

An Ethically Accepted Concept but not well known: Research Ethics Committees in Nigeria on the Concept of Benefit Sharing

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Abstract

Background: The concept of benefit sharing deals with the issue of what participants and communities ought to benefit from participation in research. There are few empirical studies that focus on the aspect of benefit sharing in clinical research. As such, this research examines the awareness and viewpoints of Ethics Review Committees in Nigeria on the current discourses related to the concept of benefit sharing.

Methods: Semi structured interviews were conducted with key stakeholders of selected Research Ethics Committees in Nigeria. Interviews were audio recorded, imported to NVIVO 10 software, transcribed and thematically analyzed.

Results: Ten interviews were conducted with members of Ethics Committees in Nigeria. Respondents expressed different understandings of benefit sharing. They considered benefit sharing as a panacea for adverse drug reactions, financial gratification and as a means of disseminating research findings. They also highlighted different ways to achieve fair benefits in research, such as the inclusion of negotiations with community representatives and the use of benchmarks on research benefits. Furthermore, respondents favor the development of legal frameworks on benefit sharing in international research.

Discussion: Research findings indicate that benefit sharing, is a well accepted ethical concept. However, it lacks good awareness among ethics committees especially when compared to the ethical concept of informed consent. The lack of awareness is analogous with the fact that there is a lack of a consistent definition among research scholars. A succinct and consistent definition is essential to boost global advocacy on benefit sharing. Furthermore, to improve good outcomes of benefits in research, efforts of the community representatives should be complemented with the expertise of ethics committees.

Conclusions: a good awareness on the concept of benefit sharing will help in improving its practice, improve its advocacy and set the pace for the development of a benefit sharing framework in clinical research.

Key words:

Benefit Sharing; Research Ethics; Ethical concepts

Background

One of the key concerns related to international clinical research conducted in Low-Middle Income Countries (LMIC) is benefit sharing. Benefit sharing pertains to the questions of what participants, communities and even host countries should accrue for their participation in research [1]. Research ethics scholars like Millum [2], Ballantyne [3,4], Schroeder [5] endorse benefit sharing as an ethically sound concept and support that something ought to be given to the participants and communities in research. Also benefit sharing has been considered to be one of the ways to promote the social value of research and contribute to the improvement of global health [6].

However, the main concerns regarding benefit sharing include the question: what exactly should be given as benefits to research participants and communities? In other words, what fair benefits research communities should accrue as result of participating in

research? Other concerns are the ethical justification(s) that benefit sharing is based on, and who are be the right recipients of benefits? Authors have argued that these concerns do not impede benefit sharing as such. For example, regarding the question of what exactly should be given as benefits, proponents of benefit sharing have argued that fair benefits can always be negotiated between research sponsors and host communities [7]. With regard to the justification(s) on benefit sharing, we have noted elsewhere that different ethical justifications on benefit sharing do not necessarily weaken the advocacy of the concept in practice. The various justifications rather provide different platforms that encourage the practice of benefit sharing in international research. For example, a benefit sharing justification that is rooted in commutative justice envisages benefit sharing solely as an instrument of exchange. This is different from a distributive justice perspective that views benefit sharing as means of fair distribution of health resources with adequate consideration to the need of the least advantaged groups [8]. For the appropriate recipients of benefits, researchers have advocated that research sponsors should engage the host communities in all the phases of research in

order to identify the right groups that ought to benefit from research [9].

While these arguments and counter arguments continue within the global ethics platform, little is documented on the perception of benefit sharing among research stakeholders in resource poor countries. Discourses on benefit sharing are often theoretical with little empirical inquiries on what the concept entails among research stakeholders especially in developing countries. For example a literature search to ascertain empirical studies that relate international research and benefit sharing reveals few publications. While some of the studies address the perception of stakeholders in a resource poor country on various forms of benefit sharing [10,11], others have examined stakeholders' understanding and the state of debate on the concept of benefit sharing [12]. Another study targets the research participants in South African communities to ascertain their perspectives on benefit sharing in international research [13]. This present study is the first empirical work that examines the discourse of benefit sharing among ethics committees in Nigeria. It identifies some key concerns on benefit sharing that could contribute to the development of a benefit sharing framework.

