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RESEARCH ARTICLE:

The San Code of Ethics Versus International Ethical Guidelines: A Cross-Cultural Analysis

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Abstract

This study was designed to compare the San (Khoisan) code of ethics against key elements of the revised Council for International Organization of Medical Sciences (CIOMS) ethical guidelines, and the World Medical Association (WMA) Declaration of Helsinki. The study aimed to identify similarities and draw inferences in applying the San code of ethics when conducting biomedical research among indigenous populations groups in Africa and globally. In-depth interviews lasting 45 to 55 minutes were conducted among a group of 12 purposively sampled biomedical researchers in South Africa. Interviews were recorded, transcribed, and analysed using thematic content analysis. Participants observed some important similarities between the San Code of Ethics, the CIOMS ethical guidelines and the Declaration of Helsinki. Nevertheless, the research discovered that San peoples were of the opinion, that community involvement in biomedical research reduces exploitation, and enhances human dignity, and should be based on mutual respect, honesty, justice, fairness, and the ethics of care.

Keywords: *biomedical research; ethical codes; indigenous populations; San; Khoisan*

Introduction

The study aims to compare the San (Khoisan) code of ethics with key elements of the revised Council for International Organization of Medical Sciences (CIOMS) ethical guidelines and the World Medical Association (WMA) Declaration of Helsinki. The objective is to identify similarities and draw inferences in applying the San code of ethics when conducting biomedical research among indigenous population groups in Southern Africa and globally. The CIOMS guidelines have been recognized as an important framework for ethical research involving human subjects (CIOMS guidelines, 2016; van Delden and Graaf, 2017). They provide guidance on various aspects of research, including specimen handling, informed consent, and health services needs and demand (CIOMS guidelines, 2016; van Delden and Graaf, 2017). The revised CIOMS guidelines emphasize the social and scientific value of research and the fair benefits for participants in low-resource settings (CIOMS guidelines, 2016; van Delden and Graaf, 2017). They also focus on capacity building and equitable partnerships in collaborative research (Ward *et al.,* 2018).

The WMA Declaration of Helsinki is another important ethical guideline for medical research involving human subjects. It provides principles for the conduct of research, including informed consent, protection of vulnerable populations, and the importance of scientific validity (Declaration of Helsinki, 2013; Tangwa, 2021). The Declaration of Helsinki has been widely adopted and serves as a reference for research ethics committees and regulatory bodies (Declaration of Helsinki, 2013; Tangwa, 2021). The San code of ethics, on the other hand, represents the ethical principles and values of the San people, an indigenous group in Africa. The San code of ethics is rooted in their cultural traditions and provides guidance on various aspects of life, including research and knowledge sharing (San Code of Ethics, 2017; Carroll *et al.,* 2022). By comparing the San code of ethics with the CIOMS guidelines

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and the Declaration of Helsinki, the study aims to explore the applicability and relevance of indigenous ethical frameworks in the context of biomedical research.

The study analysed the similarities and differences between the San code of ethics and the CIOMS guidelines and the Declaration of Helsinki. It examined how the San code of ethics addresses key ethical considerations in research, such as informed consent, protection of vulnerable populations, and the social and scientific value of research. The study also explored the potential implications of applying the San code of ethics in biomedical research among indigenous populations in Africa and globally. By conducting this comparative analysis, the study aims to contribute to the ongoing discussions on research ethics and the importance of incorporating indigenous perspectives in the design and conduct of research. It seeks to promote a more inclusive and culturally sensitive approach to biomedical research, particularly in the context of indigenous populations. The findings of the study have implications for the development of ethical guidelines and policies that better reflect the values and needs of indigenous communities.

This study involved examining the ethical implications of biomedical research among the indigenous population through the comparison of the San Code of Ethics (2017) and the CIOMS guidelines 2002; 2016) as well as the Declaration of Helsinki (2013). This would help to understand as well as determine the impact and implications of medical research among indigenous populations.

Materials and Methods

This study adopted a cross-sectional qualitative research approach and an extensive review of literature data. Thus, the qualitative arm of this study is based on an analysis of in-depth interviews conducted among twelve biomedical researchers at a South African University. The data from the interviews was analysed in combination with some international ethical codes and pertinent literature review. This reviewed international ethical code and pertinent literature formed part of the literature findings. Some of the reviewed literature included the San Code of Ethics (2017), CIOMS guidelines (2002), WMA Declaration of Helsinki (2013).

