Ethical Issues Surrounding the Exportation of Samples from Developing Countries I

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ABSTRACT

Background: This is a two-part review of the ethical issues arising from the exportation of biological samples from the developing world. With the burgeoning of research in the developing world carried out in collaboration with partners from the developed world there has been a corresponding increase in the exportation of samples for various reasons. This has raised a number of ethical issues ranging from the purpose of exporting the samples to the ownership of the exported samples.

Objective: To explore and discuss the main ethical issues arising from the exportation of samples from the developing to the developed world in general and using the case of Zambia.

Methods: A review of the current existing literature on the issue of exportation of biological samples and biobanking was carried out. Part I of the review will consider exportation of biological samples in general whereas Part II will address the Zambian situation and discuss the developments in depth.

INTRODUCTION

Biobanking has raised a lot of attention in the research fraternity[1-7]. It is known that human tissue has been stored in clinical settings for diagnostic and research purposes[8,9]. It would appear now, that research is being conducted so that samples can be collected and or stored especially from developing countries which are now hosting an ever increasing number of researches. The interest in developing countries primarily arises from the fact that these countries are also home to a number of diseases that researchers in developed countries would like to evaluate. Meslin & Quaid[8] stated that the "future of medicine will depend largely on the ability of investigators to gain access to large quantities of HBMs" – Human Biological Materials but that there were "ethical, legal and social implications of such access".

Over the past 10 years Zambia has experienced an increase in the number of research hosted in the country[10]. Based on data held by the Biomedical Research Ethics Committee in the University of Zambia's School of Medicine (UNZABREC), the Committee has experienced an increase from an average of about 6-10 research proposals a month to an average of about 15 a month. This research ranges from locally driven research to multi-centre clinical trials. UNZABREC has also noted a significant increase in the number of researchers requesting for both storage and exportation of samples to other countries. The samples are intended to be exported mainly for DNA testing. The rationale for the exportation of samples has ranged from lack of capacity to store and/or analyse the samples to study designs requiring all samples to be analyzed in one central laboratory outside the country.

The continuous request for exportation of samples out of the country reached "unprecedented levels" and a couple of years ago, Zambia's Ministry of Health put a ban on exportation of human tissue until such a time when a new and much stronger legal framework would have been put in place in collaboration with the Ministry of Justice. This study set out to determine the ethical issues surrounding exportation of human tissues from developing countries.

The specific objectives were to determine the following:

- What are the benefits of exportation of human samples to developed countries?
- What are the risks of exportation of human samples to developed countries?
- Do African Research Ethics Committees have concerns with approving research proposals requiring exportation of samples? If so what are these concerns?Is there exploitation of developing countries in the exportation of samples?

A systematic search of literature was done resulting in a review of 91 articles. This paper is part 1 of a series of 2 articles and it focuses on the outcomes of the first two specific objectives.

Globalisation and Health

Globalisation which is a versatile phenomenon is reported by Pang & Guindon[11] to be a powerful development that is presenting new challenges especially when linked to health. They report that globalisation can affect health in many ways and that consequences could be at individual or population level and that it can affect these categories directly or indirectly. They conclude that the mobility of goods and people contributes towards the globalization of health risks. Contributing to the debate on the challenges of globalization, Frenk & Gormez-Dantes[12] report that the threat of globalized information for bio-terrorism purposes is becoming a serious concern for many governments and that there was need for new

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approaches to international cooperation that would place national self-interest in the context of global mutual interest and, in this way promote international cooperation and goodwill. In relation to research, the same authors[12] have reported that developed countries are increasingly collecting information that includes population-based estimates determined by biological and physiological measures, a situation which is more pronounced in infectious disease research[13]. An additional challenge is that this biological data requires careful reassessment of ethical standards and procedures related to safety and informed consent. Other authors[14,15] have reported that there was need for ethical principles to be interpreted within the parameters of the national context in which these scientific studies take place. While information from research outcomes helps countries to make informed decisions about health, there is need to interpret it in its specific setting as generalising the information could lead to distortion of information and its use.

Some authors[16] has reported that public health is a political and social undertaking. This entails the need for good policies, good will and commitment from governments in order for the social determinants of health to be met. Meanwhile, the WHO[17] has reported that rapid advances in genetic technology and human genome research has and will become more and more important for health improvement if used appropriately, as it has potential to achieve better health for all people but concluded that there was a need for health officials to develop policies and appropriate practices. One of these we recommend should be ensuring that the social determinants of health are not attained at the expense of other people groups outside one's funding country as this would be exploitative.

Arguments on Exportation of Samples

A number of studies[18-25] have highlighted positive and negative issues related to exportation of human samples from developing countries. Those in favour of exportation of samples argue that:

Often when researchers request for storage and or exportation of samples, reasons given range from lack of expertise to inadequate storage of laboratory facilities in the host country - mainly developing countries. Sgaier[4] reporting on needs and feasibility of biobanks in developing countries, indicated that the startup costs in a developed country were as high as $120 million (for a sample size of about 500,000) while the budget for a developing country was $20-30 million for a sample size of 2-3 million.

