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Knowledge, Attitude and Barriers to Ethical Aspects of Biomedical Research by Medical Practitioners in a Tertiary Hospital

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Authors' contributions

This work was carried out in collaboration among all authors. All authors contributed substantially to the work. Author EEY played a key role in conceptualization, study design, data analysis and initial drafting of the manuscript. All authors were involved in data collection. Authors CNO and CBN did the literature search. Author UNI was involved in the initial draft. Authors EEY and UNI were responsible for language and technical editing. All authors reviewed and approved the final manuscript.

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ABSTRACT

Introduction: Ethical norms in research promote the aims of research such as knowledge, truth and avoidance of error. Observing ethics in clinical research is very important and this should be well known by all health care practitioners. The aim of this study was to determine the knowledge of doctors working in a tertiary hospital about research ethics and the barriers they encounter in the ethical conduct of research.

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Materials and Methods: A questionnaire-based survey was conducted among 215 doctors in a tertiary hospital in Nigeria to determine their knowledge of the concepts of ethics in research, their research practices and perceived barriers to ethical conduct of research. Data obtained was analysed with SPSS v 20 and reported as Tables and charts. Chi square was used to test for differences between categorical variables and a *P* value < .05 was regarded as significant.
Results: There were 108 consultants, while the rest were medical officers and resident doctors. The consultants were more active in research and 42% had between ten to fourteen published articles. There was fairly adequate knowledge of the 5 concepts of research ethics tested, with 90% who had knowledge of GCP. Common perceived barriers to ethical research conduct were poor funding and cultural beliefs.
Conclusion: There remains a gap between knowledge of ethical research conduct and actual practice. This should be addressed by improved sensitization and oversight by the regulatory agencies and the IEC.

Keywords: Knowledge; barriers; ethics; doctors; research.

1. INTRODUCTION

Clinical research aims to advance medical knowledge by studying people, either through direct interaction or through the collection and analysis of blood, tissues or other samples. Clinical research can be defined as a branch of healthcare science that determines the safety and efficacy of medications, devices, diagnostic products and treatment regimens intended for human use [1]. Ethics are norms or standards of behaviour that guide moral choices about our behaviour and our relationships with others [2]. It refers to moral principles or values that govern the conduct of an individual or group. High moral standards are required of professionals and researchers to ensure that both the process and results of research are not disputed. Ethical norms in research promote the aims of research such as knowledge, truth and avoidance of error [3]. They promote values that are important for collaboration, which is an important aspect of research and involves different classes of individuals. Ethical norms also help to ensure that researchers are accountable to the public, providing a benchmark for assessing their performance. Good ethical conduct of research cannot be over-emphasized. The Tuskegee experiment and the World War II experiments are just two examples of unethical clinical research carried out in the past [4]. Clinical trials are subjected to tight regulatory processes to safeguard the health and well-being of the members of the society.

There are 13 basic tenets of a good clinical trial, which embodies the concept of GCP [5].

Obtaining informed permission during a study is of utmost importance, and may be hampered by factors such as illiteracy and poverty in the patients. The National Research Act was passed in 1974, in response to the need for unified ethical practice in research with the establishment of the Institutional Review Board (IRB) [6]. In developing countries such as Nigeria and other parts of West Africa, many drugs and clinical devices are imported after being developed outside the country. Until recently, local trials were not conducted on drugs developed outside the country, and as such data for the local population on drug efficacy and safety were extrapolated from studies on Africans in diaspora and African Americans. However, another emerging trend has been the siting of clinical trials for new drugs in developing countries by pharmaceutical companies [7]. The siting of clinical trial sites in developing countries has been reported to be cheaper and subject to less regulation, leading to a recent trend of increasing numbers of clinical trial sites in developing countries such as India [7]. Although this is not yet applicable to Nigeria, it may become so in the near future due to its favourable demographics. The recent legal tussle between the pharmaceutical company; Pfizer and the Nigerian government following issues raised about the ethical conduct of a clinical trial in children on the meningitis drug Trovan in 1996 [8,9], underscores the need for proactive measures to ensure that GCP is enshrined in the conduct of clinical trials in Nigeria. This will require increased awareness, advocacy and training.