Aim of the Study

This study aims at examining the awareness and viewpoints of Ethics Review Committees in Nigeria on current discourses of benefit sharing through an open-ended interview. The study does not aim at questioning in order to query the activities of the various ethics committees with regards to the concept of benefit sharing but to ascertain the familiarity of the concept among the ethics committee members.

Study Setting and Methodology

Study setting

The operations of the Ethics Review Committees (ERCs) in Nigeria are governed by a central National Ethics Committee known as the National Health Research Ethics Committee (NHREC). The NHREC was established in 2005 after the infamous Pfizer Trovan trial [14]. One of the notable functions of this national body is to register, regulate as well as audit local ERCs in various institutions across the country. As such the NHREC maintains an up-to-date register of recognized ERCs in hospitals and research institutions in the country.

The study was conducted in Nigeria between June and July, 2013. To ensure that the potential stakeholders for the study are extracted from eligible ERCs in the country, we obtained an updated list of the registered ERCs from the NHREC website. As at the time of the research, nineteen Ethics Committees were found to be duly registered by the NHREC. We obtained the contact details of the various committees on the list with the intension of including all the registered Ethics Committees in the research. However, after efforts to contact the committees through telephone and email we were only able to reach fifteen committees. We could not reach four committees due to one of the following reasons: the telephone numbers were no longer functioning, the contact person no longer works in the institution or there was no email response from the person contacted. The fifteen committees that responded, an email was sent to explain further some practical aspects of the study. Ten out of the fifteen ERC responded with an affirmative answer for participation. These ten ERC were

included in the study, followed up and subsequent arrangements on the study were made.

Study Instrument: Semi-structured Interview

The study utilizes a semi-structured interview. The interview questions were designed by the authors with good guidance from research literature on how to develop and prepare interviews for data collection [15,16]. The interviews were conducted in English and questions were open-ended, which allow the respondents to freely express their views. Also question prompts were used in the course of the interviews to ensure that respondents have clearly exhausted their responses to a question. Examples of question prompts used are: "can you think of more...", "can you elaborate further on..."

The time and location for the interviews were arranged prior to the date scheduled. All the interviews were conducted in the respondents' office where they are more relaxed and comfortable. The interviews were also conducted behind closed doors with no interruptions from external parties.

Consent Process

Before the start of the research interview, a document explaining the interview process was submitted to the Kaduna State Ministry of Health Ethics Committee. At the beginning of each interview, respondents were informed that the interview would be recorded and it will be kept confidential, anonymous and will only be used for the purpose of the research. They were also informed that they can decline participation, decide not to respond to parts or whole of the questions or even demand for the discontinuation of the audio recording. All this information was audio recorded and respondents were asked for their verbal consent before the interview was initiated.

Data Analysis

The recorded interviews were imported into the NVIVO 10 software and were then transcribed. All the interviews were thoroughly coded. Four major categories were first created to represent the units of analysis of the interviews. Under each category, codes and sub-codes were generated based on the respondents' perspectives on the posed questions. The coding process was carried out independently by two coders. This double coding was done in order to validate the coding process and to ensure that the respondents' perception were exhaustively represented. The codes were then carefully verified and agreed by the two coders to ensure that they rightfully belong to the assigned major category. The codes were analyzed within the major categories using a content analysis [17].

Results

The ERC members drawn for the interview had different health professional backgrounds which include Gynaecologists, Neurologist, Statistician, Microbiologist, Pharmacist and General Practitioners. The respondents also held different positions within the Ethics committee, nonetheless majority of the respondents are heads of their ethics committees (Table 1). Respondents were asked to mention some ethical concerns they encountered or perceived as vital in research involving human subjects. Informed consent and sound methodology were the most mentioned issues. Benefit sharing was not mentioned as an ethical concern. However when prompted to further elaborate on sound methodology, the respondents mentioned fair distribution of

benefits and burden as some of the aspects that constitute sound methodology. Also, upon prompting the respondents indicate that benefit sharing is an important concept in research.

