**Genomic literacy and awareness of ethical guidance for genomic research in sub-Saharan Africa: how prepared are biomedical researchers?**

Olubunmi Ogunrin1,3, Funmilola Taiwo2 and Lucy Frith3

1Department of Medicine, College of Medical Sciences, University of Benin, (Nigeria); 2Department of Internal Medicine, Ben Carson (Snr) School of Medicine, Babcock University, (Nigeria); 3Biomedical Ethics Research Group, Department of Health Services Research, University of Liverpool, (UK)

Corresponding author: Olubunmi Ogunrin, Neurology Unit, Department of Internal Medicine, University of Benin, PMB 1154, Benin City, Nigeria. E-mail: bunmifunmi@hotmail.com

E-mail addresses: OO ([bunmifunmi@hotmail.com](mailto:bunmifunmi@hotmail.com)); FT ([drloladetaiwo@gmail.com](mailto:drloladetaiwo@gmail.com)); LF ([frith@liverpool.ac.uk](mailto:frith@liverpool.ac.uk))

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**Abstract**

Achieving the objectives of rolling out genomic research programmes in sub-Saharan Africa depends on how prepared indigenous biomedical researchers are for this type of research. We explored the level of preparedness of biomedical researchers in a sub-Saharan African country using in-depth interviews to obtain data on their understanding of genomics and genomic research and assess their awareness of the scope of the country’s code of health research ethics. Thirty biomedical researchers were interviewed. Only eight were familiar with concepts of genomics, a form of ‘genomic health literacy’. The majority were not aware of the country’s code of research ethics. This study showed that generally biomedical researchers were not genomic health literate, unaware of the code and its limitations as a source of ethical guidance for the conduct of genomic research. These findings underscore need for educational training in genomics and creating awareness of ethical oversight for genomic research in sub-Saharan Africa.

## ***Introduction***

By the year 2020, it is hoped that genomic research and the development of biobanks in sub-Saharan Africa will have achieved the objectives of the H3Africa project. These objectives include the development of capacity for health-related genomics research in the sub-continent, and large-scale genomics studies that could help define the determinants of chronic and infectious diseases among Africans through the application of genomic technology. One of the major obstacles to achieving these objectives is the shortage of African biomedical researchers with genomic research expertise (H3Africa Consortium, 2014). Adedokun and colleagues emphasised the consequence of this shortage when they stated that the poor genomics research capacity of sub-Saharan Africa could prevent the full benefits of the applications of genomics in the practice of medicine and health in the region being realised (Adedokun, Olopade, & Olopade, 2016). Hence, the educational development of African researchers in genomics and genomic research is a matter for concern. This issue will become increasingly important as in the near future the main consumers of genomics will be from low and medium income countries including sub-Saharan African countries (Williams & Tishkoff, 2011).

An important consequence of this lack of capacity is the negative effect it has on the ethical conduct of genomic research. For example, a researcher must be sufficiently knowledgeable to explain what genomics means to lay people in simple terms or translate the concept into their language for easier comprehension during the recruitment to, and informed consent processes of, research studies. A researcher’s lack of knowledge could result in misunderstanding or lack of comprehension of research details by potential research participants and this has implications for getting fully informed consent. The lack of comprehension could result in unethical practice (Beskow, Dombeck, Thompson, Watson-Ormond, & Weinfurt, 2014; Bhutta, 2004). Another reason why biomedical researchers should be adequately equipped for genomic research is that they will increasingly be called upon to translate and disseminate genomic information to individuals and the wider public as genomic research transforms our understanding of the role of genes in health and disease (Lea, Kaphingst, Bowen, Lipkus, & Hadley, 2011).

