2-21-2024

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Keywords: IRB, cross-cultural settings, decision-making, research ethics committees

Anthropologists have challenged bioethicists to incorporate more holistic approaches to applying ethics in 'real world' situations. Where bioethicists tend to use systematic philosophical approaches to moral dilemmas, anthropologists apply malleable approaches designed to be responsive to variable cultural contexts. For example, anthropologists emphasize the importance of community and the effects of social issues, political economy, and cultural tradition in decision-making. This difference in approach contributes to the contentious relationship between anthropologists and bioethicists. Despite nuanced perspectives, anthropologists have not enjoyed a durable role in shaping contemporary bioethics.

The lack of nuance becomes problematic when researchers attempt to reconcile ethical issues against a standard of morality rather than what Patricia Marshalls defines as a "culturally constituted and continually evolving" process. Reflecting on the IRB review of my work with African descendants in the United States and Nigeria, I will discuss the importance of conceptualizing bioethics as a dynamic issue, especially when working with communities abroad. Comparing these review processes is instructive about the organizational structures, influenced by culture and society, that impact decision-making in respective communities. In this presentation, I suggest that a focus on the way that IRB reviews are done can also offer insights and contextualization into community decision-making. Within a cross-cultural setting, considerations of the IRB review processes can lead to more informed conversations on bioethics and can aid researchers in applying more holistic approaches to study design.

Introduction

As anthropologists and other social scientists interact with non-Western populations, it is important to understand how bioethics can continually play a role in shaping how researchers interact with an ever-changing world. Although the disciplines have the potential to work in tandem with one another, anthropologists and other social scientists have offered critique on bioethics (Fayemi and Macaulay-Adeyelure et al. 2016, Turner 2009). Anthropologists in particular have challenged bioethicists to incorporate more holistic approaches to applying ethics in 'real world' situations. They, along with other social scientists, have especially critiqued the large number of generalities that in turn fail to account for cultural differences and overall fail to incorporate familial, social, and other community level factors when understanding ethical dilemmas and actions. In fact, because of this, bioethics has routinely been described as an armchair discipline (Turner 2009) with unintended imperialistic consequences (Fayemi and Macaulay-Adeyelure et al. 2016). Despite this, bioethics still holds promise for improving anthropological methods. In this paper, I suggest that a focus on the way that institutional review board (IRB)[1] reviews are done can be reflective of community values and consequently offer insight to study design. Within a cross-cultural setting, considerations of the IRB review processes can lead to more informed conversations on bioethics and can aid researchers in applying more holistic approaches to study design. I expand on Marshall (1992) idea of ethics as a "culturally constituted and continually evolving" process to illustrate how bioethics can be applied to study design through the IRB process. Using both a U.S. -based and Nigerian-based IRB review of my project with African diasporic populations, I illustrate the importance of conceptualizing bioethics as a dynamic issue, especially when working with communities abroad. A comparison of these review processes is instructive about the organizational structures, influenced by

culture and society, that impact decision-making in respective communities. Decision-making here refers to the ways in which IRB and ethical committees' processes are shaped and applied. This is especially important as what a community values determines what research can successfully take place. Lastly, I end with recommendations moving forward.

The dynamics of bioethics

Ethical considerations surrounding scientific and biomedical advancements started gaining prominence in the mid-1960s, although they had been present for a decade or so prior. (Pellegrino 1996, Emmerich 2011). Bioethics merged philosophy and its ideas of moral dilemmas into practical applications. During this period, acknowledged as the first phase of bioethics research in the United States (U.S.), scholars primarily focused on issues such as informed consent and the challenges associated with obtaining consent from human subjects in scientific research. (Marshal 1992). In the second phase of bioethics in the U.S., spanning from the mid-1970s to the 1980s, scholars were preoccupied with definitions of personhood, life, and death (Marshall 1992). Since the mid-1980s, discussions surrounding personhood, life, and death have continued to expand to include the importance of autonomy and the individual when dealing with ethical dilemmas. From this same period, a shift away from "moral obsession" began. "Moral obsession", or the way scholars at the time paid extreme attention to self-determination and focused on predominantly white middle, and upper-class Americans, proved to have its limits. "Moral obsession" and its framework failed to give attention to, or gave less importance to, the community and the effects of social issues, the political economy, and cultural tradition on decision making (Marshall 1992, Loewy 1991, Callahan 1984).