Respondents	Sex of respondents	Respondents' position in Ethics Committee	Perceived vital concept in Research Ethics
1	Male	Chair of Ethics Committee	Very comprehensive consent document
2	Female	Chair of Ethics Committee	Safety issues/right to refuse participation Inadvertent use of hospital resources Study design
3	Female	Secretary of Ethics Committee	Scientifically sound research Comprehensive consent documents Methodology
4	Male	Chair of Ethics Committee	Objective of study/Methodology Informed consent
5	Female	Committee member	Scientific methodology Informed consent
6	Female	Secretary of Ethics Committee	Consent document CV of researcher Scientific quality
7	Female	Chair of Ethics Committee	Consent document CV of researcher Scientific quality
8	Male	Chair of Ethics Committee	Informed consent/respect for people Scientific validity and methodology
9	Male	Committee member	Informed consent
10	Male	Chair of Ethics Committee	Methodology/Aim and objectives Informed consent

Table 1: Demographic characteristics of respondents and perceived ethical concerns in research.

We present the stakeholders viewpoints on benefit sharing in international research in four major categories: what is benefit sharing?, the process of achieving fair benefits, laws on benefit sharing in international research, and who gets what type of benefits?

What is Benefit Sharing?

In terms of what benefit sharing concept denotes, respondents expressed different awareness on the concept. This awareness focuses on three major aspects: benefit sharing as a panacea for adverse drug reactions, benefit sharing as financial gratification and benefit sharing as dissemination of research findings.

A panacea for adverse drug reactions

Benefit sharing is envisaged as something that ought to be put in place in order to cater for research participants in the event of adverse drug effects during the research. The idea by these respondents is that benefit sharing should be considered only when the need arises and it should not be a means of providing financial rewards to participants.

“It should not be viewed as financial gratification, definitely not. If during the course of participating something crops up, there should be

provision made, to make sure that is not just glossed over or swept under the carpet. If the participants need to be treated say there is adverse reaction they should be taking care of, not just left on their own or seen as their problem.”

Financial gratification and incentives were also seen to be associated with the likelihood of inducements of participants which respondents unequivocally rebuffed in research. Respondents expressed a sense of indifference and discretion on advocating for benefit sharing acknowledging that benefit sharing concept may be prone to financial inducements in research.

“We do not really want to encourage it [benefit sharing] so that it would not serve as a form of financial inducements to participants. But all the same the participants also needed to be compensated.”

Financial gratification

An opposing view from the financial inducements standpoint is the understanding that research sponsors ought to consider the inconveniences and burden they have placed on research participants. Such inconveniences should serve as the main drive to provide

benefits in monetary terms to cover their transportation, food and in some cases monetary rewards to encourage participation.

“Assuming now in your research you state that when you recruit research participants and you will invite them again to come for a day when you need to collect their information. Of course in that case you are asking someone to come back. It is inconveniencing, so we now have to tell you please provide transport for these participants. We also check the time you are going to take for sample collection, person information and data, and now say why not provide them with lunch or other incentives.”

The need for financial rewards to participants was also viewed from a purely enterprising standpoint. Respondents indicate that research sponsors want to make financial gain with tested products. They envisage research activities as a big financial venture that would subsequently generate profits to the research sponsors. As such benefit sharing is basically a means in which research sponsors should give financial benefits out of their large profits to those that contributed to the success of such enterprise.

“Of course the source of the knowledge generated from research is the patient group that you use in the research. The information that you find out from them is usually plough [sic] back into your industry that are translated into drugs and other things that can now generate a lot of profits. So really it makes a lot of sense that if you are going to do research at international level then the patient and the community from which the patient come from need to also have some benefits out of it.”