Research is one of the functions of tertiary health institutions such as the University of Nigeria Teaching Hospital. Majority of the research conducted in these institutions involve patients and in some cases may include clinical trials. The hospital has an ethics committee; Medical students, postgraduate doctors in training,

specialists and lecturers, usually carry out research in the course of their daily clinical activities. There are instances where a senior doctor may develop a research idea based on anecdotal findings in a patient or series of cases and the team goes ahead to conduct an informal research. Other circumstances such as preparation for seminars or conferences may also lead to spontaneous data collection for review. Clinical research is not traditionally a part of the undergraduate medical curriculum in Nigeria. Most of the knowledge doctors have is about the ethics and law of clinical practice, which though similar to clinical research ethics is not enough. Hence the knowledge of young medical graduates may be limited to what they read in journals or learn on the job if they are lucky to be part of a research team early in their career.

This study will help to establish the knowledge of medical practitioners about ethical conduct of research, their ethical behaviour during research and any barriers they experience to observing these ethics.

2. METHODOLOGY

2.1 Study Site

The study was carried out in the University of Nigeria Teaching Hospital (UNTH) Ituku-Ozalla, Enugu, Nigeria. This hospital is a tertiary institution, whose main functions include service, teaching and research. It is affiliated to the College of Medicine, University of Nigeria Ituku-Ozalla Campus. The College of Medicine conducts undergraduate training of doctors, dentists, nurses, laboratory scientists, radiographers, physiotherapists and dietitians. It has academic faculties made up of different cadres of lecturers including professors, who also carry out clinical duties in the teaching hospital, where they are referred to as consultants. The study duration was April to June 2017.

2.2 Study Population

The sample was drawn from all the doctors in the hospital using a random sampling method. The sampling frame was a list of all the currently employed doctors, which was obtained from the Personnel Department.

2.3 Study Design

The study was a cross-sectional descriptive study. A simple random sample was done. The sampling frame was all the doctors working in the hospital. The study population was selected by a simple random sampling technique from the sampling frame.

The minimum sample size for the study was calculated using the formula [10] $n = Z^2pq/d^2$:

Where,

n= sample population
Z= Standard deviation of 1.96
p= prevalence
q =1-p
d = standard error of 0.05

Using the study by Fadare et al [11], 66.8% had some knowledge about ethics in clinical research.

Hence,

p=0.668
q = 1- 0.668, q = 0.332
d = 0.05

Hence,

n = 1.96 x 1.96 x 0.668 x 0.332/0.05 x0.05
n = 340.

Using N (final) = n / (1+n/N) for a study with a sample population < 10,000.

Where,

N= estimated total of the study population.
N =556 (Number of doctors working in UNTH)
Nf = 340/1+(340/556)
N (final) =211.

Minimum sample size will be 211.
A 10% allowance will be made for non-responders = 21.
The sample size for the study will be 240.
The final sample consisted of 120 consultants, 85 residents and 35 medical officers.

2.4 Study Procedure

Each doctor (study participant) identified from the sample was approached and the study explained to him/her and informed obtained. The study questionnaire was then administered to the study participant and the questionnaire was retrieved. All the study participants had high proficiency in English, hence there was no need to translate the questionnaire into the local language.

2.5 Data Analysis

The data obtained from the questionnaires was entered into SPSS v 20 and analyzed. Data was recorded as frequencies and reported using Tables and graphs. Chi square was used to test for differences between categorical variables, while continuous variables were compared using Students T test. A p value of <0.05 was considered as statistically significant.

3. RESULTS

3.1 Characteristics of the Study Population

A total of 240 doctors completed the study, but only 215 had complete data in the questionnaire and these were analyzed. There were 108 consultants, 78 resident doctors and 30 medical officers. There were 162 males and 53 females, giving a male: female ratio of 3:1. The mean age of the consultants was 45.9 ± 5.2 years, while for the resident doctors and medical officers it was 34.5 ± 4.6 years.