Given the increase in collaborative research some authors[19-26] have reported that some of the benefits of storing samples in one central laboratory are that data can be analyzed in one place and when done by one group of experts reduces the margin of error. Further, this quickens the analysis process and enhances standardization. Collaborative research often involves a number of countries or research sites. Awaiting results from various sites could contribute to delayed research outcomes. The use of experts in one central place also reduces the cost of paying experts or consultants to do data analysis at various points especially in developing countries. Many developing countries have financial constraints, a problem that sometimes hampers the building of adequate storage facilities, high tech-laboratories or training of experts (in the light of the high disease burden). A benefit therefore, to developing countries, is that trials are often done on diseases which are prevalent in these countries which ordinarily would not have been researched on to inform practice. Another benefit is that it gives an opportunity to researchers (academicians and students) in developing countries to participate in research which ordinarily they would not have been able to fund.

Literature highlights more arguments against exportation of human samples to developed countries. In the light of increased collaborative research some authors[18,25,27] have raised concerns over the inadequacies in benefit sharing between researches done in developed versus developing countries. Some recommend the need for benefit sharing plus appropriate strengthening of collaboration[2,25,27,28]. The UNESCO Universal Declaration on Bioethics states in part that "the declaration must be incorporated by the UNESCO member states in to their national laws, regulations or policies in order to take effect"[29]. Additional authors[5,29,30] have raised concerns on why donors of samples do not benefit from the profits that is an outcome of their donated samples. A Kenya study[31] reports that participants were informed that they would relinquish all rights to all preparations from their samples that would have commercial applicability. This is an example of exploitation as it is not clear whether the participants in this study fully understood what they were losing in terms of property rights. While the study being described above could happen in a developed country (or funding country) the impact would not be so negative when done to benefit people in the funding country.

Some[18-25] have reported that there has been inadequate capacity building in the developing world to correlate with the amount of research that is taking place in these countries. Some of the concerns arise from the fact that in "collaborative research" the brunt (risks) of the research rests heavily on developing countries where the studies are being conducted unlike developed countries who only receive samples, analysedata or fund studies. The same authors highlight the following challenges that they say go with exportation of samples from developing countries: a lack of adequate capacity building by North (developed countries) in South (developing countries); weak research partnership between North and South and that legislation governing research appearing biased toward researchers in the North. Given that exportation and analysis of human samples is a lucrative business[18,22,25,26] it raises concerns as ownership of exported samples is forfeited. This results in a loss of intellectual property rights, and a lack of benefit sharing to participants, communities and/or host countries. The final outcome of this is again exploitation of these communities.

Another concern is the issue of blanket consenting which results in the fate of exported samples not being known. Exportation of samples tends to worsen economic disparities between North and South countries and also reduces participant adherence to research they consent to as they

become suspicious about what happens to donated samples. An example of this is an autopsy study conducted in Malawi where eye samples were collected from deceased children so as to determine the cause of death in cerebral malaria in children[32]. The study raised many ethical issues that were considered to have been a violation of cultural beliefs and practices surrounding death and dying in Malawi.

Concerning the use of human biological materials, some[8] have cautioned that legal and social protections of individual privacy and confidentiality are inadequate, placing people at risk of discrimination and stigmatization. These concerns have been raised by many others [1,14,25-26,33-35-38].

Andanda[5] quotes the Nuffield Council on why participants cannot hold a claim over their samples as follows:

> *"The right of ownership in a patent derives from the act of invention. In the case of inventions derived from human tissue, the act of invention is carried out by the person who extracted and purified the human tissue by some inventive means – and it is this invention which confers the right to apply for a patent. It follows that the monopoly is not donor of the tissue in question; he has played no part in the inventive act. Hence the donor has no right to interference with the lawful owner's exercise of his monopoly - irrespective of whether the tissue was experimented with or without his consent."*

What is highlighted above is unethical and exploitative as it firstly suggests that the researchers can collect samples without informed consent from participants. Secondly it does not place any value on the contribution of the participant. The United Kingdom's regulations uphold the autonomy of patients over their bodies but there is great discrepancy when it comes to ownership over their samples[39]. Jegede[40] asks a pertinent question: "at what point would the body tissue cease to be the property of the participant?" Regulations made for the United Kingdom should not be seen to be the ultimate for the whole world.

Andanda[5] argues that there are still some matters of concern that have not been clarified or concluded concerning research which involves participants in South about samples shipped to developed countries. Current research regulations and guidelines seem to favour the research in the developed countries. This is because the regulations indicate that once samples have been donated (and exported) participants lose rights on the donated samples[5,41].

As earlier indicated some developing countries would like to conduct high-tech scientific research but due to many factors are unable to do so. Developed countries that show intent to do research in developing countries offer a good solution but (as already indicated) specimens are usually shipped out of developing countries under the pretext that there are no facilities in-house where they can be adequately evaluated and/or stored. So a number of authors [18-23, 25] urge that researchers from developed countries are benefiting far much more out of this kind of research than they are willing to invest in host countries.

CONCLUSION

Given the above discussion it can be seen that there are more issues against the exportation of human tissue from developing countries. While this study does not advocate for no collaborative research, there is need for clear policies, guidelines and Material Transfer Agreements (MTAs) to be developed before the commencement and continuation of such research. The need for equity in research cannot be over-emphasized. Whether studies have potential benefits or harm, this too ought to be shared by both North and South and not have a situation where the North is investing the money and the South investing lives.

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