From this shift, understanding the ethical decisions of people within the

context of their community emerged in what Patricia Marshalls recognizes as a "culturally constituted and continually evolving" process. To illustrate just how much of a dynamic process bioethical issues can be, I draw on the example of U.S. Army general Walter Reed. Beginning in June 1900, Reed and his team introduced yellow fever into American soldiers and recent Spanish immigrants to demonstrate that the disease could not be transmitted through bodily fluids or direct contact (Lederer 2008). These participants willingly consented to deliberate exposure to infected mosquitoes and to the bedding and clothing of those who had succumbed to yellow fever. Revised for clarity: Those who agreed were incentivized with medical care and 100 to 200 dollars' worth of American gold, the amount varying based on whether yellow fever was contracted. At the turn of the 20th century, Walter Reed and his experiments were extremely beneficial for the U.S. as they proved useful in demonstrating how yellow fever was transmitted and how it could be controlled (Lederer 2008). Reed and the yellow fever experiments are just one example of the complexity of examining the ethics of a given situation. Some aspects of the study worth reexamining are the motives of participants who joined the study or issues surrounding informed consent and risk. Given the outcome of the study, were the actions of Reed and his team justified? This complexity can be applied to bioethical issues today: child enhancement and issues concerning genetics; increasing genetic technology; the idea that behaviors, especially undesirable ones, are genetically determined; and issues of globalization, where different countries have large discrepancies in ethical procedures (Allhoff et al. 2010, Beachy et al. 2020, Gielen 2020).

A more hermeneutical approach emerged from dissatisfaction of "moral obsession" and its framework limitations. This approach acknowledged the importance of contextualized models that consider ethnographic practices of morality rather than moral theory. Ethnographic philosophers at the time believed that this would challenge ethicists to incorporate social practice and experience

and begin to examine values in an anthropological perspective. That is to say, ethical problems would cease to be viewed against a standard of morality but instead understood as dependent on cultural and contextualized variables (Marshall 1992, Chattopadhyay 2008). As one considers this hermeneutical approach and the importance of contextualized models, study design can be a pivotal way for bioethicists to better understand the communities with which they work. Community values are inherently evident in what an ethical committee in a particular country chooses to address, highlight, and question. Consequently, the processes and decisions (i.e. organizational structures) can be indicative of historical ethical mishaps that a particular country is trying to avoid. Insights to community values can be incorporated into study design via the study question, how samples are collected, and how results are disseminated. I argue that the IRB process offers the opportunity for bioethicists and anthropologists to better understand the community with which they will work.

Cross cultural IRB reflections

The inception of the IRB was in response to the World Medical Association Declaration of Helsinki in the 1960s. It was at this time that U.S. institutions were required to provide adequate measurements to promote the wellbeing and protection of human subjects engaged in research. Although with little oversight during its inception, multiple infractions continually occurred (e.g. the Tuskegee Syphilis Study, The hepatitis experiments at Willowbrook, HIV research, The Salk polio vaccine trials) (Turner et al. 2017, Emanuel 2008). In response to these infractions, Congress passed multiple acts to further promote the protection of human subjects. The Belmont Report was monumental in promoting protection (Abbott and Grady 2011). Briefly, the report was formed under three main principles: respect of persons, beneficence, and justice. Together these principles

make up the basic ethical principles to account for when working with human subjects (The Belmont report 1978). Today, the IRB is an integral part of human subjects' protection[2]. In the U.S., there are three sections that are used to evaluate ethical research practices: risk, vulnerable populations, and compensation. Specifically, in these sections, risk examines possible adverse effects from participation; vulnerable populations address the ethics of including historically marginalized groups; and compensation discusses how and if participants will be compensated for their time. These sections of the IRB application are very different than sections under Nigerian protocol, as I will discuss later. To illustrate how these sections function in a study, I draw upon previous and prospective research done in the U.S. and Nigerian populations.

United States

My experience with the IRB in the U.S is one example of the ways in which the IRB process can be instructive about and influence study design. As aforementioned, risk, vulnerable populations, and compensation are fundamental categories in the U.S. IRB process. Because of this, the process is always geared towards adequately explaining the risk of the study to individuals and ensuring overall comfortability of those involved. In the study I draw from, there was a heavy emphasis on communicating the risk and overall purpose of the study via educational packets and live informational sessions. In regard to vulnerable populations, in the U.S, economically, or educationally disadvantaged individuals are considered vulnerable populations. In the same study, vulnerable populations were not a prominent concern, as the workshop occurred in a metropolitan area among individuals associated with higher education. Understanding how and in what ways an IRB defines vulnerable populations may heavily influence the study design process of those conducting research (i.e. who to enroll, how to protect

those enrolled). Lastly, although participants in this study were not financially compensated, a large part of that study was centered around returning information to participants, educating participants on genetics and genomics, and providing centered cultural events. Research results were also made available directly to participants using the e-mail addresses on the consent forms. Knowing the values of the community, simply through what is emphasized on the IRB can be extremely instructive on what decisions to make in terms of study design. This approach can be applied to cross cultural settings as well, as seen in the following section.

Nigeria

When compared to other countries, bioethics in Nigeria is heavily centered around research ethics as opposed to behavioral/human subjects clinical research (Ogundiran 2004). This emphasis is in part due to big ethical mishaps in Nigeria's history (Ewuoso 2016). The 1996 Pfizer's CSM Trovan trial is often cited as the primary reason formal bioethics training and regulations were introduced in Nigeria. In 1996, Nigeria was suffering from a meningococcal meningitis epidemic. At this time, Nigeria had a population of roughly 110.7 million people (world bank, "Data Catalog"), of this total, there were over 300,000 cases and 30,000 fatalities. At this time, there were no running ethical research committees. Pfizer initiated an unsupervised randomized trial of trovafloxacin. This experimental drug was intended to act as another treatment for meningococcal meningitis. The trial included 200 children, half of which were given trovafloxacin; the other half was given ceftriaxone, the standard treatment for meningococcal meningitis. After administering the drug, Carr (2003) notes that Pfizer left with their findings failing to follow participants or inform them of the risks of trovafloxacin. Shortly after, study participants not only complained about

health issues and inadequate information, but case fatalities ranged between 5–6%. Furthermore, the questionable trend of global outsourcing clinical trials, where clinical trials were exported to developing countries for the benefit of developed countries, also played a major role in Nigeria's bioethical history (Evuleocha 2012, Chima, 2006). Outsourced trials exploit poorer countries that have a high prevalence of disease, larger populations with said disease, weaker infrastructural healthcare systems, and issues with literacy. Further, although these trials offer treatment to those who might otherwise not get treatment, the fact is that these people are more vulnerable due to issues of poverty and literacy (the same categories that make people in the U.S. vulnerable)- and thus make their decision to join these trials more complicated. The Trovan trial in Nigeria coincided with attitudes geared towards fighting the HIV/AIDS and malaria crisis in African countries (Okonta 2014). To combat these issues with HIV/AIDS, more clinical trials in low and middle-income communities emerged, especially to test the efficacy of cheaper drugs. With these trials, despite some being ethically well designed, ethical goals were not being met as there were no functional ethical research committees at the time to adequately protect and inform study participants. This was in large part to a weak healthcare system, along with prerequisite knowledge of how to handle ethical issues that arose and lack of protection or protocols of protection for research participants. Because of these issues, along with the lack of accountability that both educational and scientific communities had at the time for the protection of participants (Ajuwon 2015), it was important standardized ethical review procedures be introduced in West Africa, as a whole, to protect human participants.

To address the problems with conducting and monitoring clinical trials, research ethical committees were formed in Nigeria in response to a few concerns: 1)there was a need to overcome the historical weaknesses that Nigeria had faced; 2) medical and university-based researchers needed to be educated in

ethical practices; 3) to increase the ability to conduct and ethically review human subjects research; and 4) to strengthen ethical committees across the country and to contribute to larger global bioethics discourses by producing new cohorts of bioethicists (Aminu et al 2017,Ewuoso 2016). Today, the majority of these committees are under 10 years old and are made up of primarily bioethicists. Challenges of research ethics committees in Nigeria include lack of membership diversity, resource scarcity, lack of membership training, lack of capacity to review and monitor studies, and lack of national accreditation. A recent review of the literature by Aminu et al. 2017, showed that Nigerian research ethics committees face numerous issues that impede the IRB process (e.g. lack of funding, resources, and motivation). Despite these limitations ethical committees have proven useful in insuring the overall protection of human subjects. While some issues go beyond the scope of what biological anthropologists can address, other points are suited to anthropological perspectives. One informal study found that Nigerian research ethics committees are overall lacking in opportunities for training; they especially emphasized the need for benefit assessment and for new committee members (Aminu et al. 2017). Another characteristic worth addressing is the way in which almost half of these ethical committees surveyed use identical IRB procedures and protocols independent of the risk to human subjects (Aminu et al. 2017). As I note later, characteristics such as these are important for anthropologists like myself to grapple with when applying ethics to study design.

The ethical review process in Nigeria shares similarities with the process in the U.S., but it also has notable differences. For one, ethics committees in Nigeria only meet once a month to approve proposals. In some cases, this happens at U.S. institutions, but there is more variability. In the U.S., the general review time frame could take between 2–9 weeks. In Nigeria, these times are quite similar, taking between 1–3 months. However, in Nigeria, fees are attached when filling out an ethical review proposal (Baluku et al. 2021). These fees are

dependent on one's academic status and range from 0–50,000 naira, or about 125 USD. Within the U.S. there are certain situations where IRBs also charge fees.[3] This typically happens with commercial enterprises; however, all academic research is subject to these fees within Nigeria. When working with the Nigerian ethical committee, vulnerable populations are not as highlighted as in the U.S. IRB. It is worth noting that when addressing these observations to research faculty, they did note that vulnerable populations require special permissions. My experience with the Nigerian ethical committee process has been indicative of this. The application only explicitly lays out a section specifically requiring assent for children under the age of 18 but does not have a specific question that targets other vulnerable populations. The proposal also specifically emphasizes the requirement for collaboration, noting that scholars not associated with the University must have a collaborator because of this, collaboration has been an important part of my own study design experience.

Challenges and future reflections

When working with international communities these differences must be addressed to conduct ethically grounded research. In the U.S. racialized minorities populations are considered vulnerable populations (Shi and Stevens 2021, Shi et al. 2008, UyBico et al. 2007). This is in direct contrast with Nigeria as the majority population is of the same racial background. Reconciling, in this case, how the U.S. and Nigerian populations categorize and deal with vulnerable populations is something that must be addressed, in this case, by those who work with this community. This brings attention to the importance of race in shaping everyday realties and consequently vulnerabilities in the U.S., where as race (as we understand it in the U.S.) may not be as important or relevant in the Nigerian setting where other variables like class, gender, religion, or ethnic background

may be more meaningful ways of understanding vulnerability. Similarly, as the expansion of research and technology continues to spread, conversations of who is vulnerable and in what context is pivotal for planning ethically. Similar sentiments are seen with the notion of confidentiality. Notions of confidentiality could be of particular importance to those interested in collecting or transporting DNA samples, tissues, or bones (Godard et al. 2003). Confidentiality has already begun to be a major point of contention in the U.S. alone concerning issues of repatriation, or the MOVE bombing victims.[4] The IRB processes related to confidentiality further highlights the need to continue conversations surrounding issues of risk and identification.

