring the knowledge of doctors concerning the scope of job specification of medical and clinical laboratories as enshrined in the laws of Nigeria, in order to draw attention

to the legal roles of laboratories. It is hoped that if there are gaps regarding awareness of these Acts of the law, recommendations will be made to create the needed awareness to ensure harmony in the healthcare sector.

#### **MATERIALSAND METHOD**

The study was a cross-sectional descriptive survey using semi-structured and self-administered questionnaire. A total of 216 doctors in University of Calabar Teaching Hospital, Calabar, Nigeria were randomly recruited into the study after the sample size was estimated using the Lesley Kish formula. Data was analysed using SPSS version 21.

#### Results

Table 1 revealed that majority of participants (61.1%) were 40 years of age and below. The female to male ratio was 1: 3.6 and about 19.1% had practised medicine for more than 10 years.

Table 2 showed that only 30.5% of doctors were aware of the Medical and Dental Practitioners Acts when compared to the awareness of the MLSCN Act. However, less than 26% had read both MP and MLSCN Acts.

Concerning knowledge of the job role Pathologists and Medical Laboratory Scientists, 84.7% of respondents did not know that Medical Laboratory Science was a science profession and 82.9% thought that a Medical laboratory Scientist had the same job specification as Laboratory Physician. It was noticed that 79.2% of doctors did not know that the hospital laboratory is called clinical laboratory (by Nigerian Medical Law) and it is the laboratory legally assigned to the Laboratory Physician, with the sole responsibility of carrying out diagnostic testing for patients' care. About 74.1% did not know that bench work in clinical laboratory was the responsibility of the laboratory Physician. In the study, 68.5% did not know that there is a difference between Medical Laboratory and Clinical Laboratory based on the Nigerian medical laws. They also did not know that diagnostic testing was not a legal duty of the medical laboratory.

About 14.8% knew the legal job specification for medical laboratory and 15.7% were aware that it was illegal to use result from samples analysed in

medical laboratory to treat patients.

Table 4 showed statistically significant relationship between the awareness of the MP and MLSCN Acts and the following variables: Medical Laboratory science is a science profession, legal job specifications of medical

laboratory, illegality of analysing samples in medical laboratory for management of patient, clinical laboratory being the laboratory assigned to laboratory physician and the bench work (analysis of samples) in clinical laboratory is the sole responsibility of the laboratory Physician.

Table 1. Socio-demographics characteristics of participants

Variables					Fre	equency		Percen	_
						(n = 216)		(100	<b>)%</b> )
Age	21	-	3	0	2		7	12.	5
	31	_	4	0	10		5	48.	6
	41	-	5	0	7		1	32.	9
	>5			0	1		3	6.	0
Sex	Male	•			16		9	78.	2
	Fema	ale			4		7	21.	8
Years of practice	<			1	1		5	6.	9
-	1	_		5	9		1	42.	1
	6	_	1	0	6		9	31.	9
	11	_	1	5	2		2	10.	2
	16	_	2	0	1		3	6.	1
	>2			06	5			2.	8

Table 2.Awareness and Reading of MP Act vs MLSCN Act

Variables		Frequency		Percentage	
		(n = 216)		(100 %)	
Aware of MP Act	Yes	16	4	75.	9
	No	5	2	24.	1
Read MP Act	Ye	5	6	25.	9
	N	16	0	74.	1
Awareness of MLSCN Act	Yes	9	8	45.	4
	No	11	8	54.	6
Read MLSCN Act Yes		3	2	14.	8
	No	18	4	85.	2

Table 3. Knowledge of the job role of Medical laboratory Scientist vs Clinical laboratory Physician

Variables		Frequency (n = 216)		Percentage (100%)			
MLS as a core medical profession	True	3	9	18.	1		
Figure 40 to to the mountain procession	False	12	8	59.	3		
	I don't know	4	9	22.	7		
MLS as a science profession	True	3	3	15.	3		
-	False	15	6	72.	2 5		
	I don't know	2	7	12.	5		
Lab Science same job as Lab physician	True	17	9	82.	9		
	False	3	2	14.	8		
	I don't know	5		2.	3		
Medical Lab is for MLS	True	21	1	97.	7		
	False	0		0			
	I don't know	5		2.	3		
Clinical Lab is for Lab Physician	True	4	5	20.	8		
	False	13	9	64.	4		
	I don't know	3	2	14.	8		
Diagnostic Test in Med Lab	True	14	8	68.	5		
	False	6	8	31.	5		
Diagnostic Test in Clinical Lab	True	5	1	23.	6		
	False	16	5	76.	4		
Legal job specification for MLS	True	3	2	14.	8		
	False	14	3	66.	2		
	I don't know	4	1	19.	0		
Illegality of analysing samples in med lab	True	3	4	15.	7		
	False	14	7	68.	1		
	I don't know	3	5	16.	2		
Bench work in Clinical lab solely for Lab physicians	True	5	6	25.	9		
	False	14	1	65.	3		
	I don't know	1	9	8.	8		
Responsibility of the physician in clinical lab	True	13	8	63.	9		
	False	3	5	16.	2		
	I don't know	4	3	19.	9		