The median number of years of practice for the consultants was 19 years with a range of 12 to 37 years. Their median duration of specialty was 6 years with a range of 2 – 17 years. The resident doctors and medical officers had a median duration of practice of 6 years. All the consultants were also academic staff of the university. These results are as shown in Table 1.

The consultants were of various specialties as shown in Fig. 1;

3.2 Participation in Research Activities

All the consultants had participated in original research in the past, and had published research articles. Although 56 (51.8%) of the residents and medical officers had participated in original research, only 38 (35.2%) had published a research article. The highest range of published articles by the consultants was 10-14 articles by 46 (42.9%) consultants. This is shown in Fig 2.

Only 31 (28.7%) of the consultants had previously participated in a clinical trial, with only 2 who had served as Principal Investigators during the trial. Only 8 of the resident doctors and medical officers had participated in a clinical trial and none of them was a Principal Investigator in the trial.

3.3 Knowledge of Principles of Research Ethics

The participants were tested on their knowledge of basic research ethics concepts including the Helsinki declaration, the Nuremberg Code, Good Clinical Practice (GCP), International Conference on Harmonization (ICH) and Institutional Review Board (IRB). The parameters with the highest level of knowledge were GCP and the Helsinki declaration, while the lowest degree of knowledge was for ICH.

Their knowledge of research ethics principles was computed as a total score. There was no significant difference between their total scores and their specialties (Chi square = 21.8, *P* = .271) and also their years of practice (Chi square = 57.4, *P* = .53).

3.4 Ethical Practice in Research

All the study participants agreed that obtaining approval before a study was either extremely important (90.5%) or somewhat important (9.5%). They also agreed that obtaining informed permission was extremely important (100%). In terms of actually obtaining approval from the institution IEC for all their research activities, only 61.9% always obtained approval before a study, 28.6% obtained approval sometimes, while 9.5% said they rarely obtained approval.

In terms of obtaining informed permission from study subjects, 52.4% obtained permission all the time, 42.9% some of the time, while 4.8% rarely obtained informed permission from study subjects.

These are shown in Table 2.

Table 1. Characteristics of the study population

Parameter	Consultants	Residents And Medical Officers
Age years (Mean ± SD)	45.9 ± 5.2	34.5 ± 4.6
Years of practice (Median)	19	6
Years of specialty	6	N/A

Table 2. Ethical practice in research

Attitude	Yes (%) extremely important	Somewhat important	No (%)	
Importance of Ethical Approval	90.5	9.5	0	
Importance of Informed consent	100	0	0	
Practice	**All the time (100%)**	**Most of the time (70-100%)**	**Some of the time (30-70%)**	**None of the time**
Obtains ethical approval (%)	61.9	28.6	9.5	0
Obtains informed consent (%)	52.4	42.9	4.8	0