The literature review approach for this study involved searching for relevant academic articles, books, and reports that discuss the San Code of Ethics, the CIOMS guidelines, and the Declaration of Helsinki. The search included databases such as PubMed, Scopus, and Google Scholar, using keywords such as “San code of ethics,” “CIOMS ethical guidelines,” “Declaration of Helsinki,” and “biomedical research ethics.” The search was limited to articles published within the last five years to ensure the inclusion of recent developments in the field. The selected literature was critically reviewed to identify key elements of the San code of ethics, the CIOMS guidelines, and the Declaration of Helsinki. The similarities and differences between these ethical frameworks were examined, focusing on areas such as protection of vulnerable populations, and the social and scientific value of research. The findings of the literature review informed the comparative analysis in the study and contributed to the understanding of how the San code of ethics can be applied in biomedical research among indigenous populations in Africa and globally. Overall, the extensive literature review approach provided a comprehensive understanding of the San code of ethics, the CIOMS guidelines, and the Declaration of Helsinki, and their implications for ethical research involving indigenous populations. The findings from the literature review is presented in the first part of the result section

This study adopted a qualitative methodology with an empirical approach. The qualitative method is applicable when variables involved in the research are not controlled (Daniel, 2016). The process requires the identification of research participants and for the purpose of this study, medical researchers and healthcare practitioners were identified as the target population and recruitment of participants stopped once the study achieved data saturation. The researchers applied random sampling technique in choosing the participants at the initial stage of the research. According to Bazeley (2013), the application of the simple random sampling technique proves effective in the development of a group that represents the population effectively. Here, we interviewed 12 biomedical researchers working at a research intensive South African university and the data from these interviews were then analysed in combination with data available through publications in the public domain. The demographic profile of the study participants is summarized in Table 1. The in-depth interviews lasting from 45 to 55 minutes were conducted at different University offices among participants from a medical school, as well as public health and law departments of a university, where the potential participants were first informed of the purpose of the research study, and allowed to participate without coercion, after informed consent was obtained. According to Belk (2006), interviews are effective for outlining different aspects of the topic under study. In this study, an interview guide on Southern African traditional values and Belief systems and informed consent process in biomedical ethics: perspectives on the San code of ethics (2017) was utilized although, only the theme focusing on the perspective on San code of ethics is presented in this paper.

The interview guide had open-ended questions as Speziale and Carpenter (2011) posit that open-ended questions allow the participant to include personal experiences, perceptions, and attitudes concerning the topic. The semi-structured and unstructured interviews and the open-ended questions used in the interview allowed the participants to offer information about their perceptions, attitudes, and feelings. All interviews were recorded with a voice recorder and later transcribed. The analysis of the information and data required the application of an effective approach. According to Coyle and Lyons (2013), the application of the content analysis technique allows for effective analysis of information. Çuhadar (2014) argues that this approach is effective in analysing the captured perspectives, feelings, attitudes, and thoughts of participants. Here we adopted a thematic content analysis of the available data in order to make some evaluations and thereafter, draw inferences. In this case, a manual thematic content analysis process was utilized, where key terms were sourced and coded from the data. This is the second part of a previously reported research study that looked at Southern African traditional values and belief systems and the informed consent process in biomedical research (Akpa-Inyang, 2017; Akpa-Inyang and Chima, 2021). This report is from a major theme from the previous research study that required further exploration as previously reported (Akpa-Inyang and Chima, 2021; Akpa-Inyang, 2017). Thus, this paper is derived from a major theme supported with further analysis of relevant literature to compare the San code of ethics (2017) with the revised CIOMS guidelines (2016) and the Declaration of Helsinki (2013). This allowed for further analyses regarding the San code of ethics and its implications for biomedical research among indigenous African populations.

This study was approved by the Humanities Research Ethics Committee (HREC) at the University of KwaZulu-Natal, South Africa (Akpa-Inyang, 2017). All participants were contacted via electronic mail (e-mails). Participants provided written informed consent before participation in the study, after full information disclosure. Confidentiality was maintained by safe storage of the data in a password-coded computer, and data was anonymized before reporting.

Results

In March 2017, the San (Khoisan) peoples of Southern Africa issued the first code of ethics for biomedical research designed by an indigenous African population group (Callaway, 2017). According to Daley (2017), the major impetus behind the development of the San code of ethics was due to a study that was conducted and published around 2010 which documented the genome of four San men in Namibia (Schuster *et al.,* 2010; Callaway 2017). While the researchers conducted the research study legally by obtaining appropriate ethical approvals from the Namibian government and their respective universities (Schuster *et al.,* 2010; Callaway 2017), They also obtained verbal consent from the participants through the help of a translator. However, San leaders and elders, were not happy because they were not consulted about the research study. The San leaders also questioned the verbal process of obtaining consent from San research participants (Callaway, 2017; Daley, 2017). This lack of consultation gave the San leaders the perception that researchers were only interested in fulfilling the legal processes of obtaining consent, and by doing this, they reduced the research participants to objects of research, and not research subjects according to Rachels (1986), and Callaway (2017). It has been argued that genuine and proper consent in an African context goes deeper than satisfying legal formalities it should take into consideration the norms and values of the people (Akpa-Inyang and Chima, 2021; Lindegger *et al.,* 2006). However, before diving into the details of this qualitative research study, a brief history of the African indigenous population that this study pertains to is summarised below.