African biomedical researchers need to acquire expertise in genomic research, they need to be genomically literate. Genomic literacy is the working knowledge of genomic science and its role in society, including personal decision-making (Hurle et al., 2013). Genomic literacy has different facets which include genomic science literacy and genomic health literacy. Genomic science literacy is the knowledge of basic genetics and genomics concepts and processes needed to build conceptual understanding, and the necessary mathematical knowledge to support this comprehension. Genomic health literacy is defined as the capacity to obtain, process, understand, and use genomic information for health-related decision-making (Hurle et al., 2013). The concept of genomic health literacy is not limited to the science of genomics but also includes the ethical aspects and social implications of genomic research. Therefore, the objective of promoting human genomic research and health in Africa led and managed by African investigators can only be achieved by having adequately trained researchers, trained both in the scientific and ethical aspects of genomic research (Dandara et al., 2014; Ramsay, 2015).

The conduct of genomic research and biobank governance requires a health system with ethical guidelines that biomedical researchers are aware of and can apply to their research. Several studies have shown low levels of awareness of national ethics guidelines and poor knowledge of research ethics among African researchers (Ogunrin, Daniel, & Ansa, 2016; Ogunrin, Ogundiran, & Adebamowo, 2013; Adeleye & Ogundiran, 2013). Knowledge about the level of preparedness of African researchers vis-à-vis what they understand about genomics and the existing ethical guidelines applicable to genomic research in their respective countries would aid in the formulation of relevant programs for capacity development in genomics in sub-Saharan Africa. In addition, it would facilitate equitable distribution of resources and channel collaborative efforts of institutions, research sponsors, funders, and government agencies with an interest in genomic research to address deficiencies that militate against making genomic research and biobanking a success in sub-Saharan Africa.

Despite the importance of scientific competence and ethical preparedness of biomedical researchers, few studies have investigated the preparedness of biomedical researchers to carry out genomic research in Africa. This may be related to the difficulties in assessing the preparedness of biomedical researchers. For example, there is lack of globally acceptable, definitive parameters that can be used for determining preparedness. According to Vassy *et al*, preparedness cannot be based on self-reported attitudes and perceptions because they do not necessarily correlate with skills and behaviour (Vassy, Kort, & Green, 2015). This paper will focus on researchers’ preparedness in the area of the ethical aspects of conducting genomic research. We designed a qualitative research study to explore the level of preparedness of biomedical researchers in a sub-Saharan African country, Nigeria, using in-depth interviews to obtain data on their understanding of genomics and genomic research, and assess their awareness of the country’s code of health research ethics as a guideline for conduct of genomic research. This is an important issue as such knowledge could equip them to address the ethical issues encountered in genomic research, such as: informed consent, privacy and confidentiality of biospecimens and data, and the importance of community engagement and involvement.

Nigeria has a general code of health research ethics. The code represents the collective concern of the government and the people of Nigeria to ensure scientific research is carried out to the highest ethical standard. This code applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria. All stakeholders in health research including partners in the international community are expected to respect and abide by its tenets (Federal Ministry of Health, 2007). Although it provides a protocol for material transfer agreement, which is a set of guidelines that sets out the requirements for export of biological samples out of the country, the code does not specifically address ethical issues relating to genetic or genomic research. Researchers and other stakeholders in genomic research have to be aware of this so that this lack of specific ethical guidance on genomic research can be addressed.

# ***Methods***

The data reported here are part of a larger qualitative study into informed consent and community engagement in genomic research that aimed to explore the views and opinions of potential research participants and biomedical researchers in a sub-Saharan African community on consenting to genomic research participation (Ogunrin, Woolfall, Gabbay, & Frith, 2018). We conducted a qualitative study using in-depth interviews to obtain data from purposively selected biomedical researchers. Qualitative research is valuable for studying meaning, that is, what is important to people based on their knowledge and experience and seeks answers to questions that stress how social experience is created and given meaning (Chandler, Reynolds, Palmer, & Hutchinson, 2013). Our choice of in-depth interviews to explore the understanding of genomics and level of awareness of ethical requirements for conduct of genomic research was based on the recognition that people do not merely respond to stimuli but act on the basis of their interpretations of the world around them and their experiences within it (Roulston, 2014). Therefore, to understand what biomedical researchers do, believe and think, we need to ask them.

## ***Study area***

This project was situated at a tertiary health institution in a semi-urban community in south west Nigeria. It is a community of mostly Yoruba-speaking people with either Christian, Islamic or Traditional religious affiliation. The community is situated along the trade routes between ports in Niger delta and the Yoruba mainland.