Table 4. Relationship between awareness of the MLSCN and MP Acts vs understanding the job roles of medical and clinical laboratories

Variables		Awareness	of MLSCN Act	Awareness MP Ac		P value	
		Yes	No	Yes I	No		
Lab Science as a core Medical profession	True False I don't know	8 3 1 3	3 7 4 5 3 6	1 3 2 116 35	2 6 12 14	0.83	1
Lab Science as a science profession	True False I don't know	3 2 5 3 1 3	1 10 3 1 4	3 2 112 20	1 44 7	0.001	*
Lab Science same job as Lab physician	True False I don't know	6 2 3 2	11 7 0 1	12 8 5 32 4	5 1 0 1	0.0	7
Medical Lab for MLS	True False I don't know	9 7 0 1	11 4 0 4	16 3 4 0 1	8 0 1	0.24	9
Clinical Lab for Lab Physicians	True False I don't know	3 7 5 4	8 8 5 2 5	4 5 100 19	0 39 13	0.000	*
Diagnostic Test in Med Lab	True False	3 7 6 1	11 1 7	3 9 5	5 2	0.000	*
Diagnostic Test in Clinical Lab	True False	4 4 5 4		5 1 113	0 52	0.000	*
Legal job specification for MLS	True False I don't know	3 2 3 2 3 4	0 11 1 7	3 2 94 38	0 49 3	0.003	*
Illegality of analysing samples	True False I don't know	3 4 3 6 2 8	0 11 1 7	3 4 95 35	0 52 0	0.000	*
Bench work in Clinical lab solely for Lab physicians	True False I don't know	5 2 3 8	4 10 3 1 1	5 6 93 15	0 48 4	0.05	*

<sup>\*</sup>significance

#### Discussion

The differences between the job role of medical laboratory and clinical laboratory in the Nigerian health sector have not been widely studied, to the best of the authors' knowledge. The findings from this study clearly showed that doctors are not aware of the differences between the function/ job specifications of these two laboratories in Nigeria, based on the law. However, some doctors have mistaken the medical laboratory to mean the same as the clinical laboratory and vice versa. Patients are sent to the medical laboratory and the results generated are used for patients' management by the doctors. This process of referring to a wrong laboratory is not only illegal but can endanger the life of a patient because of the short fall of the international best practice in patients' care.9

This poor awareness of the job roles of these two laboratories is not only among doctors but has also been displayed in media article by Ojerinde in 2016, which exhibited poor understanding of the scope of practice between medical laboratory scientists and the laboratory physicians. 10 He reported that medical laboratory scientists were more competent than the pathologists. There seem to be wrong comparison because these two professions have different roles in the health sector. Ojerinde (2016) also failed to observe that the names of the laboratories in the two Acts of Nigerian laws were different. Medical laboratory was consistently used by the MLSCN Act while clinical laboratory only appeared in the MP Act. 6,11

There are more media publications that assume that medical laboratory is where diagnostic testing should be conducted. <sup>12-15</sup>Osaro and Charles in a study (2014) stated that medical laboratory scientists work in healthcare sector to diagnose disease hence they are at the heart of the medical team. <sup>16</sup> He also mentioned in his article that "pathologists work in the clinics and both medical laboratory scientists and pathologists meet at annual general meetings to

brainstorm on improvement of laboratory service delivery to patient. In an article, Lidani j. made a statement that "the doctors would just look at you and say that this is what you need to take for your illness but things have changed. Today no doctor can just look at you and prescribe drugs without diagnosis. And, who does that? It is the medical laboratory scientists". <sup>15</sup>The above statement clearly shows lack of understanding of the job role of the medical laboratory and it could be very misleading to the public.

Onyedika-Ugoeze in another media publication mentioned that the rivalry in the Nigerian healthcare sector would be over because the National Industrial Court of Nigeria had ordered that government owned secondary and tertiary hospitals across the country should create a separate department that will give laboratory scientists freedom to practice their profession.<sup>17</sup> Logically, this judgement clarifies that medical laboratory scientists cannot work unsupervised in the existing clinical laboratories in the hospital across the country. Evidently, the verdict of the judgement above took cognizance of the sound knowledge of the two Acts regulating theses professions and was carefully passed in clear terms.

#### Conclusion

There is knowledge gap among doctors, concerning the difference between clinical laboratory and medical laboratory based on the laws of Nigeria. There is need to create awareness on the legal job specifications of the clinical and medical laboratories in Nigeria as ignorance of the law should not be pleaded by the clinician

#### Limitation of the study

This study did not assess the knowledge of these Acts among the Medical Laboratory Scientists and the stratification of the different specialties of the doctors which would have highlighted the knowledge of the Pathologists (Laboratory Physicians).

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#### Conflict of interest

None of the authors had conflict of interest

#### **Ethics**

Ethical approval for this study was gotten from Health Research and Ethics Committee, University of Calabar Teaching Hospital, Nigeria.

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