According to South African History Online (2020), and other published research sources; the San or Khoisan people are deemed to be the first indigenous population to inhabit Southern Africa or one of the earliest hunter-gatherer populations in Africa and globally (Schlebusch, 2012; Schuster *et al*., 2010). This indigenous African people were previously referred to as “Bushmen”. A pejorative term used by the European colonialists that is now considered derogatory (Callaway, 2017; Daley 2017). The San peoples had populated Southern Africa long before the arrival of the Bantu-speaking nations (Lwango-Lunyiigo and Vansina, 1992, Chima, *et al.,* 1998; Schlebusch, 2012), and thousands of years before the arrival of European adventurers or colonialists. The San people of South Africa have been studied by many scientists and researchers because of their rich heritage of rock art attributed to their ancestors. According to Lee (2002), the San represent an unspoiled natural humanity living in harmony with nature. However, due to some unethical research conduct, the San people decided to come up with their own code of ethics (Callaway, 2017; Daley, 2017). According to the San code of research ethics (2017), there are four principles that need to be respected and recognized so as to facilitate ethical research among the San community. These principles include are respect, honesty, justice, fairness, and care which are further discussed below:

Respect

In the first section of the San ethics code, the San people assert that they require "respect not only for individuals but also for the community" (San Code of Research Ethics, 2017: 2). According to the San culture, and as Africans, if an individual is to be respected, ideally, it should start with the community as demonstrated in previous report by Akpa-Inyang and Chima (2021). In essence, The San people demand respect for their culture which includes their belief systems, norms of behaviour, and value systems (San Code of Research Ethics, 2017). In this respect, the San Code of Ethics recommends and encourages researchers to engage with the community for the purpose of conducting research, with some level of sensitivity. This is due to the fact that certain sensitive issues are known by, or indigenous to the San people alone. However, if San customs are respected and the San peoples are given the privilege to engage fully in any research study with no assumptions, such hidden customs maybe revealed to researchers and the public at large. In other words, the San people point out clearly that for them, respect for autonomy (Chima, 2009), should include respect of their cultural values and belief systems, as well as respect for their relationship with nature and the environment in which they live. Secondly, the San people assert that respect for individuals involved in biomedical research, requires the protection of the San people's privacy at all times. This means that when the privacy of the San community is protected, the individual privacy will be inevitably protected. Finally, the San assert that respect demands that their contributions to any research studies should be acknowledged at all times (San Code of Research Ethics, 2017). This principle of 'respect' or respect for autonomy (Chima, 2009, 2018; Akpa-Inyang and Chima, 2021) was written into the San code of ethics due to the fact that the San community believed they had been disrespected in several ways. An instance being the genomics research study (Schuster *et al*., 2010), for which San leaders were not consulted; this was considered to be disrespectful to the San community (Callaway, 2017). Some of the allegedly offensive elements included photographs of individuals in their homes, breastfeeding mothers, and underage children being taken and published without obtaining proper consent from the community. As a result, the San people felt that their traditional values and social norms were disrespected (Callaway, 2017; Daley, 2017).