Dissemination of research findings

Benefit sharing was also depicted as essentially a communication of all research findings by the researchers or sponsors to the research communities. Communication was thought to be a very vital end product of research and considered obligatory by all researchers. For these respondents, an effective way to ensure communities have benefited from research involvement is to disseminate the research findings at the end of the research.

“Well I think it has to do with the post study. Ideally from my experience in bioethics, if you are conducting a research in a community, after the research is over, you are supposed to share your findings with the community. That’s how it is supposed to be, not for you to cart everything away.”

Process of Achieving Fair Benefit

Processes in which fair benefits in research can be achieved are highly talked about aspect in the discourse of benefit sharing in international research [18]. Respondents point out ways on which fair benefits can be achieved or what constitute fair benefits in research. These views are expressed in three specific categories: negotiations with community representatives, setting benchmarks for benefits and ethics committees to decide fair benefits.

Negotiations with community representatives

The respondents note that the benefits of any research ought to be negotiated between the research sponsors and the host community. Respondents suggest that the host community ought to have some good representatives that should genuinely negotiate for what benefits best suit the community.

I think this requires engaging the community and engaging researchers and sponsors. There should be a reflection of the culture in the particular setting. I don’t think one rule should apply in all. So I think maybe if there are some recommendations like round table discussions and recommendations with some amount of variations. I should also say that the representatives truly represent the community. For example, the case of Niger Delta region [Nigeria] although not related to research, but on the issue of what the oil companies are doing. Many of the representatives are not representing the community, they are representing themselves. So this really has to be people who truly have the best interest of the community at heart

However, other respondents expressed skepticism on the fairness of such negotiations considering the unbalanced negotiating power of the parties involved. These respondents believe that the negotiating power of most communities is usually weak compared to research sponsors. Such communities with weak negotiating powers would likely be taken advantage of by the research sponsors.

Setting benchmark for benefits

Reflections on the process of achieving fair benefits were also thought to be feasible through the setting of a benchmark for benefits in research. This benchmark should serve as a standard on the basis of which research benefits can be assessed. A respondent noted that such benchmark can be deliberated, agreed upon and expressed as a percentage, which can then be applied to all research.

“I think there has to be a group or a body that should debate this and come up with a benchmark or a standardized position on benefits. They body [sic] could say 5 percent or 10 percent or 3 percent or whatever that group has decided let that be applied internationally. It should be something standardized, that if you do some research like this, it should be within the range of this to that percentage that should be the benefit. Just like we know in project management, we’ve been told that roughly one should spent about 10 percent of the total grant of whatever project one is doing on monitoring and evaluation-for instance. So we should have something like 5 to 10 percent or 1 to 3 percent. Let it be a standardized thing that you can always say okay what is the benchmark? Okay apply it, without even waiting for it to be debated or waiting for the beneficiaries to argue for it or fight for it.”

Other interviewees think that whether or not the benefits of research should be sought for or negotiated depends on the type of research in question. In some types of research, participants have already some benefits through their direct participation. In that case, sponsors ought not to provide other.

“I think it will depend on the type of research. For instance, there are researches where the patients are already supported. I give you an example of HIV patients that we have on antiretroviral drugs. Researchers may want to do a survey on the knowledge or perception of a certain aspect of the disease. Those kinds of patients that are already been supported by the organization, the same organization wants to get more information from them. We will not insist on any extra benefit because participants are already supported with HIV medication.”

Ethics Committees to decide fair benefits

Owing to the growing awareness of the importance of ethics committees in assessing ethical aspects of research, respondents express the view that ethics committees should have the mandate to

decide on the fairness of research benefits. Where the benefits outlined on the research protocol are inappropriate, the ethics committee can call the attention of research sponsors to correct and calculate what they deem as the appropriate benefits. Protocols that are assessed not to be beneficial to the participants or host communities can be rejected by the ethics committees.

“There was a research in which the committee felt so negative about. It was a situation where a non-physician researcher was going to work with somebody in Obstetrics and Gynaecology to take some samples. We felt that even though the researcher was experienced enough, the benefit of that research to the patient was not sufficient and so we rejected the research protocol.”

Legal Framework on Benefit Sharing in International Research

Asides benefit sharing in the context of plant genetic resources, which has a legally binding regulation, the concept of benefit sharing in international research involving human subjects is advocated as a non-binding regulation in existing research guidelines [8]. Nonetheless, some researchers advocate to develop a legal framework on benefit sharing in international research. This section examines whether respondents would prefer benefit sharing to be legally regulated. This would mean that whenever research sponsors conduct research, they are obliged by law to provide benefits. Respondents were in favour of the establishment of laws on benefit sharing in research. For example one of the respondents expresses the need for a benefit sharing law relating the necessity of such law with the existing corruption in Nigeria:

“I really feel there should be a law. In this country [Nigeria], there is a lot of corruption and people like to cut corners. Even when there are laws people look for ways on how to evade from the laws, so how much more if there is nothing to hold them to. So without putting a law in place I am not sure there will be compliance in benefit sharing.”

A strong support for benefit sharing is also re-echoed from a standpoint that a legal backing on benefit sharing can serve as safeguard to ensure something gets to the host communities in research—otherwise sponsors would always do away with all the research benefits at the end of the research.

Yes the issue of benefit should be enforced, that's my candid opinion. Because there is no need somebody comes from the United States and conducts a research and goes away with all the benefits. It doesn't make sense, at all! There is no need somebody brings his drug from China and conduct a clinical trials in Nigeria and after that he goes back to sell the drugs in China without the participating community benefiting from it. There must be a law against these practices.

A different opinion on the legalization for benefit sharing is that such legal promulgation would only create a situation where research participants would rush for the gains in research without having thorough reflections on the possible risks of the research. Respondents reiterate that benefits of research should never be considered above the risks or other unethical practices in research. In other words the fact that participants and communities would benefit from research can never be a sufficient reason to be unnecessarily exposed to research that is highly risky.

“I agree entirely that those who bear the burden of showing that your products are scientifically sound should also accrue a lot of

benefits. But having said that, I think there should be a balance in this issue of law. You don't want a situation where once the words get out to the community that if a pharma company does research in your community, they must buy this and that and then people start allowing themselves to be subjects of research that is unethical, you know that these are vulnerable people.

Another reason why benefit sharing law should not be considered in international research is that researchers ought not to lose their autonomy. In other words, research sponsors ought to be trusted as self-conscious entities and ought to provide the right benefits of research to the host communities.

“Well it should be left to their own judgment of what they should do. They themselves (research sponsors) know the value of whatever research they have carried out and they should use the magnitude of their benefit to determine what to do in appreciation to the community. Maybe because we are a mission hospital we think people have conscience.”

Who Gets What Type of Benefit?

When speaking of benefit sharing, there is often confusion as to what it should exactly constitute. In this section respondents mentioned the various types of benefits they would recommend for research participants or communities. Furthermore, respondents are more inclined to believe that research benefits that target the community as a whole are to be preferred over individual benefits. However, they also emphasized the relevance of individual benefits.

Benefits to the research participants

The idea that research participants ought to receive benefits in monetary terms was again restated as a type of benefit to participants. Monetary benefits should accrue the participants because they would have to travel to the research centre or hospitals for appointments. However, there was a constant reiteration that such monetary benefit should not serve as inducements to participants. Making reference to a clinical research on HIV prevention, a respondent sums up:

“We have had instances where people wanted to collect data for Prevention from Mother to Child (PMCT) research. And in order to encourage participation, the participants were given some stipends. It's not like you are buying their consent but you know they will have to travel down for the questionnaire and other data collection in the field. So you give them something to offset their transport.”

Another idea that was mentioned is that the participation in research itself is a form of benefit to the participants. In the course of research, participants are likely going to benefit from the tested intervention (although in some cases they are harmed) or other forms of laboratory tests which may not be available or affordable to them in the absence of the research.

“Sometimes for instance, the drug trials that we have done in the past, the provision of the medication to the participants we require them to be free of charge as well as running their laboratory tests throughout that period. That is also some benefits that accrues to them.”

Respondents also envisaged that benefits to individual participants could arise from incidental findings during the research. When there are incidental findings whereby researchers have discovered

something not connected to the research, participants could benefit from a treatment for such incidental findings:

“Like you could just do a study and part of the basic things you are asking for could be let’s say for instance haematocrit the blood level of the patient and you discover that some of the patients are anaemic, you could make provision to help them to solve that problem that you found incidentally as a result of the study. That is a benefit to the participant.”

Benefits to the local community

Research benefits do not only entail benefits to the individual but to the local community as a whole. Respondents noted various forms of benefits that the community can benefit from hosting a research project. A well noted type of benefit is the reasonable availability of the tested medication at the end of the research. By reasonable availability, respondents are referring to making the proven intervention affordable or even free of charge to the research community. This reasonable availability should be plausible because the research sponsors would gain a monopoly of patency for a period of time and should afford to make the medication available at a subsidized price to the research community.

“You know when we are talking about drugs and private companies and patency, first when you produce those drugs you hold on the patency for quite a while and you make as much money you can from it. The community that you have done the study might not have the strength to be able to benefit from that drug. And so it will be very important that such drugs are made reasonably available to such communities at greatly subsidized if not free for people needing that medication within the community.”

Other views included the idea of developing the local content. Development of the local content would involve research sponsors to look inward in the host country and see the feasibility of manufacturing the newly proven drug locally in the country. This would go a long way in subsidizing the medication and improve the living standard of the host country.

“For drug companies it will just be wise for them not to think about their side alone, but think about how they can improve the well-being of the people. If you have conducted a research, you should ask for the manufacturing possibilities, does the country where the research is conducted have the raw materials, if they have the raw material or not you can bring them in and make arrangement to produce the drug locally.”

Some suggestions are focused on the provision of facilities and upgrades of the equipment within the institutions where the research is conducted. This provision and upgrade of equipment can go a long way in serving the hospitals while in turn serving the people of the community.

“For instance if research is been conducted, by virtue of that research, the institution is going to acquire sub-zero deep freezers and laboratory equipments. Also for example in your research you have to use a small clinic during the course of the research. Equipping it to a point where that is sustainable after you have left, those types of things you know are really important. We count that as important benefits to the hospital and to the community.”

The idea of the provisioning of equipment in institutions is closely related to provision of basic amenities which was suggested by some respondents. They noted that research sponsors should link their

research with a particular need of the community and endeavour to provide such need. For example, a respondent suggested that if a research sponsor is conducting a research on water borne disease, they can look at the community and provide for example say boreholes. This would alleviate the lack of potable water that is the main cause of the water borne disease in the community.

Benefit to the local community can also be achieved through capacity building of research and health staff. The local staff of the community hospital can be trained on how to use a recent technique or procedures in the laboratory or they can be offered scholarships on research methodology. Consequently the trained staff can in turn serve the community members for better health and research outcomes.

“There are supports that can be given to the representatives of the community by means of scholarships, this can help people from within the community to go and add knowledge which they can come back and plough back into helping the community.”

“For me human capital development for the researchers is also very good, because you don’t use people to get data for you without training them. It is wrong.”

These indicate a benefit sharing that considers the whole community.

Discussion

By requesting respondents to identify some salient ethical aspects regarding research ethics, respondents consistently outlined informed consent or the necessity of a comprehensive consent document, sound methodology and research design as the main ethical issues that should be given due attention in research (Table 1). However when prompted on what sound methodology and research design entails, some respondents elaborate fair distribution of research benefits and burden as part of a sound methodology. In general respondents easily recognized informed consent as an ethical concept, whereas they had more difficulty in recognizing benefit sharing in that respect. This could be attributed to the fact that the issue of informed consent is highly discussed in international research ethics publications [19,20]. The issue of benefit sharing however is not considered in great detail. Although the concept is recommended in ethics guidelines, it is often not adequately elaborated. In this respect, Johansen et al [21] state that in most ethics guidelines the issue of benefit sharing is only superficially elaborated and as a result this is causing vagueness in benefits arrangements in research proposals. Similarly, the lack of a good stance on benefit sharing is reflected in the Nuffield Council Report on Ethical Conduct of Health Research in Developing Countries, which does not have a substantive statement on benefit sharing. The report simply notes that the issue of benefit sharing is outside the scope of stakeholders and requires attention which would be addressed in the future [22]. This indicates the need for a more robust advocacy that would place benefit sharing as a top ethical concept in research ethics practice.