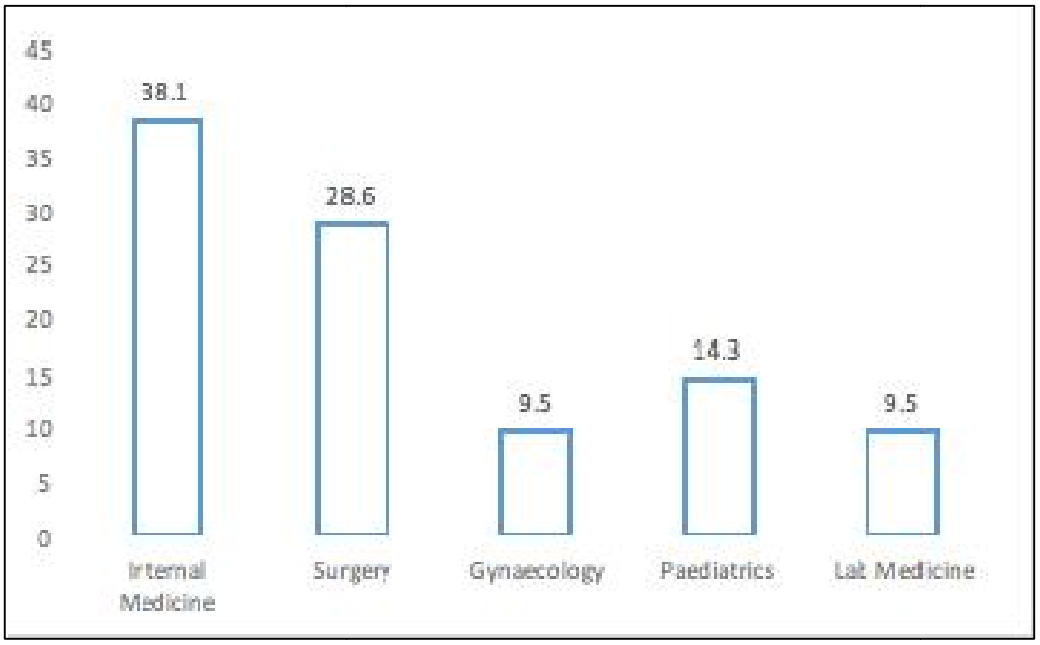

Fig. 1. Distribution of consultants by specialty

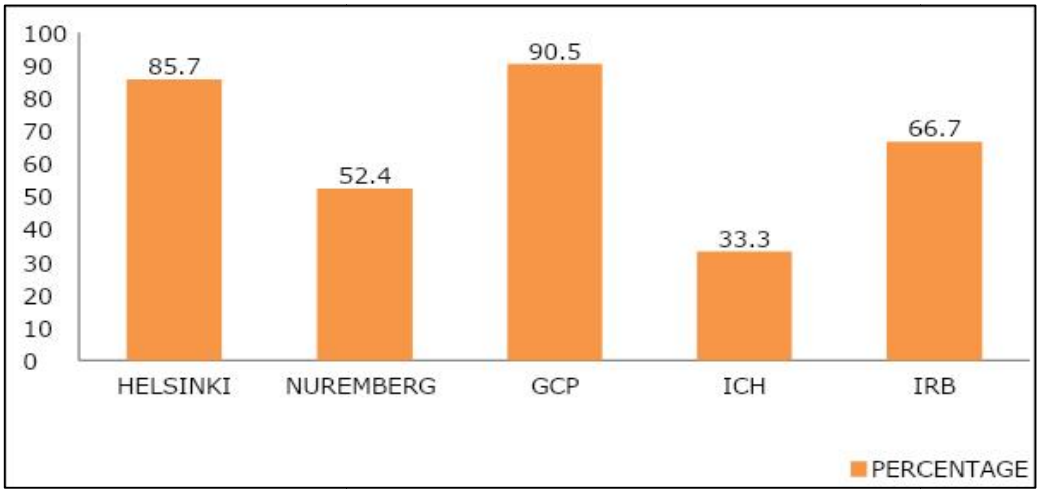

Fig. 2. Knowledge of principles of research ethics

3.5 Barriers to Ethical Practices in Research

The possible barriers to ethical practices by the doctors were examined. The barriers examined include; lack of knowledge, inappropriate guidance, illiteracy in the study subjects, poor access to the IEC, cultural barriers, difficulty in getting research participants, study subjects demanding financial inducement and poor research funding. The results are as shown in Table 3.

Table 3. Perceived barriers to ethical conduct of research

Barrier	Percentage
Inadequate knowledge of doctor	9.5
Inadequate guidance by supervisor	23.8
Poor access to IRB	19.1
Illiteracy	23.8
Cultural Barriers	28.6
Difficulty in getting research participants	19
Participants expecting financial inducement	14.3
Poor funding	57.1

4. DISCUSSION

4.1 Ethical Issues in Research

Ethical issues are a fundamental aspect of any form of biomedical research. Health personnel in academia, health institutions or industry carry out clinical research.

This study set out to examine the knowledge and attitudes of doctors working in a tertiary hospital in Nigeria about the ethics of clinical research. It also aimed to determine the possible barriers they encounter that hinder ethical conduct of research and attempts to proffer solutions to these. All categories of doctors working in the hospital were assessed in the study. The most senior doctors i.e. the consultants, who were also lecturers in the university were 108 in number.

