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SCHOOL OF PUBLIC HEALTH

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UNIVERSITY OF GHANA, LEGON

EXPLORING DELIBERATIVE ENGAGEMENT FOR GENOMIC RESEARCH AND BIOBANKING IN AFRICA: PROCEDURAL CONSIDERATIONS, CONTEXTUAL INFLUENCES AND ASSOCIATED OUTCOMES

THIS THESIS IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF A DOCTOR OF PHILOSOPHY IN PUBLIC HEALTH

BY

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DECLARATION

I, Irene H. Tsey, hereby declare that except for other people's work, which I have duly acknowledged, this thesis is the result of my own original research conducted under the supervision of Prof. Paulina Tindana, Dr. John K. Ganle, and Prof. Patricia Akweongo. I further declare that this thesis, either in whole or in part, has not been submitted elsewhere for another degree.

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DEDICATION

This thesis is dedicated to my unwavering pillars of support—my parents, Ms. Emma Buame and Mr. Prosper Attah Tsey. Their ceaseless prayers, encouragement, and steadfast belief in my journey have been the bedrock of my achievements. I express deep gratitude for their enduring love and guidance. In fond memory, I dedicate this work to my late uncle, Dr. Samuel Buame, whose invaluable investment in my education laid the foundation for my intellectual pursuits. To my sisters, nephews, nieces and cousins, your unwavering belief in my abilities and your constant cheering have fuelled my determination. This achievement is as much yours as it is mine.

May this work stand as a testament to the profound impact of familial support, encouragement, and the enduring spirit of those who have shaped my educational journey.

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LIST OF ABBREVIATIONS

AWIGEN	Africa-Wits INDEPTH Collaborative Centre for Genomics of cardiometabolic diseases
AGVP	African Genome Variation Project
CABs	Community Advisory Boards
CE	Community Engagement
CEBioGen	Community Engagement for Genomics and Biobanking in Africa
CFR	Code of Federal Regulations
CIOMs	Council for International Organization of Medical Sciences
DD	Deliberative Democracy
DE	Deliberative Engagement
DFGDs	Deliberative Focus Group Discussions
DIs	Deliberative Interviews
DNA	Deoxyribonucleic acid
ELSIs	Ethical Legal and Social Implications
FGDs	Focus Group Discussions
GINA	Genetic Information Non-discrimination Act
GWAS	Genome Wide Association Studies
HDSS	Health Demographic Surveillance System
HICs	High Income Countries
HIPAA	Health Insurance Portability Accountability Act
HIV	Human Immune Virus
H3AFRICA	Human Heredity and Health in Africa
IDIs	In-depth Interviews
KDRN	Kidney Disease Research Network
LMICs	Low to Middle Income Countries
NBAC	Nuffield Council on Bioethics
NGAP	Neuropsychiatric Genetics of Africa Population
NGRI	National Genomics Research Institute

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NIH	National Institute of Health
RECs	Research Ethics Committees
SDM	Shared-Decision-Making
SNPs	Single Nucleotide Polymorphisms
UNESCO	United Nations Educational, Scientific and Cultural Organization

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DEFINITION OF TERMS

Variable Name	**Operational Definition**
Attitudes	Participants' opinions, beliefs, and inclinations concerning genomic research, biobanking, and data sharing, including willingness or reluctance to participate.
Awareness	Participants' level of understanding and knowledge about genomic research, biobanking, and data sharing.
Biobanking	The collection, storage, and management of biological samples and associated data, typically for use in genomic research and related studies.
Contextual Factors	Factors including sociocultural elements, gender, education, age, resources, and infrastructure that may influence the implementation and effectiveness of deliberative engagement.
Deliberative Engagement	A structured process involving informed discussions among participants to address ethical issues and develop guidelines in the context of genomic research and biobanking.
Ethical Concerns	Ethical issues and dilemmas related to genomic research and biobanking, such as informed consent, privacy, data sharing, and benefit sharing.
Genomic Research	The systematic study of an organism's complete set of genes or an individual's genetic makeup to understand their function and role in health and disease
Procedural Factors	Elements related to the implementation of deliberative engagement, such as facilitator expertise, language, group size, session duration, and information delivery tools.

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ABSTRACT

Background: Ethical, legal, and social issues in genomic research and biobanking require innovative community engagement methods. Deliberative engagement offers a promising model for informed discussions and ethical guideline development but is underutilized, especially in resource-poor settings like Ghana. This study explored procedural and contextual factors influencing the implementation of deliberative engagement in genomic research and biobanking and assessed its impact on participants' attitudes towards data sharing as an ethical concern.

Methods: This study employed an experimental one-group pretest-posttest research design using a sequential embedded mixed-methods design. A total of 66 participants were selected from the Africa-Wits Genomics Network under the Human Heredity and Health in Africa Initiative in the Kassena-Nankana district of the Upper East region of Ghana. A pre-engagement baseline survey assessed participants' awareness and attitudes towards genomic research and data sharing. This was followed by a structured deliberative workshop which provided in-depth information on the significance of genomic research and the ethical considerations surrounding the sharing of genomic data with various stakeholders, including researchers, biobanks, and pharmaceutical companies. Subsequently, participants were divided into small groups for deliberations on the issues presented during the workshops. Post-engagement surveys measured changes in awareness and attitudes towards genomic research and data sharing. Additionally, focus group discussions delved further into participants' perspectives on the procedural and contextual factors that could influence the implementation of deliberative engagement, identifying both challenges and opportunities to be considered for future initiatives. The focus group discussions were recorded, transcribed, and analysed using the framework analysis technique, involving data coding and thematic identification. Survey data were exported to Stata version 13.1 MP for cleaning and analysis including descriptive

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statistics, demographic characterization, and pre- and post-engagement analysis of participant ratings on data sharing and genomic research awareness and attitudes. Statistically significant variations between the two survey time points were identified using Fisher's exact test.

Results: The study included 66 participants aged 47-67 years old, predominantly males, 43(65.2%) with many of the participants having primary 16 (24.2%) and junior high school 17(25.8%) education. Procedural factors that influenced deliberative engagement are facilitators' expertise, session duration and information delivery tools. Whereas the contextual factors that influenced deliberative engagement are group composition, group size and language. Quantitative analysis showed a significant increase in participants' awareness of genomic research from 34(51.5%) to 52(89.7%) with a p-value = 0.001. There was a significant decrease in reluctance to share biological samples and data for commercial purposes from (10)15.2% to (4) 6.8%, indicating a shift in participants' attitudes after participation in the deliberative engagement.

Conclusions: Deliberative engagement could potentially be an effective approach for community engagement in genomic research and biobanking. Policymakers and practitioners should consider and address key procedural factors for successful implementation, including facilitator expertise, language, group size, session duration, and information delivery tools. These findings provide valuable insights for promoting responsible and ethical community engagement practices in genomics research.