Similarly, respondents outlined different understanding and definitions of benefit sharing. While some of the respondents view benefit sharing from the perspective of financial obligations to the research participants, others have rejected the idea of financial incentives on the grounds that it may lead to participants’ inducements. Yet, others view benefit sharing as obligations to cater for research participants in the event of adverse drug reactions. Also, financial reimbursements to participants for food, transportation and

time spent in research participation were often expressed by respondents as benefit sharing. This is similar to an empirical study that research stakeholders envisage reimbursements as benefits as such creating a tension between the two concepts [10]. In general, researchers have expressed reservation on whether the financial reimbursements should be regarded as benefit sharing [23]. We concur with this reservation because financial reimbursements are more or less acts that aim at supporting participants to offset their expenditures as a result of their direct participation in research rather than acts of benefit sharing [24].

Furthermore, the various understandings and definitions of benefit sharing indicate that the concept of benefit sharing in international research has no consistent or a succinct definition. Again, when one makes a comparison between informed consent and benefit sharing as concepts in research ethics, there is a marked difference in clarity of definition with the former having a more coherent definition than the latter. Such non-coherent definition of benefit sharing is highlighted by Schroeder in her effort to develop a precise definition for benefit sharing. She notes that most of the definitions of benefit sharing within human genetic resources are either unclear or not definitions [1]. Furthermore, the non-consistency in definition is reflected in the PUBMED database, one of the largest databases for publications in medical sciences. A look at the MESH term for informed consent or research design or intellectual property reveal streams of definitions and meanings. Benefit sharing on the other hand, is yet to even have an entry as a MESH term in spite its long time usage in the international stage. This suggests that researchers have either been neglecting the concept or they cannot agree on a consistent definition of benefit sharing for an entry as a MESH term. There is a need to review the existing ethics frameworks so as to give benefit sharing a consistent definition and due attention in international research. A clear and consistent definition of benefit sharing is necessary as this will set the stage of global harmony on the concept. Such global advocacy and harmony can be achieved if research actors are speaking on the same clearly defined concept. A clear definition is also necessary as this would ensure more awareness on the concept among various research stakeholders which would subsequently drive the development of frameworks and international good practice.

Respondents also outlined three major ways of achieving fair benefits for research participants and communities. The first method is through negotiations with the host communities that are genuinely represented by designated community representatives. That is to say, research sponsors should negotiate with the community representatives and agree on the terms of benefits for a research. This position is consistent with the fair benefit approach that has been suggested at the Conference on Ethical Aspects of Research (2004). The participants at the conference noted that only the host population can determine the value and appropriateness of the benefits to be proposed. Outsiders are unlikely to be familiar with the economic, social and cultural context and therefore unlikely to appreciate the importance of the proposed benefits [7]. The fair benefits approach has a very good appeal as it brings research sponsors and host communities in good research harmony and enhances community engagement, which has been highly advocated in international research [25]. The second method that has been proposed by respondents is setting a benchmark for benefits such that research sponsors commit a certain percentage of their profits as benefits of research in the host community. This suggestion is analogous to the Human Genome Organizations' (HUGO) position on benefit sharing. The HUGO proposes that 1-3% of net profits by research sponsors

should be set aside for obligations of health infrastructural development in developing countries [26]. The third method suggested by respondents is that the ethics committees should hold the responsibility of deciding the benefits that suits the host communities. This position has also been recounted in existing literatures and research guidelines. For example, the WHO operational guidelines for Ethics Committees outline the role of ethics committee in ensuring that the benefits and burdens in research are fairly distributed among the research participants [27]. All the ways suggested by respondents are credible in deciding fair benefits. However, we suggest that bringing together the first and third methods would result in even better benefit sharing outcome. Ethics committees should be in close cooperation with the community representatives to work out benefits that suit the host community. A good liaison between the local ethics committee and the community representatives would result in a complementary exchange of ideas that would culminate to better and fairer benefits that reflect the need of the host community.

Most of our respondents would agree to the development of a legal framework on benefit sharing. This is an empirical backing to our earlier publication where we suggest the need for a legal framework on benefit sharing. A law on benefit sharing would go a long way in strengthening its advocacy and practice [8]. Nonetheless, a few respondents express the view that poor participants would resolve to volunteer in unethical research if they know that they are protected by a law of benefit sharing. Other respondents assume that research sponsors should be trusted to provide benefits without been compelled by the law. These points are vital, but not sufficient to function as a counter argument to a law on benefit sharing. In the process of developing a benefit sharing law, these viewpoints can be considered and ways to address them can be carefully delineated. Furthermore, laws created for benefit sharing should be subject to constant review. For example, the bioethics laws in France have been subjected to regular reviews and updates since their adoption in 1994 [28]. This would ensure a constant optimization and evolution of benefits as international research itself evolves.

One of the different ways respondents articulate as a form of benefit to participants is that individual participants would benefit from the medical care or even from incidental findings during a research. This claim maybe closely related to the problem of therapeutic misconception in research. Therapeutic misconception has been a well documented problem of research in developing countries whereby participants misunderstand the difference between the purpose of research and routine medical care [29]. Most studies documented on therapeutic misconception are on research participants and not on research ethics committees in developing countries. As such, we cannot categorically infer that respondents' comments are unequivocally a case of therapeutic misconception. We suggest more studies to determine if the notion of therapeutic misconception exists among research ethics committees in developing countries.

Limitations of the Study

The respondents in this study are recruited based on their willingness and subsequent availability for the interview. This has limited the variability of the study participants to only some regions of Nigeria. Considering the six geopolitical zones of Nigeria, we are able to get representatives from only three geo-political zones (North-West, North Central and South-East). The North-East region was not included because of the potential security risks as a result of insurgent activities. Although, we do not expect to have wide variation of

responses with the inclusion of respondents from all the geo-political regions, nonetheless the study has limited generalizability to all ethics committees in the country.

The views expressed by the respondents are mostly personal opinions and not the standpoints of the ethics committees they represent. This is because the ethics committees do not have written policy documents on benefit sharing and also show limited awareness on the concept. To this note, there is need for education on benefit sharing and other ethical principles in research among the ethics committees in Nigeria.

Conclusions

This study provides the first outlook of the perspectives of Ethics Committees members in Nigeria on benefit sharing in clinical research. The study has indicated a relatively low awareness of the concept of benefit sharing among the respondents. This does not necessarily suggest bad practice of benefit sharing in ethics review process among the respondents. More so, as indicated, the aim of the study is not to query Nigeria's ethics committees on benefit sharing but to know what committee members know about the concept of benefit sharing. Nonetheless, we are certain that a good awareness of the concept will lead to even better practice, improve its advocacy and set the pace for the development of a benefit sharing framework in clinical research. The findings of this study also suggest that benefit sharing has a wide scope as respondents view it differently. While we agree that there could be various ways that benefit sharing can be perceived, we suggest however, the need to set a boundary of what benefit sharing should be (or should not). This is necessary, in order to have a definitive nuances on benefit sharing.

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Authors Contributions

The idea of the empirical study was conceived and developed by BD and KD. Both authors contributed equally to the first drafted manuscript. BD elaborated the various stages of the manuscript with thorough revision, editing and mentoring from KD during the pre-publication process. Both authors read and approved the final version of the manuscript.

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