The consultants were mostly middle-aged and had long years of practice. This is as expected due to the long period of medical undergraduate and postgraduate training required to become a consultant. All of the consultants had participated in original research, though only a few had participated in clinical trials. Considering the fact that their work consists of service, teaching and research, this is as expected.

The low frequency of participation in clinical trials may be due to the fact that most clinical trials are carried out in developed countries. This trend is however changing gradually. According to Glickman et al., since 2002, there has been a 15% annual growth in the number of active FDA-regulated investigators based outside the US [12]. The number of countries outside the US, which have participated in clinical trials, has increased two-fold between 1995 and 2005 [12]. The large disparities between developed and developing countries in education, socioeconomic standing, and healthcare systems, and the differences in medical training, clinical practice patterns, and health infrastructure standards of care can have an impact on the quality of trials [13].

The consultants were observed to be well versed in research as about 42% of them had published between ten to fourteen journal articles, and up to 14% had published over 20 articles. It is therefore expected that they would have a good idea and practice of research ethics. The younger doctors were less involved with research, possibly because their functions consist more of service and studying for their post-graduate examinations.

4.2 Knowledge of Concepts of Research Ethics

There was a fairly adequate knowledge of the 5 concepts of research ethics that were tested among the consultants. The majority was knowledgeable about GCP and the Helsinki declaration. Their knowledge of ICH was lower than the rest. The knowledge of the Helsinki declaration may be attributed to its similarity with the Hippocratic oath usually taken by doctors at the start of their practice. There were no significant differences in the knowledge of the 5 concepts between the various specialties. In a study in Southwest Nigeria [14], 66.8% of the physicians surveyed had heard of the principles of biomedical ethics, and up to 80% had some formal education on medical ethics during their undergraduate training. However specific training on clinical trials and research is not part of the undergraduate curriculum.

4.3 Ethical Practices by Study Participants

The doctors were all in agreement that approval was either extremely important (90.5%) or at least somewhat important (9.5%) before conducting a study. This was however not reflected in actual practice as only 61.9% of them reported that they always obtained approval prior to a study, however over 90% did obtain approval for most of their research. The exact type of research in which approval was not obtained was however not elucidated as it was beyond the scope of this study, however the authors postulate that it may largely be made up of unpublished research used for local seminar presentations and audit in the hospital departments as most reputable journals only accept research articles accompanied by ethical review.

Their practice of obtaining informed consent also fell far short of their knowledge of its importance, as only 52.4% of them obtained informed consent all the time from research participants although over 94% did obtain informed consent at least most of the time. This is commendable and more efforts need to be made to ensure informed consent is always obtained. One of the major barriers reported by the researchers was illiteracy of the respondents which made it difficult to always seek informed consent.

In a study in Ibadan [14], up to 70% of the women who participated in a research on the genetics of breast cancer were able to accurately report the purpose of the study, meaning that the process of informed permission was adequate in the aspect of ensuring the study participants understood the research. This was higher than the figure obtained in our study. With a large semi-literate and illiterate population [15], especially in the rural areas, there is often no absolute guarantee that trial participants fully understand the risks involved in a clinical trial. The paucity of interpreters may also not allow proper one-on-one contact with patients to obtain their permission. Poor understanding of medical 'lingo' may also hinder patients' understanding of concepts. In addition to these, sometimes when permission is sought from the traditional rulers in a local community, the inhabitants may not wish to refuse participation in a trial, as they may fear persecution due to their refusal. On the other hand, superstitious beliefs may prevent patients from participating in a trial. One of the major criticisms of the trial of the drug "Trojan" by Pfizer in Kano, Nigeria in 1996, was that informed permission was not obtained from the trial participants who were mostly illiterate and ignorant [16]. They were also desperate for treatment during the meningitis outbreak in their community.

4.4 Barriers to Ethical Research Practices

The most commonly reported perceived barrier to ethical practices in research was the complaint about inadequate funding of research. The desire to get value for personal funds spent on research may result in the researcher trying to minimize cost. The review of a research proposal by the hospital IEC also attracts a fee and this may also discourage researchers from seeking approval. Research funding is a challenge in Africa, however there are available grants such as Welcome Trust, NIH grants, Tertiary Education fund (TETFUND), which researchers may obtain.