Overall, comparing these review processes is instructive about organizational structures that are influenced by culture and society and impact decision-making in respective communities. Insights into the organizational structures and foundations of IRBs or ethical committees are useful in designing ethical research projects as well as engaging with the prospective study community. In the U.S., the IRB process is indicative of the United States' history of exploiting vulnerable populations. Modern protocols, procedures, and guidelines are geared towards the comfortability of participants in their prospective studies. The IRB process is also indicative of the historical mishaps surrounding vulnerable populations. There are certain groups whose medical decision-making is deeply rooted in the history of ethics and the U.S. (Breathett 2018, Rothman 2017, Karel 2007, Torke 2004). Knowing this, IRB protocols should be, and seem to be, geared towards limiting the mistrust; For example, the way in which IRB and consent are geared towards increasing transparency. Nigeria is notable in that their history of bioethical catastrophes have typically arisen from involvement with international organizations. Because of this, their focus seems to be geared towards clinical protocols and securing resources. The focus on clinical practice in Nigerian ethical committee protocol is indicative of

the history that they have had with the U.S. based Food and Drug Administration (FDA) and clinical trials with different pharmaceutical companies. Because of this, consent seems especially necessary within the context of clinical trial studies. However, for observational studies, consent is not always as easily obtained in some cases. Securing resources through research is beneficial for Nigerian organizations as the literature suggests most research committees are underfunded and resourced. This is evident when viewing the IRB protocol as researchers interested in conducting a study are expected to pay review fees for every proposal. A well-run and efficiently funded IRB is a catalyst for research production in developing countries' academic centers. Despite having a great desire to contribute to global knowledge, Nigerian institutions are not securing international institutions' collaborations or funding. This is pivotal for countries such as Nigeria who at times lack reliable research infrastructure—this is not to take away from the pivotal role Nigerian institutions have in their communities. The Nigerian ethical committee process seems geared toward improving Nigerian universities' ability to contribute to global research. The U.S. process is geared towards mitigating a tumultuous and exploitative history; however, it seems that Nigeria has to contend with its tumultuous and exploitative history as well, but their issues, historical and otherwise, are different than what occurred in the United States.

I suggest that a focus on the way that IRB and ethical reviews are done can also offer insights and contextualization into decision-making. Within a cross-cultural setting, considerations of the IRB and ethical review processes can lead to more informed conversations on bioethics and can aid researchers in applying more holistic approaches to study design. Moving forward, anthropologists should be in conversation with local bioethicists, through partnership and collaboration, to further understand human subjects' participatory research. We know through the history of Nigerian bioethics that ethical education is continuously evolving,

even more so in human subjects' research, particularly as Nigerian ethics primarily focuses on clinical practice and the ethics associated with it (Ogundiran 2004). These collaborations also include community input and could serve as a way to bridge the trust between Nigerian populations, especially those outside of school settings. The West African Bioethics (WAB) training program has been fundamental in ensuring ethical procedures in Nigeria. The program includes an online diploma course, workshops, and seminars for academics, health professionals, and members of the ethics committees. The program uses a 'train the trainer 'model in which trainees, after completion of the program, become the trainers. The three major aims of this program are to 1) grow the number of ethical review research studies in Nigeria; 2) to overall strengthen Nigerian ethical committees; and 3) to create a network of bioethicists. Biological anthropologists interested in working on cross-cultural projects in Nigeria would benefit from working with such programs. In doing so, bioethics and anthropology could continue to study the importance of community, social issues, political economy, and cultural tradition on decision making, which in turn could be implemented in research design (Ewuoso 2016).

Received 16 May 2023; accepted for publication 6 February 2024.

Notes

1 In U.S based institutions, the term IRB is common, outside of the U.S. these groups are typically called research ethics committees.

2 For a more detailed overview of U.S. IRBs see Abbott and Grady 2011.

3 See the following link for an example:https://www.hopkinsmedicine.org/institutional_review_board/about/fees.html

4 Nash and Colwell 2020, "A Philly Museum kept the bones of a Black child killed in a police bombing. Decades later, it's apologizing.," n.d.).

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