Honesty

According to the San code of ethics (2017), San peoples also require honesty from all those who approach them with research proposals. They require an open and clear exchange of ideas and communication between the researchers and San leaders or elders (Callaway, 2017; Schuster *et al*., 2010). In addition, San people demand that the language in research documents must be simplified, clear, and unacademic. Complex issues must be carefully and correctly described, not simply assuming that the San people would not understand. There must be complete transparency and honest sharing of information. Such open exchange should not be patronising as previously reported by Chima (2006), in the context of biomedical research in African communities (Chima, 2006). By open exchange, The San imply that an assessment must be made of possible harms or problems for the San communities which could result from the research study or project. Such potential harms most be honestly communicated to local research participants and the community. They also argued that informed consent can only be based on honesty and open communication, which needs to be carefully documented (Chima, 2018). Honesty also means absolute transparency in all aspects of the human subject-researcher interactions; including sources of research funding, purpose of the research study, and any changes that might occur during the process of conducting biomedical research (Chima, 2004). Honesty also requires open and ongoing communication and engagement between the San community and researchers (San Code of Research Ethics, 2017). According to the San peoples, they had previously encountered lack of honesty on many occasions in the past. An example was where researchers have deviated from the stated purpose of a research study or failed to honour a promise or agreements to show the San people the data from the research study prior to publication (Callaway, 2017; Schuster *et al.,* 2010). Another example was where a biased paper was published based upon leading questions given to young San trainees. The San claimed that this lack of honesty may cause them reputational damage due to misunderstanding by the general public and this sometimes led to a breach of trust between the collaborating research organisations or researchers and San peoples. Other common examples of lack of honesty were exaggerated claims by researchers of lack of resources, and thus the researchers' inability to provide any benefits to San research participants or their communities (San Code of Research Ethics, 2017).

Justice and fairness

For the San, justice and fairness in research require that the San be meaningfully involved in proposed research studies, which includes learning about the benefits that the participants and the community might expect from any research study. These could be largely non-monetary but may include opportunities to serve as co-researchers, sharing of new skills, and research capacity building As well as secondary roles as translators and research assistants, to give some examples of benefits that may accrue the San peoples from participation in research. This will create opportunities for the San peoples as they are being researched on. They also demand that any possible benefits should be discussed with the San, in order to ensure that some benefits do actually return to the community. As part of justice and fairness, the San assert that they will try to enforce compliance with any breach of the Code, including through the use of all legal dispute resolution mechanisms. In extreme cases, this may include black-listing and publication of unethical researchers in a “black book”. Any institution whose researchers fail to comply with the San code of ethics may also be refused collaboration opportunities with San peoples in the future. Hence, they asserted that there will be “consequences” for researchers who fail to comply with the code (San Code of Research Ethics, 2017). They San peoples also claim to have encountered lack of justice and fairness in many instances in the past. Which include theft of San traditional or indigenous knowledge systems by unethical or unscrupulous researchers (Callaway, 2017; Daley, 2017). At the same time, they averred that many companies in South Africa and globally are benefitting from their traditional knowledge such as sales of indigenous plant varieties without benefit-sharing agreements (Chima, 2014), suggesting the need for further compliance measures to ensure fairness, and distributive (San Code of Research Ethics, 2017).

Ethics of care

This section of the San ethics code was rooted in mutually beneficial relationships. It is a measure which the researcher and the San community will employ through the human subject-researcher relationship. Here, the San people demand that research should be aligned to local needs, which will assist in improving the lives of San peoples. This means that the research process must be carried out with the necessary care for all involved, especially the San community. The caring part of research must extend to the families of those involved, as well as to the social and physical environment. Excellence in research is also required, in order for it to be positive and caring for San peoples. Research that is not of a highest standard might result in bad interactions, which will be lacking in care for the community. Caring research needs to accept the San peoples as they are and must take note of the cultural and social requirements of this code of ethics (San Code of Research Ethics, 2017). This ethical principle like the other above-mentioned principles was established because the San have encountered lack of care in many instances in the past. “For instance, we were spoken down to, or confused with complicated scientific language, or treated as ignorant” (San Code of Research Ethics, 2017: 3). In addition, failing to ensure that something is left behind that improves the lives of San peoples, also represents lack of care (San Code of Research Ethics, 2017).

Comparison of the San Code of Ethics with the Current ‘Declaration of Helsinki’ and CIOMS Guidelines

The San in their code of ethics categorically advocate for respect between biomedical researchers and research participants. They assert that research subjects or participants should be respected, which is similar to what the COIMS guidelines and the declaration of Helsinki advocate for. Both international ethical codes assert that biomedical research should be subject to ethical standards that promote and ensure respect for all human subjects, protect their health, human rights, and well-being (WMA Declaration of Helsinki, 2013; CIOMS guidelines, 2016). This is because while the primary purpose of biomedical research is to generate new knowledge, this goal should never take precedence over the right of individuals (Chima, 2004; Chima, 2011). The Declaration of Helsinki clearly advocates for this when it postulates that medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and right. According to the 2000 version of the ‘Declaration of Helsinki’, “in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society” (Chima, 2011).