Cultural barriers to ethics in research were also reported to be significant by 28% of the study participants. Illiteracy of the study participants was mentioned by 23%. This however can be overcome by proper education and use of the local language.

5. CONCLUSION

This study has shown that there is fairly adequate knowledge by doctors about the required ethical practices in clinical research. However, the actual practices carried out falls short of their knowledge and this was independent on years of practice or specialty. The most common barriers to good ethical practices were poor financing of research and cultural beliefs.

6. RECOMMENDATIONS

The authors recommend that there should be proper enlightenment such as regular seminars and workshops on the proper ethical conduct of research. Clinical research could also be introduced into the undergraduate curriculum.

CONSENT AND ETHICAL APPROVAL

Informed written consent was obtained from the patients before recruitment into the study. Ethical clearance was obtained from the Health Research Ethics Committee of the hospital before commencement of the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Tunis S, Korn A, Ommaya A, editors. Institute of Medicine (US) Clinical Research Roundtable. The Role of Purchasers and Payers in the Clinical Research Enterprise: Workshop Summary. Washington (DC): National Academies Press (US). Appendix V, Definitions of Clinical Research and Components of the Enterprise; 2002.
   Accessed 10th August, 2020.
   Available:https://www.ncbi.nlm.nih.gov/books/NBK220717/
2. Chin RY, Lee BY. Principles and practice of clinical trial medicine. Amsterdam: Elsevier/Academic Press; 2008.
3. Resnik DB What is ethics in research and why is it important?
   Accessed 10th August, 2020.
   Available:https://www.niehs.nih.gov/research/resources/bioethics/whatis/ 2015.
4. Kim Won O. Institutional review board (IRB) and ethical issues in clinical research. Korean J. Anaesthesiol. 2012; 62:3-12.
5. Young EE, Okafor CN. Design and regulation of clinical trials; from the laboratory to the pharmacy. South American Journal of Clinical Research 2016;3(1):1-10.
6. Ethical principles and guidelines for the protection of human subjects of research. The Belmont Report.
   Accessed 10th August, 2020.
   Available:https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/
7. Paddy Rawlinson. The Conversation. Ethics versus economics; the cost of outsourcing clinical trials to developing countries.
   Accessed 10th August, 2020.
   Available:http://theconversation.com/ethics-vs-economics-the-cost-of-outsourcing-clinical-trials-to-developing-countries-43246
8. Stephens J. Panel faults Pfizer in '96 clinical trial in Nigeria. Washington Post. 2006;A1:A21.
9. Ahmad K. Drug company sued over research trial in Nigeria. Lancet. 2001; 358(9284):815.
10. Kirkwood B. Sterne Study design, analysis and interpretation in: Essential Medical Statistics. 2nd Edition. Blackwell. 2000:395-458.
11. Fad are JO, Desalu OO, Jemilohun AC, Babatunde OA. Knowledge of medical ethics among Nigerian medical doctors. Niger Med J. 2012;53:226-230.
12. Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, et al. Ethical and scientific implications of the globalization of clinical research. N Engl J Med. 2009;360: 816–23.
13. Bhatt A. Quality of Clinical Trials: a moving target. Perspect Clin Res. 2011;2(4):124-128.
14. Marshall PA, Adebamowo CA, Adeyemo AA, Ogundiran TO, Strenski T, Zhou J, et al. Voluntary participation and comprehension of informed consent in a genetic epidemiological study of breast cancer in Nigeria. BMC Medical Ethics 2014;15:38.
   DOI: 10.1186/11472-6939-15-38
15. Yusuf MA, Ladan B, Idria UA, Halilu A. Comparative study of the state of literacy in Nigeria and Cuba. Europ Sc J. 2013; 9(19):34-44.
16. Okonta PI. Ethics of clinical trials in Nigeria. Niger Med J. 55(3):188-194.

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