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CHAPTER ONE

INTRODUCTION

1.1 Background

Genomic research and biobanking play a major role in deepening our understanding of health, diseases, and genetic inheritance, within the African continent and globally. Nevertheless, these achievements have also presented key ethical concerns and ongoing debates, many of which have not yet been resolved (Chalmers et al., 2014). These issues are related to ensuring informed consent, protecting privacy, returning results to participants, establishing responsible governance, avoiding undue commercialization, sharing benefits fairly, and managing data sharing. For example, whilst participants in genomic studies are required to provide informed consent, their involvement and the data generated can impact the families and communities they belong to, or the populations they represent (Nyika, 2009; Yakubu et al., 2018). Furthermore, the utility of stored human samples is an issue that has triggered global debates (Wendler and Emanuel, 2002; Hansson et al., 2006; Tindana et al 2014). In the African context, genomic research faces significant ethical dilemmas primarily stemming from the vulnerability of the populations involved, alongside concerns arising from past community experiences and inherent cultural beliefs and practices (Yakubu et al., 2018; Moodley & Beyer, 2019).

To address the ethical concerns surrounding genomic research and biobanking, there has been a call for innovative approaches to community engagement (O'Doherty et al., 2012). This is because the traditional approaches to engaging and seeking public opinion though useful, may be limited (Diamond & Plattner, 2008; McWhirter et al., 2014) especially when the topic is complex and community members are not familiar with concepts such as related to genomics or biobanks (McWhirter et al., 2014). This may lead to “top of the head” reactions (Diamond & Plattner, 2008), that may not contribute to decision or policy formation (O'Doherty et al.,

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2012). Furthermore, individuals might lack the empowerment needed to actively participate in ethical discussions concerning emerging technologies. Therefore, there is a call for deliberative engagement to be utilized as a supplementary model for community engagement in genomics research and biobanking (Chalmers et al., 2014; McWhirter et al., 2014).

Indeed, deliberative engagement involving the citizenry has been experimented with, albeit on small scales, to deliberate about important public issues (Diamond & Plattner, 2008). In the context of health, there is a growing literature on deliberative engagement as used in various concepts of community engagement, including "shared decision-making" (SDM), patient-centred care, and patient/care provider autonomy (Safaei, 2015). For instance, deliberative engagements have been utilized to enable informed and significant public input into a range of issues related to biotechnology, including biobanking (Burgess et al., 2008; McWhirter et al., 2014; Molster et al., 2013). Furthermore, it has been useful in several other public health settings, such as population screening for cancer (Rychetnik et al., 2013).

While advocacy for, and research on, the use of deliberative approaches to engage communities and the public in complex and emerging public health interventions are growing (Chalmers et al., 2014), this methodology has not been employed extensively, especially in resource-limited settings such as Ghana.

1.2. Problem Statement

Genomic research and biobanking have experienced significant growth globally, holding promise for advancing disease treatment and prevention (Gurdasani et al., 2015). However, this growth has raised ethical concerns, particularly in African countries, where the number of genomic research projects is increasing (De Vries et al., 2011; Yakubu et al., 2018). These concerns extend beyond traditional healthcare research, encompassing unique ethical, legal, and social issues (Bua et al., 2018; Murtagh et al., 2021). Ethical concerns include appropriate

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consent models for data and sample sharing (Gowans et al., 2011; Wendler, 2013; Nnamuchi, 2018) withdrawal of consent (Kaye, 2012; Lowenthal & Hull, 2013), ownership of human biological samples and associated data (Hawkins & O'Doherty, 2011; Lowenthal & Hull, 2013), privacy and confidentiality (Heeney et al., 2010; Kaye, 2012), and equitable benefit sharing (Simm, 2005; Dauda & Dierickx, 2013). Trust issues (Moodley & Singh, 2016), fairness in research collaborations (O'daniel & Haga, 2011; de Vries et al., 2015), past exploitation against local populations and researchers, coupled with participants' disadvantaged social and economic background, increases their vulnerability in research settings (Heymann et al., 2016), and cultural factors, also pose challenges specific to African settings. Additionally, low literacy rates and a lack of terminology in indigenous African languages further complicate genomic research and biobanking (Tindana et al., 2012).

Community engagement is recognized as a crucial approach to address ethical complexities in genomic research and biobanking in Africa (Staunton et al., 2018). However, effective and ethically sound community engagement practices, particularly in resource-poor settings, are lacking, hindering the success of genomics research and biobanking (Chalmers et al., 2014). There is an urgent need for innovative strategies to facilitate informed debate and develop ethical guidelines to address emerging concerns (Chalmers et al., 2014; McWhirter et al., 2014). While traditional approaches to community engagement are valuable, they have recognized limitations when dealing with complex or novel subjects like genomic research and biobanking, necessitating iterative dialogue (O'Doherty et al., 2012; Laws et al., 2013). For example, the traditional approaches often rely on simply providing information to community members rather than fostering a genuine two-way dialogue. Also, the traditional approaches may fall short in empowering community members to actively participate in decision-making processes related to genomic research. Additionally, traditional approaches often take a one-size-fits-all approach, assuming all communities need the same information and will engage in

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the same way. This fails to recognize the diversity of communities and their needs, interests, and concerns (O'Doherty et al., 2012).

Deliberative engagement methodology has demonstrated its value in various settings, offering a new dimension to community engagement in genomic research (Chalmers et al., 2014). However, its utilization remains limited, with most studies conducted in advanced countries like Canada, the USA, Australia and New Zealand (O'Doherty, & Secko 2008; O'Doherty et al 2012; Rychetnik et al. 2013). Furthermore, while there has been substantial scholarly focus on various aspects of deliberative engagement like its internal proceedings and effects (Grönlund et al., 2015; Christensen et al., 2017; Himmelroos et al., 2017; Strandberg et al., 2019), limited attention has been given to the core factors influencing its effectiveness (Koskimaa et al., 2020), particularly contextual factors in low-income settings like Sub-Saharan Africa. Empirical research on deliberative engagement in genomic research and biobanking in Ghana and other African countries is scarce (Tugendhaft et al., 2021; Thaldar et al., 2022). Therefore, this study aims to address the gaps in knowledge by examining the procedural and contextual factors influencing the implementation of deliberative engagement in Ghana in genomic research and biobanking. By identifying these factors, the study intends to contribute to the development of effective community engagement strategies that can address ethical complexities and promote responsible genomic research and biobanking practices in Africa.

1.3 Research Questions

1. What are the procedural factors that could influence the implementation of deliberative engagement in genomic research and biobanking?
2. What are the contextual factors that could hinder or enable the implementation of the deliberative engagement in genomic research and biobanking?

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3. What are participants' perspectives on potential challenges and opportunities that could influence the implementation of deliberative engagement in genomic research and biobanking?
4. Will participation in a deliberative engagement session affect awareness and attitudes of participants on data sharing in genomic research and biobanking?

1.4 Objectives of the study

1.4.1 General Objective

The main objective of this study is to examine the procedural and contextual factors that could influence the implementation of deliberative engagement in genomic research and biobanking in Ghana.

1.4.2 Specific Objectives

The specific objectives of the study are to:

1. Explore procedural factors that could influence the implementation of deliberative engagement in genomic research and biobanking in Ghana.
2. Explore contextual factors that could hinder or enable the implementation of deliberative engagement in genomic research and biobanking in Ghana.
3. Explore participants' perspectives on potential challenges and opportunities of using deliberative engagement to engage stakeholders in genomic research and biobanking in Ghana.
4. Assess the effect of deliberative engagement on participants' awareness and attitude towards data sharing in genomic research and biobanking.

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1.5 Justification

Whilst deliberative engagement has proven effective in various contexts, its implementation and impact in sub-Saharan Africa remains underexplored (Tugendhaft et al., 2021; Thaldar et al., 2022). This study addresses these gaps by examining the procedural and contextual factors that could influence the successful implementation of deliberative engagement in genomic research and biobanking in Ghana. It aims to shed light on whether participating in deliberative engagement sessions could lead to meaningful changes in awareness and attitudes regarding genomic research, biobanking, and data sharing. The findings from this research are expected to offer valuable insights into the challenges, opportunities, and context-specific strategies that could inform future implementation of deliberative engagement practices.

Additionally, this study contributes to the enhancement of community engagement practices, which could potentially promote ethically robust approaches in the field of genomic research and biobanking. Furthermore, this research contributes to better understanding of deliberative engagement in genomics research and biobanking in Sub-Saharan Africa. This knowledge provides a foundation for future research and policy development.

1.6 Chapter summary and outline of the thesis

The current chapter (1) introduced the research background with emphasis on the concept of deliberative engagement as a promising model for community engagement in genomics research and biobanking. The chapter articulated this study's research problem, objectives, questions, and justification.

The rest of the thesis is organized as follows: Chapter two (2) is the literature review encompassing relevant literature, theoretical framework, key concepts, previous studies, and existing gaps. Chapter three (3) focuses on the study's methodology, covering research design, data collection methods, analysis techniques, ethical considerations, reflexivity, positionality,

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and potential limitations. Chapters four (4) and five (5) present findings. Chapter six (6) delves into a discussion of the study's findings and limitations. Finally, Chapter seven (7) summarises the study, draws conclusions, and makes recommendations for policy, practice, and future research.

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CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

The overarching goal of a literature review is to offer valuable insights into the existing body of knowledge within the research field, providing information on what has been explored and what areas require further investigation (Boote & Beile, 2005; Snyder, 2019). A narrative review was employed to explore the definitions, utility, governance, and ethical considerations of genomic research and biobanking. Furthermore, it examines the concepts of community engagement, shedding light on its core principles, underlying assumptions, limitations, and challenges. The review also examines procedural and contextual factors, challenges and opportunities related to the implementation of deliberative engagement in genomic research and biobanking.

The literature review process involved exploring a variety of sources to ensure a comprehensive understanding of the topic. Initially, a rapid review was conducted, followed by further exploration to include a diverse range of relevant literature.The process involved a semi-structured trial-and-error approach, utilizing various combinations of keywords to identify relevant articles. Eventually, the key criterion of community engagement, combined with related concepts like deliberative engagement, genetic/genomic research, and biobanking, was used to refine the search. To manage the number of articles, a thorough examination of abstracts was conducted. Selected articles were then read in-depth and relevant information identified and synthesized.

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2.1 Conceptual definitions and clarifications

2.1.1 Genetic and Genomic research

Genetic and genomic research involve the study of genes, with genetic research focusing on specific genes and genomic research encompassing the entire set of genes, known as the genome (Nyika, 2009). This distinction is exemplified in studies such as those examining the gene associated with Sickle Cell Disease, where only the relevant aspect of the DNA is analysed (Nyika, 2009). While genetic and genomic research can be categorized based on the utilization of genetic information, the term 'genetic research' is commonly used to refer to both types(Nyika, 2009). For the purpose of this study, "genomic research" will be employed as an inclusive term covering both genetic and genomic aspects.

2.1.2 Bio-banking

Biobanking involves the collection and storage of biomaterial, predominantly blood, saliva, and urine, alongside demographic and health-related donor information (Johnson et al., 2011). The biospecimens and anonymized data stored within biobanks serve as valuable resources for medical researchers, facilitating further investigations and enabling multi-centre and cross-disciplinary studies (Awadalla et al., 2013; Manolio & Collins, 2013; Toh & Platt, 2013).

2. 2 Ethical issues in genomic research and biobanking in Africa

Globally, genomic research and biobanking have stirred controversies, encompassing concerns such as consent, privacy, return of results, governance, funding, commercialization, data sharing, and benefit-sharing (Chalmers et al., 2014). In the African context, ethical challenges are compounded by vulnerability and community-specific issues rooted in past experiences, cultural beliefs, and practices (Yakubu et al., 2018; Moodley & Beyer, 2019). Successful genomic research in Africa necessitates addressing concerns related to community

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engagement, broad consent, and the potential implications of sharing DNA samples and genetic data to mitigate risks of stigmatization and harm (Yakubu et al., 2018).

The evolution of biobanking from routine practices to a source of ethical, legal, and social debates began in the 1990s, challenging established research ethics norms (Hoeyer, 2008). Genetic research introduces unique risks and benefits distinct from other health research, necessitating a nuanced ethical framework (Nyika, 2009; Moodley & Beyer, 2019). Additionally, technological advancements and collaborative studies extend beyond geographical and cultural boundaries, requiring careful consideration of ethical implications (Nyika, 2009).

While high-income countries have developed legislative frameworks to address these issues, low-income countries, including many in Africa, are in the early stages of establishing structures for genetic research and biobanking (Nyika, 2009; de Vries et al., 2017). The H3Africa framework underscores the importance of authentic community engagement, aligning with the African communitarian worldview (Mbiti, 1969; Yakubu et al., 2018).

2.3 Community Engagement in biomedical research

2.3.1 Community engagement

Community engagement has gained recognition as essential in global health research, as championed by ethicists, funders, and the 2016 CIOMS guidelines (King et al., 2014; van Delden & van der Graaf, 2017). Community engagement is generally defined as the process of working with groups of individuals bound by location, or distinct interest, to mitigate issues affecting their well-being (Davis, 2011). In the field of health research, it includes a range of activities and procedures, such as conveying meetings with members as well as representatives of a community, collaborating with community advisory boards (MacQueen et al., 2001;

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Campbell et al., 2015), and collaboratively designing and carrying out research with community involvement (Tindana et al., 2007a; Adhikari et al., 2016).

2.3.2 Definition of 'community'

A standard definition for community has not been established (Tindana et al., 2007b). The word "community" has been utilized to explain the interactions among people basically on geographic conditions (Tindana et al., 2007a). Nonetheless, in recent times it has been recognized that people who share immediate surroundings may not of necessity represent community, because they may be different in terms of respect to value systems as well as other cultural features that are more germane to the social concept of community (Tindana et al., 2007b). Some are of the view that the definition of community must be based on the common identity shared by its members (Campbell & Jovchelovitch, 2000). This means an individual may belong at the same time to several religious, vocational, or ethnic communities, or communities with different values and ambitions but reside in a particular geographic area. While Tindana et al. (2012) defined community in relation to shared ethnicities, languages and location, Seeley et al. (1992) defined community as the population under study defined by a geographical area. Lemke et al.(2010) more specifically defined community in the context of genomic research as the multiple stakeholders affected by, or interested in, biobanking and genetic research. Others also define community as a cohort of people united by at least one or more common characteristic(s) such as geography, ethnicity, shared interests, values, experience, or tradition (Sapienza et al., 2007; Brunton et al., 2017).

Despite the complexities of defining community, the definition of community to a great extent should depend on the type of proposed research, the goal of engagement and the context in which the research is carried out. In genomic research, the "community" that should be the focus of attention could be groups of individuals with the same disease that is to be researched, their family members - since family medical history and biological materials may be attained

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from them for genetic analysis. My next focus of discussion is on why community engagement in genomic research and biobanking?

2.3.3 Why CE in genomics and biobanking?

In their 2010 study, Lemke et al. highlight the ethical duty of researchers to engage with biobank participants through CE. This engagement is not just about utility, but about recognizing and honouring the volunteers' contribution as an inherent good. Additionally, researchers lay the foundation for fostering mutual trust and respect, igniting public interest and participation in their work, leading to more relevant and impactful research outcomes when they identify and address community needs through active engagement (Lemke, et al., 2010). Lemke et al. (2010) describe CE as ‘an important step in ensuring that biobank research is conducted in an ethical, locally suitable approach, including a variety of community involvement used to inform, consult, involve, collaborate with or empower communities’(Lemke, Wu, et al., 2010) . Others have indicated the purposes of CE in genomics research to include establishing trust in a biobank (McCarty et al., 2011), guarding against a loss of trust in science (O’Doherty & Hawkins, 2010) or to enhance the professionalization of biobanks (Hewitt, 2011). Researchers like Ormond et al. (2009) highlight a critical distinction in biobank community engagement. They advocate for a model of constant interaction and exchange of ideas with community members, rather than simply informing them and collecting their data. O'Doherty & Hawkins (2010) focus on a critical gap: how conversations with biobank communities translate into actual policy changes. Lemke et al. (2010) add another gap: the lack of practical guidance for designing effective CE approaches specifically for biobanks and their participants.

The Human Heredity and Health in Africa (H3Africa) Initiative (Rotimi et al., 2014) recognises CE as one of the fundamental elements for the successful implementation of genomic research and biobanking (H3Africa, 2014). This is because of the ethical concerns about informed

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consent, privacy rights, and fair return of results are entangled with legal and methodological complexities surrounding governance, funding models, commercialization potential, and equitable benefit sharing, all of which complicate the establishment of these resources (Hoeyer, 2008; Knoppers et al., 2012). Growing evidence suggests target communities might not fully understand scientific methods and the logic behind crucial aspects of genomics research, like sample and data sharing. This underscores the importance of CE in building informed consent through pre-engagement and education (Hahn et al., 2017). Tindana et al. (2017) advocate for CE in genomics research and biobanking for several reasons: CE empowers participants through knowledge, facilitates knowledge exchange, and fosters a collaborative learning environment where researchers and communities learn from each other. They emphasize the importance of researchers actively listening to and integrating community perspectives on both the research process and the specific disease under study. This understanding becomes particularly crucial when considering the potential risks of genetic research, where high literacy levels may not be a prerequisite (Nyika, 2009). In this context, effective communication is essential, requiring information that is easily understandable to meet community expectations and prompt necessary actions(Tindana et al., 2017). Community engagement (CE) serves as a platform for negotiating a shared understanding that integrates biomedical explanations of illness with traditional and culturally sensitive interpretations (Hahn et al., 2017).

In biobanking, integrating community inputs is crucial for planning and managing governance frameworks that prioritize community interests (Laurie 2011). Genomic research, unlike other biomedical studies, has far-reaching effects on families and communities, emphasizing the importance of engaging ordinary community members from which participants are drawn (Nyika, 2009; Moodley & Beyer, 2019). Ensuring community-wide awareness and consent minimizes the risk of community displeasure stemming from discovering undisclosed research affecting them (Nyika, 2009). Privacy and confidentiality are paramount in genomic research

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due to the potential inference of information about non-participating individuals, necessitating engagement with stakeholders beyond researchers and participants (Tindana et al., 2015; Moodley & Beyer, 2019). Genetic information disclosure may unearth personal or family secrets, impacting relationships and causing social issues, affecting both participants and non-participants within the same group (Moodley & Beyer, 2019). Proactive efforts to minimize stigmatization risks, integrated into project timeframes and budgets, are essential, with community engagement emerging as a valuable method for this purpose (Nyika, 2009; Moodley & Beyer, 2019) Recognizing the ethical implications of genomic research and the necessity for community involvement in biobank governance, community engagement becomes pivotal for garnering public support and acceptability, particularly in the African context (Moodley & Beyer, 2019).

However, the feasibility of traditional community engagement (CE) approaches in the context of genomic research and biobanking, particularly in sub-Saharan Africa, has been questioned (Moodley & Beyer, 2019). Some argue that while certain CE approaches may be applicable across diverse health research types, their effectiveness can be influenced by local, social, and cultural contexts (Adhikari et al., 2016; Pell et al., 2019). Recognizing the ethical implications of genomic research and the imperative to build public trust and garner public input, there is a call for innovative approaches to engage populations (Chalmers et al., 2014; McWhirter et al., 2014). Commonly employed methods like surveys and focus groups, aimed at facilitating open dialogue between researchers and communities, come with inherent limitations, particularly in addressing complex issues (Godard et al., 2004; Avard & Knoppers, 2009; Gottweis et al., 2011; Chalmers et al., 2013). Criticisms have been raised, highlighting deficiencies in the consultative process, such as restricted discussion topics and a focus on project support rather than meaningful consultation for improvement (Wallace, 2005; Petersen, 2007; Hoeyer, 2008; Kim et al., 2009b;). This underscores the urgent need for practical tools that can effectively

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facilitate community engagement in the context of genomic research and biobanking (Rowe and Fewer 2000; Gauvin et al. 2010).

Community Advisory Boards (CABs) have historically played a role in bridging the gap between research teams and communities, addressing ethical challenges, and contextualizing risks and benefits(Cox et al., 1998; Strauss et al., 2001; Quinn, 2004). However, in the context of genomic research and biobanking, their limitations, including potential lack of broader community representation, have become evident (MacQueen et al., 2015; Moodley & Beyer, 2019). While CABs contribute valuable insights, there is a growing demand for more robust community involvement beyond advisory boards, as these are often perceived as tokenistic and ancillary to research (MacQueen & Auerbach, 2018). Resources allocated to CE and CABs are frequently limited and susceptible to budget cuts, emphasizing the need for exploring alternative approaches that ensure transparency and genuine representation (Moodley & Beyer, 2019). Considering the complex implications of CE, trust issues, and the evolving concerns with CAB limitations, my research aims to explore alternative models, recognizing the importance of introducing diverse community opinions and concerns. To complement existing methods and broaden community input, traditional assemblies, qualitative research, and deliberative processes are gaining traction (Lemke et al., 2012; Vreeman et al., 2012; Woodsong et al., 2006; Tindana et al., 2014). There is a growing call for innovative CE approaches, especially for complex topics like genomic research and biobanks (Tindana et al., 2017). However, for these approaches to be effective, they must foster significant dialogue and generate public trust. Deliberative engagement has gained recognition globally as one such strategy.

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2.4 Deliberative engagement as a model for community engagement in genomics research and biobanking

Deliberative engagement in the context of health research describes a method for involving communities in navigating the complex ethical landscape of new technologies, stemming from the political concept of deliberative democracy (McWhirter et al., 2014). While some scholars in the health field use "deliberative democracy" and "deliberative engagement" interchangeably, I have chosen to employ the term "deliberative engagement" in this study for clarity and specificity. This method goes beyond traditional focus groups by actively informing participants and encouraging open dialogue. As they gain new knowledge and consider diverse viewpoints, participants are empowered to revise their initial opinions, leading to a richer understanding of complex issues (McWhirter et al., 2014).

Deliberative forums have brought informed public voices to diverse biotech issues like biobanking, across Canada, US, and Australia (McWhirter et al., 2014). While encompassing various methods like citizen juries, the term also signifies a more structured community consultation process (McWhirter et al., 2014). McWhirter et al. (2014) highlight the success of deliberative engagement events in public health, specifically citing their effectiveness in population screening programs for cancer. Over time, the use of deliberative methods in public participation for health care priority setting has increased. While not all studies in the initial review employed these methods, the proportion involving at least one deliberative approach grew steadily. By the 2000-2006 period, 37% of the studies examined included a deliberative element (Mitton et al., 2009). This trend indicates a growing recognition of the value of involving the public in decision-making through structured and facilitated discussions. To date, this methodology has not been employed extensively, and Africa has been slow in catching up with the use of deliberative engagement (Thaldar et al., 2022).

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2.4.1 Key elements, philosophical and politico-ethical justification for using deliberative engagement based on the concept of deliberative democracy

While the boundaries and precise definition of DD remain debated, a core principle shared across its various theoretical strands is the critical role of informed and deliberative public input in democratic governance (Bohman & Rehg, 1997). Some DD theorists, like Gutmann and Thompson (1997), champion an ideal of "reciprocal reasoning," where citizens and officials must justify collective decisions as acceptable to all those impacted. In essence, DD posits a high expectation for citizens' ability to deliberate, reason together, and reach at least some level of agreement on the common good (Kim et al., 2009b). One of the key characteristics of DD is that it is a process that combines technical expertise, rational decision making, public values and preferences in decision making (Renn, 1998). In other contexts, such as in designing environmental policies, efforts have been made to utilize DD towards the enhancement of competence in the decision-making process, and for assigning a fair share of responsibility in managing environmental activities to those who are or will be affected by the potential consequences. Although technical know-how is acknowledged to be necessary, it is inadequate for making practical decisions in some contexts. Some scholars are of the view that, in the absence of public values and preferences, such decisions are not legitimate (Carcasson & Sprain, 2010; O'Doherty et al., 2012; Moodley & Beyer, 2019; Koskimaa et al., 2020;).

Considering that society is plural with varying value systems and worldviews, questions have been asked pertaining to who can legitimately assert the right to decide on the values or preferences that must guide communal or shared decision making, especially when the well-being and lives of humans are at stake? More specifically, questions have been asked pertaining to how society must address important but unresolved ethical issues in research with human participants—issues without clear guidance in the current regulations (Kim et al., 2009b). A genuine concern is whether it should continue to be the usual approach, in which stakeholder

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groups lobby those with the power to make or implement policy, or the opinions of ordinary citizens that demonstrate a shared common good, towards informing policy (Kim et al., 2009b).

The term deliberation emphasizes the manner and steps involved in reaching a decision, independent of who participates in the process (Stern & Fineberg, 1996; Rossi, 1997). Hence, the basis for a discussion to be labelled 'deliberative' is for reciprocal dialogue of arguments as well as reflections and not decision making based on the status of the participants. Additionally, deliberative processes must be guided by the recognized rules of a coherent debate. Participants must engage in a collaborative process to reach a decision. This requires them to agree on a specific decision-making process, such as voting, sorting viewpoints, consensual decision making, or involving a mediator. Importantly, arguments must be grounded in factual evidence and relevant knowledge, ensuring all perspectives are represented. Transparency is crucial, with participants disclosing their values and using logical reasoning when interpreting evidence. Finally, a structured format should be employed to process information, promoting clarity and fairness. By adhering to these principles, participants can engage in a meaningful and productive dialogue that leads to a well-informed decision. This has however been critiqued to be far from the reality. The concept of deliberation transcends closed circles like elite conferences to encompass public forums. This inclusivity requires actively involving communities whose values and interests are impacted by policy decisions. They must be equipped to effectively articulate their concerns and participate in the exchange of arguments. How these voices ultimately translate into policy remains a complex issue in policy development (Kingdon, 2002), and the weight given to public opinion varies depending on the context and subject matter (Kim et al., 2009b). However, the fundamental principle is that public opinion is not merely a metric to be measured and influenced, but a valuable source of guidance for shaping policy. Critics might argue that public surveys on complex ethical issues capture uninformed opinions unworthy of trust, citing the public's lack

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of scientific expertise (Kim et al., 2009b). However, this doesn't negate the potential of thoughtful public input. Recognizing the crucial interplay between thoughtful deliberation and equitable representation, some scholars propose "deliberative democracy" as a more precise term to capture the ideal of involving all affected parties in a meaningful decision-making process (Cohen, 1997; Rossi, 1997; Chess et al., 1998). For complex decisions affecting large populations, deliberation balances scientific data with local knowledge and experience (Cramer et al., 1980; Dietz, 1987). When faced with uncertain outcomes, careful deliberation is crucial to identifying the best approach for managing decision-making uncertainties and striking fair and efficient trade-offs between overly cautious and insufficient protective measures. Furthermore, deliberation addresses the broader concerns of the affected groups and the public at large. Deliberation fosters common ground on complex issues by allowing participants to learn from each other's perspectives on both scientific and non-scientific knowledge (Webler et al., 1995; Pidgeon, 1997). It can also lead to a common understanding of each party's stance and perceptions and therefore support a renewal of each actor's opinions (Warren, 1993; Tuler, 1996). Deliberation unlocks creative problem-solving, offering new solutions and win-win outcomes. It broadens society's awareness of options, interpretations, and potential actions related to the issue at hand (Wynne, 1992; De-Marchi and Ravetz, 1999). This process can foster understanding, reduce conflict, explore new perspectives, inform policymakers, and pave the way for fair and optimal solutions, even compromises or tolerated consensus (Fiorino, 1990). Deliberations can be organized in several forms. A diverse toolbox exists for implementing deliberative democracy in policymaking, ranging from traditional methods like advisory committees and public forums to innovative approaches like participatory budgeting and online crowdsourcing (Bacow & Wheeler, 1984; Bua et al., 2018). Notable examples include structured models like Deliberative Polling, Citizens' Juries, and 21st Century Town

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Meetings, which facilitate informed public engagement on specific issues (Fishkin, 1997; Crosby et al., 2005; Lukensmeyer et al., 2005).

Government agencies can drive DD through direct engagement, as seen in Western Australia's 40 deliberative sessions with the public between 2001 and 2005 (Gregory et al., 2008). Conversely, some approaches simply gather citizen views through polls or consultations, informing policy discussions without necessarily requiring consensus (Chambers, 2003). This push for DD has even led to legal frameworks like Italy's Tuscany Law (2007), Scotland's Community Empowerment Act (2015), and the UK's Sustainable Communities Act (2007).

There are however factors (design and context factors) associated with the functioning of these deliberative processes especially related to their institutionalization (Font et al. 2014: p.6–8). The design factors for example are related to how a specific participatory deliberative process should be designed such as who should participate, and how participation should be organized. The contextual factors have to do with institutions and structures (Bua et al., 2018). These factors could result in various constraints depending on the level of resolvability.

In the past (Jonsen, 1998) and even in recent times(Yakubu et al., 2018), the common approach to addressing ethical issues has been to turn to experts. Despite their influence on human subject research regulations (Yakubu et al., 2018), expert panels face several limitations. Appointed through political processes, they often lack the diversity and representativeness necessary for robust bioethical decision-making. Additionally, their specialist viewpoints can overshadow the moral intuitions of ordinary citizens. Furthermore, the risk of bias and special interest representation is heightened by the absence of reliable data on public opinions and the exclusion of key stakeholders from the deliberation process.

Scully, Banks, & Shakespeare (2006) examined the moral arguments used by lay people deliberating on the ethically complex question of "social sex selection" (i.e., parents using

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preimplantation genetic diagnosis to fulfil their wish for a boy or girl child). The study revealed that ordinary citizens possess the capacity to articulate core moral values, challenge them, if necessary, acknowledge the complexities of conflicting ethical considerations, and defend their positions with rational arguments.

To comply with regulations on emergency research without consent, research ethics is increasingly incorporating DD methods. Surveys, interviews, and public meetings have been used to assess "community consultation" requirements, revealing variations in public acceptance of emergency research across different communities and consultation methods (Baren & Biros, 2007; Contant et al., 2006). Two deliberative studies on medical records research, one in the VA and one in British Columbia, have yielded contrasting results. While Damschroder et al. (2007) found no significant attitude shifts due to their non-facilitated deliberations, they identified a strong link between trust and veterans' preferences for consent in medical records research. In contrast, Secko et al. (2009) observed significant attitude changes, with respondents becoming less supportive of mandatory re-contact and less certain about subject withdrawal rights after deliberation.

Thus, in the context of genomic research and biobanking, deliberation has been highly recommended as an approach for CE to include public inputs in decisions regarding complex ethical issues while being used to engage relevant communities at the various levels of CE. Despite strong theoretical and case-study support, empirical research on public deliberation remains limited, and the little research that has been conducted is in the context of high-income countries.

2.4.2 Procedural factors affecting deliberative engagement

The deliberative process fosters an environment where participants actively learn and engage with new information, typically presented through written materials or expert presentations. It

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emphasizes balance, ensuring all perspectives on an issue receive due consideration. The process encourages participants to become social decision-makers, considering and incorporating diverse viewpoints while still expressing their own individual values and perspectives (as illustrated in Figure 1). This approach is supported by several studies (Burkhalter et al., 2002; delli Carpini et al., 2004; Jacobs et al., 2009).

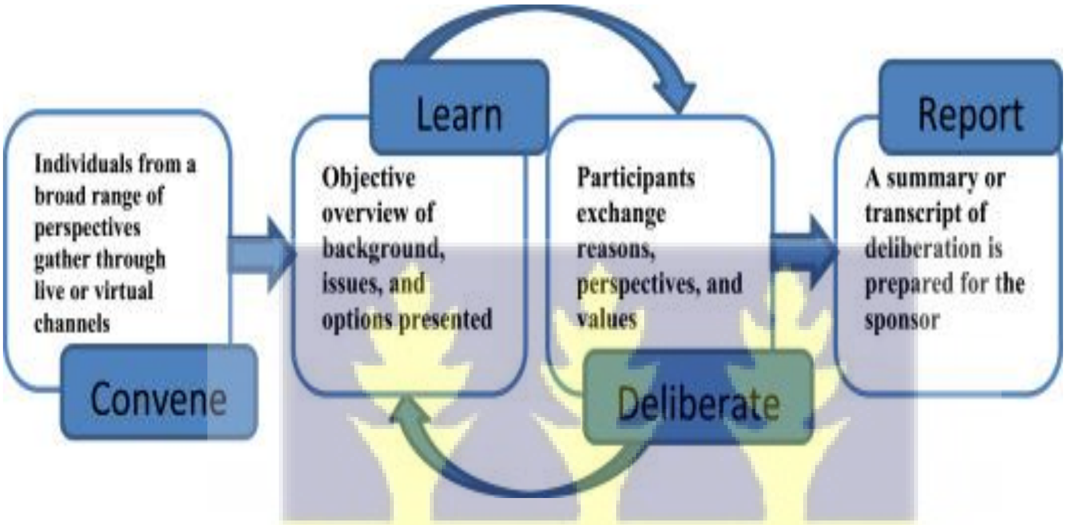

Figure 1:Deliberation Engagement: process and core elements (Carman et al., 2015).

Fishkin (2009, p 33-43) has identified five requirements to ensure a robust and inclusive deliberative process These are presented in Table 1.

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Table 1: Five requirements for a high-standard deliberative process

CONDITION	**DEFINITION**
Information	"The extent to which participants are given access to reasonably accurate information that they believe to be relevant to the issue."
Substantive balance	"The extent to which arguments offered by one side or from one perspective are answered by considerations offered by those who hold other perspectives."
Diversity	"The extent to which the major positions in the public are represented by participants in the discussion"
Conscientiousness	"The extent to which participants sincerely weigh the merits of the arguments."
Equal consideration	"The extent to which arguments offered by all participants are considered on the merits regardless of which participants offer them."

Similarly, when organizing a deliberative process, it is crucial to consider various design elements. These elements encompass the choice and identities of participants and facilitators, transparency, the format, duration, and the governing principles of deliberation. In selecting participants for deliberations, one must consider the inclusion of hard to reach or underrepresented views. The choice of the number of participants should be guided by the objectives and principles of the deliberative process. While some recommend ten to fifteen participants as an effective size (Moynihan et al., 2008), there is no universally ideal group

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size. Balancing the trade-offs between quality and practicality also becomes necessary (Rothwell, 2013). Larger groups that encompass all pertinent perspectives and engage in more extended deliberations may be preferable in cases involving contentious health technologies, especially when significant ethical concerns are raised regarding the technology. Deliberative processes can take various forms, including virtual settings (as seen in Brazil, Scotland, England, and the Netherlands)(Oortwijn et al., 2022) and most recently in South Africa(Thaldar et al., 2022), in-person meetings, or a combination of both. Participants may engage in discussions during a single session, across multiple sessions, simultaneously, or at different times (Mendonça et al., 2022). The benefit of face-to-face deliberation lies in its potential to enhance communication among participants, but this must be weighed against the risk of dominant participants exerting undue influence, which could impair group decision-making (Mendonça et al., 2022). Various techniques, such as nominal group methods, consensus-building approaches, and expert elicitation techniques, can be employed to mitigate these challenges. It is also important to determine the requisite level of deliberative rigour and to assess what is feasible within the constraints of available resources (Mendonça et al., 2022). Formulating the rules for deliberation necessitates careful consideration of the process's objectives, the participants involved, and the way they will engage. These rules encompass guidelines governing how participants interact, share their perspectives, the timeframe within which these interactions occur, and regulations regarding the specific information or topics open for discussion. As previously reported, the rules governing deliberation have a more significant impact on the outcomes of deliberation compared to the identities of the participants or the information considered (Janis, 1982). In cases where multiple deliberative forums exist and consistency in approaches is deemed necessary, the rules of deliberation assume heightened significance.

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For deliberative processes designed to yield an opinion, such as providing advice or recommendations, the rules play a critical role in determining the procedure that leads to the conclusion of deliberation (Oortwijn et al., 2022). When it comes to choosing which drugs to cover, various governing bodies around the world utilize different mechanisms. In the Netherlands, for example, consensus-building prevails, while France and Scotland rely on majority voting. Meanwhile, countries like Australia, Brazil, and England combine elements of both approaches. Deliberative processes aimed at forming an opinion may also need to address how to manage disagreements, which could involve establishing rules for voting (Oortwijn et al., 2022). In contrast, processes centred around gaining insight into divergent viewpoints, setting expectations, constructing narratives, and empowering patients and communities will prioritize participatory dialogue approaches (Oortwijn et al., 2022). Towards further supporting the deliberative process to enhance effectiveness and empower participants, it is important to (i) structure interactions to cultivate participants' sense of meaningful engagement (Gibson et al., 2005), (ii) proficiently convey information to enhance the deliberation process (Schlander, 2021), and (iii) present comprehensive guidelines for reference (Oortwijn et al., 2022).

Differences in power among participants, which can be attributed to factors such as gender, wealth, ethnicity, seniority within organizations, and education are challenges to effective deliberation (Gibson et al., 2005; Shayo et al., 2012). Addressing these power disparities involves fostering an equitable exchange of perspectives among participants. This often involves a central mediator (such as a chair or facilitator) whose role is to I delve into the individual preferences and underlying assumptions held by all participants, present these viewpoints to others, and strive for a shared understanding of the issues at hand (Oortwijn et al., 2022).

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A significant concern is that participants may experience social pressure to conform to the group's preferences, leaving them unsatisfied with the process (Janis, 1982). They might also be susceptible to cognitive biases or confirmation biases, which can be further influenced by social factors (Kao et al., 2018). Given that decisions can be swayed when one member of the group dominates the discussion, the significance of rigorous and impartial facilitation or an equitable approach to information exchange cannot be overstated (Kahan et al., 1994). Effective participation necessitates a shared and unambiguous comprehension of accessible information and its interpretation (Shayo et al., 2012). Participant comprehension of the presented information, which may include scientific evidence, is enhanced using suitable communication channels (written, spoken, or both), the structure of reports, linguistic clarity, and ensuring mutual agreement on how information is identified and synthesized.

When conveying intricate technical information, participants' levels of literacy should be considered, and appropriate support mechanisms (such as training or preparatory sessions) introduced to prevent avoidable misunderstandings. This could encompass the adoption of standardized methods for producing simplified summaries and allowing participants adequate time to address any misunderstandings before deliberation commences. NICE, through its Public Involvement Programme, directly trains and assists patient and caregiver organizations, their representatives, and even individual patients and caregivers in England. This empowers them to actively engage in discussions and share their perspectives during crucial deliberative meetings. Also important is whether and what form of compensation should be offered to participants in deliberative processes. This can potentially enhance willingness to participate and foster more robust engagement. In countries like Canada, Poland, the Netherlands, and England, there are established governmental policies on providing financial compensation to participants (Wranik et al., 2019).They can adopt established governmental policies on providing financial compensation to individuals serving on public agency committees that

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represent the public in deliberative forums. Monitoring and evaluation are essential for assessing whether a deliberative process is accomplishing its desired objectives. It also helps to identify areas that are effective, and opportunities for improving the process. The initial step should involve providing a thorough account of how a desired change is anticipated to occur because of a deliberative process within their specific context. This should encompass the necessary resources (inputs) and the justification for this change.

To evaluate the extent to which the desired change has occurred, the outcome of a deliberative process could be assessed. Questionnaires, interviews (Mercer et al., 2020), review of documents, or in-person meetings conducted with participants are various means to evaluate deliberative processes. Inputs could be solicited regarding the process used to create the evidence report, as well as how experts and stakeholders perceived the process in terms of equity, transparency, timeliness, the extent, and effect of participation (Oortwijn et al., 2017). Requirements for monitoring and evaluation includes identifying who will perform the assessment, the methodologies that can be employed, and the available assessment tools.

The option of developing or customizing established tools, like checklists or questionnaires, to gather feedback could be considered. Alternatively, qualitative techniques such as focus groups and in-depth interviews with key stakeholders who are either directly or indirectly engaged in deliberative processes for periodic assessments could be utilised.

Research confirms that deliberative approaches have been tested in various decision-making settings, organizations, and issue areas (Abelson et al., 2007). Research on participant evaluations of deliberative meetings revealed positive feedback on the facilitated discussion, equal opportunities to contribute, facilitator expertise, sufficient time for in-depth exploration of issues, and clear communication of information and meeting objectives (Abelson et al., 2007; Abdel-Monem et al., 2010). Most importantly, they viewed the deliberative meeting

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approach as a useful way to bring citizens together to discuss complex issues (Abelson et al., 2007). Dissatisfaction with the timing of background materials (received just 2 days before the meeting) marred an otherwise generally positive perception of the deliberative approach among some participants (Abelson et al., 2007).

2.4.3 Contextual factors affecting deliberative engagement

Literature shows that deliberative engagement is not a technical procedure that is replicable without considering its context. Instead, there is an increasing recognition of the dynamic interactions among contextual factors such as the type of society, the influence of cultural norms, and global dynamics on community engagement (Fox, 2015). De Vente et al.(2016) acknowledge that context does have some impact on outcomes, and they underscore the greater significance of effective process design in shaping engagement results. Einsiedel (2002) highlights the influence of organizational culture, decision type, and timeframe on the success of public involvement processes. Beyond community, institutional, and political contexts (Abelson, 2001), researchers are increasingly interested in how context shapes evidence generation for policymaking (Dobrow et al., 2004; Lomas et al., 2005). While context can be broadly defined as the environment for any action, recent efforts have focused on identifying specific organizational characteristics like culture, leadership, decision-making systems, and internal/external factors for performance assessment (McCormack et al., 2002; Dobrow et al., 2006).

2.4.4 Challenges and Opportunities for using Deliberative Engagement in Genomic Research and Biobanking

A recent review on deliberative engagement to understand the challenges and opportunities of its utility in health care shows that time constraints, absence of monetary incentives, deeply ingrained professional interests, information disparities, practical feasibility issues, financial

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considerations, the wide range of decision types, and contextual complexities were the key challenges (Safaei, (2015).

In terms of potential opportunities, the literature underscores the importance of achieving a clearer understanding of public engagement and policy goals, genuine dedication from authorities to involve the public, the documentation of evidence demonstrating the effectiveness of public participation, the creation of decision support tools for patients, the training of healthcare professionals in Shared Decision-Making (SDM), and the utilization of diverse and adaptable leadership approaches for engagement tailored to specific settings. Although outcome utility is not the key focus of my study, one key challenge to the use of deliberative engagement has to do with connecting the results of deliberation with the established political system because policymakers often hold distinct views and expectations compared to those who consider deliberation as the sole legitimate foundation for policymaking decisions(Ryfe, 2005). In other words, how is the deliberative process expected to influence policy choices?

A study by Molster et al., (2013), explored some practical challenges associated with implementing deliberative engagement in the context of health in Australia. Some challenges mentioned included inadequate time for small group discussions, underrepresentation of minority ethnic communities and younger population, and recruitment in English (Molster et al., 2013). Towards facilitation, several approaches have been recommended to attract community members that are hard to reach to participate which include giving room for attendance during work hours without losing their pay (Molster et al., 2013). Other challenges reported were limited equitable access to participation for potential participants with family and work commitment during the time of the engagement (Molster et al., 2013). Also, a challenge for most deliberative engagements is sampling bias (Molster et al., 2013).

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2.4.5 How deliberative engagement affects attitudes.

Some scholars have advocated for research that explores the extent to which particular deliberative components influence the outcomes of such endeavours, especially since there has been limited research conducted in this particular domain (El-Shami et al., 2015). At the core of using deliberative engagement is the underlying belief that perspectives may solidify or potentially undergo transformation due to the deliberative procedure (Abelson et al., 2003; Hall et al., 2011). A study by Nicholls et al. (2016) investigating how deliberative processes affect participants' and evolution of attitudes showed that for some variables, a change in attitude (either positively or negatively) was observed whilst some recorded no change at all after going through the deliberative process.

Tomlinson et al. (2018) in a study that examined how participation in deliberative engagement affected views of participants on the use of donated bio samples showed that participants were less likely to find broad consent and project-specific consent adequate. Other studies that examined the effect of education and deliberation on participants' attitudes on the use of donated samples suggested that the process led to an increase in awareness and concerns about some issues (Tomlinson et al., 2015; De Vries et al., 2016;) The study also showed a decrease in support for a type of consent after participation, which implies that participants had realized a concern which had become more obvious following deliberation (Thomas et al., 2014).

Deliberative engagement sessions involving patients and members of the public to investigate their perspectives on expanding the sharing of genomic data for clinical purposes revealed that the process facilitated a higher degree of involvement with the subject matter compared to what could have been accomplished through surveys or conventional focus group sessions (Hassan et al., (2020). Furthermore, the deliberative engagement sessions, which was a single day's programme, led to noticeable changes in participants' viewpoints (Hassan et al., 2020). Tomlinson et al. (2015) observed a similar decline in participants' willingness to donate tissue

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for commercial profit-generating patents after they were informed about this possibility. These findings indicate that participation in deliberative engagement can lead to changes in attitudes.

2.5 Theoretical Framework

The theoretical framework for my research is based on the realist evaluation and theory of change. According to Pawson & Tilley (1997, p. 2), “when one evaluates realistically one always returns to the core theories about how a programme is supposed to work and then interrogates it - is that basic plan sound, plausible, durable, practical and, above all, valid?”. Basically, both theories of change and realist evaluation have emanated to fill the gap in policy and programme evaluation (Blamey & Mackenzie, 2007). They assert that questions of efficacy and effectiveness have proven complex to answer in research because it considers programmes as a collective body through which beneficiaries are managed, and where contextual factors are conceptualized as “confounding variables” that require the evaluator to control (Blamey & Mackenzie, 2007). This results in programme outcomes being summed across different groups of individuals in diverse contextual settings and across the numerous and diverse indices of a single social programme (Blamey & Mackenzie, 2007). Meanwhile the context of a programme must be emphasized as imperative in understanding how complex programmes bring about changes in outcomes (Blamey & Mackenzie, 2007). For example, this study looked at the context in which deliberative engagement is implemented could influence its outcome. External factors such as the demographic characteristics of participants, type of community, their location as well as structural issues could influence the outcome of deliberative engagement. In simple terms, if deliberative engagement has been successfully used in a specific context, it does not mean it should be successful in different contexts.

In parallel to the theory-based evaluator, programmes are not monolithic, people are not inactive recipients of opportunities to enhance their health, wealth and social standing offered

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through several efforts, and context is fundamental to understanding the relationship between programmes and outcomes (Blamey & Mackenzie, 2007). Context itself is multidimensional and functions at a range of levels. These could be political, social, organizational, and individual dimensions.

This study looked at how these dimensions of contexts could influence the execution as well as participants' perspectives on the utility of deliberative engagement as a model for genomic research and biobanking in Sub-Saharan Africa. Contextual factors such as the political environment, historical experience as well as trust between researchers and the communities could influence implementation and use of deliberative engagement as an approach to community engagement. Other potential factors at the structural or organizational level include local regulations, policies, guidelines, funding, government agencies interest and support for community participation in governance, practical feasibility, group composition, technological literacy and environment, communication context, availability of information materials, expert knowledge, time/duration, capacity, relevant literature, and legitimacy of outcome. According to literature, factors such as favourable policy climate, appropriate regulations, professional and legal standards, availability of information and tools, cost-effectiveness, framework of indicators for monitoring progress, funding and feasible implementation plan may influence the utility of deliberative engagement for community engagement in the health setting (Ryfe, 2005). Context, therefore, could be the main factor to uncovering the conditions in which, and the motivation for, a particular intervention to work. Blamey & Mackenzie (2007) argue that program effectiveness hinges on its context, encompassing factors beyond implementers' control. Both theories of change and realist evaluation approaches stress that ignoring context severely undermines confident attribution of impact and limits future replication or generalizability of successful interventions.

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Unlike theories of change (Blamey & Mackenzie,(2007), realist evaluators have a more specific intention to find out programme theory. The theory prioritizes exploring the psychological and motivational mechanisms that trigger behavioural modifications (Blamey & Mackenzie, 2007). Realist evaluators criticize the epistemological assumptions underlying hypothesis testing and controlled trials (Pawson & Tilley, 1997). They argue that such approaches, based on a "successionist" logic of isolating cause-effect relationships through controlled settings, ignore the crucial role of context in shaping program outcomes (Blamey & Mackenzie, 2007). When these outcomes, in a statistically methodical manner, achieve the anticipated change, the intervention can be attributed to be causally associated with its outcomes. Realists, however, adopt a generative method to attribute. Therefore, apart from looking for patterns between interventions and their outcomes, it also focuses on the generative process by which the relationship is formed. What this means in practice is that the realist evaluator tests out whether theories are worth their cost by tracking the outcomes evolving from specific method and context structures. Similarly, instead of settling on the fact that deliberative engagement has the potential as an approach to community engagement in the context of genomic research and biobanking, it is imperative for my study to explore a range of potential elements on the concept as well as their influence. Upon successful testing, the promising generative mechanisms embedded within specific patterns could be adopted by other interventions aiming to alter community-level behaviour (Blamey & Mackenzie, 2007; Pawson & Tilley, 1997).

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Regarding the resource effects of utilizing theory-based approaches, it is reasonable to say that both theories of change and realist evaluation are expected to be more time consuming than other traditional approaches that do not reveal the theory underlying interventions. The theories of change approach necessitate extensive time investment due to the need to involve and collaborate with a wide range of stakeholders. Moreover, reaching agreement on clearly articulated theories that are specific enough for testing their feasibility and testability adds to the iterative and time-intensive nature of this approach (Mackenzie & Blamey, 2005). Additionally, the approach's commitment to enhancing programme delivery and the process of integration and outcome requires the formulated theory to be re-examined over the course of the intervention. