African Researchers' Perceptions and Expectations of the Benefits of Genomics Research in Africa: A Qualitative Study

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DECLARATION

I, Nchangwi Syntia Munung, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Introduction

Genomics research raises a number of ethical, legal and social issues (ELSI), one of which is the concept of benefit sharing. While benefits and benefit sharing are difficult to discuss because of questions on what needs to be shared, with whom and by whom, it cannot be pushed to the side-lines especially as it is a way of promoting justice in health research and of ensuring that research is of social value to study communities. In this study, we explored the perceptions and expectations of African genomics scientists on the benefits of genomics research to Africa.

Method

This was a qualitative study and we adopted a grounded theory approach. I conducted 17 in-depth interviews with genomics researchers in Africa to explore their perceptions of benefits and benefit sharing in genomics research in Africa. Transcripts of interviews were imported into QSR-NVivo 10 for thematic analysis. A thematic analysis of informed consent documents used in 13 genomics studies in Africa was also done to explore how research benefits are documented.

Results

Research collaboration, research capacity building and access to genomics medicine were perceived to be the main benefits of African genomics science (AGS). In terms of research collaboration, there were perceived fears of exploitation of African researchers and research participants, and the non-sustainability of AGS. To address the problem of exploitation, African researchers expressed the need for fairness in AGS through transparency and equity in research collaborations, enhancing research oversight, African ownership and leadership of AGS, community engagement and research capacity building. In terms of genomics medicine, African genomics researchers perceived that AGS would have an impact on healthcare in Africa in the area of diagnosis, pharmacogenomics and public health. However, there were concerns around access to genomics medicine by African populations, lack of capacity for genomics medicine in Africa and the need for AGS to focus on Africa's healthcare priorities. There was however limited awareness of the concept of benefit sharing among African genomics researchers though they perceived it is as an important concept for AGS. Interviewees suggested that benefit sharing could be in the form of research capacity building, feedback of study findings, science education, community projects and the sharing of profits.

Conclusion

Current genomics initiatives in Africa have the potential of improving the research and healthcare landscape in Africa. However, there were concerns around exploitation and non-sustainability of AGS which would have to be addressed.

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Chapter 1 Introduction and Literature Review

1.1 Introduction

There is global interest in genomics research and there have been calls for an African genomics science (AGS) on the basis that an entire continent could be left out of the promise of genomic medicine if they are not included in future genomics studies (H3Africa Consortium, 2014, Need and Goldstein, 2009, Rosenberg et al., 2010). If we accept that genomics has the potential to revolutionize medicine and healthcare (WHO, 2002, Peprah et al., 2015), there is also the danger that if appropriate care is not taken, it could widen the existing global health inequity gap (Singer and Daar, 2001, Hardy et al., 2008). It is arguably as a response to this risk that we are currently witnessing a huge drive in genomics research in Africa. These large scale population genomics projects plan to source for and store large numbers of human biological samples and data that could help scientists answer questions on the impact that gene-gene and/or gene-environment interactions may have on human health (Gurdasani et al., 2015, H3Africa Consortium, 2014, Ramsay et al., 2011).

The excitement for an AGS has also met with strong calls for attention to be paid to the ethical, legal and social issues (ELSIs) of genomics research in Africa. It is therefore not surprising that the literature, either through philosophical debates or empirical studies, is already highlighting some of these ELSIs especially as they apply to Africa. Some of the major ELSIs discussed to date include: informed consent models currently used in genomics research in Africa (Munung et al., 2015-In press), research participants' understanding of concepts in genomics research (Traore et al., 2015, Tindana et al., 2012, Marshall et al., 2014, Igbe and Adebamowo, 2012) stigma and ethnic group harm (de Vries et al., 2012a, Tekola et al., 2009a), ethics review of genomics research (de Vries et al., 2015a, Ramsay et al., 2014, Sathar et al., 2014), sample storage and secondary use (Tindana et al., 2014, Barchi et al., 2015), community engagement (Marsh et al., 2010, Tindana et al., 2015, Rotimi et al., 2007, Campbell et al., 2015, Folayan et al., 2015, Marsh et al., 2009), ownership of human biological materials (Moodley et al., 2014), the creation of cell lines (de Vries et al., 2014), feedback of genetic research findings (Marsh et al., 2013), regulation of genomics research (Sathar and Dhai, 2012, Staunton and Moodley, 2013) and perceptions of study benefits in genetic studies (Appiah-Poku et al., 2011). Some of these discussions have been very broad and touched on a number of possible ethical challenges that could be encountered in AGS (de Vries et al., 2011, de Vries et al., 2012b, Nyika, 2009, Wright et al., 2013). Some have received considerable attention in recent times whilst others have received minimal attention. An example of the latter is benefit sharing. Very few authors (Ramsay et al., 2014, Ndebele and Musesengwa, 2008, Nyika, 2009, de Vries et al., 2011) have commented specifically on the

concept of benefit sharing in AGS and these authors, with the exception of Ndebele and Musesengwa (2008), have only flagged it as an ethical issue without much discussion. While it may be true that benefits and benefit sharing are difficult to discuss because of questions of what needs to be shared, with whom and by whom (Simm, 2005), considerations of benefits and benefit sharing cannot be silently pushed to the side lines. This is because due consideration of the likely benefits of AGS could build trust amongst research stakeholders in AGS and ensure that AGS in fact delivers on its promise to reduce the global health inequity gap.

In the research leading up to this dissertation, I explored the perceptions and expectations of African genomics scientists on the benefits and risks of genomics research to Africa. Based on the results, I argue that unless the actual benefits of AGS are identified and the challenges carefully addressed, human genomics research will not be a mainstay in Africa and may only serve to widen the health equity gap.

1.2 Literature Review

In this chapter, I will review the literature on genomics research in a bid to: identify pertinent concepts in genomics, present some past and present African genomics initiatives and describe the ethical challenges of genomics research in Africa. To start with, I will describe what I understand genetics and genomics to be also compare and contrast genetics and genomics, which are two closely related terms but with some subtle differences.

1.2.1 Genetics and Genomics

Genetics refers to the study of specific individual genes and their role in inheritance. Simply put, it is the way certain traits or conditions are passed down from one generation of family members to another. For example, genetics plays a crucial role in understanding why most men in a family are bald or colour blind. It also plays a major role in heredity and health. Examples of genetic or inherited disorders include sickle cell anaemia, cystic fibrosis and Huntington's disease.

Genomics, on the other hand, is a relatively recent term (McKusick and Ruddle, 1987) that describes the study of all of a person's genes (the genome), including interactions of the genes with each other and with the person's environment (non-genetic factors). Genomics includes the scientific study of complex diseases such as cardiovascular disease, diabetes, and cancer because these diseases are typically caused more by a combination of genetic and environmental factors rather than by single genes. By studying gene-gene and gene-environment interaction, scientists hope to better understand genetic susceptibility to disease (Weatherall et al., 1997, Segal and Hill, 2003) and how gene interactions with non-genetic factors such as lifestyle (diet, exercise and smoking), could provide clues on how the development of complex multifactorial genetic

conditions such as cancer, diabetes and hypertension could be prevented (Hernandez and Blazer, 2006).

In recent times, there has been a shift from Mendelian genetics (study of single genes) to whole genome sequencing. However, both genetics and genomics offer increasing hope and optimism for new and improved therapies, treatments, diagnostics and prognostic methods for some complex human diseases (WHO, 2002, Khoury, 2003, Sander, 2000), thanks to improved technologies such as next generation sequencing

So what then is the difference between genetics and genomics? The main difference is that genetics is the study of the functioning and composition of a single gene while genomics addresses all genes, their relationships with each other and with the environment in order to identify their combined influence on the growth and development of a disease. What this means is that medical genetics would, for example, be concerned with inherited single gene disorders (Mendelian disorders) while human genomics goes far beyond genetic disorders to include the understanding of gene function in multifactorial diseases such as diabetes, HIV/AIDS and cancer.

1.2.2 Peculiarities of Genomics Research

Genomics research, unlike most other types of biomedical research, usually requires research collaborations and the establishment of a large network of scientists, mostly across different countries and continents. This is because of its interdisciplinary nature, the need for high-throughput technology, access to unique populations and, in the case of population genomics research, the need for large sample sizes and for samples and data to be stored in biobanks (Nyika, 2009, Collins et al., 2003, Meldrum, 1995). Genomics therefore appears to be moving biomedical science from its typically individualistic nature whereby you had a research team working mostly by themselves, to a collaborative one which requires the sharing of samples and data between researchers in order to expedite the generation of robust results (Wright et al., 2013, Nyika, 2009). In Africa, genomics research often involves the cross-border movement of human biological samples for the purpose of analysis. This is due to a lack of the required technology, limited human capacity for genomics analysis and the near absence of biobanks (Karikari, 2015, H3Africa Consortium, 2014).

Another peculiarity of genomics research is that it may not have a defined end point and could last for many years. Usually, samples and data that are stored in the biobanks are shared by different researchers working on different projects, thereby making it difficult, if not impossible, to anticipate all the possible studies that could be carried out on the samples and the end date of these studies. This is in contrast to clinical research and most other forms of biomedical

research which are designed to test a hypothesis, are focused on a specific disease or health condition and is usually completed within a predictable and limited time frame.

Bio-banking research and population genomics studies also pose unique challenges to existing bioethics frameworks (McGuire et al., 2008, Tabor et al., 2011, Caulfield et al., 2008) . In Africa, it raises a number of unanswered questions and challenges (de Vries et al., 2011, Nyika, 2009, Wright et al., 2013), including how it should be governed and for whose benefit (de Vries and Pepper, 2012, Ndebele and Musesengwa, 2008).

1.3 African Genomics Science (AGS)

Studies into the genetic basis of disease in European populations have made major advances in the past few years, yet similar studies in sub-Saharan Africa have been slower to develop (Need and Goldstein, 2009, Rosenberg et al., 2010). For example, only four (HIV Susceptibility, Malaria, Tuberculosis and Podoconiasis) of the thousands of genome wide association studies (GWAS) done till date, have been conducted exclusively on African populations despite Africa's rich genetic diversity and high disease burden (H3Africa Consortium, 2014, Rotimi and Jorde, 2010). Many therefore argue that if this scenario persists, the benefits of the genomics revolution could elude the continent or have limited impact on humanity as a whole (H3Africa Consortium, 2014, Peprah et al., 2015, Haga, 2010) and this would in fact be undesirable. Many have therefore recommended that Africa joins the genomics revolution so that African populations could harness the benefits of genomics (H3Africa Consortium, 2014, Ramsay et al., 2011)

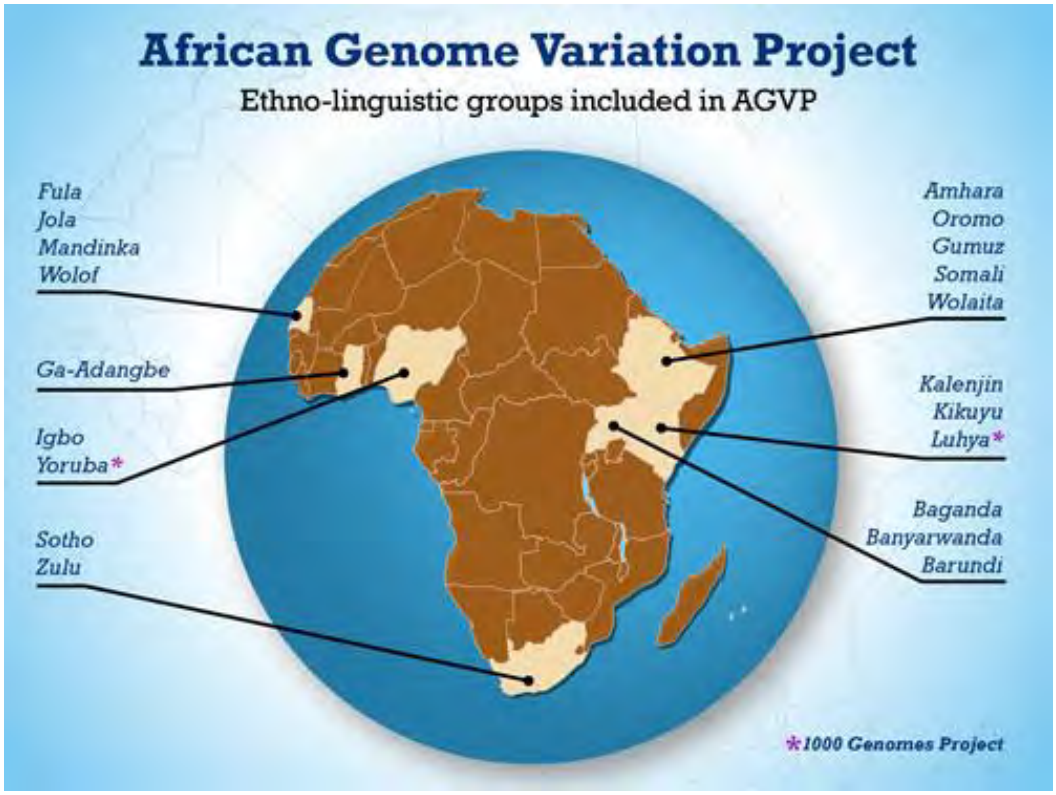
Equally, some authors have highlighted the impact genomics could have in narrowing the health inequity gap between rich and poor nations and in enhancing reasonable access to simple, cheap and effective health services in LMICs (Singer and Daar, 2001, Ogudiran, 2005). Many have therefore suggested that the time is past when African countries will have to wait for the North to make advances in genomics and later import it at a high cost (Seguin et al., 2008). It is a combination of these arguments and perhaps others that has led to the recent drive towards African genomics science (AGS) with the creation of a number of African genomics initiatives most notably the Human Heredity and Health in Africa (H3Africa) and the African Genome Variation Project (AGVP)

1.3.1 African Genome Variation Project (AGVP)

The African Genome Variation Project is an international collaborative human genomics research project with funding from UK-based charity the Wellcome Trust. It involves a wide collaborative network of scientists, primarily from the African Partnership for Chronic Disease Research. The AGVP has as one of its objectives, the genotyping of 2.5 million genetic variants in over 1400 individuals from 18 ethno-linguistic groups (figure 1) across seven African countries (Kenya,

Nigeria, Uganda, Ethiopia, Ghana, the Gambia, South Africa) (Gurdasani et al., 2015, Tachmazidou I for the AGVP Investigators, 2013). It is hoped that the study will provide new information about genetic and genomics structure in African populations and ethnic groups. The AGVP is also assessing the feasibility of applying commercially available genotyping platforms to investigate African populations and developing new platforms that could be used in African populations. Genotyping of the majority of samples collected for the AGVP is being done at the Welcome Trust Sanger Institute and the data generated will be submitted to the European Genotype Archive (EGA) to facilitate future GWAS. It is also hoped that this project will provide a global resource for researchers, facilitate genetic studies in Africa, foster collaboration and synergies among contributing parties, build capacity in Africa for next-generation sequencing (NGS) and also develop local resources for public health and genomics research in Africa.

Figure 1: Map showing different African ethno-linguistic groups included in the AGVP



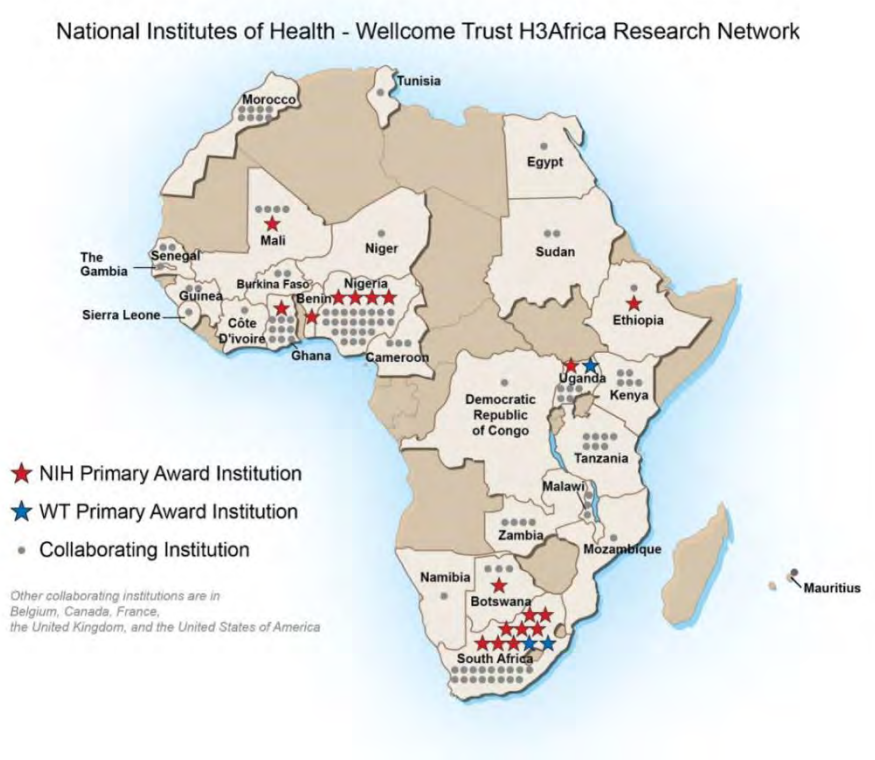
Source: https://www.genome.gov/27559699 accessed 28th March 2014

1.3.3 Human Heredity and Health in Africa (H3Africa)

A second large scale genomics research project currently underway in Africa is the H3Africa project. This project was established in 2010 with funding from the U.S. National Institutes of Health (NIH) and the Welcome Trust, in partnership with the African Society of Human Genetics

(AfSHG). With over 70 million dollars in funding, the H3Africa initiative plans to enhance the ability of African scientists to apply genomics in health research in Africa (H3Africa Consortium, 2014).

Figure 2: **Map showing countries in Africa with H3Africa projects. Source**: (H3Africa Consortium, 2014)



H3Africa research projects cover research on a wide range of health problems such as cardiovascular diseases, diabetes, febrile illness, neurological disease, podoconiasis, respiratory diseases, sickle cell anaemia, stroke, tuberculosis and schizophrenia. On the whole, it is anticipated that approximately 75,000 samples would be analysed as part of the H3Africa project (H3Africa Consortium, 2014). The H3Africa initiative also includes four biobanking projects, a bioinformatics network and six projects that will explore the ethical, legal and social issues (ELSI) of genomics research in Africa (http://h3africa.org/consortium/projects accessed 28 November 2015). All the biobanking projects are charged with establishing H3Africa biobanks in Africa in Nigeria, South Africa and Uganda (H3Africa, 2013). These biobanks would store samples collected from one or more of the 23 H3Africa project sites and the bioinformatics network will provide support for data analysis (H3Africa Consortium, 2014). All H3Africa projects are hosted in African institutions and are led by African-based investigators. H3Africa hopes to be able to measure its

success, through the number of publications in high impact journals, effective data and sample release, the establishment of full-scale biorepositories or biobanks, increased availability of funding for AGS and extension of funding by the current H3Africa funders.

1.4 Ethical Issues in Human Genomics Research

Despite global interest and optimism on the potential of human genomics research in improving health, there are a number of ethical, legal and social issues (ELSIs) around population genomics research in Africa (de Vries et al., 2012b, Murray and Livny, 1995, Nyika, 2009, Wright et al., 2013). In most cases, these ethical issues are shaped by the need to establish biobanks (biorepositories), the use of high throughput technology and the unavoidable need to engage in collaborative research (Nyika, 2009, Roche, 2009, Wright et al., 2013). While these ELSIs could be the same in all parts of the world, most remain a serious challenge in Africa especially as AGS is still at its infancy and most of these ELSIs have not been discussed in finer detail (de Vries et al., 2012b, Nyika, 2009). Many have also suggested that ELSI discussions in Africa need to take into consideration the culture of the people so as to ensure that the adopted frameworks and procedures meet the needs of African populations (Rotimi et al., 2007, Wright et al., 2013)

Current ESLI debates in AGS have focused on informed consent usually around consent models that maybe most appropriate for AGS (Tekola et al., 2009b, Olaitan et al., 2014). This has led to a number of empirical studies on informed consent comprehension in genomics research in Africa (Igbe and Adebamowo, 2012, Marshall et al., 2014, Tindana et al., 2012, Traore et al., 2015) and the development of informed consent guidelines and templates for use in AGS (H3Africa Working Group on Ethics and Regulatory Issues, 2014b). This template provides guidance on how concepts in genomics research could be conveyed to potential research participants in simple language.

Ethical issues in AGS are made worse by weak research oversight systems in most African and the lack of regulation for genomics research (Nyika, 2009, Sathar and Dhai, 2012, Staunton and Moodley, 2013, de Vries et al., 2011). Interactions with members of research ethics committees (RECs) as a means of engaging them in discussions of ethics of genomics research, have seen REC members express concerns about informed consent for future use of samples and data, community engagement, governance frameworks for biobanking research in Africa and benefit sharing (de Vries et al., 2015a, Ramsay et al., 2014, Barchi et al., 2015). Most of the concerns raised by REC members in Africa are linked to the peculiarities of genomics research discussed above.

The export of samples from Africa for research purposes has raised a number of concerns amongst African researchers and bioethicist with many arguing that this has made African researchers appear like field workers or sample collectors (Kilama, 2003, Harris, 2004). Storage

and export of samples for the purpose of sharing also raises a number of ethical issues mostly around ownership of samples and access to data (Barchi et al., 2015). These concerns are closely linked to fears of exploitation and unfair competition between researchers in resource poor countries and those in scientifically advanced countries (Jao et al., 2015).

Feedback of genetic findings is also a major ethical issue in genomics research and there are arguments on whether or not it is appropriate to return genetic results to study participants and if researchers have the obligation to return results (Jarvik et al., 2014, Rabino, 2003, Knoppers et al., 2015). For some commentators, feedback of genetic findings should be done when the results are "medically actionable"(Green et al., 2013) while others maintained that feedback of genetic findings could in fact promote trust and collaborations with participating communities (Kerasidou, 2014). Feedback of genetic findings also raises concerns around discrimination by insurance providers and employers (Nowlan, 2002, Billings et al., 1992)

Some have argued that research participants do not necessarily need to understand the scientific jargon associated with genetics in order to understand the benefits and risks that are associated with genomics research (Nyika, 2009) and that ethical issues in AGS go far beyond informed consent mostly because of the collaborative nature of genomics research, storage of samples for future unknown use (van Schalkwyk et al., 2012), historical experiences of exploitation of African populations in international health research (Ballantyne, 2005, Edejer, 1999) and whether African countries will, in fact, benefit from their participation in population genetic research (Appiah-Poku et al., 2011, Ndebele and Musesengwa, 2008).

1.5 Benefits of Human Genomics Research

In the bioethics discourse, benefits in health research is enshrined in two main ethics principles: Beneficence and Justice (Beauchamp and Childress, 2001). Beneficence refers to the ethical obligation of maximizing benefits and minimizing harm in health research. It requires that the benefits of research outweigh the risks to research participants. In most cases, the principle of beneficence is combined with the ethics principle of non-maleficence (avoiding harm). The principle of justice refers to the ethical obligation of treating an individual in accordance with what is morally right, that is giving each person what is due to them. In health research, this mostly translates to distributive or social justice, which entails the equitable distribution of both the burdens and benefits of research (Emanuel et al., 2004). The principle of justice therefore requires that health research be responsive to the health needs of the communities in which it is carried out (Glantz and Annas, 1998, Bhutta, 2002).

The topic of benefits in health research however remains largely unexplored in the area of research ethics (Johansen et al., 2008) and notions of benefits in genomics research have not

been clearly defined. As genomics research apparently becomes a mainstay in Africa, discussions on its impact will need to take center stage as it will be critical to have discussions on how AGS could benefit Africa and therefore avoid exploitation and distrust that is said to be common place in most international health research projects in Africa (Ballantyne, 2005, Chu et al., 2014, Musolino et al., 2015). However, a major question is what are these benefits?

1.6 Benefit Sharing

Major substantive argument for benefits in genetics and genomics research have been in the context of discussions on benefit sharing. Benefit sharing is an important benchmark for ethical research in developing countries (Emanuel et al., 2004). It has its roots in different interdisciplinary fields such as law, ethics and intellectual property rights and has been proposed as a means of building trust and reciprocity with potential research participants (Knoppers, 2000). However, it has received very little attention in human genomics research despite concerns that if care is not taken, African countries as well as other LMICs may not benefit from genomics research (Brown, 2002, Ndebele and Musesengwa, 2008, Nyika, 2009).

1.6.1 Definition of Benefit Sharing

The Organization of African Unity (OAU), defines benefit sharing as "Benefit sharing is the sharing of whatever accrues from the use of biological resources, community knowledge technologies, innovation or practices" (OAU, 2000). In human genetics/genomics research, there is no universally accepted definition for benefit sharing. However, what has been mostly used in the literature on human genetic and genomics research is the definition proposed by Schroeder (2007, page 208) *"Benefit sharing is the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers to achieve justice in exchange, with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services without providing unethical inducements"* (Schroeder, 2007). This definition highlights advantages/profits (benefits) as what needs to be shared. However, if benefits depends on, and are determined by, needs, values, priorities and cultural expectations (Hugo Ethics Committee, 2000a), then Africa will need to decide what they expect as benefits of AGS.

1.6.2 Benefit Sharing: From Biodiversity to Human Genetics

Benefit sharing has its origins in international law and has mostly been used in the context of access to and use of non-human genomics resources as part of a common heritage (Simm, 2007a, Schroeder, 2006). In plant genetics, it has provoked huge debates, leading to the Convention on Biological Diversity (CBD) which emphasized the need for fair and equitable sharing of benefits that arise from the use of genetic resources (UNEP, 1992). However, what constitutes fair and

equitable benefits remains a major controversy (De Jonge, 2011). The United Nations Environmental Program, however maintains that this will depend on the value systems on which the judgment is based (UNEP, 1992).

Following continued debates on what constitutes fair and equitable benefits, the Bonn guidelines (Secretariat of the Convention on Biological Diversity, 2002) were developed and this was closely followed by the Nagoya Protocol on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization"(CBD, 2011). The Nagoya Protocol, adopted in Nagoya, Japan in 2010 with more than 100 countries as signatories, provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising from the utilization of genetic resources. Based on the Bonn guidelines, both monetary and non-monetary benefits could accrue from the use of genetic resources and this includes, for example: sharing of information; research collaboration; technology transfer; contribution to education; research capacity building (both human and infrastructural); social recognition; research funding; joint ownership of intellectual property rights and royalties and licensing fees. It further states these benefits should be shared with all those who participated in the scientific and/or commercial process.

Since the CBD, the discourse on benefit sharing has gradually walked its way into clinical and genetic research and there have been strong calls to develop an ethic of benefit sharing in human genetic research with the aim of ensuring reciprocity, fairness and justice in human genomics research (Knoppers, 2000, Hugo Ethics Committee, 2000a, HUGO Ethics Committee, 2000b). It has also been suggested that the CBD would be very relevant in human genetics particularly as it situates benefit sharing in the context of genetics research, provides examples of benefits and risks of genetic research and a relevant starting point for discussions on benefit sharing in human genetics (Sheremeta and Knoppers, 2007).

1.6.3 Benefit Sharing Arguments

Different arguments for and against benefit sharing have been raised in the literature (Dauda and Dierickx, 2013, Knoppers, 2000, Schroeder, 2007, Simm, 2005) and this mostly relates to altruism, risks of participating in research, property related arguments and fairness. In terms of altruism, it is believed that the participation of people (research participants, funders and sponsors) in genomics research is guided by altruistic motives and that the idea of giving back or deriving personal benefits need not take precedence and should be seen as a moral duty (Harris, 2005). This has been likened to donating money for humanitarian purposes where such donations would not be accompanied by expectations of personal benefits (Forsberg et al., 2009). Property related arguments are enshrined in the idea that the genome is part of the human heritage and that whatever comes out as a result of genomics research should be shared with everybody and not

necessarily with individuals (Hugo Ethics Committee, 2000a). Arguments based on fairness are enabled in the principle of justice, most especially distributive justice, and the main idea is that people who bore the risks of participating in research should share in the benefits (Simm, 2005, Participants in the Conference on Ethical Aspects of Research in Developing Countries, 2002). In most cases, this has been the strong argument for benefit sharing.

1.6.4 National/International Research Guidelines and Benefit Sharing

A number of international guidelines have passively touched on benefit and benefit sharing in international health research. Some of these guidelines include the CIOMS (CIOMS, 2002), the Nuffield council of Bioethics and the Human genome organization's statement on benefit sharing(Hugo Ethics Committee, 2000a). A review of how international guidelines and some national research ethics guidelines in Africa document benefits and benefit sharing has been done by Lairumbi and colleagues (2011) and is presented in Figure 4 (Lairumbi et al., 2011a). Worthy of note is that the guidelines in some African countries clearly outline the need for benefit sharing and highlight the importance for research to be of social value to the community

Figure 3: Forms of Benefit Sharing as Documented in Research Ethics Guidelines (Lairumbi et al., 2011a)

Research Ethics Guidelines/Report/Code	Form of Benefit sharing				
	Access to Unproven Interventions	*Provide H/care*	*Capacity Building*	*Support to health system*	*Post Trial Access*
Declaration of Helsinki (WMA)2008	✓				✓
Council for International Organisation for Medical Sciences(CIOMS) 2002	✓		✓		✓
Council for International Organisation for Medical Sciences (Epidemiology) 2007		✓			✓
National Bioethics Advisory Commission Report 2001	✓		✓		✓
Nuffield Council on Bioethics Report 2005			✓		✓
International Conference on Harmonisation –(GCP) 1996	✓				
Council of Europe 2003	✓				✓
HUGO Statement on Benefit Sharing 2000		✓	✓		
UNESCO Declaration on Bioethics and Human Rights 2005	✓	✓	✓	✓	✓
UNAIDS 2007		✓	✓		
Guidelines by the |Kenya National Council for Science & Technology 2004			✓		✓
Ethiopian National Health Research Ethics Guideline(2005)		✓			✓
National Guidelines for Ethical Conduct of Research Involving Human Subjects by the Sudanese National Ministry of Health (Directorate General of Health Planning and Research)	✓	✓			✓
Guidelines for researchers and Ethics Review Committees in Zimbabwe (Medical Research Council of Zimbabwe) (2004)	✓				✓
Ugandan Guidelines by the National Council for Science & Technology 2006			✓		✓
S. Africa MRC (2005)				✓	
Nigeria National Code of Health Research(2006)		✓	✓	✓	
Brazil 1996	✓	✓			✓
India Council on Medical Research (ICMR) Code 2000		✓	✓	✓	

1.6.5 Discussions on Benefit Sharing in Some Low and Middle Income Countries

Discussions on benefit sharing are not new to most developing countries. And some low and middle income countries, mostly in the Asia have made great strides in developing regulations for genomics research which incorporates guidance on benefit sharing (Yoshizawa et al., 2014). Many have also argued that having open discussions on benefit sharing could in fact build trust amongst all stakeholders in collaborative genomics research (Chen and Pang, 2015). The effect of failing to discuss benefit sharing in health research can be seen in the case of the avian flu vaccine research in Indonesia (Sedyaningsih et al., 2008) where the Indonesian government stopped the sharing of samples in the midst of a global influenza scare despite requirements that viral samples be shared for global good (Franklin, 2009). Though Indonesia had started sharing samples, when they learned that WHO had given isolates of the samples to an Australian company to develop a vaccine, the Indonesian government decided to not continue sharing samples until there was a global mechanism in place for the equitable sharing of the research outcomes and products with LMICs (Sedyaningsih et al., 2008, Roos, 2008). They argued that samples that were provided freely by HICs were being used by companies in wealthy countries to develop vaccines and other products that are unaffordable in LMICs and that if this was to continue, the discrepancies will become wider, the poor, poorer and the rich, richer. They therefore asked that WHO gives a guarantee that Indonesia will share in the benefits derived from research on the samples and would keep the patents. They were further disgruntled by the fact that research publications that were a result of research from H1N5 samples collected in Indonesia did not include Indonesian authors and results of analysis were being presented at international conferences without notifying the Indonesian government. Based on the reports, the Indonesian government maintained that there was a breakdown of trust. The lesson from this is the importance of having open discussions about benefit sharing in international health research. Similar experiences have been documented in Kenya (Andanda and Cook Lucas, 2007). In all, both cases led to strong calls for justice and the equitable sharing of benefits.

1.6.6 The Human Genome Organisation (HUGO) and Benefit Sharing

In the year 2000, the human genome organization released one of the most authoritative statements on benefit sharing in genomics research (Hugo Ethics Committee, 2000a). In this statement, the make suggestions for mechanisms (both monetary and non-monetary) that could be used to effect benefit sharing in human genomics research. Some of these include: technology transfer, capacity building, provision of healthcare, reimbursement of costs and using percentage of royalties for humanitarian purposes. HUGO's statement on benefit sharing received a lot of interest from the scientific community, media and industry, especially the aspect of sharing profits, that it had to release a clarification article (HUGO Ethics Committee, 2000b) that details some of their envisaged models for benefit sharing. In this article the HUGO ethics committee

acknowledges that benefit sharing could go beyond monetary profits to include improved healthcare services and at the very minimum, a thank you letter and a small token gift (where culture allows). In the clarification article (Page 88), the HUGO ethics committee writes:

"Whereas: we all share a common genetic heritage, there are different definitions of community, communities may have different beliefs about what constitutes a benefit, and genetic research should foster health for all human beings, the HUGO Ethics Committee recommends: 1) that all humanity share in, and have access to the benefits of genetic research 2) that benefits not be limited to those individuals who participated in such research 3) that there be prior discussion with groups or communities on the issue of benefit sharing 4) that even in the absence of profits, immediate health benefits as determined by community needs could be provided 5) that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation and 6) that profit-making entities dedicate a percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts".

1.6.7 H3Africa and Benefit Sharing

H3Africa makes provision for benefit sharing. In its white paper, it is stated that all projects**,** depending on the outcomes of the research, will address issues related to benefit sharing and intellectual property. In addition, the H3Africa statement on **"**High-Level Principles on Ethics, Governance and Resource Sharing **(**http://h3africa.org/about/ethics-and-governance**)** states that **"***where appropriate, research networks and programs should establish mechanisms to ensure the equitable sharing of benefits with the communities participating in the research – this might take the form of contributions to capacity and skills development, or the specification of appropriate licensing terms that ensure access to healthcare benefits derived from the research"*. Unlike other international documents and guidelines that mention benefit sharing without stating what (benefits) needs to shared, the H3Africa initiative appears to be one step ahead in suggesting appropriate forms of benefit sharing that individual projects could consider.

1.7 Study Justification

Globally, genomics research has led to novel insights into the relationship between human genetic variation and health and there is little doubt that genomics will become a mainstay in biomedical research and in contributing to the understanding of the biology of diseases (Green and Guyer, 2011). It is therefore not surprising that African researchers have taken interest in genomics research and are leading a number of African genomics initiatives as evidenced by the number of genomics studies currently being funded by the H3Africa Initiative (H3Africa Consortium, 2014) and the African Genome Variation Project (Gurdasani et al., 2015). However, this rapid growth and interest in genomics research is occurring largely in the absence of

empirical data on the ethical, legal and social issues around genomics research in Africa, most especially as it pertains to AGS.

Most of the ethical, legal and social issues surrounding genomics research are shaped by the impact of technological development and collaborative research that characterizes genomics research (Nyika, 2009). One of the key challenges relates to benefit sharing. Benefit sharing in collaborative health research is an internationally recognized concept and an important benchmark for ethical research in developing countries (Emanuel et al., 2004). However, benefit sharing has received far little attention in discussions on human genomic research despite concerns that if care is not taken, Africa may not benefit from its participation in genomics research (Brown, 2002, Ndebele and Musesengwa, 2008, Nyika, 2009). It is only until recently that benefit sharing is gaining prominence in the ethics of international collaborative research (Lairumbi et al., 2012, Lairumbi et al., 2011b) and increasingly, there are questions on how to promote research that is of benefit to Africa (Chu et al., 2014, Ndebele and Musesengwa, 2008). There are equally concerns on the appropriate approach to benefit sharing, the beneficiaries of genomics research and the dilemma of what constitutes benefit in genomics research (Dauda and Dierickx, 2013, Schroeder, 2006, Schulz-Baldes et al., 2007, Simm, 2005, Simm, 2007b).

Studies in HICs on the perception of risks and benefits in genomics research have shown that perceived benefits usually outweigh concerns about risks (Oliver et al., 2012, Tabor et al., 2012). Participants in this study described three main benefits to genomics research, namely advancement of research that will help family members, advancing research that will help others with a similar condition, and advancing general medical knowledge (cf. Page 110, Oliver et al., 2012). These two studies however did not specifically focus on the perception of risks and benefits. In Kenya, a qualitative study on benefits in health research showed that that community members were of the opinion that tokens of appreciation (e.g. cash, water purification tablets) educational materials on the related study, medical benefits, and educational benefits that could outlive the study in the communities could build trust in researcher-community relations (Njue et al., 2014, Njue et al., 2015).

A study in Ghana (Appiah-Poku et al., 2011) on the perception of research benefits in an African genetic epidemiology study on tuberculosis showed that research participants perceived the generation of new knowledge, finding the cause of diseases, as well as the control, eradication and prevention of disease as some of the benefits of participating in the study. This study included only research participants and no other stakeholders. The primary focus of the study, and the article, was to examine the understanding of and beliefs on genomics research by African research participants. This study did not also explicitly explore research participants' perceptions on benefits in genomics research. A similar study in Kenya on benefits and challenges of data

sharing in public health research showed that key benefits were concerned with the promotion of public health and challenges included fairness to primary communities in which data was collected, unfair competition between local researchers and their collaborators in HICs and the 'misuse' of data (Jao et al., 2015).

While considerable descriptive work has documented the benefits of health research, far fewer data are available on the perception of benefits in genomics research and particularly genomics research in Africa. In the face of evolving regulations and guidelines for genomics research, it is critical that we explore the perceptions and expectations of benefits (and its counterforce, risks) by key stakeholders involved in genomics research in Africa as well as their understanding of the concept of benefit sharing. The absence of an empirical understanding of how genomics research in Africa could benefit patients means that, despite good intentions, African genomics science may not manage to actuate benefits for African participants and researchers, thus failing to contribute to reducing global health disparities. A better understanding of benefits of genomics research could also generate empirical data that will inform ongoing policy discussions on what would constitute more equitable genomics research. Data on the perceived/expected risks and benefits of genomics research could provide leads on the assessment of actual benefits of genomics research and recommend practical steps on the equitable sharing of benefits to protect the interest of African researchers and research participants.

1.8 Research Question and Objectives

The research question for this study then was: “What are African researchers’ perceptions and expectations of benefits and risks of genomics research in Africa?” by:

1. Examining how benefits are explained in informed consent forms used in H3Africa genomic research;
2. Documenting African researchers’ perspectives and expectations of risks and benefits of genomics research in Africa;
3. Exploring how African researchers think the perceived benefits could be provided and the responsibility for providing such benefits.

In the next chapter, I will present the research methodology that was used to explore these research objectives.

Chapter 2 Methodology

In this chapter, I[1] will discuss the research strategy and design that we adopted for this study, the justification for selecting the design/approach and how it has guided data collection, analysis and interpretation. Firstly, I will give an introductory background to the grounded theory approach in qualitative research and why we chose this approach to explore researcher's perspectives and expectations of the benefit of human genomics research in Africa. Secondly, I will describe the data collection process which consisted mainly of sourcing informed consent documents used in different genomics research projects across Africa and one-on-one in-depth interviews with genomics researchers in Africa. I will conclude by describing the process of data analysis. In the course of writing, I will define all relevant terms as they arise in the text.

2.1 Research Design

We used qualitative research methods to explore the research objectives. This methodology was particularly appropriate because we sought to explore what participants perceived to be the benefits of human genomics science to Africa. Qualitative research methods are recommended when the research requires an exploration of what or how participants think of a phenomenon (Patton, 2002). For this study, we explored African researchers' perceptions and expectations of the benefits of African genomics sciences (AGS) by asking the following questions: 1) what are the benefits of human genomics research to Africa, 2) How could genomics research be made more beneficial for Africa and 3) What are the expectations for benefit sharing in the context of genomics research in Africa.

The strategy of qualitative inquiry that we used in designing this study is the grounded theory approach (Glaser and Strauss, 1967). Grounded theory is a qualitative research design that allows the researcher to generate a general explanation (theory) of a process or action as shaped by the views of participants (Creswell, 2009). It is a set of inductive and iterative techniques designed to identify categories and concepts within text which are then linked into theoretical models (Corbin and Strauss, 2008, Glaser and Strauss, 1967). In explaining the use of qualitative research methods and the grounded theory approach, Strauss and Corbin (1998) captures it thus

"If someone wanted to know whether one drug is more effective than another, then a double blind clinical trial would be more appropriate than grounded theory study. However, if someone wanted

[1] In this chapter, "I" is used to refer to the student investigator and "we" to the student investigator and the supervisor(s).

to know what it was like to be a participant in a drug study [..], then he or she might sensibly engage in a grounded theory project or some other type of qualitative study" (Strauss and Corbin, 1998).

Simply put, grounded theory is a set of methods based on a systematic yet flexible guidelines for collecting and analysing qualitative data with the aim of developing theories that are 'grounded' in the data (Charmaz, 2008). This process, which has been described as deceptively simple (Kvale, 1996), involves: 1) reading verbatim transcripts of interviews or data or text, 2) identifying themes, 3) comparing and contrasting themes and identifying structure among them, and 4) building theoretical models while constantly checking them against the data (Bernard and Ryan, 1998)

The primary form of data collection in the grounded theory approach is one-on-one interviews with the researcher going back and forth between data collection and data analysis (Glaser and Strauss, 1967). Memoing or memo-writing is also a key aspect of this approach and it involves writing down field notes and ideas as data is being collected and analysed (Birks et al., 2008). Memo-writing is a crucial method in grounded theory. It allowed me to constantly converse with myself, get "immersed" in the data, fine-tune data-collection and to develop my ideas in the course of data collection and analysis (Charmaz, 2008).

2.1 Research Population and Study Setting

In this section, I will give a description of the study population and explain why we chose this study population for our study. I will also provide a brief account of how sampling was done.

2.1.1 Sampling

For this study, we used both purposive sampling and theoretical sampling.

2.1.1a Purposive sampling

It is a strategy in which particular settings, persons or activities are selected deliberately in order to provide information that cannot be gotten in other ways. This method of sampling is a non-probability based strategy and it allows the researcher to focus on particular characteristics of a population that are of interest and which will best enable her to answer the research questions. Purpose sampling is widely used in qualitative research and it is aimed at selecting information-rich participants for in-depth study of a topic of interest (Patton, 1990). In our study, the chosen research participants were genomics researchers in Africa.

2.1.1b Theoretical sampling

It is a process of data collection whereby the researcher simultaneously collects and analyses the data in order to decide what data to collect next (Coyne, 1997). In this study we used theoretical sampling to identify participants (genomic researchers in Africa) that could provide more detailed information on themes that were emerging from the data and to check if new themes were still emerging.

2.1.2 Study Site

All interviews were done in two main sites. Twelve interviews were done during the fifth H3Africa Consortium meeting in Dar-es-salaam, Tanzania. This meeting is part of the H3Africa bi-annual meeting and it brings together genomics researchers from different African countries. It was therefore an ideal avenue to meet genomics researchers from different African countries. Five interviews were done in Cape Town, South Africa in a location chosen by the participants based on their convenience.

2.1.3 Study Participants

Study participants were researchers in Africa who were actively involved in human genomics research. Most of the researchers recruited into this study were members of the Human Heredity and Health in Africa (H3Africa) Consortium. This consortium is an African-led genomics research initiative with funding from the National Institute of Health, USA and the UK based charity-The Wellcome Trust (H3Africa Consortium, 2014). This group of researchers was purposively selected because we were certain that they were actively involved in genomics research and were also involved in multisite genomics projects in Africa.

I also interviewed other genomics researchers in Africa who were not part of the H3Africa consortium but who were known to be currently leading genomics research projects in Africa.

2.2 Data Collection Methods

Overall, the data collection had two main parts: 1) Sourcing informed consent documents used in ongoing genomics research projects in Africa and 2) one-on one in-depth interviews with genomics researchers in Africa.

2.2.1 Sourcing of Informed Consent Documents

H3Africa researchers were contacted by email to request copies of the informed consent documents and all supporting materials used in the recruitment of research participants at the different research sites. For ease of management of the informed consent documents we received from the investigators, all files were imported into EndnoteX7, a reference manager

software. A total of forty-one (41) informed consent documents were reviewed. Of these, three (03) were in French and thirty-eight (38) in English. These informed consent documents were for thirteen (13) different genomics projects in Africa. These projects were engaged in sample collection in twenty-two (22) African countries across multiple sites.

2.2.2 One-on-One Interviews

One-on-one interviews were the primary form of data collection. In qualitative research, an interview is often viewed as a conversation between the interviewer (researcher) and the interviewee (research participant), in which the interviewer asks questions and the interviewee responds accordingly. In this study, I did semi-structured, in-depth, one-on-one interviews with genomics researchers in Africa. These interviews were guided by a set of open ended questions (Appendix 2) developed to explore researchers' perceptions and expectations of benefits and benefit sharing in AGS. These questions however changed and improved over time based on themes that were emerging from initial data analysis and also on the professional background of the interviewee. For example, when the interviewee was a clinician-researcher, I explored more the clinical benefits of genomics research to Africa. When the interviewee was a bioinformatician, I emphasised on benefits to and risks of data sharing to Africa. The interviews were conducted in such a manner as to make it conversational. As the researcher, I first shared information about myself with the participant so as to establish the trust and rapport that is necessary for this type of conversation. Before the start of each interview, I also asked interviewees if they had any questions about the research and research procedures.

2.2.3 Pilot Interviews

The interview questions (interview guides) were pilot-tested twice, first with two genomics researchers and secondly with a bioethics researcher. This was to check if questions were suited to the objectives of the study and if they were understandable. The responses to the pilot interviews helped us to modify and further develop the interview guide which was used with the actual study population. The pilot study proved useful in providing valuable leads to be pursued in the actual in-depth interviews. All pilot interviews were done in October 2014. Two pilot interviews were done in the presence of one of my supervisors and she provided feedback for modifying questions in such a way that we could best answer the research questions.

2.2.4 Main Interviews

Interview questions explored issues regarding benefits and risks of genomics research, data and sample sharing, necessary conditions towards a more beneficial genomics research in Africa and perspectives on the ethics concept of benefit sharing

We identified genomics researchers who were working in research institutions in Africa. Most of them were part of the H3Africa consortium. Firstly, we sent emails to twenty eight (28) genomics researchers in Africa inviting them to be part of the study. In the email, I explained, briefly, the purpose of the study and the study procedures. For those who responded positively, I e-mailed the informed consent documents to them. For those who did not respond, I sent reminder emails after a reasonable period. During the face to face meetings, I again explained the study objectives and procedures to all potential participants. In cases where the potential research participants did not respond to the email but where present at the fifth H3Africa meeting in Tanzania, I approached them during the meeting and asked if they were willing to be part of the study. Some research participants were only invited to the study during the H3Africa meeting in Tanzania. In this case, it was usually after following their presentations during the meeting and deciding that having an interview with them could enrich the data. Only those who agreed to be part of the study were interviewed. The study participants were interviewed between September 2014 and June 2015. For convenience, I did most (12) of the interviews in November 2014 during the 5th H3Africa consortium meeting in Tanzania. The rest (5) of the interviews were done in Cape Town, South Africa. In total, 17 interviews were done with genomic researchers in Africa, of which three were female and 12 were male. Interviewees were based in research institutions in 8 different African countries.

Before the start of the interviews, I confirmed with the participants that they were happy to have the interview audio-recorded (this was also included in the information sheet to study participants). This was to ensure accurate transcription. In the course of the interviews, I also took hand written notes. This was to record important points emerging from the interviewees and to follow up these emerging themes with the interviewee or other interviewees

All the interview questions were open ended. This allowed for research participants to respond freely and openly to all the questions (Jacob and Furgerson, 2012, Kvale, 1996). It also allowed for probing and/or follow-up questions when necessary. This was to encourage interviewees to elaborate on and/or clarify a response to a question (Denzin and Lincoln, 2005)

On a whole, in-depth interviews provide deep insights into a research topic. Such insights are generally not available to researchers working with large survey samples. It could also direct the design of quantitative surveys on the study topic. They are known to be the most suitable approach when seeking rich data that highlights individual perceptions and expectations of the topic under study.

2.2.5 Memo-Writing

As stated above, memo writing constitutes a major aspect of qualitative research. In the course of data collection and analysis, I kept field notes and memos. After most interviews, I reflected on the conversation and wrote down what my thoughts were about the interview. These were usually notes to myself about themes that were emerging strongly from the interviews and why the interviewee would have perceived it as such. For example, the perceptions and expectations of a clinician-scientist and his on a particular aspect of genomics research could differ from that of bioinformatician without a background in medicine.

Some of the memos were about the progress of the study and the different changes made during the data collection process following discussions with my supervisor and/or themes that were emerging in the preliminary analysis. For example, as I progressed with data collection, I wrote "*following discussions with my supervisor, we have decided that based on the data we already have with one category of interviewees, it may be better to stick with that category until we attain saturation, rather than bring in a new category. This is also essential for the feasibility of the study. However, I would have loved to work with this category and this maybe lines for future research in the study area-affaire a suivre*".

Also, in discussing this research with other experts in the field, I took memos of their suggestions on the study topic. In some instances, this helped improved on the interview guide. For example, one expert in bioethics suggested that it was important to explore the conditions that had to be in place for Africa to benefit from genomics research. This was incorporated in all the interviews that followed and eventually formed a critical part of the data analysis.

The memos not only helped in improving data collection but also informed the literature review section of this thesis. For example, after one of the interviews, I noted that the interviewee frequently made reference to how other LMICs in Asia have embraced genomics science and are using it for the benefit of their people. This has helped in designing the literature review with a section of benefit sharing discussions in other low and middle countries.