In addition, both the COIMS guideline and the Declaration of Helsinki state that it is the duty of the physicians and researchers who are involved in biomedical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and maintain confidentiality of the personal information of research subjects (WMA Declaration of Helsinki, 2013; CIOMS Guidelines, 2016). This relates to what the San people are advocating for when they assert that respect for individuals used in research requires the protection of the San's privacy at all times. Furthermore, the San people point out clearly that for them, respect includes respect for their culture as well as respect for their relationship to nature and the environment. A similar demand is requested in section 11 of the Declaration of Helsinki (2013), that medical research should be conducted in a manner that minimizes possible harm to the environment. Similarly, Article 17 of the UNESCO Universal Declaration on Bioethics and Human Rights (2005) requires that:

> *Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.*

In addition, both the Declaration of Helsinki (2013) and COIMS guidelines (2016) postulate that all medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefit to them and to other individuals or groups affected by the condition under investigation (CIOMS, 2016; Declaration of Helsinki, 2013). This is in line with what the San are advocating for under fairness, justice and care (San Code of Research Ethics, 2017).

Nevertheless, the above-mentioned principles postulated by the San are and not very different from the CIOMS guidelines or the Declaration of Helsinki, because both international ethical codes emphasize that potential benefits of research should outweigh any anticipated harms. Consequently, previous work has been conducted by some researchers on perceived benefits or based on risk/benefit analysis to participants in therapeutic research by Newburg and others (1992). In some instances, these benefits are direct outcomes like the clinical benefit human subjects receive through the testing of drugs or vaccines during clinical trials, or the knowledge gained from learning whether some clinical interventions are effective (CIOMS, 2002). Other guidelines propose that research should not be carried out in communities in developing countries, if the benefits cannot be made reasonably available or the benefits are not accessible to those communities that carried the burden of the research (CIOMS 2016, Chima, 2011: 151-194; 2004, 2006). The latest version of the Declaration of Helsinki (2013) asserts that: "Physicians must immediately stop a study when the risks are found to outweigh the potential benefits, or when there is conclusive proof of positive and beneficial results." So, there are similar objectives between the San code of ethics (2017), the CIOMS guidelines (2016) and the Declaration of Helsinki (2013). However, the qualitative aspect of this paper will present some biomedical researchers' perspectives on the new San code of ethics with the aim of pointing out how similar or dissimilar it is to standard international ethical codes.

Similarities

Both the San Code of Research Ethics and the Declaration of Helsinki emphasize the importance of informed consent and the protection of vulnerable populations. The Declaration of Helsinki, developed by the World Medical Association, outlines ethical principles for medical research involving human subjects, including the necessity of obtaining informed consent from participants, ensuring their autonomy, and prioritizing their welfare ("World Medical Association Declaration of Helsinki", 2013; Carlson *et al.,* 2004). Similarly, the San Code mandates that researchers must seek community approval and ensure that participants are fully informed about the research, thereby respecting their autonomy and cultural values (Schroeder *et al.,* 2019; Schroeder *et al.,* 2020). Both documents advocate for fairness and respect in the treatment of research subjects, highlighting the need for ethical engagement with participants. Moreover, the CIOMS Guidelines, which provide ethical guidance for biomedical research, also align with these principles by stressing the importance of respect for persons, beneficence, and justice (Langlois, 2007). The San Code, while specifically tailored to the San community, echoes these values by insisting on fairness, respect, care, and honesty in research interactions (Schroeder *et al.,* 2019; Mudd-Martin *et al.,* 2021). This shared emphasis on ethical treatment and informed consent illustrates a common commitment to protecting the rights and dignity of research participants across different ethical frameworks.

Differences

Despite these similarities, there are notable differences in the scope and focus of the San Code compared to the Declaration of Helsinki and CIOMS Guidelines. The San Code is unique in that it is the first indigenous code of ethics developed in Africa, specifically addressing the historical and cultural context of the San people (Schroeder *et al.,* 2019; Schroeder *et al.,* 2020). It incorporates indigenous knowledge systems and emphasizes community engagement and oversight, which are often less pronounced in the more universally applicable frameworks of the Declaration of Helsinki and CIOMS Guidelines. The San Code requires researchers to adhere to community-approved research protocols, reflecting a localized approach to ethical research that prioritizes the community's voice and agency (Mulder, 2023). In contrast, the Declaration of Helsinki and CIOMS Guidelines are primarily designed for a broader audience and do not specifically address the unique cultural considerations of indigenous populations. While they advocate for the protection of vulnerable groups, they may not fully account for the specific historical injustices faced by communities like the San, which have been subjected to exploitation and marginalization in research contexts (Czech *et al.,* 2018). This difference highlights the need for culturally sensitive adaptations of ethical guidelines when working with indigenous peoples, as the San Code explicitly seeks to empower the San community and ensure that their rights and interests are at the forefront of research endeavours (Schroeder *et al.,* 2019; Schroeder *et al.,* 2020). Thus, while the San Code of Research Ethics shares core ethical principles with the Declaration of Helsinki and CIOMS Guidelines, such as informed consent and respect for participants, it also introduces unique elements that reflect the specific cultural and historical context of the San people. The San Code's focus on community engagement and indigenous knowledge underscores the importance of tailoring ethical frameworks to the needs and values of specific populations, thereby enhancing the ethical landscape of research involving indigenous communities.

Qualitative Research Findings

The sample population (n = 12) comprised five females and seven males aged between 34 and 74 years. The sample included four professors, six academic doctors, and two practising medical doctors (clinicians). The demographic characteristics of the research participants are as shown in Table 1.

Table 1: Demographic characteristics of the study population

Participants	Age (years)	Race	Gender	Field of Research or Clinical Practice
Participant 1	64	White	Female	Clinical Research Laboratory
Participant 2	38	Indian	Female	Clinical Trials
Participant 3	72	Indian	Female	Paediatric Nephrology
Participant 4	53	African	Female	Chair BREC
Participant 5	46	African	Female	Medical Technologist in Clinical Pathology
Participant 6	39	African	Male	Gynaecologist
Participant 7	57	White	Male	Medical Researcher
Participant 8	56	African	Male	Medical ethics, informed consent, and Traditional Medicine
Participant 9	37	African	Male	General Practitioner
Participant 10	65	White	Male	Bioethics Committee
Participant 11	34	Coloured	Male	Medical Law
Participant 12	74	White	Male	Medical Law

*The term 'Coloured/s' is a non-derogatory term used to describe a multiracial ethnic group native to Southern Africa, with ancestry from more than one of the various populations inhabiting the region, including Khoisan, Bantu, Caucasians, Austronesian, East Asian, or South Asian (Akpa-Inyang and Chima, 2021).

The data presented below is from the theme on the perspective of participants on the San code of ethics in relation to other international ethical guidelines.

Table 2: Code names for research participants

Codes	Interpretation
F	Female
M	Male
R	Respondent
Number	Age of the respondent

For instance, RM74 will refer to a respondent who is male and aged 74.

The study participants perceived that the code of research ethics presented by the San is not fundamentally different from other international ethical codes. It was thought that even though they have put it in a very simplified language it still advocates for the same issues advocated for in CIOMS guidelines (2002, 2016) and the declaration of Helsinki (2013). Participant RM37 stated:

> *I think it is an integrated form of what the four pillars of medical ethics entail, but it is empty on community level because the issues of respect, the issues of recognising the chain of command are not there in medical ethics. This is because the medical ethics, code and pillars are informed by the Western-European tradition.*

This suggests that, if one comes with the Western derived ethical principles, and try to implement them in African communities, the person will directly be ignoring the cultural values and way of life of the people, and it may be considered disrespectful. So, with the San code they are advocating that researchers' give them what is their due which is respect, honesty, care, justice and fairness in return for their collaboration with the work of the researcher. Some of the participant actually equate these to the demands required by most ethical codes. Participant RM56 stated:

> *The few things that I have identified is that (1). Is respect, and that is what the San are saying that they want to be respected. Respect for autonomy is universal; in other words, people must be treated with respect. The San say, we don't want to be exploited, in other words, if there is any benefit, we want it to be shared and we want to be told you cannot just come and exploit us. They say we want researchers to care about what we are doing because they don't care about us. In other words, all these are included if you look at the new declaration of Helsinki in 2013; if you look at section 19, you find out that it is actually there…. Rights of vulnerable population groups that they must be involved in the decision-making process and this part is newly added to the declaration.*

Based on the criteria of vulnerability as defined by the Joint United Nations Programme on HIV/AIDS (UNAIDS, 2015: 49; Chima, 2007), and the declaration of Helsinki (2013), most African communities, because of their relatively poorer education, their lack of resources to obtain quality healthcare, poverty and issues of therapeutic misconception would be classified as being vulnerable peoples (Chima, 2007). Consequentially, Africa is considered as a place where majority of people are vulnerable because many of them lack basic means of survival as well as the above-mentioned limitations and the San maybe classified into this category. This puts them in a position where all ethical codes are supposed to take cognisance of their existence. According to the revised CIOMS guidelines (2016) and the National Bioethics Advisory Commission, USA (NBAC, 2001), ethical standards when dealing with vulnerable people have to be of the highest possible standard. Therefore, researchers should ideally not deal with vulnerable African communities the same way they are dealing with people who are not vulnerable, or who have more choices.

According to participant RM56, *"As a researcher, one has to pay special attention to the rights and dignity of vulnerable population groups".*

So, in that line of thought, the ethical code designed by the San people is appropriate for their community. Moreover, if the code is implemented by researchers, it will not only be just a code of ethics for the San (Khoisan) peoples, but it will be a tool that will engender ethical medical research and practice among indigenous populations globally and may encourage other African communities to come together and produce a research code that is applicable not only in Africa, but also applicable to other marginalized and indigenous population groups elsewhere. In this light, participant RF53 stated:

> *Maybe they are now saying to us as Africans we need to define the informed consent and biomedical guidelines in an African way because the way we defining it is in a European or Western way, you know maybe they want us to come up with a new definition because we are communal, we are communal beings.*

As shown above most of the participants affirm the appropriateness and the necessity of the San code of ethics, however, it will be necessary to note that the implementation of this code might develop lead to ethical dilemmas, which is necessary to explore.

The current practice of biomedical research ethics is rooted in the Western-European tradition as postulated and reported previously (Akpa-Inyang and Chima, 2021; Akpa-Inyang and Adam, 2023). This is because when research is conducted in Africa, or when research ethics committees in Africa are reviewing a research protocol, they aim to protect individual rights or respect for individual autonomy (Akpa-Inyang and Chima, 2021; Akpa-Inyang and Adam, 2023). So, if a research proposal/protocol is focusing on an individual and the researcher is planning to go and conduct research among people who do not think individually, or are more communal in nature, there is bound to be a conflict or ethical dilemmas or moral conflicts (Akpa-Inyang and Chima, 2021). Participant RF53 touched on this when she asserted:

> *When we do research in biomedical research, we aim for a person or a participant, we don't aim for those are the people surrounding that person. So, we would say in biomedical research the person's privacy is violated because now you are talking, you want to talk to the mother, you want to watch the mother breastfeeding during the research, you don't want these guys to be there or before you do that you must involve other people.*

If the people surrounding the person or human subject as mentioned by RF53 are involved, looking at the biomedical principles, it can be argued that the privacy of the research participant and that of the researcher is compromised but in the context of African traditional values and belief systems it will be seen as a good thing, as it will prevent exploitation. As the San people averred, if things are done properly and San leaders are respected and informed about every step of a research project, the humiliating act of taking pictures of children and breastfeeding mothers and presenting them at international fora without proper consent will not be happening. One of the participants sharing her view on this stated:

> *When we see the horrible pictures of African people. You see them at conferences where they have taken the African children and African mothers suffering and you wonder did someone give permission for them to show those pictures?" (RF53).*

So, there could be moral conflicts; because in one way, the San code will prevent exploitation; but on the other hand, if looked at with the general ethical code and norms as postulated by the Western tradition (Beauchamp and Childress, 2013; Akpa-Inyang and Adam, 2023), it could be argued that the participants individual rights and privacy have been compromised.

Further, some of the participants stated that another source of conflict with the San code of ethics might arise in the aspect of community consent as opposed to individual consent. This is because if an individual goes against the decision of the community, it might lead to "ostracization" and stigmatization (Famoroti *et al.,* 2013) of the individual by their community if it is not properly managed. According to RM56:

> *What happens if the San community represented by the leaders say it is okay to conduct a research and a particular individual says No, I do not want to take part? The community might say oh, you don't want us to benefit from the research which we have already agreed that it will be of benefit to the family.*

So, it might lead to exiling the person from the community with the thought that he or she does not have the benefit of the community at heart. Thus, there could be a conflict between the rights of the individual versus the rights of the community. In this case, it will be necessary to develop an approach that will take into account the community as well as the individual.

Discussion

As outlined in the introduction, in March 2017, the San people of South Africa produced the first research ethics code designed by an indigenous African population (Callaway, 2017; Daley, 2017; San Code of Ethics, 2017). This was motivated by the fact that numerous studies had been conducted among the San population groups, and these studies were perceived negatively by the San population groups (Schuster *et al*., 2010; Callaway, 2017; Daley, 2017). The San leaders argued that while the researchers were ethical in following the general legal principles of obtaining gatekeepers letter from the government, and approval from the university research ethics committees, the consent process was inadequate from their point of view. According to Daley (2017), the researchers did everything legally, by obtaining appropriate ethical approvals from the Namibian government and their respective universities. In addition, they obtained verbal consent from the participants through the help of a translator However, the San (Khoisan) leaders were not happy because they were not consulted about the research study, and they questioned the verbal process of obtaining consent from the participants (Callaway, 2017). This gave the San leaders the perception that researchers are only interested in fulfilling the legal process of obtaining consent and this, relates to Rachels (1986) observation that the researchers reduced such research participants to 'objects of research' and not 'human subjects'. The San demanded that they require respect, honesty, justice and fairness, and care ethics from researchers who come to them to conduct research. They also demand that their leaders and community members be involved in the consent process to reduce exploitation and disrespectful act towards their culture, environment, and people.

However, these San demands as shown by this qualitative research study, are not fundamentally different from what other international ethical codes already articulate. It can be described as more or less like an integrated communal form of the four ethical principles of biomedical research and practice (Chima, 2004, 2009, 2018; Beauchamp and Childress, 2013). The San advocates for respect and in their ethical code which is similar to the ethical principle of respect for autonomy (Chima, 2009, Beauchamp and Childress, 2013). In other words, the San are saying we want our community and the people to be treated with respect. The same goes with ethical principles of beneficence, non-maleficence. They also advocate that they do not want to be exploited and that benefit should be shared equally and that researchers should care about what they have, what they are doing and who they are, which is embedded in the principle of distributive justice (Chima, 2009; 2011; Beauchamp and Childress, 2013. This is also similar to what is presented in the declaration of Helsinki (2013), section 25, which states:

> *Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees (Declaration of Helsinki, s25, 5).*

This gives room for community and family involvement in the consent process. However, the San are of the opinion that community consent and involvement in research reduces exploitation and thus, supersedes individual consent. This study discovered that the ethical code designed by the San people is appropriate for their community. Furthermore, the implementation of the code will engender ethical practice during biomedical research in Africa as it will advocate for the communal consent process that will allow Africans to identify with and internalize medical research and practice in Africa. It will further motivate other African communities to come together and deliberate using common African cultural norms of behaviour and belief systems to develop a research code that is applicable in Africa and other indigenous communities globally. However, it must be noted that implementation of the San code might create a moral dilemma, worth exploring. The current practice of medical ethics is rooted in the Western-European tradition as postulated earlier reported aspect of this study (Akpa-Inyang and Chima, 2021). This is because when research is conducted in Africa or when ethics committees are reviewing a research protocols, their primary focus is on the individual. If a research proposal/protocol is focused on individuals' and the researcher is planning to go and research among people who do not think individually, or who think and operate communally, moral conflicts or ethical dilemmas may arise.

This study also discovered that another source of potential conflict with the San code of ethics might be in the aspect of predominance of community consent as opposed to individual consent. This may occur where an individual decides against the decision of the community, it might lead to "ostracization" of the individual from the community if it is not managed properly. For instance, where a particular community, using their own code decides that the research is necessary for the development of their community and that participants should take part because it is safe. However, within that community a particular individual may decide that he or she will not take part, this might lead to discrimination or stigmatization against that individual in the community as it may be perceived that he or she does not have the benefit of the community at heart. Therefore, there could be a conflict between the rights of the individual and the rights of the community. In this case, an approach must be developed that will create a balance between communal and individual rights. This is where the development of an alternative approach to ethical decision-making becomes appropriate.

Conclusions

There are apparent similarities between the San code of ethics and international ethical codes such as the declaration of Helsinki and the CIOMS guidelines especially in the aspect of respect, justice, and ethics of care. However, there are some differences in the perceptions of predominance between individual versus community rights. The San are of the opinion that community involvement reduces exploitation, therefore community rights and decision-making should precede individual rights. Nevertheless, participants were of the opinion that the ethical code designed by the San is appropriate for their community. Furthermore, the implementation of the code will engender ethical conduct of biomedical research in African indigenous communities and advocate for the communal consent process that may allow Africans to identify with and internalize ethical biomedical research and practice in Africa. It may further motivate other African communities or indigenous populations elsewhere, to come together and deliberate using common cultural norms of behaviour and belief systems to develop a research code that is applicable in African and other indigenous communities globally. The study was an engagement with stakeholders (researchers at an African University). This was sufficient for this limited study. However, an engagement with the San people to hear their views and what influenced the development of a new ethical code for research within their community would have given more insight on the research study. Future studies should be directed at qualitative or other empirical studies among indigenous population groups, such as the San people, to hear their own point of view.

Declarations

Interdisciplinary Scope: The article exemplifies an interdisciplinary approach by integrating insights from biomedical ethics, African ethics, medical research, and medical law. The intersection of these fields allows for a comprehensive analysis of ethical frameworks applicable to biomedical research involving indigenous populations. Biomedical ethics provides the foundational principles guiding ethical research practices, while African ethics introduces culturally embedded values such as communal decision-making, reciprocity, and relational autonomy.

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