## ***Study participants***

Participants were purposively selected from biomedical researchers practising as clinician-researchers in an academic-health research facility within this semi-urban community. They were primarily clinicians who engage in research in their respective medical or surgical specialities. As genomic research gains acceptance and momentum among biomedical researchers in Nigeria, it is pertinent to have a baseline assessment of the level of preparedness among a group of general medical researchers who are potential stakeholders in this type of research – a form of ‘expert public opinion’. Three researchers who were engaged in genetic research were included to compare their responses with other researchers who did not work in genomics.

### ***Ethics approval***

Ethics approval were obtained from an institutional research ethics committee in Nigeria (Reference number ADM/DCST/HREC/1792) and the ethics committee of an institution in UK (Reference number IPHS-1415-LB-270).

# ***Recruitment***

One of the authors (OO) approached the biomedical researchers personally and through an institutional contact. They were given an information sheet and opportunity to ask questions about the research. Consent was obtained in the form of a signature after giving adequate time for each of them to study the information. Recruitment was done at the first contact except for a few instances when the biomedical researcher specifically asked for more time to study the research details. All the biomedical researchers approached agreed to participate.

## ***Study design***

We conducted semi-structured in-depth interviews, in which several key questions were asked to define the areas to be explored but also allowed the interviewer or interviewee to probe and pursue an idea or response in more detail. This interview format is flexible and allows for discovery or elaboration of information that is important to participants, and which might not have been previously thought of as pertinent by researchers. A topic guide that contained questions on a) what they understood by genomics and genomic research; b) if they were aware of the code of health research ethics; and c) what they thought the code covered regarding genomic research, was used to guide the interview process.

## ***Data Collection***

A convenient date and time of interview was arranged and the interviews were held in the biomedical researchers’ respective offices. The interviews were conducted by one of the authors. On the day of interview, the interviewer introduced himself (without details of professional status or academic background) and the purpose of the interview. Information on genomics was not provided in advance of the interview so that researchers’ understanding of this area could be ascertained.

It was emphasized that there were no right or wrong answers, rather the goal was to explore what they understood about genomics and genomic research, and ethical guidelines for genomic research as stipulated by the national code of health research ethics. The interview topic guide includes the following questions: a) Have you heard of genomic research before? b) What do you understand about genomic research? c) What do you think is the significance of genomic research? d) Are you aware of the National Code of Health Research Ethics? For those who were aware of it: e) How did you find out about it? f) Do you think the Code, as it is presently, sufficiently covers the conduct of genomic research in Nigeria? The interview process was not restricted to these questions as each interviewee was encouraged to share their experiences from previous research they have conducted and other relevant life experiences.

Each interview session lasted between 45 minutes and one hour ten minutes (average of 55 minutes). All the sessions were audio-recorded (with participant consent) and notes were taken by the interviewer to supplement the recording. The audio-recorded data were transcribed verbatim after each interview and compared with the notes.

## ***Data Analysis***

The methodological design was adapted from grounded theory (Glaser & Strauss, 1967) and the constant comparative method was used for the data analysis (Silverman, 2000). Data were iteratively analysed, and as themes evolved during the analysis these were further probed during the subsequent interview sessions to achieve saturation and clarity of data. The coding of the data was aided by Atlas-ti qualitative software (Cincom Systems Inc., GmbH Berlin, 2016). The initial or open coding yielded themes which were subjected to selective coding to identify common and explanatory categories.

Quality of data was ascertained by 1) ***coder reliability index*** (this involved open-coding of the data by two researchers using a similar coding frame and this yielded a coder reliability index above 90 percent which reflected an acceptably high degree of similarity) ; 2) demonstrating *reflexivity* by allowing unrestricted expressions and opinions of the biomedical researchers through the use of probes to clarify and eliminate ambiguities (Curry, Nembhard, & Bradley, 2009); and 3) ensuring *scrutiny and analysis of deviant cases and discordant views*, accounting for the contradictions emerging from data and providing plausible alternative explanations for these phenomena. This improved the rigour and credibility of our study (Mays & Pope, 1996; Parker, 2009).

***Results***

# Demographics of study participants

Thirty biomedical researchers were interviewed, comprising of 16 males and 14 females, with a mean age of 40.4 (SD 5.4) years and age range of 33 to 56 years. Most of them were involved in clinical science research, only three were engaged in laboratory-based genetic studies as previously stated under study participants. All but 2 were Yoruba. Details of the demographics are presented on tables 1 and 2.

**Table 1 Summary of demographics of biomedical researchers**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Frequency |  |
| Age distribution | ***Male***  31-40 years  41-50 years  51-60 years  ***Female***  31-40 years  41-50 years  51-60 years  ***Total***  31-40 years  41-50 years  51-60 years | 8  6  2  11  3  0  19  9  2 | Male  Mean: 42.4 (SD 6.2)  Median: 40.5  Range: 35-56 years  Female  Mean:37.5 (SD 3.1)  Median: 38  Range: 33-43  Total  Mean: 40.4 (SD 5.4)  Median: 39.5  Range: 33-56 years |
| Sex distribution | Male  Female | 16  14 |  |
| Level of education | Primary  Secondary  Tertiary  Postgraduate | -  -  -  30 |  |
| Area of research | Basic sciences  Clinical sciences  Genomic research | 8  19  3 (Laboratory-based) |  |
| Ethnicity | Yoruba  Igbo | 28  2 |  |

**Table 2 *Details of demographics of biomedical researchers***

|  |  |  |  |
| --- | --- | --- | --- |
| ***Serials*** | ***Sex*** | ***Age*** | ***Area of research*** |
| BR1 | F | 37 | Paediatric |
| BR2 | F | 38 | Ophthalmology |
| BR3 | M | 42 | Psychiatry |
| BR4 | F | 40 | Ophthalmology |
| BR5 | M | 51 | Microbiology |
| BR6 | F | 40 | Renal Medicine |
| BR7 | M | 35 | Cardiology |
| BR8 | M | 45 | Community Health |
| BR9 | M | 41 | Microbiology |
| BR10 | F | 35 | Surgery |
| BR11 | F | 41 | Community Health |
| BR12 | M | 37 | Surgery/Urology |
| BR13 | F | 38 | Neurology |
| BR14 | F | 42 | Chemical Pathology |
| BR15 | M | 49 | Radiology |
| BR16 | F | 34 | Cardiology |
| BR17 | F | 33 | Cardiology |
| BR18 | F | 40 | Endocrinology |
| BR19 | M | 37 | Pathology |
| BR20 | M | 38 | HIV/AIDS |
| BR21 | F | 43 | Renal Medicine |
| BR22 | M | 50 | Laboratory (Genetic) |
| BR23 | M | 38 | Haematology |
| BR24 | M | 56 | Radiology |
| BR25 | M | 44 | Laboratory (Genetic) |
| BR26 | F | 36 | Community Health |
| BR27 | M | 37 | Paediatrics |
| BR28 | M | 39 | Pulmonology |
| BR29 | F | 35 | Cardiology |
| BR30 | M | 40 | Laboratory (Genetic) |

*Legend – BR refers Biomedical Researcher*

***Understanding of genomics and genomic research***

The responses of the biomedical researchers generated themes which reflected how much they **understood** about genomics and genomic research. The major themes revealed a continuum that represents an increasingly complex form of **understanding**, from *unfamiliarity*, *genomic science literacy*, to *genomic health literacy*. Genomic science literacy is determined by responses that describe genomic research as research on genes and its scientific applications while genomic health literacy by responses that refer to the human genome, its utility and health-related benefits. The objective of representing the themes along this continuum is not to label a response but to illuminate and contextualise the views held by the researchers.

Eight biomedical researchers were unfamiliar with concepts of genes and lacked genomic literacy. They had heard about genes but did not talk about genes and genetic research except when prompted. Also, they did not talk about the human genome and its healthcare applications even when given cues. Some of them acknowledged that they did not know anything about genomics as exemplified by this dialogue between one researcher and the interviewer.

***Interviewer:*** *Can you please tell me what you understand by genomics?*

***Biomedical Res3:*** *Yes, genomics, genomics, genomics (muttering repeatedly)*

*As ethics? (probing)*

***Interviewer:*** *No, not as ethics. I just want to know your understanding of genomics or research in genomics.*

***Biomedical Res3:*** *It has to do with people’s perceptions and views about**different things.*

***Interviewer:*** *No, like when scientists do research in genomics… have you heard of it before?*

***Biomedical Res3:*** *I have not heard about it before. So, you can enlighten me*

One researcher pointed out that genomic research is novel to the country therefore researchers are not familiar with it.

‘*However, it seems genomics research is relatively new to us in this country. It seems a bit new to us. Many people are not aware of and have not done any work (research) on genomics here in Nigeria, for instance I am not aware of it’* ***Biomed Res 16***

Approximately half (fourteen) of the biomedical researchers showed genomic science literacy by talking about genomics research in the context of genes and genetic research. These researchers did not relate genomics or genomic research to the human genome and its applications to healthcare. Examples of their responses are stated below;

*‘I think genomic research has to do with the genes’* ***Biomed Res 4***

*‘Genomics research (kind of) entails genetic research, molecular research into the aetiology of some disease conditions’* ***Biomed Res 14***

Another researcher with genomic science literacy said genomic research has to do with DNA and genetics, but eventually admitted that he did not have much understanding of what genomics is.

*‘I know that you’re looking at the DNA, you’re looking at genes, it has to do with genetics, so you’re mapping out genes to know if you have this gene. I don’t have much knowledge, but I think that’s what it entails’* ***Biomed Res 8***

Eight, including the three genetic researchers, displayed *genomic health literacy.* They talked about the human genome and its applications to health care especially in relation to sickle cell anaemia. This is not unexpected because sickle cell disease (SCD) is a genetic disease prevalent in Africa, especially West African sub-continent (Grosse et al., 2011). Two of these researchers used examples of disease markers like APOe and BRCA, the genetic markers for apolipoprotein E and breast cancer respectively, to illustrate health-related applications and benefits of genomics.

‘*Genomic research test for genes which are components of the genome, it’s like someone being born with sickle cell anaemia, there is nothing you can do about it. You can only say ok, I know this child has sickle cell or this person has APOe gene, I’ll try and control hypertension, make sure the cholesterol isn’t raised. I’ll make sure he has lifestyle modifications which you should do for all patients anyhow without APOe or not’* ***Biomedical Res7***.

Another researcher talked about wider health applications of genomic research:

*‘Well, I know that when you talk of the genomics, it has to do with the genome. And I know that recently, not long ago, they did genetic mapping. I think that is a way of identifying diseases, then we will be able to find solutions to diseases such as diabetics, hypertension, and so on. The potential benefit is huge. But at the same time, we talk about designer babies, where couples will be able to define the kind of baby they want, there is this opportunity for parents to specify the kind of traits they want from their children’* ***Biomed Res 16***

There was no difference in the responses of the three researchers who were involved in genetic research and the other five researchers who were genomic-health literate. Also, there was no difference in responses from the biomedical researchers based on their areas of research.

***Ethical preparedness of researchers***

We explored the ethical preparedness of the biomedical researchers for genomic research from their responses to questions that assessed their awareness of the Nigerian National Code of Health Research Ethics (NCHRE) and whether the code addresses the conduct of genomic research.

The NCHRE addresses most ethical issues relating to research with human participants, including independent ethical review of protocols, composition and responsibilities of ethics committees, risk/benefit assessment, the informed consent process, principle of distributive justice, data and safety monitoring, confidentiality, community engagement, protection of research participants and ethical dissemination of research results. A peculiarity of the code is the inclusion of community advisory boards for the implementation of community engagement processes.

However, the code does not address standards of care, embryo and genomic research although it stipulates guidelines for material transfer agreement (MTA) which is the only specific guideline applicable to bio-banking and genomic research. This agreement is a documentation of details of storage (duration, manner, responsible contact) and export (country of destination) of biological samples outside the country, and such MTAs must be approved by the institutional ethics committee. There is no mention of what type of consent process should be used for genomic research, governance for bio-banking of bio-specimens, and guidelines for feedback of results of genomic research to participants. Indigenous and foreign researchers are required to be aware of and comply with the NCHRE to conduct research in Nigeria.

The analysis of their responses yielded a continuum of degree of awareness:

1. Theme A: Lack of awareness of Code and its limitation
2. Theme B: Awareness of Code but lack of awareness of its limitation
3. Theme C: Awareness of Code and its limitation

### Lack of awareness of Code and its limitation

Eighteen of the researchers were not aware of the National Code of Health Research Ethics and could not comment on whether the Code addressed the conduct of genomic research and were unaware of its limitations regarding ethical guidelines for conduct of biobanking in Nigeria. One of the researchers, in response to questioning during the interview, asked pensively, *‘how many of us are aware of the code?’* ***(Biomedical Res10)*** implying low level of awareness of the code among researchers in the country.

***Interviewer:*** *Lastly, have you come across the Nigerian Code of Health Research Ethics before?*

***Biomedical Res10****: I just heard of a committee sometime five, ten years ago. But I don’t know how active they are*

***Interviewer*** *(explaining): This is not about a committee. It is about a code. There is a code of*

*health research ethics…*

***Biomedical Res10:*** *I have not heard about that. All I know is that each institution has ethical committee subject to a national one*

***Interviewer*** *(cuts in): Yes, there is the national one.*

***Biomedical Res10:*** *ok*

***Interviewer*** *(explaining): The code is actually the legal document* (researcher interjected)

***Biomedical Res10***(interjected with a question)*: How many of us are aware of the code?*

### Awareness of Code but lack awareness of limitation

Seven researchers were aware of the code but could not say if the code addressed the conduct of genomic research. Four of these biomedical researchers who were aware had heard of the code during preparations for postgraduate fellowship research because they were required to obtain ethics approval for their fellowship theses. Certification of successful completion of the informed consent course, an integral part of the code, is a pre-requisite for ethics approval. The remaining three knew about the code due to attendance at seminars on ethics of human subjects’ research held in their institutions or through attending the ethics committee’s meetings.

*‘I am aware. I got to know about it because I have been participating in research, for up to 5 years, during my training as a senior resident now as a consultant and am a frequent attendee at the meeting of ethics and research committee of my teaching hospital. I know quite a number of things that are involved and that is why from the national code, institutions step it down to have their own local adaptation of such, so am aware of research code.’* ***(Biomedical Res19)***

*‘Yes, I am aware. I heard about it when I was writing my research a couple of years ago. I was referred to the website to look at the inform consent format. I didn’t read through the code before I got the informed consent section.’* ***(Biomedical Res17)***

However, often they could not assess the code’s coverage of genomic research because they had never read the whole code. Two researchers who had read the code several years ago could not remember the contents as they had not had the opportunity for refresher courses or seminars. This dialogue illustrates this point:

***Interviewer:*** *Thank you very much. Have you heard of the Nigerian code of health research ethics?*

***Biomedical Res8:*** *Yeah, I have heard about it because I had the opportunity to attend a workshop on ethics and research.*

***Interviewer:*** *Have you read through it?*

***Biomedical Res8:*** *It’s been long, but I can’t remember again but I think I have a book on it, but I can’t remember, and I have not attended a seminar recently.*

### Awareness of Code and its limitation

Only five of the 30 biomedical researchers knew of the code and said that the code did not adequately address ethical conduct of genomic research in Nigeria. Three of the five were the genetic researchers.

*‘Knowledge of medicine is getting more genomic, disease concept these days are now being linked to the genome whereby we look at disease not just as a morphological appearance but a possible genetic basis down to the level of the DNA, I am aware that the you cannot find guidelines on how to carry out genetic research in the code, especially when it comes to use of blood samples and genetic data’* ***Biomed Res 22***

*‘I don’t think it addresses it very well, because I had opportunity to attend one workshop in Abuja on genetic research, that’s about 3 years now. It was one of my supervisors that invited me.’* ***(Biomedical Res 25)***

One of the two who were not involved in genetic research mentioned that the code addressed the issue of material transfer agreement (MTA).

*‘Also, I attended a seminar two or three years ago when we were starting the University. At the seminar, one of the things they taught us was that informed consent must be at the level of a JSS 3 student. We were also taught about the material transfer agreement which I think talks about transfer of specimens to other countries’* ***(Biomedical Res 5)***

The three genetic researchers did not talk about the MTA and they did not differ in level of awareness of the limitations of the national code to guide genomic research when compared with the other two researchers who were similarly aware of the code’s limitations.

## ***Discussion***

**Knowledge of genomics and genomic research**

This study demonstrated that our participants, who are clinician-researchers, were more genomic-science literate than genomic-health literate. Those who were genomic-health literate had an understanding of human genome and related genomic research to familial genetic disorders in their environment like sickle cell disease. This finding corroborates the observation of an earlier study that reported that knowledge of genomic tests was limited to paternity and sickle cell genotype tests among Nigerian Africans (Fagbemiro & Adebamowo, 2014).

Our themes have parallels with the theory-based framework proposed by Smerecnik *et al* in terms of ascending level of knowledge. Smerecnik’s framework distinguishes between three different types of knowledge of genetic risk factors namely, awareness knowledge, how-to (practical) knowledge, and principles (theoretical) knowledge. This framework graded knowledge of genetic risk factors from levels of awareness to a better understanding of how they impact health (Smerecnik, Mesters, de Vries, & de Vries, 2008). This continuum of levels of knowledge is also illustrated by our themes and allows for assessment of how deeply an individual understands the concepts of genomic research.

The majority of studies on levels of understanding of genomic medicine were conducted among health-care providers like clinicians, not strictly among scientists-researchers, although clinicians do engage in genomic research. Researchers should possess appropriate knowledge and skills in genomic medicine to make them competent educators of potential research participants before seeking their consent. Studies by Jeffrey et al, Marzuillo et al and Laskin et al clearly documented knowledge gaps in genomic health literacy and emphasised that this constitutes a potential limitation in ensuring high ethical standards of informed consent due to misinformation and poor comprehension (Botkin et al., 2015; Marzuillo et al., 2014; Laskin et al., 2016).

For example, knowledge gaps were demonstrated by Merdad *et al* when they assessed knowledge about biobanking, collection and storage of bio-specimens, an integral part of genomic research among healthcare students at King Abdulaziz University in Saudi Arabia, and observed that 56% and 73% of the students were unaware of the Human Genome Project and biobank respectively. They concluded that there was a notable lack of knowledge about biobanking and the human genome project among the students and recommended that healthcare curricula should be enhanced by including educational programs on genomic medicine (Merdad et al., 2017).

Low levels of genomic health literacy found among the biomedical researchers in the current study could serve as a barrier for developing culturally and linguistically appropriate communication strategies to pass information to potential research participants during the consenting process, prevent community-based participatory research and the successful implementation of genomic research in the community. To remove this barrier, genomic health literacy is a critical issue for researchers to consider as they prepare to engage with genomic research.

Adequate understanding of genomics and the use of appropriate communication techniques are required to successfully implement genomic research. An Italian study showed that adequate knowledge of genomics is the strongest predictor of positive attitudes towards genomics research among public health professionals (Marzuillo et al., 2014). Furthermore, limited genomic literacy in general, due to lack of genomic health educators, may adversely impact on the public’s understanding and use of genomics in health care. Communicating genomics information in ways that maximize understanding and promote public interest and participation is very important given the rapidly expanding capabilities of genomic technologies (Lautenbach, Christensen, Sparks, & Green, 2013). This demands that researchers must possess a higher level of understanding of genomics than their intended or potential research participants. These observations underscore the importance of improving the knowledge, not only of pure genomics, but also of the associated ethical issues among biomedical or clinician-researchers who are interested in genomic research.

**Ethical preparedness of researchers**

Advancements in genomic technology have produced ethical issues that must be addressed by researchers. Lack of adequate ethics training and preparedness places researchers in a position where they might be unable to effectively assess and resolve the ethical dilemmas presented to them (Zawati, Cohen, Parry, Avard, & Syncox, 2015). This might result in the unethical conduct of research. When researchers are aware of inadequacies of existing national ethical guideline for conduct of genomic research, they can campaign for the code to be revised and updated. Our study demonstrated a low level of awareness of the country’s ethical code among the researchers and therefore, there is little ethics support in terms of guidelines for these researchers.

A Canadian qualitative study that explored healthcare professionals’ knowledge, attitudes and perceptions of genomics showed that although their study participants have little knowledge about genomics, they cited the importance of and called for stringent regulatory oversight of genomic research to ensure public protection (Weir, Morin, Ries, & Castle, 2010). The findings of this study are similar to our finding regarding the poor knowledge of genomics. But in terms of awareness of the need for robust guideline for ethical conduct of genomic research, our findings differ from the Canadian study because majority of our study participants were not aware whether the existing national code covered genomic research.

## ***Limitations***

This study was limited to one institution in one geographical region of the country, therefore it may not reflect the genomic health literacy and level of ethical preparedness of biomedical researchers in other institutions or regions of the country or the sub-continent. This limitation is typical of qualitative studies. The number and spread of biomedical researchers were not meant to be representative of researchers in the country. Rather, the focus was to explore views and perceptions of a purposively sampled group of participants who are stakeholders in genomic research.

***Conclusions***

Most of the biomedical researchers in our study were not genomic health literate and most of them were only familiar with concepts of genes and genetic research. They were also unaware of the national code of health research ethics and its inadequacies as a source of ethical guidance for the conduct of genomic research. These findings showed the poor level of preparedness of these biomedical researchers for genomic research. Therefore, the starting point for building capacity for genomic research in sub-Saharan Africa is the formulation and implementation of robust educational programmes on genomic health literacy. The development of regulatory systems that can produce robust ethical guidelines to guide African researchers carrying out genomic research will be key in ensuring that the objectives of the H3Africa project can be successfully reached.

## ***Best Practices***

Creating awareness and improving the knowledge of the national code of health research ethics among biomedical researchers can aid the ethical conduct of genomic research and ensure protection of prospective research participants. The gap in genomic health literacy among biomedical researchers who will provide the information to participants during the informed consent process needs to be addressed. It is also important that clinicians are included in these conversations to aid integration of genomics into the practice of medicine. Further, policy makers and national ethics committees should include specific guidelines for the conduct of genomic research in national codes; such as acceptable informed consent processes, standards of review of genomic research protocols by ethics committees, effective bio-bank governance structure, privacy of bio-specimens and data, culturally-sensitive community engagement strategies, communication of genomic studies and clear policies on feedback of results of genomic testing.

## ***Research Implications***

Further research on genomic literacy and ethical awareness among biomedical researchers in other institutions and regions in Sub-Saharan Africa would identify knowledge gaps which can be addressed by funding agencies to prepare researchers for successful implementation of genomic projects. Surveys could be conducted with numerous biomedical researchers in African countries to get a broader view of degree of knowledge and awareness.

### ***Educational Implications***

Sub-Saharan African countries involved in genomic research should organize seminars and/or training courses for indigenous scientists to educate and build capacity in genomic health literacy. A possible strategy to resolve genomic illiteracy is through communal conversations among biomedical researchers. This approach recognises biomedical researchers as a community of scientists with shared common interests and values. The objective of this approach is to encourage the exchange of information and ideas on genomics and genomic research among biomedical researchers, thereby improving their knowledge and competence. This can be achieved through conferences and round table discussions.

As genomics and personalized medicine develop to become part of routine medical diagnosis and treatment, it may become imperative to incorporate training in genetics and genomics medicine in the undergraduate and postgraduate curricular of relevant disciplines in higher education to bridge the existing knowledge gap. By so doing, medical graduates would be better prepared for the challenges of genomic research and its medical applications.

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