In the course of transcribing, I also kept notes. These notes where useful in identifying concepts that were emerging and how they relate to each other (Birks et al., 2008). It also helped in identifying potential areas worth exploring in the next interviews. Sometimes these were just unanswered questions to myself.

The field notes and memos were also brought in during the analysis process. Generally, I used memo writing to ensure that I retained thoughts which would otherwise have been lost (Glaser, 1978).

2.3 Data Analysis

We did a thematic analysis of the interview transcripts with the objective of identifying, examining and recording themes within the data. Thematic analysis is the most common form of analysis in qualitative research and data analysis. it is usually structured and entails developing open categories and detailing additional categories with the aim of developing a theory or explanation(Thomas and Harden, 2008). This theory is then represented as a diagram, a hypothesis or as a discussion (Strauss and Corbin, 1998). As already stated above, this study was designed using the grounded theory approach to qualitative research studies. This approach requires back and forth movement between data collection and analysis. This allows for the identification of patterns that are emerging from the data and also in informing subsequent data collection (Strauss and Corbin, 1998). It is for this reason that I started data analysis following the first few in-depth interviews.

The first stage of data analysis began with the transcription of interviews. This was done verbatim from the audio recordings. To ensure accuracy of the transcript, after completion of the transcription, I reviewed the transcript while listening to the audiotapes. In some instances, some sections of the recordings were not clear and this made transcription of the section difficult. When it was the case, I indicated it in the transcript using "….."

I also listened to all the interviews at least twice and read printed versions of the transcripts a number of times. The aim of this process was to "get to know" the data and to gain a general sense of and insight to the information and ideas that the interviewees were conveying. The purpose of this approach is to familiarise or become intimate with one's data and it has been recommended by a number of authors (Charmaz, 2008, Creswell, 2009, Patton, 1990).

NVivo 10, (QSR International Pty Ltd, 2012), a qualitative data analysis software was used to support and facilitate data analysis. All transcripts and informed consent documents were imported into the software for further analysis.

2.3.1 Coding

I used inductive thematic coding for data analysis. The purpose of thematic analysis is to identify patterns of meaning across a dataset which provides an answer to the research question (Braun and Clarke, 2006, Ritchie et al., 2013). These patterns are identified through a rigorous process of data familiarisation, data coding and the development and revision of themes.

Codes are defined as labels that assign symbolic meaning to descriptive information compiled during a study and are usually attached to chunks of data of varying sizes (Miles et al., 2014).

They are usually a word or a short phrase that is symbolically assigned to the data (interview transcripts, field notes, pictures) under study (Saldana, 2013).

During the data coding process, I started with open coding. This allowed me to heuristically develop codes as I moved along with data collection and to ensure that the codes were empirically grounded in the data (Figure 4). This coding scheme led to the development of both parent and child nodes. For example, there was a parent node on "Requirements for beneficial genomics for Africa" and child nodes that included: translation, community engagement, science education etc.

Figure 4: Screenshot showing nodes after first round of coding

Name	Sources	References	Created On	Created By
Arguments for benefit sharing	1	1	3/4/2015 11:25 PM	NSM
Aspirational benefits	2	8	3/4/2015 4:01 PM	NSM
Attitude towards benefit sharing	2	4	3/4/2015 8:57 PM	NSM
Awareness of benefit sharing	1	1	3/4/2015 7:43 PM	NSM
Benefit to research participants	2	2	3/4/2015 9:10 PM	NSM
Benefit to the scientific community	2	4	3/4/2015 3:56 PM	NSM
Benefits of data and sample sharing	1	2	3/4/2015 7:31 PM	NSM
Clinical benefits	2	6	3/4/2015 4:04 PM	NSM
Conditions required for Africa to Benefit	2	12	3/4/2015 3:59 PM	NSM
Responsibilities	2	4	3/4/2015 8:40 PM	NSM
Cost of genomics technology	1	4	3/4/2015 10:54 PM	NSM
Examples of genomicsor genetics in the clinic	1	1	3/4/2015 4:06 PM	NSM
Experience in genomics	1	1	3/4/2015 9:35 PM	NSM
General benefits	2	3	3/4/2015 3:55 PM	NSM
H3Africa and Benefit sharing	1	1	3/4/2015 9:01 PM	NSM
H3Africa related benefits	2	4	3/4/2015 4:08 PM	NSM
Key actors for benefit sharing discussions	2	5	3/4/2015 8:17 PM	NSM
Limitations to pragmatic benefit sharing in Africa	2	3	3/4/2015 8:35 PM	NSM
Measures to be taken	2	10	3/4/2015 9:06 PM	NSM
perspectives on Hugo's statement	2	3	3/4/2015 7:48 PM	NSM
Disagreements	0	0	3/4/2015 8:06 PM	NSM
Limitations	2	5	3/4/2015 8:05 PM	NSM
Support for HUGO	2	3	3/4/2015 8:06 PM	NSM
Project-related benefits	2	3	3/4/2015 8:26 PM	NSM
Recommended forms of benefit sharing	2	10	3/4/2015 8:14 PM	NSM
Research and Profit	1	1	3/4/2015 11:16 PM	NSM
Risk to participants	1	4	3/4/2015 4:22 PM	NSM
Risk to research participants	1	1	3/4/2015 7:35 PM	NSM
Risk to researchers	2	3	3/4/2015 7:37 PM	NSM
Risks to community	2	4	3/4/2015 9:08 PM	NSM
Suggestions on how genomics research could be made more beneficial	2	3	3/4/2015 8:56 PM	NSM
Support for discussion on Benefits	1	1	3/4/2015 8:23 PM	NSM

After this first round of coding, I discussed the definition of codes with my supervisors. Following the discussions, we improved on and fine-tuned the codes. Some codes were condensed into a single code, others were deleted. After this, we, separately, coded the same dataset using the codes from the first round of coding. We discussed our differences, harmonized and improved on the definition of the codes. During this second round of coding, new codes also emerged from the data.

We again, separately, did a third round of coding on the same dataset (but different from that used in the second round of coding). We then checked if we used, roughly, the same codes for the same chunk of data and if the coding scheme we had at the moment was working for us when we coded separately. At this stage, we realized that there were very slight differences in the coding. All differences were again discussed and an agreement reached within the team. I then applied the revised and final coding scheme to the remainder of the interview transcripts and informed consent documents. Team coding allows not only for the clarification of code definitions but also serves as a good reliability check to ensure that team members have an unequivocal and common vision of what codes mean and which section of the data best fits the codes (Miles et al., 2014)

For codes that had huge data sets, Microsoft Excel 2013 was used to further break up the codes and to critically identify very specific content. For example, Microsoft excel was used to further split the code “Key players for benefit sharing”, in a bid to identify the key players e.g. government leaders, patient organisations, researchers, research ethics committees, community advisory boards etc. We had avoided this in the NVivo coding as this would have led to fractionation of the data. Figure 5 shows a screenshot of the final coding scheme

Figure 5: Screenshot of Nodes after Second Round of Coding

Name		Sources	References
Africa Genomics Science		13	26
Benefit Sharing for Genomic Research in Africa		0	0
Awareness		16	41
Benefit sharing justifications		8	13
Challenges for benefit sharing		14	27
Forms of benefit sharing		14	36
H3Africa and Benefit sharing		3	4
Key Players		12	32
Recommendations for Benefit Sharing in Africa		16	50
Benefits of Genomic research in Africa		2	2
Advancement of science		12	31
Capacity Building		14	40
Economic Benefits		6	8
Examples of Genomics in the Clinic in Africa		14	21
H3Africa related benefits		14	40
Health-related benefits		17	49
Research Cooperation		9	21
Science education and community engagement		4	9
Data and sample sharing		16	50
Demographics		17	19
Generic and interesting		14	29
'More Beneficial' Genomics in Africa		20	124
Perspectives on HUGO statement on Benefit sharing		15	24
Research and commercialisation		10	23
Risks		17	41

2.4 The Researcher's Position

Qualitative research interviews usually require considerable interviewing skills on the part of the researcher. Coming from the biomedical sciences, I had very little experience in qualitative research and most of the previous empirical work I had done had employed quantitative research methods. To achieve the transition from quantitative to qualitative research methods, I familiarised myself with the literature on qualitative research methods. This was done under the guidance of my supervisor.

As a novice in qualitative research, I also had to closely monitor my interviewing skills, critically appraise the interviews and ask others for comments on whether I was asking the right questions, whether I was able to easily pick up clues are and if I gave interviewees enough time to respond to the questions (Britten, 1995, Patton, 1990). To achieve this, I did two mock interviews with PhD students involved in genomics research. This was done in the presence of my supervisor. For each interview, she provided feedback on my interviewing skills and highlighted the areas that

needed improvement. This process helped improve on my interview skills. After this stage, I did all the interviews, both pilot and main interviews alone and discussed emerging themes with my supervisor.

As an H3Africa trainee interviewing H3Africa researchers, most times it was hard to decipher if the research participants accepted to be part of the research because they were all part of the H3Africa Consortium and if they thought this was some sort of an evaluation. I therefore had the duty of establishing rapport with the interviewees, but at the same time ensure that I maintained neutrality with regards to the responses of the interviewee (Patton, 2002). Most times I did this by either nodding my head when the interviewee was speaking or intercepted with words like "yeah", "okay" and "right". In other cases, I provided feedback with the aim of letting the interviewee know that the purpose of the interview was being fulfilled, that that this was not wasted time and that they were providing some very useful information. For this purpose I used phrases like, "This is the first time I am hearing of that", "I have never thought of it in that way" etc.

2.5 Ethical Considerations

Before the start of the study, we applied for and obtained research ethics clearance (appendix 3) from the University of Cape Town, Faculty of Health Science Research Ethics Committee. This approval was obtained in September 2014. Before the interviews, I sent, by email, information on the study objectives and procedures to research participants. In most cases, this was done at least two days before the interviews. The aim of sending information sheet to research participants prior to the interview was so that they could make, first hand, an informed decision of whether or not they would like to be part of the study. At the start of the interview proper, I also explained the study procedures to the research participants, informed them of their right to withdraw from the study at any time (before publication of results), that their participation in the study was entirely voluntary, assured them that confidentiality will be maintained and asked if they were still willing to be part of the study. After this, the participants were asked if they were still willing to be part of the research study and if they were okay that the interviews be audio-taped. If they were, I requested that they provide written informed consent. After the interviews, participants were reminded that they could still withdraw from the study at any time before the results were published or written up as a thesis.

All audio recordings and informed consent forms were available to the student and the supervisor only. Once the interviews were transcribed all sources of identification were removed and replaced with codes. For example, names were replaced with R-01, R-12 R-17 (R= Researcher or interviewee ; R01= Researcher or interviewee 1) etc., names of countries were replaced with

"Country X", "Country Y" and names of projects with "Project A", "Project B" etc. This was to ensure that confidentiality was maintained at the highest possible standard.

2.6 Study Limitations

In the course of data collection, it was hard to tell if the researchers felt obliged to participate in the study especially as most of them they were Principal Investigators or co-investigators within the H3Africa consortium. This was also so because I am a student on an H3Africa Project. However, I constantly reminded interviewees that this was a research study and not an evaluation and that responses would be kept confidential.

Also, and as stated above, most of the interviews were done during the 5th H3Africa Consortium meeting. This meeting had a pre-conference workshop on sickle cell anaemia and a dinner presentation on the 2014 Ebola Epidemic in West Africa. These two events may have had an influence on the examples interviewees gave of the clinical benefits of genomics research to Africa.

Another limitation of this study is that five of the seventeen interviews were done with South African based researchers. This may appear as an over representation of South African based researchers. However, of the twenty-one (21) H3Africa projects at the time of this study, the principal investigators of ten (10) projects (almost half the total number of projects) are based in research institutions in South Africa. This therefore accounts for the relative large representation (5/17) of South Africa based researchers in the study.

Equally, a study on benefits and risks of AGS should ideally capture the perspectives of key stakeholders: research participants, researchers, REC members and the funders/sponsors of the research. For reasons of feasibility, this current study could only focus on one major stakeholder; genomics researchers. However, a few studies have captured the views of other key stakeholders. Our study will further build on this and provide grounds for expanding the study to other stakeholders.

2.7 Summary

In this chapter, I have introduced and discussed the study methodology and provided a rationale for the choice of this methodology. I also presented the qualitative research that I used in this study which includes: purposive sampling, semi-structured one on-one interviews, memo writing and a systematic and concurrent data collection and data analysis procedure. In the next chapter, I will present the findings of this study.

Chapter 3 International Research Collaboration: A Benefit of African Genomics Science

In the literature review chapter, I presented the characteristics of African Genomics Science (AGS) and showed that most genomics research projects in Africa are sponsored by funding agencies in Europe and America and involve north-south and south-south collaborations. Collaboration in scientific research, especially for complex studies like genomic research, is on the rise. Usually these collaborations are between researchers in scientifically advanced countries in Europe and America and researchers in LMICs, in what is commonly referred to as north-south collaborations.

North-south research collaborations are seen to be beneficial for both sponsoring countries and host countries. In LMICs, collaboration is believed to enhance scientific capacity through the transfer of expertise, the provision of research facilities and access to funding for researchers in LMICs (Wagner et al., 2001, Oldham, 2005). For scientifically advanced countries, it could facilitate access to research participants (Schulz-Baldes et al., 2007) and to unique sites and populations (Oldham, 2005).

However, international research collaboration is not without debate in terms of its risks and benefits. As may be expected, the literature is filled with theory-based debates on the ethics of externally funded collaborative research in Africa (Costello and Zumla, 2000, Edejer, 1999, Robison, 1998, Caballero, 2002). Many argue that north-south research collaborations tend to be asymmetrical and for the advantage of researchers in developed countries who benefit from the publications, scientific advancement and patents while their African counterparts are reduced to sample collectors (Musolino et al., 2015, Wonkam et al., 2011a). These inequalities in north-south collaborations has led to a perceived risk of exploitation (Chu et al., 2014).

Exploitation in collaborative research occurs when the benefits and risks of research are unfairly distributed (Ballantyne, 2005). However, there is no consensus on what constitutes fairness in international collaborative research in Africa. In our study, most African genomics researchers echoed this fear of exploitation and suggested what they think needs to be done to ensure AGS is equitable and fair. In this chapter, I present the perceptions and expectations of African genomics researchers on the benefits and risks of AGS.

3.1 Advancement of AGS

The first benefit of AGS as expressed by all interviewees is that it would lead to the advancement of science in general, and genomics science in particular. This would be through having a clear understanding of the role of human genetic inheritance in health. In the literature, proponents of AGS argue that the past few years has seen major advances in understanding the genetic basis of disease in populations of European descent yet this progress has not been matched by similar genomics studies in sub-Saharan Africa (Gurdasani et al., 2015, Rosenberg et al., 2010, H3Africa Consortium, 2014). This viewpoint was echoed by many scientists interviewed as part of this study. They were of the opinion that having a dedicated AGS project would ensure that Africa is on the same level, in terms of human genomics research, as other parts of the world.

> *This opportunity will allow us to bring genomics in Africa to a level that is comparable to other parts of the world and it could potentially lead to new therapies and treatment strategies that are relevant, needed in Africa for which we couldn't do by using results from genomics research from other parts of the world either because of the differences in the inheritability of the different conditions in Africa compared to other parts of the world or because of the gene-environment interactions in different parts of Africa and that is different from what you see in other parts of the world (R-01)*

Research into the genetic basis of disease requires high-throughput genotyping technologies, large sample sizes and an understanding of human genome sequence variation. Interviewees were of the opinion that Africa has this rich genetic diversity and that AGS could result in the design of health interventions that are more responsive to African populations.

> *Africa is simply the origin of humans, it has a very vast reservoir of genetic diversity, so I think if we understand the diversity within us, this will open up avenues for better control of disease because the whole diversity is here, so if you can find some useful genetic markers it will beneficial for understanding diseases in Africa.(R-08)*

While on the one hand, Africa has a rich genetic diversity and could easily provide access to large sample sizes needed for population genomics studies, because of the unfortunate disease burden in the continent (Schulz-Baldes et al., 2007),on the other, it lacks the technology needed for genome wide association studies (Nyika, 2009). Interviewees described this unfortunate situation and were of the opinion that they way out is to collaborate with researchers in scientifically advanced countries who have the required technology but may not have easy access to large

samples sizes and populations that exhibit a rich genetic diversity. By collaborating, each person would be contributing one thing or the other.

> *This part of the world has not got the necessary equipment to carry out certain experiments. The way to go is to collaborate. By collaborating, each individual group brings in particular expertise. So if we are working on African genomics then the first thing that the African scientists can bring in is the African genome and then the other people can come in from other sides and bring in their expertise and all that. (R-17)*

The above quote show that African genomics scientists acknowledge the need for collaboration and that by collaborating with researchers and funders in scientifically advanced countries, African scientists and institutions would benefit from funding as well as knowledge and technology transfer. Despite these perceived benefits of collaboration, interviewees voiced two main challenges for African Genomics Science, namely: 1) The risk of exploitation and 2) the non-sustainability of current African genomics initiatives.

3.2 The Risk of Exploitation

As initially stated, exploitation in collaborative research occurs when the benefits and risks of research are unfairly distributed (Ballantyne, 2005). In the interviews, two main groups were identified as being vulnerable to exploitation, namely: African research participants and African genomics researchers.

In terms of exploitation of research participants, many bioethics commentators have focused attention on clinical research. The arguments have mostly been around standard of care for research participants and access to post trial benefits (Wendler et al., 2004, Emanuel et al., 2004). In our study, exploitation of research participants was mostly expressed in terms of withholding information on the risks of participating in genomics research. Interviewees were of the opinion that research participants are vulnerable to exploitation if researchers are deceptive and fail to inform research participants of the potential risks of human genomics research.

> *People could be deceptive, not giving proper information, and then at the end of the day, it is too late, and I think you know, people need to be told all the possible negative consequences and medical consequences of these research and all that, which may not be the case (R-10)*

While withholding information from research participants could, in part, be due to challenges in conveying research procedures to participants and the pressure to recruit desired sample sizes before the end of a funding period, for some researchers, the risks of exploitation of study participants is exacerbated by the problem of weak research oversight systems in most African countries. For them, this is even made worse by low health and research literacy levels in African countries especially in rural areas.

> *There is always the risk, you know, the risks of manipulating genes. We don't have strong IRBs in many African countries, we don't have strong communities that can say that, you know, this is not good. So in many cases, sometimes what happens is that people can be tricked because they need to get some medicines. Unless like I said we build the capacity of African institutions, African IRBs, you know we don't have strong institutional review boards that can challenge and follow up, what is ongoing in these studies (R-10)*

In terms of exploitation of African researchers, this was always expressed in relation to north-south collaborations as opposed to south-south collaborations. When interviewees talked about the risks of exploitation of African researchers, it was always associated to past experiences of north-south collaborations whereby foreign (non-African) researchers obtained biological samples from Africa without the intention to develop scientific capacity in the continent, in what has been often be described as safari science or parachute research (Harris, 2004). Some interviewees therefore felt that if care is not taken, African scientists, in current African genomics initiatives could be reduced to sample collectors.

> *It could be that African researchers, as it has happened before, are just being used for collecting materials and that is a very big potential because if you don't have capacity to analyse, make sense out of it, you just collect the material and the data and send it to people who can analyse and that could be a benefit not only for publication of an article but longer term benefit of patents and discoveries. Things are being discovered. Those are some of the potential risks. (R-07)*

One of the major factors that could escalate exploitation of African genomics scientists was the notion that most African research institutions have limited human and infrastructural capacity for genomics research compared to their counterparts in scientifically advanced countries.

> *Our capacity just to handle the data first, to analyse them, to handle the sample, to analyse them or even to have research means in terms of funding after H3Africa to take advantage of those samples or data is by far limited as compared to our international partners that are in the same project. Despite the fact that, people seem very sensible to the fact that we should be given a little bit of time to publish our data first before the data is made available or the sample is made available to other international scientists, but clearly we will never have the same capacity and funding that investigators in the US or Europe will have. So clearly, we might in some areas or in some projects be left behind because of that and I think we really need to have this discussion as open as possible so that once again we don't end up being exploited as H3Africa (R-05)*

These views corroborate the asymmetry of collaboration in international research conducted in LMICs and how this exposes researchers in LMIC to exploitation (Musolino et al., 2015, Silverman, 2005)

3.3 Non-Sustainability of AGS

The second risk of AGS as expressed by interviewees is the non-sustainability of ongoing genomics research in Africa. The literature has a number of philosophical debates on how non-sustainability of collaborative health research in Africa galvanizes the risks of exploitation and the phenomenon of safari science or parachute research (Harris, 2004). Some African researchers are of the opinion that sometimes they feel like "poor prostitutes" always having to move where money is (Wolffers et al., 1998). This view was articulated by the majority of the African genomics researchers I interviewed. These researchers felt that the non-sustainability of AGS would mean that African researchers have to continue seeking for new collaborations, the risk being that they would end up following the research agenda of northern collaborators and funding organisations.

> *African researchers establish collaboration where money is, so they will follow international investors in Europe and in America. But the danger to that is that they will be working on a question that is designed by European and American investigators and not on their own questions. So they will be working for the research questions of those collaborators. So what will happen if we design our own research questions to take advantage of the biobank? Will we still be able to have the amount of funding as we are having now in H3Africa to respond to our own question? So, clearly, African governments, African research agencies have to make sure that they advantage of these biobank, otherwise you will see that after H3Africa that the biobanks will benefit more the international scientists because they will have more resources, they will have more personnel and we might end up be working in collaboration again with international scientists on their agenda and not our agenda (R-05)*

As expressed by the researcher above, there is a strong feeling of uncertainty amongst African genomics researchers on continued funding for AGS. This is so because current funding for AGS is predominately from funding agencies in the North. And interviewees felt that this puts them more at risk should current funders stop funding AGS after biobanks have been established. When interviewees expressed these fears of uncertainty about funding, it was clear that the major fear was one of exploitation.

> *I think the funding was just for three years. But if they decide now to stop the funding we are in trouble. And genetic research will not serve for anything for us. I will just think that these guys, they wanted just to get DNA from us and that is all. (R-09)*

Also, fears of non-sustainable funding system for AGS once sample collection for current genomics initiatives is over coupled with Africa's limited capacity for biomedical research, compounded fears of exploitation. Some interviewees were therefore of the opinion that non-sustainability of the initiatives could mean that AGS would be to the advantage of their Northern collaborators.

> *There is always the danger that those outside Africa will take better advantage of the data and the specimens, better and at the expense of African investigators who are working with limited resources and I don't know how we can make those type of things better rather than to put in place policies that will try to minimize that this happens. (R-01)*

A complication is that the benefits of genomics research are likely to be in the long term when there is a clear understanding of the role of human heredity in health and AGS is moved past the lab to translation phase. For some interviewees, this opens more room for exploitation. The non-sustainability of African genomics projects and the lack of capacity for biomedical research would mean that they will not be part of innovative and commercial developments that are the outcome of AGS. This will imply that current research would at later stages, accumulate wealth and scientific advancement for people in developing countries. This was mostly expressed in terms of IPs and patents

> *I guess one of the other thing is the IP exploitation, right, using this research to generate wealth for countries and companies outside Africa and the same too for academic institutions. They are gonna generate academic advancement for people in other countries which does not necessarily apply the same here (R-12)*

To further demonstrate how this could make African populations vulnerable to exploitation, one interview mentioned how the CT scan, which was developed in Africa, was patented in Europe at the expense of the African continent. Some interviewees felt that this was so because there is always a disproportionate advantage in international collaborations often in favour of northern collaborators.

> *R-17: We know that in terms of research, there has been a disproportionate advantage. The west has been benefiting, examples are here at X, we have work that was done on the CT scan, you know, the CT scan was discovered here but it was patented in a western country. There are lots of examples where things just go. That I do worry much in terms of patents, I think there must be strong agreements to say if there is anything that is discovered on that, an African researcher must be linked to that.*

3.4 The Way Forward: Achieving Fairness for the Benefit of Africa

The expressed fears of exploitation would have to be allayed in order to establish trust in north-south collaborations set up as part of AGS. For some bioethics commentators, fears of exploitation in international collaborations could be curbed if there is a mechanism in place to ensure fairness (Kilama, 2003, Silverman, 2005) and this suggestion has been extended to the discourse in collaborative genomics research in LMICs (de Vries et al., 2015b, Mduluza et al., 2013). Some authors (Costello and Zumla, 2000) and funding institutions in the north (e.g. the Netherlands Development Assistance Research Council, the Swiss Commission for Research Partnerships with Developing Countries) have even proposed theoretical models that could be used by researchers in HICs when they collaborate with researchers in LMICs. However, there is no empirically grounded information on how these could be achieved in the context of collaborative health research in Africa and more so for human genomics research. In the interviews conducted as part of this study, African genomics researchers expressed the desire for fairness in collaborations set up as part of AGS. They suggested a number of ways that fairness and justice could be achieved. These include: a) enhancing research oversight b) effective community engagement in host countries c) transparency and centralized decision making, d) equity in collaborations, and e) ownership and leadership of AGS by Africans, f) ensuring sustainability of AGS

A. Enhancing research oversight in Africa

Interviewees mostly expressed the need for appropriate oversight of research in terms of building capacity for research ethics review in Africa and for the informed consent process for genomics studies to carefully detail study procedures and risks and benefits of genomics research. Interviewees were of the opinion that capacity building for research ethics review in Africa would be important for ensuring that there are checks and balances for curbing exploitation of African research participants, communities and researchers.

> *I mean in ethics, they have been challenged to think far beyond just the compensation for travel, for time and everything and now we are going back to genes and our family and heredity challenges. So even our ethics communities have been touched to think far more (R-13)*

Another way of overcoming exploitation, as expressed by interviewees, was having regulations in place for genomics research in Africa. The problem of weak regulatory systems for biomedical research in Africa has been documented elsewhere (Caballero, 2002, Staunton and Moodley, 2013). In the interviews, African researchers were of the opinion that this would have to be addressed.

I think the laws in many African countries are very weak or are non-existent in terms of regulating genomics research. So I think there has to be steps taken to ensure that lack of a regulatory system is not taken advantage of. (R-02)

In terms of informed consent, a content analysis of informed consent documents used in H3Africa genomics projects revealed that all consent forms had a statement on the risk and benefits of genomics research to study participants. A majority of the forms usually had risks explained in terms of slight pain in collecting blood and loss of confidentiality and benefits included access to healthcare services. Equally, these consent forms explained concepts in genetics and genomics in different ways with the aim of increasing comprehension. The results of the analysis have been documented in a journal article (see Appendix 4) on informed consent for genomics research in Africa (Munung et al., 2015-In press) and some would be reported in this dissertation under the health benefits of AGS (Chapter5).

B. Community engagement

The important contribution of communities to health research and genomics research has been discussed by some authors (Marsh et al., 2011, Campbell et al., 2015, Tindana et al., 2015) and this was resonated by interviewees. African researchers expressed the need for effective community engagement as a means of checking exploitation of host communities. Based on interviewees' perspectives, community engagement for genomics research in Africa would ensure adequate buy-in of research projects and also give study participants and host communities a voice in the discussions on African genomics. This they believed would also be important in building trust between researchers and study communities

I think it again comes back to how much the people participating in the research have a voice, have the knowledge of exactly what the research entails and then a voice in saying how these things should not be used. But, when there is that gap between people who are doing the research and people taking part in it, then that communication may not be as balance and equal, that I think maybe is one of the reasons why they are H3Africa is involving African researchers and African institutions in the hope that they will represent their participants. They will represent the people who are being studied in a better way, there will be a voice. I think we also need to go back to the communities, there are a lot of different interest groups, not everyone might be talking to everyone. (R-04)

Despite the perceived importance of community engagement, some interviewees felt that community engagement for many African genomics projects is not as active as they would want. For some interviewees, this was because current funding does not take into consideration

community engagement activities. They therefore hoped that funders would be able to consider community engagement initiatives as integral parts of projects.

> *I think that there is a limitation in terms of funding, because the donors or sponsors of such studies don't necessarily grant money towards community engagement. So even for our own projects, the community engagement outreach has been sponsored separately not with study funds but with external funding and fund raising. So I think that donors, like the NIH could consider funding community engagement activities as part of the funding towards the studies. (R-02)*

C. Transparency: Setting rules of engagement and centralized decision making

As stated above, allaying fears of exploitation and building trust would be key for a successful AGS. Another way of achieving this as suggested by interviewees was to ensure that there is transparency in the collaborations. For some interviewees this would require that the rules of engagement be developed.

> *I think importantly around developing the rules of engagement, so, making sure that Africa benefits from the research, not just H3Africa research but that this kind of work done in Africa, I mean, setting the pace, that this is how genomics research should be done in Africa so that Africa benefits (R-12)*

Some interviewees further stressed that these discussions on the rules of engagement should be open and documented and that this should be done even at high policy levels such as the African Union.

> *I think we need to sign charters, put something on paper, written so we know everything and we are not just talking about benefits but have it on paper so that we have a document that binds us to this, rather than just say, okay, there will be this benefit. But if there is no document, then there is nothing binding. It is something that we should do, even if it means putting up such a charter at the AU, because it will be binding and we have the mandate. There is an example back in the university where she was collaborating with this guy. They had drafted a document which gives them processes to follow. So people have to be sensitized, they have to be careful but it is important to sign this necessary documents and you need to consult a legal expert. (R-08)*

Recently, some authors have recorded how collaborators in the north have often dictated what needs to be done and in some cases said their southern collaborators were hired to do research and should implement as requested (Moyi Okwaro and Geissler, 2015b). In our study, it would appear that interviewees would not want such a scenario especially as they expressed need for African scientists to be involved in all central decision making on the use of samples collected as

part of genomics research in Africa and for African authors to be involved in publications that emanate from the secondary use of these samples. This also highlights fears of non-sustainability of AGS and that African scientists would be left out in the long run.

> *There should also be regulatory procedures that will make sure that the African scientists are involved and are central to any decision involving the use of the samples and are actually involved in the publications and the intellectual property that emanates from such processes. African scientists should be at the centre of all of this. So it is not disadvantaging anyone (R-06)*

D. Equity in research collaborations

Another way of curbing exploitation and achieving fairness, as suggested by interviewees, was for there to be equity in collaborations set up as part of AGS.

> *If at the negotiation table we are not on the same platform, you know, it will not really be fair. That is the only thing I can say. So if they are talking about sample sharing, it should not be done in an unfair manner such that the intellectual property is lost outside the continent (R-06)*

These would require that African researchers are not just perceived as sample collectors by their southern collaborators but that collaborators be at the same intellectual level. When one interviewee talked about this, it was also in light of past experiences of north-south collaborations. Interviewees however felt that this can only happen if there is capacity building in terms of training for African scientists.

> *We must have a critical mass of people who can talk the language of genomics, who can, you know, when there is collaboration their participation is equal. Because, I think we have seen too much of the scenario where people just come to Africa to collect the samples and African scientists are collecting and characterizing but they are not actually involved in the genomics studies which are downstream. All of that is done by the partner in the western world. And I think we need to make sure that we can be more equal in terms of our partnerships. Maybe not in terms of funding but certainly in terms of intellectual contribution. (R-03)*

E. African ownership and leadership of AGS

The perceived fears of exploitation also led to the expressed need for African ownership and leadership of AGS. For most interviewees, it was now time for Africa to take the bull by the horn and lead genomics studies on African populations.

> *Because I think that African genomics studies need to be interpreted and contextualized in as far as an African based person understands the scenario. I think that is really important (R-02)*

This was also expressed in the feeling that it wouldn't be appropriate for strangers (the western world) to be lead in discussions on AGS

> *Well I think that it [African ownership] is a good idea in the sense that we will not have a stranger telling us our story that is the positive part of it. (R-16)*

Thirdly there was the expressed wish for AGS to be led by African scientists, a suggestion that has also been echoed by a number of funding agencies. This was expressed by some interviewees who felt that current African genomics initiatives such as the H3Africa the projects are truly led by Africans.

> *First of all, African scientists should be involved in doing this research. It should not be research that comes from outside Africa, being implemented by non-Africans researchers in Africa. (R-14)*

This perception is similar to what Okwaro and Geisler reported in a recent ethnographic study on scientific collaborations in transnational HIV research where the term "local PI is increasingly being used as a way of showing local leadership of research whilst they are being used to implement projects designed by northern collaborators (Moyi Okwaro and Geissler, 2015a). This point was projected in the interviews done as part of this study with some interviewees of the opinion that in current genomics initiatives, some African scientists are being used as PIs to fulfil funding requirements (of an African PI) meanwhile the research agendas are those of non-African scientists.

> *What we know is there is a lot of non-African PI led work happening within and not African P.Is doing the critical thinking when that is what we should be spearheading for, writing grants. So normally we get an African person as the lead investigator because they need to do that politically, because the grant writing agency requires that. So the idea is generated out of Africa and the science is led in Africa. (R-12)*

This highlights fears of African scientists being used as field workers, in these collaborations.

F. Ensuring sustainability

Based on interviewees' perspectives, the sustainability of AGS would require commitment and funding from a number of stakeholders including African governments, funding agencies and genomics researchers.

In terms of commitment of African governments, interviewees felt that African governments and agencies can no longer take a fence seat. Even when this is not through providing funds for research, they expected that their governments would be beneficiaries of the information on the benefit of AGS and thereby work with African scientists in creating research-friendly environments. This they felt could be through formulating policies that would prevent exploitation of African scientists and communities.

> *The government needs to be involved because the government plays an outside role in most African countries. So without the government, even if they are not going to help with the funding, it is important that they should be made aware that is possible to do it. In terms of policies and support, they are important. (R-11)*

Some interviewees were of the opinion that taking a fence seat would also mean that African research communities would have no choice than to accept any offer that comes from their northern partners even when it is not for the benefit of Africa. They therefore expected African governments to set aside funding for genomics research.

> *African governments should try as much as possible to set budget for community research, genetic research. Otherwise it becomes like something that has come from abroad and whatever they do, we will take it because they are the ones who are giving the money. (R-10)*

Secondly, some interviewees were of the opinion that current funders of AGS could address worries of non-sustainability through providing funding for follow-up of current projects and for maintaining biobanks established as part of AGS. One interviewee proposed a model that could be used by H3Africa, which is through gradually decreasing funding instead of a sharp cut-off once sample collection is over.

> *I worry a lot about sustainability of the biorepositories, I worry about sustainability of the scientific systems. We need to make sure that we can sustain this in the long term. I think it will be much easier to do that if there was a long term commitment from the funding agencies somehow, you know, it doesn't have to be a 100%, it could be on a sliding scale where it decreases with time. I think this is not something which works in a 5 year grant. That is*

very very dangerous. If NIH just says this not their priority anymore, it doesn't want to renew the scheme then I think a lot of it is just gonna collapse. (R-12)

It is a combination of all these that some interviewees felt that the benefits to Africa of current African genomics initiatives would have to be measured by the impact of these collaborations and the sustainability of current African genomics initiatives

R-17: I think what I want to say is that H3Africa would be different from other consortiums that have come and we should start to see from 5 years that this is actually a revolutionary program otherwise it would tend out to be one of those things that was an organized way to really collect samples from Africa and ship them and after 5 years; bye bye. Now research starts to happen in western countries, with African samples, without an African researcher. For me that would be the pinnacle.

3.5 Summary

In this section, I have demonstrated, through empirically grounded data, that while African genomics researchers acknowledge the benefits of collaborating as part of AGS, there was a perceived risks of exploitation of African researchers and research participants in north-south collaborations set up as part of African genomics initiatives. To allay these fears, African genomics researchers have proposed a model of collaboration that would ensure that there is fairness and justice in AGS. This would require that African genomics initiatives integrate the following: enhanced research oversight, effective community engagements, transparency and centralised decision making, and African leadership and ownership of AGS.

Chapter 4 Research Capacity Building: A Perceived Benefit of African Genomic Science

In the chapter on international research collaboration as a benefit of AGS, I presented the perceptions of African genomic scientists on the benefits and risks of international health research collaborations and their expressed desire for equity, fairness and transparency in international collaborations set up as part of AGS. One way in which interviewees perceived this could be achieved is by ensuring that African genomics researchers are on the same intellectual level as their collaborators in scientifically advanced countries. I also demonstrated that most collaborative health research in Africa is characterized by the export of samples to research institutions in Europe or America due limited human and infrastructural capacity to do the required scientific analyses. Many have therefore said that this leads to parachute science or postal research in Africa and that African scientists are being treated as field workers or sample collectors (Harris, 2005, Musolino et al., 2015). To address these problems, many African genomic researchers argued for the need to build research capacity in Africa.

Research capacity building is "the process of empowering individuals, institutions, organizations and nations to: a) define and prioritize problems systematically, b) develop and scientifically evaluate appropriate solutions and c) share and apply the knowledge generated" (Lansang and Dennis, 2004). The importance of building health research capacity in LMICS was first highlighted in 1990 by the Commission on Health Research for Development (COHRED, 1990) and it is said that it is too important a strategy to be left to chance (Nchinda, 2002). Research capacity building has also been proposed as a means of addressing exploitation of African researchers in international research collaborations (Chu et al., 2014). Different forms of capacity building have been described in the literature, including: creating centres of excellence for health research, training of research scientists, provision of research infrastructure and the establishment of networks to support researchers in LMICs (Lansang and Dennis, 2004, Nchinda, 2002). Despite these suggestions, some authors are of the opinion that African researchers are in the best position to identify the research capacity needs of their institutions (Whitworth et al., 2008). Little, however, is known of what African genomic researchers perceive and expect of research capacity building initiatives in Africa especially in the context of AGS. In this chapter, I present the perceptions and expectations of African genomic scientists on capacity building as a benefit of collaborative genomic research to Africa.

Overall, all interviewees mentioned research capacity building as a major benefit of AGS. Three main categories of capacity building were identified by interviewees as a benefit of AGS to Africa: human capacity building, infrastructural capacity building and funding for research

4.1 The Importance of Research Capacity Building in AGS

It has been suggested that international health research in LMICs should promote justice in global health and one that way this could be achieved is through building research capacity in LMICs (Pratt and Loff, 2014). Equally, in addition to the discussions on exploitation reported in chapter 3, some authors also argue that the risk of exploitation of LMICs in international research collaborations is made worse when funding agencies perceive that limited research resources in LMICS would lead to loss of negotiating power, and set about creating collaborations that are highly in their favour (White, 2002). In our study, similar views were echoed by some African genomic researchers who suggested that global justice could be achieved if international research collaborations build research capacity in LMICs such that researchers in LMICs have a comparable level of research capacity as their counterparts in scientifically advanced countries.

> *I think we need to build the capacity of institutions from the south, because most of the research work that we are talking about are usually funded by the north, the NIH and any other institutions from Europe or Canada. so we need to build the capacity of southern institutions, we need to build our south –south relationships, you know, and to build the capacity of southern collaborators, southern investigators and in that way also build the capacity of the communities to have the necessary level and latitude, you know, to say that, this is what we want. Otherwise it becomes like something that has come from abroad and whatever they do, we will take it because they are the ones who are giving the money. (R-10)*

This fear of weak research systems and past experiences of exploitation of African researchers has led to the recommendation that that that it is now time for researchers in LMICS to move from construction workers to being architects (Coloma and Harris, 2009). This description fits the expressed need (See chapter 3) for African scientist to move beyond "sample collectors" to "scientist" who are on an equal intellectual platform as their collaborators in scientifically advanced countries

> *I think that African genomic studies need to be interpreted and contextualized in as far as an African based person understands the scenario. So I think that is really important (R-03)*

When they talked about research capacity building it was in three forms, human capacity building, infrastructural capacity building and the provision of funding

4.2 Human Capacity Building for Genomics Research in Africa

Human capacity building for genomic research was mostly discussed by interviewees in terms of training opportunities for African scientists. Training of researchers in LMICs who are part of

collaborative research programs, has been recommended by a number of actors and described as the core of any research capacity building initiative in LMICs (Lansang and Dennis, 2004). To this effect, a number of funding programs such as the Wellcome Trust and the Bill and Melinda Gates foundation have dedicated training programs for early-career research scientists in Africa. Equally, the H3Africa initiative underscores the training of African masters and PhD students as a major component of its capacity building efforts for genomic research in Africa (H3Africa Consortium, 2014). In our study, interviewees identified three major areas in which African genomic initiatives have been of benefit to Africa in terms of human capacity building

The first way in which AGS has contributed to capacity building in Africa is training the next generation of African genomics scientists. As stated above, training of Masters, PhDs and post-doctoral level scientists has been designated as a core component of research capacity building initiative in LMICS (Lansang and Dennis, 2004, Nchinda, 2002). This form of capacity building was also articulated by African genomic scientists as one of the key benefits of current AGS. All interviewees were of the opinion that this has been a major benefit of AGS to Africa

> *In terms of building capacity, training and giving opportunities for many African students like yourself. So that will accelerate capacity within Africa. (R-05)*

Most interviewees described the training of young African scientists currently spans a number of research areas such as training in laboratory genomic techniques and research skills like good laboratory practice.

> *We are going to train people on how to extract DNA, we are going to, especially in Country A, in Country B, we are trying to train people to get good laboratory practice not only for this project but for future projects. (R-09)*

For some interviewees, genomic research programs in Africa have given them an opportunity to send postgraduate level students to scientifically advanced research institutions in Europe and America for graduate training. Such programs have been used as a means of transferring research skills especially when there is no available expertise in the African country

> *We currently have two trainees from Country Y [LMIC] at Country Z [HIC] at the Z college of Medicine, doing their rotation of laboratories towards their PhDs in genomic sciences and genomic medicine. We also have three from Country X [LMIC] and we are expecting two more from Country Y [LMIC] next year. (R-02)*

Interviewees were also of the opinion that training could also be in the form of establishing academic degree programs in African universities. In the bioethics literature, many have said that

long term research capacity building strategies that are aimed at developing undergraduate and postgraduate research programs in African universities and research institutions would be vital in sustaining of health research in LMICs (Lansang and Dennis, 2004, Adewole et al., 2014, Kellerman et al., 2012). In terms of long term capacity building efforts, some interviewees were of the view that African genomic initiatives have been instrumental in developing academic programs in genomics at African universities.

> *We are working with the faculty of health sciences in both Country X [LMIC] and Country Y [LMIC] at the respective universities to create masters level programs, PhD level programs in genomics and bioinformatics. So really, we hope that that will be a lasting and sustainable benefit to those countries, is by having a local program in genetics and genomics (R-02)*

4.2.1 Enhancing research-associated skills of African genomic researchers

African genomic researchers also acknowledged the importance of training in research skills as a benefit of AGS. Besides training for academic degree purposes, some authors have also proposed that capacity building efforts in LMICS should include training in research associated skills so as to complement the academic degrees of emerging PhD-level scientists (Lansang and Dennis, 2004). In the interviews for this study, African genomic scientists also stressed the need for this form of capacity building and mentioned that H3Africa, as an African genomic research initiative, is addressing this aspect of capacity building and is providing training in grant writing, manuscript writing, project management, statistics etc.

> *Capacity building in our research to help young African researchers, develop themselves in many fields related to research: statistic, epidemiology.. I was in Country X, I think it is in March or April, for a training organized by one of the institutions involved in this H3Africa initiative, Institute X and I went there for training on manuscript writing, how to write a paper. It was for one week. Through this project, I have developed some skills in writing grant proposals and it helped me to know exactly which kind of word to use (R-09)*

4.2.2 Training in Science and Ethics Review

The second way in which AGS has been of benefit to Africa is in training in science and ethics review. Besides the problem of limited training opportunities for African biomedical researchers, the problem of weak research oversight systems in Africa has been chronicled as a challenge to health research in Africa (Kass et al., 2007, Nyika et al., 2009a, Nyika et al., 2009b). Many bioethics commentators argue that this makes Africa more vulnerable to exploitation especially in research fields like genomics with may be relatively new to REC members in Africa (de Vries et al., 2012b, Nyika, 2009, Ramsay et al., 2014). These commentators further recommend that immediate action be taken to build the capacity of RECS in Africa to review genomic research, a view backed

by a recent empirical study of REC members in Botswana (Barchi et al., 2015). In our study, interviewees also articulated such concerns but were of the opinion that current African genomic initiatives are taking this into consideration and are investing in capacity building of African RECs to review multi-side genomic studies.

> *Another thing which is already happening that is good is involving the ethical review committees in giving them additional training in genomics research because that is a new area for a lot of the IRBs. In Country X we found that the IRBs had not reviewed this type of research before and this caused a lot of delay in terms of getting approvals and feedback from them but things improved after one of the IRB members attended the last consortium meeting for the special session for ethical review committees and so I think those kind of activities are very helpful. (R-02)*

For some interviewees, research ethics capacity building in current African genomic initiatives has helped to improve research oversight for most genomic studies in Africa especially in the context of obtaining informed consent and community engagement activities.

> *I can almost be sure that if you visited any study site at the beginning of H3Africa and visit them now, the way the will be consenting and engaging with the community will be completely different, I mean in ethics, they have been challenged to think far beyond just the compensation for travel, for time and everything and now we are going back to genes and our family and heredity challenges. So even our ethics communities have been touched to think far more (R-13)*

4.2.3 Establishment of Research Networks

An important additional feature of human capacity building mentioned by the interviewees relates to the value of creating genomic research networks in Africa. Besides training, the creation of scientific networks that could serve as platforms for the exchange of ideas and for mentorship purposes has been also been proposed by some authors and funding agencies as a means of building research capacity in LMICs (Sitthi-amorn and Somrongthong, 2000, Whitworth et al., 2008). Also, African genomics initiatives such as the H3Africa have created research networks such as H3ABioNet (http://www.h3abionet.org/) which provides bioinformatics support to African genomics researchers. In our study, some interviewees perceived that the H3Africa initiative has provided them with a platform to work with and share research experiences and challenges with other African researchers and that this has been useful in building their capacity to do genomic research.

There are a lot of investigators that I have met here, that I know that even the work I am doing will be enriched and easier and may probably have more impact because I have met collaborators that I can work with (R-13)

4.3 Building Infrastructure for Genomics Research as Part of Capacity Building

Besides human capacity building, infrastructural research capacity building at the institutional level has been a major target of research capacity building initiatives in LMICs (Lansang and Dennis, 2004). An opinion that was shared by most interviewees. For some interviewees, having the appropriate research infrastructure means that African researchers have the tools required to solve Africa's health problems.

Now, the other beauty of it is, you know, it has really emphasized on building infrastructure in Africa, getting Africans, giving Africans the tools to solve their problems. (R-13)

This echoes opinions that has been documented in the section on collaborative health research where interviewees expressed the desire for African problems to be solved by Africans Interviewees identified two main types of infrastructural that are a benefit of collaborative AGS to Africa: provision of laboratory equipment and the establishment of biobanks

The lack of appropriate technology as well as the use of obsolete research equipment in Africa is a serious impediment to biomedical research in the continent (Makoni, 2009, Zofou et al., 2011, Isoun, 2007). The lack of equipment and technology has also been advanced as a reason for the export of samples from Africa especially when high-throughput technology is required, as is the case with genomic research (de Vries et al., 2012b, Langat, 2005). In our study, many interviewees acknowledged this challenge and proposed that the acquisition of research equipment for high-throughput genotyping be included as part of capacity building efforts for AGS. They were also of the opinion that this type of capacity building is currently happening in collaborative genomic research in Africa.

In terms of infrastructure, we are building capacity at Q University and university of Country X [LMIC] to do genome sequencing and to get their sequencers, their Lumina sequencer and so all of those tools will help in the building of infrastructure in the different laboratories. (R-02)

Some interviewees also perceived that having such infrastructure would limit the export of human biological materials from Africa and enable African scientists to work on national research priorities. To illustrate this point, some interviewees made reference to how this has solved the problem of export of human biological countries in other LMICs such as India, China and Mexico.

> *We should not just be thinking that anything we want to do, we have to collect samples and send to Europe, samples to China, samples to America. We need to build the capacity that we can do work in Africa. If that is the case then we can produce things that will be valuable and useable in Africa. And I think that is just what has been done in several other countries like India. It is very difficult now to take anything out of India for analysis. Most of the researches don't do that because they are trying to build their capacity. (R-14)*

This again highlights the need for an African ownership of genomic research which I presented in the previous chapter.

Another type of infrastructural research capacity perceived to be a benefit of AGS is the establishment of biobanks in Africa. Biobanks are "repositories where organized collections of human biological materials, and associated data from large numbers of individuals, are collected, stored and distributed for the purpose of scientific investigations or public health use" (Chen and Pang, 2015, Yuille et al., 2008). In recent times, there has been great interest in bio banking research and the last two decades have seen a proliferation of biobanks in Europe and America (Kaiser, 2002) and a few in Africa (Abayomi et al., 2013, Sirugo et al., 2004). The justification advanced for the establishment of biobanks in Africa is that it would facilitate genetic and genomic research on African populations (Chen and Pang, 2015, H3Africa Consortium, 2014). Most of the genomic researchers I interviewed for this study shared this perspective and voiced that establishing biobanks in Africa as part of collaborative genomic research in Africa is a big benefit to biomedical research in Africa.

> *One big advantage of having a biobank in Africa is that it really puts all of our resources together. I think that is very huge for Africa, to begin with. And it is a way of putting our resources together and giving us the infrastructure to produce high quality research that nobody in the world is gonna argue it because we are using international standards. (R-13)*

4.4 Provision of Funding

The lack of research infrastructure (laboratories, biorepositories, databases) coupled with a dearth of funding for biomedical research in Africa has held back African scientists from carrying out rigorous research (Adewole et al., 2014, Park, 2014). Some authors have therefore argued that funding mechanisms should be used as drivers of change for biomedical researchers in Africa (Whitworth et al., 2008). Many interviewees were also of the opinion that H3Africa, as a genomic initiative has enabled African scientists to do genomic research through the provision of funding for large scale genomic research.

> *For researchers, what it is really doing is, it's building their capacity to do research, to do large scale research that they haven't done before because it costs a lot of money to do this type of research(R-15)*

Also, through funding for genomic research in Africa, interviewees hoped that genomic researchers would be able to maintain their laboratories and procure other scientific research objectives irrespective of whether it is an H3Africa project.

> *I think by definition, H3Africa is a good thing. It's good because it will provide the opportunity to jumpstart some of the research. Maybe it will accelerate some of the research that was already happening in Africa (R-05)*

Based on the above quotes, the major beneficiaries of capacity building, as perceived by interviewees, are researchers and research institutions in Africa. Though for some interviewees this benefit somehow trickles down to the public as a whole when the research results are being translated into public health.

> *So the immediate beneficiaries of capacity building are the researchers but the benefits of this capacity building are going to go down to the people, the participants, if a new treatment comes up. So the benefits of capacity building are a little indirect to the public. The immediate beneficiaries will be the people doing the work (R-08)*

4.5 Challenges in Genomics Research Capacity Building in Africa

While research capacity building is unquestionably a way of improving health research in Africa, it still remains an un-met challenge especially in sub-Saharan Africa (Nchinda, 2002, Ramsay, 2002) and is made worse following the end of funding for a designated research capacity building project (Lansang and Dennis, 2004). Despite the above cited benefits, a majority of interviewees were of the opinion that this is just a step in the process of capacity building for genomics research in Africa. In the interviews, African genomic researchers identified two major challenges of capacity building efforts for genomic research in Africa: non-sustainability in terms of retaining trained scientists and the challenges in maintaining research infrastructure

4.5.1 Retaining trained African genomics scientists in Africa

Brain drain has been identified as a major problem in many African research institutions and the continent has witnessed the constant migration of African scientists to scientifically advanced countries that offer better research opportunities and financial security (Sitthi-amorn and Somrongthong, 2000). Some authors have also suggested that the training of African scientists through study abroad programs has seen trainees in LMICs wanting to stay with collaborators in scientifically advanced countries (Pang et al., 2002). Though it is a challenge that has been

identified decades ago and described as a serious impediment to biomedical research in Africa (Whitworth et al., 2008), it remains a cause for worry especially for African genomic science (H3Africa Consortium, 2014). Interviewees in our study, also expressed this fear of non-sustainability of capacity building efforts established as part of genomic initiatives in Africa and they worried that trained genomic scientists could possibly leave African institutions when current research funding is no longer available

> *I will just take an example, people who train you at the end of the day they do not absorb you. So there should be proper planning. It could be beneficial if it is clear that this people who are to be trained will come back (R-16)*

Many authors who have acknowledged the problem of brain drain in Africa have claimed that the lack of an enabling research environment as well as mechanisms to discourage the movement of local scientists escalates the problem of brain drain (Pang et al., 2002). This challenge was also articulated by interviewees and many hoped that having the right infrastructure and a favourable research and academic environment would not only maintain trainees but lead to a brain gain in Africa.

> *I have met a lot of young African researchers in the diaspora and they want to come back and there is nothing for them to come back to. So, it is not just about the number of projects, it's the capacity, the facilities and the institutions so that there is position for someone to come and they are going to be provided have the resources to do research. So, projects like this one actually builds the institutions themselves and the researchers themselves. But they then need to guard and create more positions and opportunities. It makes research in Africa exciting and they want to come back. (R-15)*

Another way to address the problem of brain drain, as suggested by interviewees was for local universities or research institutions to assure trainees of faculty positions in home universities. Some authors have reported that such an approach is currently addressing the problem of brain drain in Uganda through the Makerere university fast track junior scholarship program that mentors and retains biomedical and clinical researchers (Whitworth et al., 2008). In our study, one interviewee explained how their genomics project has adopted this approach and now insists that home institutions provide faculty positions to trainees as a pre-requisite for co-opting trainees in the project. This, they perceived, would ensure that trainees return to their home countries with enough skills to compete for grants and sustain ongoing genomic projects.

> *We want these trainees to come back and do research that benefits their own countries and so there is an agreement with the host institutions there will be faculty positions available for them when they complete their degrees, so they will be able to go straight to those faculty positions and to be able to use the*

infrastructure that we have been building in the meantime to continue their genomic research, to apply for additional grants and to nurture their own students one day. (R-02)

A third approach suggested by some interviewees as a means of ensuring a critical mass of scientists in Africa, not necessarily in terms of preventing the migration of African scientists, was for African governments to invest in science education at non-tertiary levels. A solution that has also been proposed by Whitword and colleagues (Whitworth et al., 2008). Some interviewees proposed that current genomic initiatives in Africa could partner with Ministries of Education in Africa, to design programs that could improve science literacy levels in Africa, especially in the context of genomics.

I think that for Africans to benefit from genomic research, you have to build the capacity for the research to be conducted in Africa by Africans. I also think that we need to have basic science literacy in these countries and for that, you need to partner with the ministries of education, help them to create curricula that provides that kind of science literacy in genetics and in genomics. (R-02)

4.5.2 Maintaining Biobanks

As already indicated above, a majority of the interviewees perceived that the establishment of biobanks in Africa is one of the greatest benefits of AGS. However, most interviewees feared that maintaining these biobanks would be a serious challenge to host institutions, a problem that has been highlighted as a challenge for bio banking in South Africa (Abayomi et al., 2013). The lack of resources and/or the unwillingness to maintain research infrastructure has been reported as a major impediment to biomedical research in Africa (Laabes et al., 2011). This was also a major worry expressed by most of our interviewees. Many African genomic scientists had a perceived fear of the non-sustainability of biobanks established as part of H3Africa genomic initiative. They were of the opinion that after the funding period for H3Africa, host countries and institutions may not be able to run these biobanks in terms of providing operational cost and maintaining international standards for bio-banking.

Maintaining the biobanks is a very very huge problem, because you need to pay cost for the material, cost for people working there, and pay permanent workers for a very very long time. So the sustainability of the Biobanks will probably be a problem after H3Africa. (R-05)

To solve the problem of sustainability, there have been many calls for African governments and the private sector in Africa to invest in biomedical and genomic research in particular as a way of sustaining research capacity building efforts in the continent (Abayomi et al., 2013, Laabes et al., 2011). Some argue that if African governments invest in health research, African countries would

be able to develop indigenous research capacity that responds to their needs (Lansang and Dennis, 2004). This notion was also expressed by interviewees as a means of maintaining the biobanks established as part of African genomic initiatives.

> *What I know will be essential will be for African governments to invest more in biomedical research and development at all levels and for African governments and the private sector to improve the health research systems that are currently in place in many African countries. Those efforts will benefit not just genomic research but all aspects of health research aspects (R-01)*

Lansang and Daniels (Lansang and Dennis, 2004) further suggest that the responsibility for sustaining health research capacity building in LMICS rests primarily on local governments who have the responsibility of creating an enabling environment for health research, a view shared by many Africa genomic scientists interviewed as part of this study. Many Interviewees were of the opinion that the responsibility for building capacity for genomic research in Africa, for a sustainable AGS would to a large extent depend on the political will of African governments

> *The responsibility can be in our different countries; of course that is why we have to own it. Given our stage, governments should look at how we can be part of this. What we can see now is that people paid for this research not because they have money but because they had a vision. I think we also need to have that vision that this is what we want to do. (R-14)*

The above quotes suggest that African genomic researchers perceived that if having the right capacity for genomic research as their collaborators in the south, is a requisite for an African ownership of AGS and as a way of curbing exploitation in north-south collaborations.

4.6 Summary

In this section, I have presented the perceptions and expectations of African genomic scientists on research capacity building as a benefit of genomic research to Africa. Based on interviewee's perspectives, benefits of capacity building in genomics in Africa can be identified at the individual level and at the institutional level though both are interrelated. At the individual level, this involves the training of scientists, networking and the availability of funding for research. At the institutional level it is the provision of infrastructure for genomic research. However, African genomic researchers identified a number of challenges in sustaining these capacity building efforts and expressed the need for African governments to support AGS so as to ensure sustainability through the retention of genomic scientists in African research institutions and the maintenance of biobanks set us part of genomic research in Africa. In the next section, I will present the health benefits of AGS.

Chapter 5 Genomic Medicine in Africa: A Perceived Benefit of African Genomic Science

Genomic medicine is one of the fastest growing fields in medicine (Siwo et al., 2015) and it is defined as "an emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use."(NHGRI, 2015). Based on information from the website of the US National Human Genome Research Institute (https://www.genome.gov/), genomic medicine is already making impact in the fields of oncology, pharmacology, rare and undiagnosed diseases, and infectious disease.

Following the completion of the human genome project in 2001 (International Human Genome Sequencing Consortium, 2001), and the complete sequencing of some Khoisan and Bantu genomes from southern Africa (Schuster et al., 2010), there has been so much enthusiasm about the revolutionary impact genomic medicine would have on healthcare globally and many have suggested that Africa has to be part of the genomics revolution (Gurdasani et al., 2015). Some even argue that genomic medicine would have a greater on impact healthcare in Africa than in many parts of the world given the continent's rich human genetic diversity and high burden of disease (Siwo et al., 2015).

Despite the enthusiasm, some authors are of the opinion that the potential of the genomic revolution for the benefit of Africans in Africa is premised on the ability to overcome significant challenges in genomic research and healthcare sector in Africa and a lot would have to be done for genomic medicine to be available to African patients in Africa (Ramsay et al., 2011). In this section, I unpack the perceptions and expectations of African genomic researchers on the promise AGS holds for improving healthcare in Africa and how AGS could be used to improve global health equity. I will first present their perceptions on how genomics medicine would be of benefit to Africa, secondly I will present the challenges for genomic medicine in Africa and how these could be overcome to ensure that genomic medicine is available to patients in Africa.

Overall, when interviewees talked about AGS and improved healthcare it was in four main categories: research-related healthcare, diagnosis, pharmacogenomics and public health.

5.1 Research-Related Healthcare

Ancillary care and access to healthcare in research settings remains a topical issue in bioethics and the debates are guided by the question of whether health researchers owe study participants any ancillary care (medical care that their study participants need but that goes beyond what is

required to do the science safely). However, access to healthcare in research settings has been reported as a major motivating factor for research enrolment in Africa (Burgess et al., 2009) and similar reports are documented on the perception of research benefits by study participants in non-therapeutic studies (Thiessen et al., 2007). In our study, a majority of African genomic researchers perceived that one of the direct benefits of genomic research to Africa is that it is providing healthcare, which would otherwise not have been available, to research participants. This was mostly in terms of non-genetic related healthcare like routine clinical care for diabetes, hypertension, tuberculosis or simply the return of non-genetic test results

> *One of the benefits is that we are going to communities that don't often have access to healthcare and just by virtue of the fact that they are part of the study, if we detect something like hypertension, we will refer them to existing infrastructure where they can get care. (R-03)*

Provision of healthcare was also the most documented benefit in informed consent documents used in genomic studies across Africa and which we analysed as part of this study. Most of the informed consent documents had statements like the following as a benefit of participating in the study.

> *You may not receive any personal benefits from being in this study. However early detection of health problems if present, free diagnostic tests and the satisfaction of being in a research study that ultimately helps others and may lead to a greater understanding of this disease is of great benefit.*

However, there was controversy amongst interviewees on this form of benefit. Some interviewees felt that providing healthcare to research participants is a requirement and should not be considered a benefit. Though some interviewees maintained that such healthcare was usually more thorough than routine.

> *That is a very limited benefit. I think it is something of course that in most cases you have to do. So if you are seeing a patient, if you are seeing a participant for some condition, then in many cases you have to provide some sort of care. (R-04)*

Participants did not mention return of genetic test results, and only one informed consent document described an intention to return genetic results to study participants(Munung et al., 2015-In press).

5.2 Genetic Diagnosis or Molecular Testing

One of the most direct ways in which interviewees perceived that genomic science can impact on healthcare in Africa is in improved diagnosis for disease. Genetic diagnosis or molecular

testing has been described as the core to prevention and treatment strategies that take individual variability into account (Collins and Varmus, 2015). Many geneticist also argue that more precise diagnosis would facilitate precise treatment and/or management of a disease and that it is fast becoming a crucial diagnostic tool not only for inherited genetic conditions but also for infectious diseases (Netto et al., 2003). In the interviews, most African genomic researchers said that AGS would improve disease diagnosis in Africa especially for multifactorial genetic conditions like cancer.

> *There are specific genes that are specific to the African context for example BRCA1 and 2. There is diagnosis of the genetic conditions that has to do with genetics, I can't think of an example that is really specific to Africa but eh, it has to do with most of the work that has been done in other places (R-04)*

While the literature has a number of examples of how molecular testing is currently being used in HICs for the diagnosis of specific health conditions, there is little information on its routine use in clinical settings in Africa. When I asked interviewees of examples of the use of molecular testing in clinical settings in their home country or other African countries, the majority had no examples. When they did, it was for monogenic or Mendelian conditions like sickle cell anaemia.

> *There are many examples, in the United States where I am. I am originally from Country X, so I don't know if there is a direct application of new findings in genomics in Country X, What I do know is that sickle cell disease is a genetic disease that has various components to it and some of the genetic findings about diagnosis, screening, management of the disease are being applied to variable extents in different parts of Country X depending on the resources, at least in the area of diagnosis. (R-01)*

The use of molecular diagnosis for monogenic conditions is not new. However, the growth of genomics has facilitated genetic testing for monogenic diseases (Urban, 2015) and many interviewees felt that this would have had an impact on healthcare in Africa. One interviewee mentioned how genomics is used in his home country for prenatal screening of sickle cell anaemia and Down syndrome.

> *I am using genomics in the clinic in Africa. I remember to have established a genetic service in Country X in 2007. We had started genetic diagnosis before for Disease A and for chromosomal abnormality in Country X in 2009 and we are able to say if a child is affected with sickle cell anaemia from three months of pregnancy, affected with Down syndrome from three months of pregnancy.(R-05)*

The literature has it that the diagnosis of cystic fibrosis is one area where molecular testing has developed and is currently available in the clinic in most HICs (Dequeker et al., 2008, Langfelder-

Schwind et al., 2014). In the interviews, it was also mentioned that molecular testing for cystic fibrosis is one area in which genomics has had an impact on clinical care in Africa. However, it was not clear if such testing was available in clinics in Africa.

> *One of the direct benefit has been designing new diagnostic studies that are appropriate for mutations that occur in African populations One example is cystic fibrosis which everybody thought only occurred in European populations but we have shown that it also occurs in African populations and the mutation profile is different. So it's very important that in Africans you test the correct mutation profile, so that will be one benefit from the diagnostic point of view (R-03)*

In an effort to promote genomic medicine, the US National Institute of Health (NIH) in 2008 established the undiagnosed diseases program (UDP) as a platform to provide answers to patients with rare conditions that elude routine diagnosis and as a means of advancing medical knowledge about rare and common diseases through the use of genomic technologies such as exome sequencing (Gahl et al., 2012). In our study, some interviewees also perceived that such application would benefit healthcare in Africa.

> *One of the biggest tools for immediate application is clinical sequencing where there are immediate applications in Europe and America, in which you have a child who comes in with an unknown illness, you do all the tests, and all of them turns out to be negative. So you do not know what the diagnosis is and many times, you can just sequence actually find out that ,oh, this is actually, it is exactly this gene that is responsible for this and in some cases there is some drug that you can give in order to correct that. So that is one of the applications in the clinical setting. So in fact that is what has led to the rush to try and get sequencing as early as possible. You don't want to wait for results for more than one week; you want to get the results within 48 hour. (R-11)*

In summary, interviewees perceived that molecular diagnosis of disease would be of great benefit to Africa as it would improve on precision diagnosis and reduce waiting time for medical test results

5.3 Pharmacogenomics

Pharmacogenomics is the study of how genes affect a person's response to particular drugs. It is a relatively new field and it combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) with the aim of improving the efficacy, safety and dosing of medications (http://ghr.nlm.nih.gov/handbook/genomicresearch/pharmacogenomics). In our study, pharmacogenomics was perceived by all interviewees as one way in which Africa could harness the benefits of genomic research. In the literature, it has been argued that the efficacy

of current drugs in the market is limited (Urban, 2015) and that the proportion of patients who respond to treatment using current drugs ranges from 25-80% (Spear et al., 2001). Some authors therefore propose that genomics could remedy this situation through improved drug targeting (Urban, 2015). In our study, all interviewees echoed this viewpoints and perceived that genomics would provide more personalized therapy in Africa both at the population and individual level, through the identification of medications that work best, or better still not appropriate, for certain population groups in Africa.

> *If you think of pharmacogenetics, then study of a certain population might show that, for example, certain variation affecting the metabolism of a drug is in high prevalence in this population and it could indicate that may be the drug shouldn't be used or should be used in a lower dose to be effective, so at the population level, this might be applicable directly. (R-04)*

A typical example of how pharmacogenomics is changing the health landscape is the US FDA recommendation that prescription of warfarin be based on genotype specific information and genotype-specific dose ranges (Wang et al., 2011). In the African context, studies have shown that the use of a dosing algorithm for Efavirenz-based chemotherapy guided by inclusion of pharmacogenetics data could improve management of HIV in African populations (Nemaura et al., 2012). This is so because the genetic allele CYP2B6*6 (it cause slower rates of metabolism for several drugs, including Efavirenz) is higher in African populations than that in Caucasians (Masimirembwa and Hasler, 2013). In this study, the example frequently mentioned by interviewees is the promise of using pharmacogenomics to improve treatment outcome, at the population level in Africa, for anti-hypertensive medication and clinical management of HIV.

> *By looking at differences in disease progression particularly with HIV we are looking at what is the genetic basis for children who are infected at birth and they don't get symptoms until age 10 older versus rapid progressors, which are children who are born with HIV and who develop the disease within 6 months or so. And so by teasing out those genetic reasons we may be able to improve their treatment or prophylaxis to delay onset of HIV or to target HIV prevention at very genetic levels and stages of disease progression. So not necessarily personalized medicine but definitely, the methodologies that will be geared towards sub-Saharan African children (R-02)*

> *It could also be something like medication for hypertension, because we know that there are many and often, for the doctors, it is about trial and error and finding the right one. But if we had a better knowledge of what is appropriate for the greater majority of the people in a population, you could always start with the one that is more effective. (R-03)*

5.4 Public Health Genomics

In the past years, most genomic research has focused on genetic variation and diseases and many are of the opinion that knowledge of risk of developing a disease could be important in designing preventive measures and in educating at-risk individuals or populations on the need for adopting healthy lifestyles (Coyle, 2009, Thirlaway and Davies, 2001). In our study, most interviewees perceived that AGS would have a great impact on public health as illustrated in the quote below

> *I think there are different public health messages that will come out of the research and I think public health messages are one of the great benefits to most of Africa. (R-03)*

When interviewees discussed the public health benefits of AGS, it was in two main areas: Determining susceptibility to disease and disease surveillance especially in epidemic situations

5.4.1 Determining Genetic Susceptibility to Disease

Genetic susceptibility or genetic predisposition is defined as an increased likelihood of developing a particular disease based on a person's genetic makeup. For example, certain mutations in the BRCA1 or BRCA2 genes greatly increase a person's risk of developing breast cancer and ovarian cancer. It is one of the applications of genomics that has been suggested to be of significant importance for healthcare in Africa especially in determining susceptibility to polygenic conditions such as hypertension and cancer and infectious diseases like malaria, TB and HIV (Hill, 1999, Newport and Finan, 2011). In our study, many African genomic researchers shared this view. For these researchers, this was mainly through screening populations to decipher genetic predisposition to certain health conditions. This, they perceived, would be useful in early identification of preventive measures for individuals or populations at risk of developing a particular disease. When interviewees talked of this form of benefit, they mostly referred to polygenic non-communicable diseases such as stroke, cardiovascular disease and cancer rather than to infectious diseases.

> *I was really interested by one of the presentations on neurologic disorders and genetics in Mali. I was really excited because if you go to a family and you see that in this family we have some symptomatic disorders and maybe, many of the other members of the family are asymptomatic, you could screen them. When you do your screening, you could see whether they have the DNA for the disease or they could develop the disease in the future and maybe you could help them. (R-09)*

When interviewees did not mention polygenic disorders, the made reference to the use of genomic tools for the management of monogenic conditions such as new-born screening for

sickle cell anaemia and were of the opinion that this is one area in which genomic medicine is currently improving healthcare in Africa.

> *We have a national program in Country X that we established for detection and diagnosis of congenital abnormalities of urogenital malformation and this program has been running for 5 years. Every single day, we have patients, families who need some genetic consultation and genetic technology for diagnosis and genetic technology for their guidance and their care (R-05)*

In the literature, some have argued that knowledge of genetic risks can inform or motivate beneficial lifestyle changes (Coyle, 2009, Burke et al., 2006), though some authors argue that this hypothesis would need further testing (Marteau and Lerman, 2001). Some empirical studies have demonstrated that knowledge of risk of developing a disease may or may not influence lifestyle changes (Thirlaway and Davies, 2001, Heshka et al., 2008). In our study, a majority of the interviewees perceived that African populations could benefit from genomic research if studies on genetic susceptibility to disease educate populations genetic risks and healthy lifestyle that could prevent or limit disease progression.

> *I think that there is a lot of preventive measures that is based on educating our population and really advising them even if it is just guidance in terms of what you eat and how you leave, try and make sure that if you are in the sun for 10 hours, you try and put on a hat and have clothing and all of that. So I really believe that preventative genomic research is just as important as therapeutic. Right now we know enough to really move out and use the information that we have to educate our populations. Let them benefit from that as we continue to do the research. (R-13)*

5.4.2 Disease Surveillance

A second area in which interviewees perceived AGS would have an impact on public health in Africa is in disease surveillance. The use of genomics in disease surveillance was been highlighted in the literature and it has been said that genomics is currently transforming modern infectious disease surveillance and the investigation of outbreaks (Struelens and Brisse, 2013) . Many even suggest that genomics has transformed the way in which public health professionals fight epidemics and pandemics for high profile infectious diseases such as tuberculosis, HIV, influenza, salmonellosis and Ebola (Lienau et al., 2011, Struelens and Brisse, 2013, Gire et al., 2014). In our study, some interviewees also perceived that this is one way in which genomics has and would be of benefit to Africa. Those who talked about disease surveillance frequently referred to how genomics was instrumental in the fight against the 2014 Ebola outbreak in West Africa.

> *At the NIH clinical center, when there is an outbreak of a pathogenic bacteria in the clinical setting and, there is a sequence to track where it is coming from*

and how it has spread, that knowledge helps in control just in the same way they have used sequencing to track how the Ebola virus has mutated and spread. It is clinical, it is not just for research purposes. (R-11)

5.5 Translational Health Benefits

There has been great expectation that increased understanding of genetic determinants of disease would be rapidly translated into novel therapeutic and prophylactic interventions (Burgner et al., 2006, Hill, 1999, Hernandez and G, 2006). Some genomic researchers also expressed this expectation and were of the opinion that understanding disease susceptibility in African population could would be useful in designing and developing novel therapies that that would be effective for African populations

The benefit is that we will know what the markers or predictors or protective factors are for certain diseases and that will also help to identify those who are at higher risks and then target such people for better preventive efforts or monitoring efforts for early detection. In the end, it will improve health by preventing diseases or by enhancing early detection and early treatment. (R-06)

5.6 Towards Using Genomics for Improved Healthcare in Africa

While genomics holds lots of promise for the management of disease, the literature only has few examples of its use in the clinical setting and in most instances it is in HICs (Gladding, 2013 , Ma et al., 2012). It is for this reason that many authors have raised the question of whether people around the world would be able to access genomic medicine or if genomic medicine would be for a lucky few in industrialized countries (Seguin et al., 2008). This raises debates on whether genomics could in fact improve global health equity. As already demonstrated, African genomics researchers expressed the prospects of genomic medicine in Africa. However, many are of the opinion that genomic medicine is not yet available in most of Africa. This was due to a number of roadblocks which would have to be addressed. The major challenges that stood out in the interviewees were: translation of results of AGS into beneficial clinical applications, the need for capacity building in genomic medicine, identifying heath genomics research priorities for Africa and a healthcare system that is prepared for genomics medicine.

5.6.1 Translation of Genomics Research

A number of authors have argued for the need for genomic research in Africa to include a translational phase (Tiffin, 2014) and some are of the opinion that it is now time to move beyond promise to practice (Urban, 2015). While many authors support the need for translation, some commentators argue that the high cost of implementing genomics research findings could lead

to disparity in healthcare between countries and between HICs and LMICs (WHO, 2002, Seguin et al., 2008). To overcome the high cost of translating genomic research, some authors have suggested that researchers communicate and engage with key stakeholders (Burke et al., 2006, Daar et al., 2004). In our study, most interviewees expressed the need for a translational phase of AGS and were also of the opinion that it would require public-private partnerships.

> *The scientific community who knows the value of this, the clinicians who need this to treat their patients better, can constitute an advocacy or pressure group and approach international bodies who are already aware of the advantages of this and convince their governments to support these initiatives (R-06)*

Fears of the high cost of translating AGS led to a perceived fear of exploitation of African populations. Coupled to the high cost of translation, some authors have argued that inequalities in healthcare could be made worse by intellectual property rights In our study, some interviewees were also of the opinion that translation usually involves innovation and issues of patent and IPs and if this was to happen for genomics in Africa, it would put African populations at risks of exploitation because this could lead to increase cost of genomics medicine making it unaffordable to African populations

> *when it comes to translational research, those who have greater capacity to do that sort of research will benefit most because the results of basic research is shared, but the products of more translational research tend to be protected; intellectual property rights, patents and if there is a product, there is the risk that those participating in the research might find themselves less able to afford these things because their countries are less able to afford the more specific translational research. (R-04)*

5.6.2 Focusing AGS on Africa's Health Priorities

Some authors have suggested that if AGS plans to improve global health equity, it would have to focus on Africa's health priorities (Ramsay et al., 2011) Also, the importance of focusing genomic research on infectious diseases has been recommended as one way in which Africa could benefit from genomics technology (Burgner et al., 2006, Hill, 1999, Newport and Finan, 2011, Struelens and Brisse, 2013). In our study, most interviewees were of the opinion that if the results of AGS are to be translated to useful bedside applications in Africa, AGS would have to focus on Africa's healthcare priorities.

> *It [genomic research] has to be directed at the problems of public health interest to Africa, we need to align with our healthcare priorities and identify issues where there may be problems. I guess what we should probably be worried about is doing research which probably doesn't meet our needs or just touching on tiny fraction of the disease and then expect that the risks of doing the study are justifiable. (R-12)*

For most interviewees, this would require that AGS focuses on population genomics of diseases like HIV, Malaria, tuberculosis or others with a high incidence in Africa. This was not to say that other diseases are not important but just a matter of focusing on Africa's health priorities

> *I really do think that we should have something that is mostly disease oriented and population genomics oriented. I think there is lot of population genomics going on now, but I think it should be disease oriented and probably disease that are specific, severe and frequent on the African continent example is HIV, another example is TB. I think anything that really is a huge burden. I am not saying that the others are not important. They are important but it is just the scale of priorities. (R-05)*

In other LMICs in Asia and Latin America, genomics research has had great impact in the diagnosis of microbial and parasitic infections such as Leishmaniasis and dengue fever (Harris et al., 1996). Many interviewees also suggested that focussing AGS on microbial genetics would be beneficial to African populations.

> *Genomics is a component that must be taken into account in terms of personalized medicine but there are a whole lot of other issues like microbiome which would contribute a huge part to understanding. Personalized medicine but it would need contributions from other fields like microbiome (R-17)*

5.6.3 Capacity Building for Genomic Medicine in Africa

A second challenge for genomic medicine in Africa is the lack of adequate capacity for genomic medicine in healthcare settings in Africa. Many have argued that the future of genomic medicine in Africa would be determined by the availability of the required capacity (Siwo et al., 2015, Wonkam and Mayosi, 2014, Masimirembwa and Hasler, 2013, Ramsay et al., 2011). Interviewees, cited lack of capacity for genomic medicine as one of the challenges of having genomic medicine in Africa. For some interviewees, this could be curbed if current initiatives start building capacity for translational genomic research in Africa.

> *What could be done is building capacity for translational research, eh, I think they should be a change of attitude, I mean translational research just has to be funded somehow but maybe more than similar to the way basic research is funded. (R-14)*

The lack of adequate healthcare infrastructure for genomics medicine has been listed as a major challenge to having genomics in the clinic in Africa (Ramsay et al., 2011). This was also articulated by interviewees who perceived that there would be a need to build health capacity in Africa for molecular diagnosis

It is going to be the capacity to do the testing, right, so you have to put the laboratory infrastructure. The reality is that diagnostic laboratory infrastructure in most Africa countries is very poor, there are exceptions to that but that is the case in many poor African countries and even, you know, even some of the rich African countries even Nigeria it is not fantastic. So laboratory infrastructure needs to be in place. (R-12)

Some authors further argue that besides the high cost of translating genomic research in Africa and the lack of infrastructural capacity, there is a lack of professional understanding of genomics in most African countries (Wonkam et al., 2006). To this effect, some have argued that the future of genomic medicine in Africa would, to a large extent, depend on the availability of highly skilled clinical genomicist in Africa (Siwo et al., 2015, Wonkam and Mayosi, 2014, Ramsay et al., 2011), a challenge that was also expressed by some interviewees. They felt that Africa is yet have the required expertise in genomic medicine and would benefit from training in medical genetics, genetic counselling, molecular diagnosing etc.

Part of the issue is not whether you have genomics in the clinic. Part of it is whether it can be used in the clinic, if the man power exists to use the technology, the man power that it requires. Not every country has the man power. So, you will also need to have trained staff and that is going to take quite a while, It's not like the experts are so many, so you need to train a whole lot more. Otherwise, you end up with a situation where people actually do have fantastic machines but with no one to use them. You heard the talk, when someone was talking about having a powerful HPLC machine and it is not being used because there is no one to use them. (R-11)

Some authors have therefore suggested that building capacity for genomic medicine could go hand in gloves with genomic research (Wonkam and Mayosi, 2014).

5.6.4 A Prepared Healthcare System for Genomic Medicine

Another major challenge for the practice of genomics medicine in Africa is lack of access to data sets and availability of robust computational systems in African healthcare settings (de Vries et al., 2015b, Siwo et al., 2015) and a relatively high cost of genomic medicine (Phillips et al., 2014, Shabaruddin et al., 2015, Singer and Daar, 2001). Similar views were mentioned by interviewees and are discussed below.

5.6.4a Non-Availability of Patient Electronic Records in Most African Countries

The importance of having patient electronic records in the practice of genomic medicine has been discussed in the literature (Kannry and Williams, 2013, Scheuner et al., 2009). In 2007, the US-NIH launched the Electronic Medical Records and Genomics (eMERGE) Network that has a primary goal of developing and applying approaches to research that combines DNA

biorepositories with electronic medical record (EMR). Following the success of eMERGE phase 1 (focus was on research), the eMERGE network transitioned to a phase (2 August 2011 - July 2015). A key goal of eMERGE Phase II was to "explore best avenues of incorporating genetic variants into electronic medical records for use in clinical care such as improvement of genetic risk assessment, prevention, diagnosis, treatment, and/or accessibility of genomic medicine" (http://www.genome.gov/27540473 Accessed 24th September). The absence of a robust electronic medical record system in most African countries was a concern to some interviewees who felt that this would be a serious challenge to the practice of genomic medicine in Africa.

> *I think the major challenge across Africa is keeping electronic records of patients because we need to be able to have electronic records. Secondly, I think harmonization of phenotyping is very important so that if you are calling this in Zambia it is the same as what you are calling in Egypt. Because sometimes it is useless, you start aggregating data that is saying different things and you don't find any significance. (R-17)*

5.6.4b Cost of Genomic Medicine

The affordability of genomic medicine has been a centre of debate for many years (Phillips et al., 2014, Alyass et al., 2015, Shabaruddin et al., 2015) and some have argued that the high cost of genomic medicine could limit access to personalized medicine in Africa and thereby widen the health inequity gap between HICs and LMICs (Seguin et al., 2008). Some interviewees were also of the opinion that genomic medicine is currently expensive for African populations and that this is made worse by the absence of national health insurance schemes in most African countries. However, most of the interviewees were of the opinion that this should not be a deterrent to AGS especially it would be useful to those who could afford

> *For me, many people will not afford it because we do not have universal health coverage like many western countries. So it is a very expensive commodity and you see people dying for something which can be treatable. But the point is that should not deter us from trying to understand the genetic impact, the role of genetics in disease causation which ultimately would help, even at least for people who can afford, you know, it means something. (R-10)*

However, there was a lot of disagreement on the perceived high cost of genomic medicine amongst interviewees. In the literature, though there appears to be an agreement that genomic medicine is relatively expensive, some authors argue that the cost of genomic technology is going down (Siwo et al., 2015, Urban, 2015) and that for some health conditions, genomics medicine offers a cost effective approach that conventional methods (Alyass et al., 2015, Shabaruddin et al., 2015). An example is the cost effectiveness of warfarin genotyping (Epstein et al., 2010). In our study, interviewees who were of the opinion that the cost of genomic should not be a

problem were also of the opinion that the cost of technology is gradually going down. Some narrated how this had been the case with ARVs and antimalarial where at the very beginning, people had argued that it will not be affordable to patients in Africa. Some even hoped that genomic medicine would be subsidized as has been the case for antimalarial. Their discussions were much of optimism

> *I don't think we must be put off by those issues now, people had said that for ARVs 20 years ago, when antiretroviral were in the hundreds of thousands of Rands or dollars a year. People said there is no way it could be used in Africa. Now, we could still be in that position and I think we need to press ahead and trust that efficacy and technology will get us there (R-12)*

> *If you look at the case of malaria, people were discussing that they should not introduce the Artemisinin based combination therapy because they were very very expensive, but for nowadays it is affordable. Of course, we have been receiving money from the donors that make it subsidized. It will be same for genomics. (R-14)*

Some interviewees also perceived that having medical insurance or community health schemes in African countries could be a way towards improving access and cost for genomic medicine.

> *We also need to design universal health coverage, something that has to do with subsidies and whatever. There are countries that are trying, the community health programs in which communities contribute and this subsidize treatment with whatever resources based on the contribution. So we need to go to that kind of direction. (R-10)*

To address issues of cost and accessibility, a call to action by African and other world leaders have been proposed as a way of ensuring that genomic medicine as accessible and affordable to African patients (Wonkam and Mayosi, 2014, Singer and Daar, 2001). A point also echoed by some interviewees who suggested there will be a need for genomic medicine buy-in by African governments.

> *Because I think there are obviously the majority of the populations who don't have medical aid and if you want it to be of benefit to them, you have to have the state buy in to paying for it. And then of course they are going to be much happier to pay for it, if it's not so expensive. So I think that is something that one really needs to work at. (R-03)*

Some interviewees therefore hoped that Africa would learn from the experience of other HICs and develop healthcare systems in Africa in order ensure access to genomic healthcare for all who need it in Africa.

But what is important whether there is a national scheme or not is the need to commit more resources to healthcare and to do so, you need a way that takes the best of what we know about well-developed healthcare systems and the best of what is cost effective and try to develop schemes for local environments, whether national or regional within Africa that can be sustained in the long run and that affords everyone, a reasonable assurance of being able to receive genomic healthcare when they need it. (R-01)

5.6.4c Public Education in Genomic Medicine

It has been proposed that for Africa to harness the health benefits of genomics medicine, current African genomics initiatives would have to develop and implement educational strategies that would inform the medical fraternity in Africa as well as the African public about genomics and ethical issues in genome research and personalized medicine (Ramsay et al., 2011, Wonkam et al., 2006). In the interviews, some African researchers also echoed this viewpoint and were of the opinion that public education in genomic medicine could lead to public investment in genomics medicine.

We first have to educate them about what is pharmacogenomics. You cannot engage a person if they don't understand what it is. How do you convince them to invest? Most of the politicians in Africa, most of the time, they do not understand this. You have to engage them through education. (R-16)

5.7 Genomic Medicine for Africa?

As demonstrated above, many African genomics scientists are of the opinion that genomics would be of great benefit to Africa. However, some were also of the opinion that Africa still has a long way to go in terms of genomic medicine and that it would take a long time to have genomic medicine in most African countries.

I think everything is just new. Maybe in the future future future. I may not be there to see it or probably to witness it. But we need to do things step by step. So, right now, I don't think it's possible to have genomics or genetics in peripheral health facilities in my village, even in Town A, I don't think (R-09)

And while genomics has been described as a revolutionary solution to Africa's healthcare problems (H3Africa Consortium, 2014, Gurdasani et al., 2015), some interviewees felt that genomics may not be all that revolutionary as has been presented

So I look at it as a component that would assist but not as a panacea to healthcare. (R-17)

This was because Africa has burning healthcare needs that may not necessarily need genomic medicine to address and further argued that genomics medicine would be of benefit to Africa if AGS focusses on Africa's healthcare priorities. In the literature, some have argued that genomics that is focused on infectious diseases would be of great benefit to Africa especially as the continent faces a high burden of infectious diseases (Burgner et al., 2006, Hill, 1999, Newport and Finan, 2011, Struelens and Brisse, 2013). To some interviewees, genomics is against the cost-benefit ratio for the management of most of Africa's burning health needs. However, they were hopeful that genomics may lead to some public health changes and educate practice in tertiary healthcare institutions in Africa.

> *There are not likely to be massive public health interventions based on genomics, in the short term because there are so many pressing needs for healthcare in Africa which are much less expensive and are more a priority in terms of pneumonia, TB, HIV, malnutrition, infant mortality, those are the kinds of things which are urgent healthcare needs and genomics, is against the cost-benefit ration or the cost effectiveness of genomic interventions will be much higher than the cost of many basic interventions like children vaccination, so it's probably not gonna result in massive changes in the short term in broad public health but I think it is gonna start educating practice at tertiary care settings but it's a long term goal. (R-12)*

Also, many have argued that the high cost of genomic medicine coupled to the near absence of regulatory frameworks for genomic medicine is a serious ethical challenge and that LMICs cannot afford to waste their limited healthcare resources on ineffective diagnostics and therapies (Boulyjenkov and Schapper, 2007). A view also echoed by some interviewees.

> *You have to talk about the ethics or the willingness to spend an equivalent of 50,000 dollars on one patient, when you think that, that could probably buy vaccines for 40,000 people. (R-11)*

In this section, I have presented the perceptions of genomics researchers on the health benefits of AGS which includes healthcare for research participants, improved diagnosis, personalized medicine and public health benefit. I have also presented what they perceived to be the challenges of genomic medicine in Africa and what they think could be done to overcome some of these challenges. The results show that while there is a promise for genomic medicine in Africa, genomic medicine is still unavailable in most African countries and is arguably not the best solution to Africa's healthcare problems.

Chapter 6 Awareness and Perceptions of Benefit Sharing amongst African Researchers

In the literature review section, I mentioned that most African genomic research involves north south collaborations and are funded by agencies in the north, falling into the category of international health research. I also mentioned that the bioethics literature is filled with debates on the ethics of international health research conducted in LMICs. In the previous chapters, I showed that there was a perceived fear by African genomic researchers that African populations could be exploited in genomic research in Africa and that interviewees proposed fairness and equity in north-south collaborations in Africa as one way of addressing concerns of exploitation. I also demonstrated that the perceived fear of exploitation is made worse by weak research oversight systems in Africa and challenges in translating research findings into health products/services. One way to address these fears of exploitation is the proposal that international heath research should be of social value (Simm, 2005, Simm, 2007a). Many strategies have been proposed as a means of achieving the social value of health research and one of such is benefit sharing (Lairumbi et al., 2011a, Stewart and Sewankambo, 2010). The concept of benefit sharing has increasingly become part of regulatory frameworks in biomedical research and many bioethics commentators have highlighted benefit sharing as one of the key ethical issues for consideration in genomic research in LMICs (Lairumbi et al., 2011a, Ndebele and Musesengwa, 2008, Ramsay et al., 2014). In this chapter, I present the knowledge of the concept of benefit sharing amongst African genomic researchers and their arguments and expectations of benefit sharing in the context of human genomic research in Africa.

6.1 Knowledge and Awareness of Benefit Sharing amongst African Genomics Researchers

As indicated in the literature review section, there is no universally accepted definition for benefit sharing. In the bioethics literature, it is acknowledged that though benefit sharing has been a topical issue in bioethics debates for more than two decades and has gained prominence in international law, research ethics and philosophy, it is accompanied with lots of controversies on what it entails and what its definition is (Dauda and Dierickx, 2013, Schroeder, 2007). When Schroeder first documented this problem, she commented that "for more than 15 years of entering into international law, benefit sharing still has no entry in the Oxford English Dictionary and remains a technical word not used in everyday academic language (Schroeder, 2006). This challenge still appears to be a problem in AGS especially as many African genomics researchers had not or barely heard of the concept of benefit sharing. When asked whether they were familiar with concepts of benefit sharing, typical responses were:

Benefit sharing, no, is it a new concept? Benefit sharing? So do you mean that after the research people will get lots of money to share? (R-09)

I have come across the term but I must say I am not a research ethicist and so my understanding of benefit sharing is really global general understanding. I think mutual benefits, as simple as that (R-05)

Some authors have proposed that the definition of benefit sharing would depend on the context in which it is being used (Dauda and Dierickx, 2013). For example, in the context of access to and use of genetic resources, Schroeder defines benefit sharing as "the action of giving a portion of advantages or profits derived from the use of genetic resources or traditional knowledge to resource providers in order to achieve justice in exchange"(Schroeder, 2007) . In the context of international research, Simm argues that benefit sharing is often viewed from the perspective of what participants, and by extension, their communities ought to receive as compensation for their participation in research (Simm, 2007a). Despite limited knowledge about benefit sharing amongst interviewees, those who attempted to describe benefit sharing used a definition that is similar to what is proposed by Simm (Simm, 2007a) as illustrated in the quotes below

Benefit sharing (silence) it sounds like a fancy term (Laugh). I guess it could be lots of things like making sure that the benefits are shared, you know, to participants and society, between countries and yeah, I don't really know. (R-12)

It is not so clear to me. I have heard about it before. I don't think I am informed about it. I think for example, it means, if I participate in a study and if for example, results of the study can be used for something, even that for which is not my sample I could sort of benefit from the reaps of that of that, even when it is not direct. (R-08)

When I explained to interviewees what the concept of benefit sharing is and asked them if they felt it is an important concept in AGS, most agreed and suggested that the concept would need open discussions in research ethics debates on genomics research in Africa.

It is critical, specifically if you are working in genetics (R-05)

Definitely, I think it is important enough to be discussed because if you never discuss these things on the table you will never put it out there and it is not gonna happen. (R-13)

6.2 Justifications for Benefit Sharing

Many arguments have been raised on the importance of benefit sharing in human genetic research (Berg, 2001, Sheremeta and Knoppers, 2007, Simm, 2005) and the debate is ongoing. In

the literature, many bioethicist have proposed different justification models for benefit sharing and their justifications rely on three main approaches: a) Solidarity-the outcome of genetic research are sufficient benefits for all, b) Reciprocity-those who cannot benefit directly from genomics research should qualify for some form of benefit while those who do should not and c) altruism should be a guiding principle for contributors to human genetic research (Schroeder, 2007, Berg, 2001, Dickenson, 2004, Williams and Schroeder, 2004). In our study, we asked African genomics researchers on what their argument and justifications for benefit sharing in human genomics research in Africa would be. There was a mixture of the arguments cited above but many argued against altruism. When I asked researchers if we should be talking about benefits in AGS despite arguments of altruism as a guiding principle of research, many argued that it would be problematic and some felt that it would be a post-colonial mentality. For example

> *That is in an ideal world but the world is not ideal. We should talk about benefit specifically if you are in the context of Africa. Because anytime you say we shouldn't be talking about benefit, it reminds me for instance of those days of colonialism, you are supposed to close your eyes on everything and just do it. So I think, we should be talking about benefits in the context of Africa. But when they world will be ideal, then we wouldn't talk about benefits (R-05)*

The above quote highlights fears of exploitation mostly backed by past experiences of biomedical research in Africa and suggestions that population genetic research in Africa may be another mechanism for HICs to benefit at the expense of LMICs (see chapter 3). When another interviewee expressed this perception, it was linked to what s/he described as helicopter research and the idea that since African populations have been exploited before in north-south collaborations, it would not be fair to use altruism as a guiding principle for human genomics research in Africa.

> *I have seen things before genomics, you see, even in the past, people from outside the continent, come to Africa, enrol people, collect samples and go away. They publish, they set up good labs, they have good grants, but nobody, where they did the study, grasps any benefit or whatever. They don't even know the findings of the study and such helicopter research still continues in some African countries. So that is not right. (R-11)*

Also, justifications based on the model that the outcome of genomics research was for the benefit of all was not popular amongst interviewees and is similar to what has been argued by Schroeder (Schroeder, 2007). Though in the context of human genomics research, some have argued that the benefit is for the advancement of science and that to put forth arguments on benefit sharing would be premature, many interviewees were against this. For example

But even advancing science anyway, what for? Advancing science is also good but what for? At the end of the day we have to give back to the community. For me, it is very difficult to see that as just for the sake of advancement of only science, there should always be embedded or inclusive benefits. (R-10)

R-15. So I mean, I can see that [Altruism and advancement of science] in some instances but how do you tell that to somebody who probably doesn't have much and they are never gonna see this knowledge. They are never going to read the scientific papers. So what are they going to see? They see nothing. So, I mean it would be nice for them to benefit in some way and so I will not subscribe to that [Altruism and Advancement of science].

As demonstrated in the quotes above, justifications for benefit sharing based on altruism and the idea that human genetic research is for the benefit of all was problematic to most African genomics researchers-a view shared by some bioethicists (Schroeder, 2007, Berg, 2001, Weijer and Miller, 2003). In our study, many interviewees preferred a justification model based on the risk of participating in genetic studies and because their samples are being used-an argument that is supported by some bioethics commentators (Schroeder, 2007, Dickenson, 2004, Ndebele and Musesengwa, 2008). When interviewees talked about justifications for benefit sharing, it was mostly on the argument that those who bore the risk of the research or provided samples for human genetic research should qualify for benefits

I think it will be based on this, individuals have participated in research, they have given their time, they have provided resources, they have provided their samples for the research and so these benefits that come out from research should really be shared with the community. That will be my argument (R-13)

Equally, and as seen above, discussions on benefit sharing amongst interviewees were also centered on addressing exploitation and the need for fairness. One interviewee compared it to the mining industry whereby because the land of the people has been used for commercial gain, it was normal for the community to participate in the benefit

I think it is not a bad concept in the sense that like yesterday, somebody, you know, you are mining on his land and getting gold out of it and that somebody, that community, should benefit from it if it is their land or their ancestral land. It is a nice concept bearing in mind that it needs to be done in a responsible way. (R-12)

6.3 Forms of Benefit Sharing

In the bioethics literature, many bioethics actors have proposed different forms of benefit sharing in the context of health research (Participants in the Conference on Ethical Aspects of

Research in Developing Countries, 2002, Lairumbi et al., 2012) in general and genomics research in particular (Hugo Ethics Committee, 2000a). In a workshop that brought together African researchers and bioethicist, participants came up with a fair benefit framework for international research conducted in Africa (Participants in the Conference on Ethical Aspects of Research in Developing Countries, 2002). The framework includes amongst others: capacity building, access to healthcare, public health measures and the sharing of financial rewards. In our study, interviewees also suggested some of these as forms of benefit sharing for collaborative genomics research in Africa.

6.3.1 Capacity Building as a Form of Benefit Sharing

Capacity building has been suggested as a form of benefit sharing by many authors (Schulz-Baldes et al., 2007) and is recommended as a form of benefit sharing by a number of international and national research guidelines (Lairumbi et al., 2011a). In our study, all interviewees identified capacity building as a benefit of genomics research to Africa (see chapter 4). A majority also mentioned capacity building as a form of benefit sharing. Two types of capacity building were suggested as forms of benefit sharing in collaborative genomics research in Africa: Research capacity building and capacity building for medical care.

In terms of capacity building for medical care in Africa, one researcher suggested that for genomics research in Africa, research projects should be able to leave behind medical equipment for used for clinical care once research is over.

> *If you have a project in genomics related research, for me the benefit sharing for that specific project, let's say for Disease A, I have been working with an American collaborator, the first thing is that in Country X there is no place where neonatal screening is done. Because neonatal screening is not done but because we are doing Disease A, we will be doing the minimum phenotyping, which is haemoglobin electrophoresis. I will request from my international collaborators, as part of the project, an HPLC machine that will be left after the project, so that when we finish the project, that specific machine will be used for neonatal screening that has nothing to do with genomics research but that has to do with detecting patients early, so that they have treatment. (R-05)*

> *In many places in Africa, it is the research projects that actually lead to so many things being done. For example, new born screening, so many things have been as a direct result of research. It wasn't research that made it so, but that provided an opportunity for things to change. So I don't undervalue that at all (R-11)*

In terms of research capacity building, some interviewees felt that this would be one way of benefit sharing in AGS. As already demonstrated in Chapters 3 and 4, some interviewees

perceived that research capacity building would address fears of exploitation and ensure equity in collaborations set up as part of AGS. A similar argument has been put forth in debates on benefit sharing in LMICs (Schulz-Baldes et al., 2007). In our study, some interviewees also saw this as an appropriate form of benefit sharing

> *Another way for me is capacity building. Actually, there is no better benefit than capacity building. I think every singular project should have students that are studying at PhD level. Some of them they are already PhD, they are trying to carve out their own research, they have to know how to write grants, to know how to draft research questions that is appropriate for their settings. So if each of the projects that we have include those, for me, it is good enough in terms of benefit sharing because much research in genetics will not be necessarily marketable. (R-05)*

6.3.2 Feedback of Study Findings

Feedback of research findings has been recommended by the ethics committee of the human genome organization as a form of benefit sharing in genomics research (Hugo Ethics Committee, 2000a, HUGO Ethics Committee, 2000b). In our study a majority of the interviewees were of the opinion that feedback of study findings should be one form of benefit sharing. This was so because they perceived that that since the benefits of genomics research may be long term and may not necessary lead to new therapies that could be made available to study communities one way was be to provide study communities with public health messages that are an outcome of the studies

> *I think it will be a message and a message could be conveyed in so many different ways appropriate to the community, whether it is on paper radio or on television and I think that will be a message which will be is the results emanating from the H3A studies and what the significant public health messages are, and kind of making that known as widely as possible. So you might do it on a country basis because you might have to tailor it to the country and I think that is in a way benefit sharing (R-03)*

The provision of public health messages that could be beneficial to study populations has also been proposed by a number of researchers and bioethicist as a way of achieving fair benefit for research in LMICs (Participants in the Conference on Ethical Aspects of Research in Developing Countries, 2002, HUGO Ethics Committee, 2000b). In our study, many interviewees were of the opinion that feedback of study findings to study populations may lead to beneficial lifestyle changes. An argument that has been put forth by some authors and demonstrated by empirical studies that information on disease risks even when not medically actionable could lead to beneficial lifestyle changes and/or personal and family decision making(Fernandez et al., 2003, Shalowitz and Miller, 2005). However, return of genetic results whether at individual or

population level remains an unresolved debate (Bredenoord et al., 2011) that has mostly focused on genetic and genomics research in HICs. In our study, interviewees felt that this was one way of sharing the benefits of genomics research with study participants.

> *I see it [Feedback of results] as a benefit because it is knowledge and when it is research it is the discovery of knowledge. So if you have that knowledge, you are better off than if you did not and that is the way I look at it. And this could be at the family level, at the community level, at any level. (R-11)*

In a systematic review of perceived risks, psychological and behavioural impacts of genetic testing (Heshka et al., 2008), the authors recommended that it is worth pursuing patient education and improved educational strategies following genetic testing as a means of improving beneficial lifestyle changes. In our study, some interviewees expressed similar views and were of the opinion that feedback of results especially at the community level should be accompanied by community education on healthy lifestyles for disease prevention.

> *If you identify things which could help in behavioural change, then absolutely you have some responsibility of educating the population around that. For example, if you have a project on drug abuse and you refer people to social workers but maybe that is not enough, we need to have an education program for the community and educate them on how big the problem is. (R-12)*

Though many genomics researchers identified return of results as a benefit and a form of benefit sharing, and that information on genetic risk of developing a disease should be accompanied by education and information on appropriate lifestyle changes as a form of benefit sharing, only one of the informed consent form that was used in genomics research projects across Africa had the option of returning genetic test results to study participants(Munung et al., 2015-In press).

6.3.3 Science Education and Community-Related Projects

Many have argued that the low science literacy levels in many LMICs are a barrier to genomics research especially in aspects of understanding informed consent, medical genetics and in developing policies for genomics research in Africa (Wonkam et al., 2006, Kibuka-Sebitosi, 2007, de Vries et al., 2011, Nyika, 2009, Ramsay et al., 2014). Such limited understanding could open room for exploitation of study participants and communities (see chapter 3). In our study, many interviewees suggested that community oriented activities and public education in the sciences could be a form of benefit sharing. One interviewee captured it in the following way

> *We should do community engagements, education, return of results. That will benefit everyone directly, irrespective of if that is the end of the research and no one ever does it again. (R-11)*

Interviewees also suggested that public education in the sciences could be a form of benefit sharing. In the literature, it has been suggested that improving education in genome science is needed at all levels in society both by specific audiences and the general public as a way of increasing public awareness of genetics issues (Munn, Skinner et al. 1999). Munn and Colleagues further argue that many scientists have found that an effective way of achieving such education is through high school biology courses. A majority of those who suggested this form of benefit sharing were of the opinion that it could be through science education in secondary schools.

> *I think if you want to look at benefits to maybe a wider scope of people, you could look at maybe improving science curriculum at schools nationwide and that is something that we are currently looking at in Country X and guided through our communication and outreach, which is how to improve science education in the schools. So, I think that is where I will start. (R-02)*

Some African genomics researchers were also of the opinion that science education and effective community engagement as a form of benefit sharing would lead to buy-in of the research by the community and address issues of transparency because the community would then see the research team as a partner in promoting genomics research.

> *So in the form of education and even engaging the communities, so the community sees you as a partner and people that are interested in them. So you don't really give them anything, so just the knowledge, the information is good. (R-13)*

However, many genomics projects in Africa do not have dedicated funds for community engagement. Some researchers suggested that proper engagement with the community would require that genomics research sets aside a portion of the funding for community engagement and that could be used to support community oriented projects mostly science and math education because it is related to project activities

> *I think it will be presumptuous for us to say how we could give back and it is a question we need to ask the communities, right, and to identify what resources you have, in order to give back, so actually for every H3Africa project, we should be setting aside 5% or 10% or whatever of the funding for community projects and all that and then one would engage with the communities on how best they will like to see that money used and I mean, it will be nice to see it used for some education for the community including science education and math education, those kind of things which are related to what we do and you will need to have them in this discussion. (R-12)*

6.4 Perceptions on HUGO's Statement on Benefit Sharing.

One of the most authoritative statements on benefit sharing in human genomics research was made by the ethics committee of the Human Genome Organization-HUGO (Hugo Ethics Committee, 2000a). These guidelines recommend "1) that all humanity share in, and have access to the benefits of genetic research 2) that benefits not be limited to those individuals who participated in such research 3) that there be prior discussion with groups or communities on the issue of benefit sharing, 4) that even in the absence of profits, immediate health benefits as determined by community needs could be provided, 5) at a minimum, all research participants should receive information about general re-search outcomes and an indication of appreciation, and 6) that profit-making entities dedicate a percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts" (Page 366) . HUGO's recommendation was echoed by interviewees in this study.

It is undeniable that private industries would be indispensable in translating genomics research findings into tangible healthcare products and procedures that will benefit individuals and society as a whole (Caulfield et al., 2003, Berg, 2001, Weijer and Miller, 2003). However, some have argued that if commercial firms were to benefit from publicly funded research, they should repay society. In defining benefit sharing, Schroder's definition comprises not only the sharing of advantages but also of profits generated as part of research (Schroeder, 2007). Also, the HUGO ethics committee recommend that at least 1-3% of the profits generated as part of research be given back to the community that participated in the research (Hugo Ethics Committee, 2000a). In the interviewees, when I asked African genomics researchers of their perception of HUGO's suggestion that commercial companies give back 1-3% of profits generated as part of translating genomics research findings to study communities, many were of the opinion that it was a good way of going about benefit sharing and suggested they would request for more. The quotes below illustrate this perspective

> *I will like them to give us 10% instead of 3% (R-09)*

> *I buy it [HUGO's statement]. I will even ask for more. The multimillion pharmaceutical companies are going to make millions, billions. So it is a good idea and I wouldn't be ashamed to say it should be 5% instead of 3 (R-08)*

For some authors Simm, 2007b, Chadwick and Hedgecoe, 2008), arguments against benefit sharing in human genomics research has always been based on the claim that discussions on benefit sharing justifies attempts to commercialize and make profits from the human genome. Also, the arguments suppose that participation in genomics research in based on altruism and that advancing medical knowledge and new therapies should be sufficient benefits. However, as

demonstrated before in this chapter, many interviewees did not support these claims. Also in discussing sharing of profits as a way of benefit sharing, many of the interviewees did not shy away from discussing commercialization and profit in the context of human genomics research in Africa.

> *So I am very careful about profits, because, honestly, not a lot of research ends up in profit that you will give back to the community. But in the event, in cases where there are clear profits as a result, maybe a drug is discovered, and a pharmaceutical company makes huge profit as a result of that, I totally support that and that something comes back to the community in terms of knowledge, in terms of education, in terms of improving their welfare. (R-13)*

To support HUGOs position on the sharing of profits, some interviewees argued that this was because commercial companies usually make a lot of profit, a perception that has also been expressed in the bioethics literature (Berg, 2001). For these interviewees if companies were to make money from genomics research it would only be fair for them to give back to study communities.

> *the reason that comes up frequently is simply that sometimes people work hard to do research and others commercialize the patents, commercialize that and become very rich whereas the researchers who did the work, the communities that participated, derive no benefits whatsoever. That is what has led to a lot of this. For genomics research, the big impetus was the attempt initially of certain companies to patent gene sequences or genes. Like the breast cancer gene, BRCA1, which a company actually successfully patent and they had to go to court and all that stuff. (R-11)*

Despite the support for HUGOs approach to benefit sharing, especially the aspect of profit, a majority of interviewees expressed concerns about the practicability of sharing profit generated by commercial companies. Some expressed concerns about responsibility for managing the money especially in the African context where corruption prevails and there is limited capacity for such activities.

> *Who is going to manage that money? I think we don't have any established, foundation to do this. We have a lot of corruption in our countries, so we will just send two million dollars to the ministry of health and then they buy their cars. I think corruption will be a major setback for doing this kind of thing and also, I think, lack of qualified personnel to handle this. (R-09)*

To address the problem of management of funds given back to communities as a percentage of profits, some interviewees suggested that a task force could be set up to look at benefit sharing and issues of profit and to engage with communities on best ways of sharing profit. One

researcher suggested that an initiative such as the Global Alliance could be used for such purposes.

> *I think that is something some of these International projects like the global alliance you have heard about, and you sort of wonder if there shouldn't be a global project which looks at fairness in terms of IP issues, like what will be fair in terms of giving back to where it came from in the first place.(R-03)*

Another challenge was how the profits were to be used should a pharmaceutical company choose to give back a percentage of the profit to the community that participated in the research. Some interviewees suggested that this would need dialogue with the community and that it should be related to the initial projects and therefore health-oriented, a suggestion that has also been proposed by a number of bioethics commentators (Berg, 2001, HUGO Ethics Committee, 2000b). For example one researcher suggested if it was a diabetes project, then maybe the profits could be invested in improving the diabetes ward of a hospital in the community or the national diabetes control program.

> *For example a hospital based study and people are looking for individuals who have diabetes, cancer. How do you benefit them? I guess you can go back to the hospital and give them 1-2% and say this is for better wards for the patients. I think maybe that is possible. (R-03)*

However a majority of the interviewees were of the opinion that if pharmaceutical companies were to give back, it would be appropriate for the communities to decide on how the profit should be invested. This again highlights the importance of community engagement.

> *I think it is not actually possible to prescribe a specific way but the important thing is to make sure that the people have a voice, from the research participants, their communities, their local health authorities, the research institutions and the country as a whole. The more people have a voice, the more it can work (R-04)*

A second challenge was that of identifying the population or community to give back to. In his paper on the ethics of benefit sharing, Berg argues that if profit is generated from research on a whole population, the recipients of the shared benefit should be the whole population(Berg, 2001). Many interviewees felt that identifying the right population would be a serious challenge and this has also been acknowledged by HUGO's ethics committee (Hugo Ethics Committee, 2000a, HUGO Ethics Committee, 2000b) especially as most genomics research in Africa includes populations from different countries and or regions in the same country

> *Who is the community that contributed to the research? It is not always definable. You are recruiting two hundred people from one major university*

teaching hospital. Who is the community? It is in a hospital. It is not their homes and it is not the participants. So I think the concept is good, the execution is very messy and probably not possible simply because it is hard to define what the community is. (R-11)

In the literature, difficulties of identifying the right population have been linked to the idea that translation of genomics research takes a while and that a lot of time would have passed between the original sampling of people and when a product is developed it may be hard to identify the community (Berg, 2001)- a view also expressed by some of the interviewees in our study.

Sometimes it is difficult to know, if you have done research and then 10 or 20 years later, you want to go back to the community and you do not know whether that community still exists as a community. That is sort of why it is important to identify the leadership of the community because who do you go back and who do you give the 1-2% to? You know, you have to identify the community very carefully (R-03)

Equally, the lack of regulatory frameworks for benefit sharing both at the international level and at national level in most African countries has been documented as a serious challenge to benefit sharing in global health research conducted in Africa (Lairumbi et al., 2011a, Lairumbi et al., 2012). In the interviews, some genomics researchers also highlighted this lack of regulatory frameworks as an impediment to practical benefit sharing in genomics research in Africa especially if a commercial product was to be developed as part of research activities.

I will also say that should the issue of benefit sharing turns to a commercial product, then it should be taken seriously because there is no frame work for dealing with. Even right now for people to ship samples, to execute material transfer agreements, are not easy and many African projects struggle with for a very long time. (R-11)

6.5 Summary

Benefit sharing has been proposed as one way of addressing the risk of exploitation of study populations especially in the context of genomics research. It is also a central topic in debates on the social value of health research. In our study, interviewees had limited knowledge of the concept of benefit sharing but when briefed of what it is, were of the opinion that it was an important concept. Interviewees identified Capacity building, feedback of study findings, community oriented projects and science education as possible forms of benefit sharing in AGS. Their argument for benefit sharing was based on the fact that those who bore the risk of genomics research and who provided samples for genetic resources in Africa should also qualify for a share of the benefits.

Chapter 7 Discussion and Conclusion

In recent times, Africa has witnessed an increase in the number of population genomics studies some of which include the African genomics variation project (Gurdasani et al., 2015, Tachmazidou I for the AGVP Investigators, 2013) and the H3Africa initiative (H3Africa Consortium, 2014). One leading rationale for this increasing interest is the argument that Africa's rich genetic diversity could provide clues to understanding human heredity and health, thereby advancing personalized or precision medicine, on the continent and globally. But whilst there is much enthusiasm on the impact genomics could have on improving healthcare globally (Masimirembwa and Hasler, 2013, Collins and Varmus, 2015, Green and Guyer, 2011), there are concurrent debates on access to and high cost of genomic medicine (Alyass et al., 2015, Phillips et al., 2014, Shabaruddin et al., 2015), if Africa will benefit from its participation in genetics and genomics studies (Ndebele and Musesengwa, 2008), and whether Africa is being used as a research site for studies that may only benefit populations in high-income countries (HICs) (WHO, 2002). It is therefore understandable why one of the major ethical concerns in AGS relates to justice and its possible applications, most particularly benefit-sharing. In the research leading to this dissertation, I sought to explore African researchers' perceptions and expectations of risks and benefits of AGS. The data analysis showed three broad, yet inter related, categories of benefits. This includes: research collaboration, research capacity building and genomic medicine.

7.1 International Research Collaboration

Many African genomics scientists interviewed as part this study were of the opinion that one of the key benefits of AGS is that it gives African researchers the opportunity to be part of a global genomics network. This is because current African genomics initiatives provide a platform for African scientists to learn from one another, advance knowledge on human heredity and health and access funding. Similar benefits have also been highlighted by many authors (Oldham, 2005, Schulz-Baldes et al., 2007, Wagner et al., 2001, Raza, 2005). While research collaboration is perceived as a benefit of AGS to African scientists and research institutions, one may argue that this benefit accrues to all stakeholders and should be considered a win-win partnership for all parties involved in AGS.

7.2 Capacity Building as a Benefit of AGS

Research capacity building was perceived by all interviewees to be a benefit of current AGS and this benefit can be grouped in three sub-categories: 1) training of African genomics researchers, 2) infrastructural support and 3) training in REC review of genomics research.

In terms of training of genomics scientists, most interviewees mentioned that the training of postgraduate students in interdisciplinary genomics fields such as epidemiology, bioinformatics and bioethics is a general boost to biomedical research in Africa. These views are consistent with what is proposed in the H3Africa white paper and also recommended by some authors (Nchinda, 2002, Lansang and Dennis, 2004, Dandara et al., 2014). Another aspect of training that interviewees suggested is a benefit of AGS is the training of African scientists in research-related skills such as manuscript and grant writing. Many hope that by having such skills in Africa, in addition to required infrastructure for genomics research, African researchers will move from the historical position of sample collectors to genomics scholars (Lansang and Dennis, 2004, Dandara et al., 2014) who are able to propose, design and conduct research collaborations that are of relevance to Africa and who can equally make significant intellectual contributions in genomics collaborations.

Institutional research capacity building is the second form of capacity building that was perceived by interviewees to be a benefit of AGS. A major benefit in this sub-category is the establishment of biorepositories in Africa. Biorepositories are undoubtedly a big resource for biomedical research and well curated biorepositories in Africa could foster international research collaborations, south-south collaborations and promote biomedical research in Africa (Abayomi et al., 2013, H3Africa Consortium, 2014, Nchinda, 2002). Despite this, bio-banking research raises a number of ELSIs, most importantly issues to do with ownership of samples and access to samples stored in biobanks. The question of who owns human biological materials collected as part of research, has also been raised by research participants (Moodley et al., 2014). However, little is known on preferences for ownership of human biological samples collected as part of AGS. This will need wider discussion amongst different research stakeholders. Equally, questions of access to samples and data stored in biobanks remain a center of debate. While in the case of data there is a general push towards open sharing (The GAIN Collaborative Research Group, 2007), discussions on access to stored samples remain relatively premature. These ELSIs will need wider discussions and engagement in order to build trust in AGS

The third capacity building effort mentioned by interviewees consists of training of REC members in ethics review of genomics research. A number of authors have suggested that the lack of capacity for ethics review of genomics research in Africa puts African populations at risks of exploitation (de Vries et al., 2011, Nyika, 2009) and that funding initiatives ought to identify the areas where training is required and act accordingly (IJsselmuiden et al., 2012, Nyika et al., 2009b). Empirical studies have also shown that REC members are not familiar with pertinent concepts in genomics research (Sathar et al., 2014, Barchi et al., 2015). This is made worse by the absence of guidelines for genomics research in most African countries (Staunton and Moodley, 2013). One way in which H3Africa is approaching this is through developing research ethics

guidelines and templates that could facilitate genomics research oversight in Africa. Examples include informed consent templates (H3Africa Working Group on Ethics and Regulatory Issues, 2014b) and guidelines for community engagement (H3Africa Working Group on Ethics and Regulatory Issues, 2014a). H3Africa is also engaging with REC members to discuss how ethical issues raised by AGS could be addressed (de Vries et al., 2015a, Ramsay et al., 2014). However, more would have to be done in this regard most likely in the development of training modules on ethics of genomics research. Some of these are already available through the global health trials network (https://globalhealthtrainingcentre.tghn.org/introduction-reviewing-genomic-research/ accessed 14 November 2015) and may be adapted to meet the needs of RECs in Africa.

7.3 Genomic Medicine as a Benefit

A third major benefit of AGS as perceived by interviewees is access to genomic medicine in Africa. Genomic medicine, it can be argued, is the force behind the global genomics revolution and there are concerns that African populations may miss out on genomic medicine (H3Africa Consortium, 2014) because most genomics studies have primarily focused on populations of European descent and the outcome cannot be applied to African populations (Rosenberg et al., 2010, Need and Goldstein, 2009, Ramsay et al., 2011). The major areas in which interviewees perceived that genomic medicine would be of benefit to Africa are: improved diagnosis, pharmacogenomics, development of new drugs and therapies for disease management and public health. The impact of genomics on healthcare in Africa is already visible and it is nowhere more evidenced than its use in the 2014 Ebola outbreak in west Africa where genomics tools were used in tracing the evolution of the Ebola virus (Park et al., 2015) and in improving diagnosis and surveillance (Matranga et al., 2014). Also, some sub-Saharan African countries have recently introduced medical genetics services in their clinical set-ups (Wonkam et al., 2011b)

7.4 Risks of AGS

In the interviews, three main risks or challenges of AGS were echoed by African genomics researchers. They include: 1) exploitation in collaborative partnerships, 2) non-sustainability of AGS and 3) limited access to genomic medicine in Africa.

7.4.1 Exploitation

As already discussed, interviewees perceived that being part of a collaborative genomics network was a benefit of AGS to African researchers and research institutions. However, they expressed fears that they could be exploited in research collaborations set up as part of AGS. When interviewees talked about the possibility of exploitation, they linked it to inequalities in north-south collaborations and historical experiences of exploitation in research collaborations in Africa. This perception has also been echoed in theoretical bioethics debates (Edejer, 1999,

Silverman, 2005, Kilama, 2003) and many argue that this is caused by inherent inequalities in the research environment between HICs and LMICs (Jentsch and Pilley, 2003, Ogden and Porter, 2000, Rakowski, 1993). Despite the fact that exploitation of African researchers in international collaborations has been flagged years ago, the problem still persists. This is exemplified by a recent case in Kenya where some Kenyan researchers sued the management of their institution (a north-south research partnerships) for scientific exploitation and modern day slavery (Nordling, 2012). These fears may still prevail because little has been done in synthesizing what African researchers perceive of and expect from international research collaborations and how their perceptions have shaped international health research in Africa. The results of this study brings to light the perceptions and expectations of some African genomics researchers on collaborative health research. However, large scale studies maybe useful in capturing the views of a wider population of African health researchers.

7.4.2 Non-Sustainability of AGS

A second risk of AGS is non-sustainability. This applies both to the non-sustainability of collaborative partnerships and to capacity building efforts. In terms of non-sustainability of collaborative partnerships, and by extension AGS, the main concern was the continuity of current research projects. When interviewees discussed this risk, they mostly linked it to exploitation of African scientists. The overall perception was that if current AGS projects, such as H3Africa, were to end after current funding phase, it would imply that it was another organized mechanism for collecting human biological samples from Africa. The lack of long term research collaborations has also been discussed by a number of authors and some have described this scenario as parachute science whereby researchers in HICS come into Africa, collect samples and leave with the samples without the intention of developing research capacity in Africa (Harris, 2004, Kilama, 2003). It has been suggested that long term collaborations could minimize these fears and facilitate equitable collaborations (Chu et al., 2014). It is therefore recommendable that African genomics initiatives work towards establishing long term research partnerships in the hope that it would build trust amongst collaborators and facilitate future research collaborations.

7.4.3 Non Sustainability of Research Capacity Building efforts

In terms of non-sustainability of capacity building efforts, concerns were mainly expressed in two major areas a) retention of trainees in African institutions and b) maintenance of infrastructure.

7.4.3a Retention of trainees in African research institutions

The problem of brain drain in Africa has persisted for a long time and many authors argue that it negates research capacity building efforts in Africa (Nchinda, 2002, Sitthi-amorn and Somrongthong, 2000). Unfortunately, the solution to the problem of brain drain is not

straightforward. Some projects within H3Africa are addressing this by having as requirement that trainees who selected into the programs are guaranteed research positions in their home countries. This is one important way of countering brain drain and one which has been recommended by some authors (Nchinda, 2002). However, it may work best for tenure track researchers and may leave out many young African graduates who may, unfortunately, not be employed in academia and research due to high unemployment rates in their countries. Equally, one may argue, based on the international convention on human rights that such an approach to fighting brain drain infringes on the right of an individual to work wherever they want.

7.4.3b Maintaining Infrastructure

Currently, the H3Africa initiative is pilot testing the establishment of biorepositories in three African countries: Nigeria, Uganda and South Africa. While interviewees saw this as a rich resource for biomedical research in Africa, they also described an associated challenge of maintaining these biorepositories, a major one being that of sufficient operational costs once international funding is no longer available. Many African countries, including those that may be considered economically advanced, have power shortages. The three host countries for the biorepositories are experiencing serious challenges in electricity generation and processing. This means that the biorepositories will need alternative energy sources, if the quality of the samples are to be maintained. This increases cost and places a burden on African governments who are still struggling to invest in basic biomedical research. It also increases the possibility that one day, samples would have to be moved to HICs to avoid compromising the quality. To address this problem, some authors have proposed that large academic biobanks in Africa develop a paying customer base that could generate funds and support the running cost of biorepositories (Abayomi et al., 2013). However, such an approach would have to pilot-tested and Africa would need to draw on the experiences of successful biobanking projects in other continents. Also, despite the limited interest to invest in biomedical research by governments either because of other competing national interest or a lack of will, African researchers would have to engage and encourage their governments to invest in health research. This could be through creating research friendly environments through, for example, the development of country regulation for health research, the provision of infrastructure for research and facilitating opportunities for collaborative research (e.g. visas, waiving custom fees for importation of scientific equipment) in their respective countries. Equally, African researchers would have to explore alternative methods and/or sources of funding for health research in Africa. This could, for example, be through, crowdsourcing. Al these could enable African genomic research and health research in general to survive in an environment where there is limited funding for health research. Limited Access to Genomic Medicine

There is great promise that genomics may contribute to improving healthcare in Africa (Alyass et al., 2015, Green and Guyer, 2011, Sander, 2000). However, there were concerns amongst interviewees on the challenges of implementing genomic medicine in Africa and whether or not genomics will be a panacea to Africa's healthcare needs. Many arguments have been put forth on the impact genomics research could have on global health (Singer and Daar, 2001, Green and Guyer, 2011, Hardy et al., 2008, Sander, 2000). Some argue that if care is not taken, genomics may help widen the already existing inequities in global health between HICs and LMICs (Singer and Daar, 2001, Pang, 2002, Bustamante et al., 2011, Hardy et al., 2008) and may constitute just another mechanism for HICs to benefit at the expense of LMICs (WHO, 2002). These fears may be valid considering that while genomic medicine is already making headway in HICs e.g. the genotype specific use of warfarin (Epstein et al., 2010), little is known of its actual use in Africa as demonstrated by a lack of specific examples (with the exception of diagnosis of sickle cell anaemia and down syndrome) on the use of genomic medicine applications in Africa. Proponents of genomics medicine will need seek ways of introducing genomics in the clinic in Africa and it may require public-private partnerships and investments (Wonkam and Mayosi, 2014).

7.5 Proposed Solutions to Addressing Risks in AGS

Interviewees also proposed a number of ways in which the potential risks of AGS could be addressed to ensure that Africa benefits from genomics research. In the next few paragraphs, I will discuss these proposed solutions.

7.5.1 Transparency

Many interviewees expressed the need for transparency and fairness in AGS. They perceived that this would be important in building trust and minimizing exploitation. A number of bioethicist have also emphasized the importance of rigorous transparent procedures in international research (Parker and Bull, 2009). A quick look at H3Africa policies shows that the initiative is approaching this through development of guidelines and policies that could facilitate collaboration (de Vries et al., 2015b). An example is the H3Africa data sharing policy (http://h3africa.org/images/DataSARWG_folders/FinalDocsDSAR/H3Africa%20Consortium%20Data%20Access%20%20Release%20Policy%20Aug%202014.pdf). One of the objectives of this policy statement is to ensure that there is the fair sharing of data and samples between collaborators. However, H3Africa would have to ensure that the application of this statement remains transparent and supportive of all parties involved in AGS. This is so because if data generated by researchers in Africa are exploited by their partners in HICs at the expense of African researchers and institutions, it would undermine long term health research collaboration in Africa (Parker et al., 2009, Foster and Sharp, 2007). As Parker and Bull (2009) put it, these are

internal ethical issues in collaborative health research in LMICs that have to be adequately addressed.

Another area that would require transparent models is the ownership of intellectual property rights for innovations that are an outcome of AGS. Interviewees perceived that this was one area where there is a high potential for exploitation of African scientists. One example that was frequently cited is the CT scan that was developed in South Africa and patented in Europe. The H3Africa initiative however provides little guidance on intellectual property rights. In its white paper, it is stated that each genomics project would, "depending on the outcomes of the research, address issues related of benefit sharing and intellectual property". The paper makes no further mention of intellectual property. Also, little is known if individual research projects within H3Africa have policies on intellectual property. African genomic initiatives would need to think through the issue of ownership of intellectual property, propose recommendations for wider discussions and develop guidelines on ownership of intellectual property.

7.5.2 Equity

Many interviewees were of the opinion that the problem of inequitable research collaborations could be partly addressed if African researchers are empowered to make substantive intellectual contributions to AGS. They suggested that this could be achieved through research capacity building. Many authors have proposed that research capacity building in Africa. Research capacity building has also been recommended as one way of addressing exploitation of African research communities and of ensuring that health research in LMICS is sustainable (Chu et al., 2014).

7.5.3 African Leadership and Ownership

Many interviewees expressed the need for an African ownership and leadership of AGS. They were of the opinion that African healthcare problems need to be addressed by African scientists who understand the African healthcare context and that it would be inappropriate for 'strangers' (non-Africans) to tell the story of African genomics. The importance of having local researchers leading or directing research collaborations in Africa has also been proposed by some authors who suggest that it could maximize benefits and minimize harm in inequitable research collaborations (Chu et al., 2014). Some commentators also argue that African leadership would ensure that the major diseases and health problems in LMICs are analysed and addressed by local scientists who understand the context (Nchinda, 2002, Wolffers et al., 1998). Other authors have illustrated that this leadership approach has been successful in designing research collaborations that are beneficial to African populations, for example the Ubuntu clinic in Khayelitsha, South Africa and the Rakai health sciences program in Uganda (Chu et al., 2014).

The H3Africa initiative is addressing this through ensuring that grants are awarded to African scientists in African institutions (H3Africa Consortium, 2014, de Vries et al., 2015b). However, some African researchers echoed concerns that though the grants are awarded primarily to African research institutions, some of the research agendas are driven by collaborators in HICs and researchers in African institutions are only being used or are allowing themselves to be used to meet funding requirements. H3Africa has also proposed that future research on all samples stored in biobanks in Africa must include an African investigator and that for three years following the establishment of the biobanks, samples would be made exclusively available to African researchers or research teams that have a plan for building research capacity in Africa (de Vries et al., 2015b). While the aim of this may be to address fears of exploitation, it raises questions of whether or not it is justifiable to include an African researcher in a project on the sole basis that the research samples were collected in Africa. Such an approach to achieving fairness would need to be further discussed.

7.5.4 Science Education

Interviewees also perceived that science education could be a form of benefit sharing in AGS. Arguably, investing in science education would have an impact on AGS and in ushering genomic medicine into Africa. After all, genomic medicine like other medical sciences, would be most effective if it is presented to an educated and prepared public. In the context of H3Africa, one of the H3Africa's research projects, CAFGEN, is taking this direction and is using comic books and social media as a means of improving public understanding of genomics in Botswana. Their approach is typically Afrocentric and one can only hope that it will be extended to other African countries

7.5.5 Community Oriented Projects

Many interviewees were of the opinion that benefit sharing in AGS could also be in the form of community oriented projects aimed at improving health infrastructure in host countries. For example, a genomics research project on diabetes could improve the diabetes ward in the host community. Some interviewees however argued that though this is one way of ensuring that research is of social value, current African genomic initiatives do not fund this form of community activity. Typically, most community engagement activities for health research in Africa have focused on building trust in study communities and having community-buy in of the research projects while little attention has been given to improving host communities. Considering that genomics research, unlike clinical trials, is unlikely to lead to a therapeutic intervention or vaccine that may be made reasonably available to study populations, one may recommend that funders of AGS consider community oriented projects as part of the funding package of AGS.

7.5.6 Feedback of Study Findings

Feedback of study findings was another form of benefit sharing proposed by interviewees. They suggested that feedback of study findings to study populations and communities could be generic and include information of genetic predisposition and health information on lifestyles that could prevent or delay disease development. A view that is also supported by some authors (Coyle, 2009, Thirlaway and Davies, 2001). However there is little empirical information on feedback of genetic findings in Africa. A review (annex 4) of consent forms used in genomics research projects in Africa showed that only one project planned to return genetic findings to study participants (Munung et al., 2015-In press). There is also little guidance on feedback of genetic findings in Africa and one may wonder if it is appropriate to feedback genomic findings that are not medically actionable. This will need wider debates and would benefit from the development of appropriate guidelines.

7.5.7 A Prepared Healthcare System

A challenge to having genomic medicine in Africa is the lack of human capacity for genomic medicine. Currently, Africa has limited skilled genomics practitioners. For example, in 2013, South Africa had about one medical geneticists for every 4, 450,000 individuals (Kromberg et al., 2013). Also, general practitioners have limited knowledge of genetics and genomics (Wonkam et al., 2006). If genetic medicine is to be available in Africa, current genomics initiatives would have train medical geneticists, genetic counsellors and laboratory technician skilled in molecular testing and bioinformatics (Siwo et al., 2015, Wonkam and Mayosi, 2014). Also, there will be a need to improve on the keeping of patient electronic records in Africa, as this is critical in delivering genomics medicine (Kannry and Williams, 2013, Scheuner et al., 2009). Frameworks that would link biobanks in Africa to medical records, as is the case with the US-NIH eMERGE network, maybe adopted as a means of ensuring that genomics is available in the clinic in Africa

7.5.8 Focusing AGS on Africa's Healthcare Priorities

Another consideration to getting genomics to the clinic in Africa is the need for current genomics research projects to focus on the disease burden in Africa. The CIOMS guidelines recommend, as a means of avoiding exploitation, that research conducted in LMICs and sponsored by HICs should be of relevance to LMICs (CIOMS, 2002). Some authors have also argued that this will ensure that countries benefit from their participation in genomics research (Ndebele and Musesengwa, 2008). Currently H3Africa has 16 wet lab projects categorized into two major groups, communicable and non-communicable diseases (H3Africa Consortium, 2014). In the communicable disease group, research is on population genetics of HIV, tuberculosis, respiratory diseases in children, febrile fever and trypanosomiasis while in the non-communicable disease group, the focus is on: cardiovascular disease, diabetes, schizophrenia, stroke, neurological

disease, and cervical cancer (H3Africa, 2013). While it has been argued that Africa is facing a double burden of both communicable and non-communicable diseases (de-Graft Aikins et al., 2010, Mayosi et al., 2009), current reports by the World Bank show that the disease burden in Africa is mainly in the area of maternal and child health, tuberculosis, HIV and malaria (The World Bank, 2013). It would therefore important for AGS to focus more on these diseases and on diseases where the cost-benefit ratio for clinical management is in favour of genomics applications

7.5.9 Translational Phase for African Genomics Science

To overcome the problem of access to genomics medicine, many interviewees suggested funding for H3Africa extends to a translational phase. However, many perceived that it may take a long time to get results that would be easily translatable to clinical benefits in Africa. This may in fact be debatable following the recent announcements by Human Longevity Inc. and Discovery Ltd that they will be providing whole exome, whole genome and cancer genome sequencing to discovery health insurance clients in South Africa (Cookson, 2015). With such an announcement, one may arguably say that the reality of genomics medicine has arrived on the African continent.

Also, one of the strongest arguments put forth in the literature against genomic or personalized medicine is its high cost (Phillips et al., 2014, Shabaruddin et al., 2015). Some interviewees perceived that a national health insurance scheme could curtail cost. This raises concerns about genetic discrimination especially as many African countries lack regulation for genomic medicine. Secondly most African countries lack a coordinated national health insurance scheme. This will therefore imply that only those who can afford health insurance would access genomic medicine. However and in general, the cost of genomics medicine was not perceived by interviewees to be a major problem and may were of the opinion that, like ARVs and most antimalarials, the cost of genomic medicine will decrease over with time. This would however require public private partnerships that could provide such services (Wonkam and Mayosi, 2014)

7.5.10 Government Commitment

To address concerns of non-sustainability of AGS, some African genomics scientists suggested that African governments invest in and promote AGS not only in terms of funding but in developing policies that could facilitate genomics research in Africa. The call for African governments to invest in biomedical research is not new. In 2008, following the Bamako declaration, African governments pledged to set aside 2% of their Gross Domestic Product (GDP) for health research (The Lancet, 2008). Seven years thereafter, many are yet are to keep to their commitment and many African countries still committing less 1% of their GDP to research either because of competing interest with other national needs or a lack of political will (Nordling, 2013, Paruk et al., 2014). It is therefore questionable how government interest in AGS would be

garnered. Some authors have suggested that H3Africa starts engaging with African governments (Dandara et al., 2014) and one may suggest that the African Society of Human Genetics (AfSHG) as one of the three active partners in H3Africa, plays this role.

In recent times, some have shied away from engaging African governments in science and technology discourse on the grounds that it has always been the same story and an unmet promise. Of course, African governments may have competing challenges that prevent them from keeping to the Bamako declaration. However, engaging policy makers in such discussions could lead to the development of policies that allows research to flourish. In the Bamako declaration, African governments had in fact expressed the desire for robust ethical and regulatory frameworks that could protect their populations from harm and promote public trust in research. Only policy makers can successfully push such an agenda. However, the AfSHG and other African led initiatives such as the African Academy of Sciences and the recently constituted Accelerating Excellence in Science in Africa may have to be drivers of such change.

7.5.11 Sharing of Profits

The last form of benefit sharing echoed by interviewees is the sharing of profits and some supported HUGO's proposal that 1-3% of profits generated as a result of genomics research be given back to study communities (Hugo Ethics Committee, 2000a). However interviewees echoed the complexities of sharing profits: who takes responsibility for such a task and how do you identify the community to give back to. Many interviewees however suggested that should there be profit, an institution such as the global fund for health or the AfSHG should take responsibility in ensuring that profits are shared with study communities. Another concern is that of defining a community and identifying which community rightfully gets the share of the profit. This problem has been raised in the literature (Schroeder, 2007, Simm, 2005) and one for which no consensus has been reached. The HUGO ethics committee however suggests that benefits be distributed more broadly (Hugo Ethics Committee, 2000a).

7.6 Key Actors in Benefit Sharing

In terms of key actors in benefit sharing, interviewees perceived that this should be RECs, research participants and community advisory boards. They were mostly of the opinion that communities be given a voice in determining what they consider benefits and how issues of benefit sharing may be addressed in their populations. This, they perceived, would be relevant in improving transparency and allaying fears of exploitation. The importance of giving communities a voice in deciding benefits and discussing benefit sharing has been well illustrated in the hoodia benefit sharing case (Wynberg et al., 2009). However, this can only happen if all

stakeholders involved in genomics research in Africa recognize the importance of benefit sharing and the role communities can play.

Responsibilities for benefit sharing were mostly assigned to funders. In the literature, there is no consensus on who has responsibility for providing benefits. However, if benefit sharing is approached from the perspective of social justice, as perceived by interviewees, then the responsibility would be on all stakeholders involved in research, as recommended by the UNESCO declaration of human rights, the national bioethics council and guidelines of some African countries (Lairumbi et al., 2011a).

7.7 Conclusion

African Genomics Science has great potential in unlocking questions around human heredity and health. However, much would have to be done to address fears of exploitation and the non-sustainability of genomics research projects in Africa. To achieve this, one guiding question that would need to be answered by all stakeholders is whether or not AGS is driven by an African agenda or directed by international imperatives to extend the genomic revolution to Africa because of Africa's rich genetic diversity and ease of access to samples due to the high disease burden in Africa. African genomics scientists have expressed fears of exploitation and concerns that African populations may not be able to access genomics medicine. These concerns would have to be addressed in order to establish trust and ensure fairness.

The H3Africa initiative is addressing this through supporting cutting-edge genomic research that will generate important findings and discoveries as well as serving as a vehicle for research capacity building in Africa. However, before H3Africa, Africa has been host to a number of international genomics initiatives such as the international HapMap project (The International HapMap Consortium, 2003) and the MalariaGen project (The Malaria Genomic Epidemiology Network, 2008) and interestingly, all these initiatives had acknowledged the problem of research capacity in Africa and promised to invest in research capacity building in Africa. More than 10 years thereafter, this lack of research capacity still prevails. H3Africa has the challenge of making a difference, avoiding duplication of efforts and ensuring that its capacity building efforts are evenly distributed across Africa in order to prevent a research divide in the continent, as is already the case in north-south collaborations. While H3Africa may have the duty to promote equity and social justice, the success of AGS would have to be a shared responsibility and African governments and researchers must also play an active role in ensuring that genomics remains a mainstay in Africa.

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Appendices

Appendix 1 Informed Consent Documents to Study Participants

Title of Study: Stakeholders' Perceptions and Expectations of Risks and Benefits of Genomics research in Africa: A qualitative study

Introduction

We would like to invite you to take part in a research study that aims at investigating stakeholders' perceptions and expectations of benefits and risks of genomics research in Africa. This study is part of an MSc Medicine (Bioethics) within the Rheumatic Heart Disease Genomics (RHD Gen) project at the Department of Medicine, University of Cape Town. It is not an audit or trial. This form explains the research study. Please, read it carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study.

Objective

The objective of this study is to explore stakeholders' (researchers and REC members) perspectives and expectations of genomics research in Africa. This could generate empirical data that would inform ongoing discussions on benefit and benefit sharing in genomics research in Africa. It will also provide leads to the assessment of the actual benefit of genomics research and recommend practical steps to protect the interest of African researchers and research participants.

The Researchers

This is a an MSc in Medicine (Bioethics) research project executed by Nchangwi Syntia Munung, based at the Department of Medicine, University of Cape Town. It is supervised by Prof. Bongani Mayosi and Dr. Jantina de Vries, both at the University of Cape Town.

Participants

We plan to talk to researchers within the Human Hereditary and Health in Africa (H3Africa) Consortium and to members of RECs in Africa that have attended the H3Africa consultation meeting.

Methods

If you agree to participate, we would like to discuss with you what you perceive as benefits and, to a lesser extent, risks of genomics research in Africa. We can talk to you at a location that you choose – either at work or somewhere else or via telephone or Skype call. The conversation will last approximately one hour. It will be audio taped – the recordings will be written down after which they will be destroyed. At the end of this project, all sources of potential identification will be removed from the transcripts, and the transcripts may be deposited in an archive. The interview will be done in English.

Confidentiality

We will keep what you have said to us private. When we write the discussion down it will not have your name on it but a code. The information collected will be kept in restricted access offices and on password-secured computers We will not publish entire interviews, but it is important that you understand that excerpts may be used to report on this study, for instance in the thesis or publications. If this is done, a piece of text from your interview will appear together with a code (for example, 'R1, EC1). If we deposit the transcripts in an archive, we will make sure that any information that could identify you is removed.

Voluntariness and right to withdraw

Your participation in this research project is voluntary. If during the interview or at a later date you have second thoughts, then please feel free to withdraw from the study. We can terminate the interview at any time, and the recording will be destroyed.

Risks/Discomforts

There are no physical risks in this study. However, you might feel upset or worried to when answering some of the questions. To minimize this, please, feel free to choose not to answer any questions you do not want to.

Anticipated Benefits

If you decide to participate in this study, you will receive no direct benefit. However, your contribution will inform ongoing discussions on benefit and benefit sharing in genomics research in Africa.

Compensation

You will not receive any compensation for participating in this study.

Contact Information

If you would like more information about this research project before/after deciding to participate, please contact Nchangwi Syntia on mobile phone (+27) 604227239 or by email (MNNNCH001@myuct.ac.za) You could also contact Dr Jantina de Vries (+27) 021 650 5716 or Prof Bongani Mayosi (+27) 021 406 6200.

If you think you have not been treated fairly or have been hurt by joining this study, please contact the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town on 021 406 6338 or write to Shuretta Thomas, Human Research Ethics Committee, Room E52-24, Old Main Building, Groote Schuur Hospital, Observatory 7925, Cape Town.

Consent Form

Stakeholders' Perceptions and Expectations of Risks and Benefits of Genomics research in Africa: A qualitative study

Have you been provided with sufficient information about the study? Yes ☐ ☐

Have you had an opportunity to ask questions and discuss this study? Yes ☐ ☐

Have you received satisfactory answers to all your questions? Yes No ☐ ☐

Do you understand that your participation is voluntary, and that you are free to withdraw from the study at any time? Yes No ☐ ☐

Do you agree to take part in this study? Yes No ☐ ☐

Signature……..Date…….

Name in block letters ...…….....

Investigator Statement

I confirm that I have carefully explained the proposed study to the participant.

Signature……..….Date…….

Name in block letters……...

Appendix 2: Template Topic Guide for Interviews with Researchers

Stakeholders' Perceptions and Expectations of Risks/Benefits of Genomic research in Africa

- ✓ Introduce self, Introduce study
- ✓ The aim of this study is to explore the perspectives of relevant stakeholders (researchers and Members of research ethics committees) on the risk and benefits of genomic research

Specifically this interview aims to:

1. To explore researchers' viewpoints on the risks and benefits of genomic research in Africa.
2. To explore how stakeholders think the perceived benefits could be provided
3. Explore the viewpoints of researchers on the responsibility for providing benefits in genomic research
4. Why am I interviewing you, not audit/trial, voluntary

Interview-Approximately 1 hour, Explain why recording
Confidentiality reminder – interview transcripts not shared with H3Africa
Any questions? Consent form and signing of the form

A. Background

1. So just quickly, could you briefly describe me your H3Africa research project
2. What is your current position in the project (P.I, Co P.I)
3. How long have you been involved in genetic and genomics research

B. Benefits of Genomics research

1. What do you think are some of the benefits of genomics research to Africa? (clinical, patients, your national population, research participants, healthcare)
2. What are the specific benefits of the genomics research you are currently involved in?
3. How could these benefits be made more practical? Whose responsibility
4. At what stage of the research project should cited benefits be made available?
5. In explaining/describing benefits to participants and to ethics committees- which of the cited benefits are you more likely to talk about?

C. Clinical Applications

1. Can you envisage the use of genomics in the clinic?
2. How do you think this could be feasible in Africa?
3. Whose responsibility

4. Do you have any specific examples of how genomics is being used in a clinical setting within Africa or in your country?

D. Data /sample Sharing

1. Does the project involve sample/data sharing? (What type?)
2. What are the benefits of data and sample sharing? How will this benefit Africa (participants, researchers etc.)
3. What do you feel about data and sample sharing? Is it important?
4. The H3Africa policy advocates for exclusive access of data/samples for African researchers for 3 years. What is your take on this?
5. Examples of research that should not be done on samples/data originating from your research?
6. What do you think are some of the risks of data and sample sharing to Africa

E. Benefit Sharing

1. Have you come across the term benefit sharing?
2. What does it mean to you?
3. Do you think it is an important concept in genomics research? Africa? why
4. How do you think this concept could be addressed more in genomics research?

Do you think that there is a chance that genomics research may affect African communities? How?

F. Closing Section

1. Considering all that we have discussed, how do you think genomics research could be made more beneficial to Africa?
2. Do you think there is need for further discussions on benefits and benefit sharing in genomics research?
3. Anything else they would like to add?
4. Any questions about further research process, timeline etc.?
5. Interested in research results? (permission to re-contact)

Appendix 3: Research Ethics Clearance

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

08 September 2014

HREC REF: 618/2014

Dr J de Vries
UCT Centre for Clinical Research
J52-16
OMB

Dear Dr de Vries

PROJECT TITLE: STAKEHOLDERS' PERCEPTIONS AND EXPECTATIONS OF BENEFITS OF GENOMIC RESEARCH IN AFRICA: A QUALITATIVE STUDY (MSc-candidate-N Munung-) sub-study of 466/2008

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2015.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

We acknowledge that the student, Nchangwi Synthia Munung will also be involved in this study.

Please quote the HREC reference no in all your correspondence.

Yours sincerely

pp *Signed*
PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.

HREC 618/2014

Appendix 4: Review of Informed Consent Docuents Used in Different Genomics Projects in Africa(Munung et al., 2015-In press)

OPEN ACCESS

PAPER

Obtaining informed consent for genomics research in Africa: analysis of H3Africa consent documents

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ABSTRACT

Background The rise in genomic and biobanking research worldwide has led to the development of different informed consent models for use in such research. This study analyses consent documents used by investigators in the H3Africa (Human Heredity and Health in Africa) Consortium.

Methods A qualitative method for text analysis was used to analyse consent documents used in the collection of samples and data in H3Africa projects. Thematic domains included type of consent model, explanations of genetics/genomics, data sharing and feedback of test results.

Results Informed consent documents for 13 of the 19 H3Africa projects were analysed. Seven projects used broad consent, five projects used tiered consent and one used specific consent. Genetics was mostly explained in terms of inherited characteristics, heredity and health, genes and disease causation, or disease susceptibility. Only one project made provisions for the feedback of individual genetic results.

Conclusion H3Africa research makes use of three consent models—specific, tiered and broad consent. We outlined different strategies used by H3Africa investigators to explain concepts in genomics to potential research participants. To further ensure that the decision to participate in genomic research is informed and meaningful, we recommend that innovative approaches to the informed consent process be developed, preferably in consultation with research participants, research ethics committees and researchers in Africa.

INTRODUCTION

The global interest in genomic and biobanking research has led to an evolving understanding of appropriate consent models for use in these types of investigations.[1 2] Consent models range from specific consent for the collection and use of human biological samples and data in a particular project to broad and blanket consent for all future uses, with several options in between.[3–5] Tassé *et al*[3] identified the following consent models currently in use: (1) broad and blanket consent; (2) tiered consent with different options for sharing and secondary use; (3) presumed consent for sharing; (4) recontacting or reconsenting for sharing; (5) waived consent; and (6) no consent (because no data with identifiers is used). In addition, some projects are exploring possibilities for dynamic consent, where research participants can provide consent on an ongoing basis using social media.[6 7]

Most analyses of consent forms used in biobanking and genomic research[8 9] have focused on research taking place in Europe and North America. While there is now a small literature on consent for biobanking and genomics research in resource-limited locations, including African settings,[10–16] many questions remain. For example, there are few data on the use of broad consent for health research in Africa including how key concepts in genetic and genomic research such as data and sample sharing, biobanking and reuse of samples collected as part of research are explained to research participants.

The Human Heredity and Health in Africa (H3Africa) Consortium is a collection of research and infrastructure projects seeking to apply genomics methodology to diseases affecting African people.[17] Currently, H3Africa involves 26 funded projects: 15 genomics research projects, 4 biobanking projects, 6 Ethical, Legal and Social Implications projects and a pan-African bioinformatics network, H3ABioNet. Most of the genomics research projects involve several research sites across Africa. In 2014, the H3Africa Consortium developed guidelines for informed consent, which also contain template text for use in the development of project-specific consent documents (http://www.h3africa.org). These guidelines are not prescriptive and H3Africa researchers determine the most appropriate consent model considering the needs of their study population as well as their country-specific ethical and legal norms.

The development of H3Africa has prompted African researchers to grapple with the complexities around informed consent for genomics and biobanking research. The purpose of this paper is: (1) to describe how complex concepts in genomics are explained in consent documents used by H3Africa investigators; and (2) to explore consent models that are currently used in H3Africa projects.

METHODS

We sourced informed consent documents used in H3Africa projects. We contacted principal investigators (PIs) of the 15 genomics projects and the 4 biobanking projects. PIs were contacted via email and asked for copies of informed consent

CrossMark

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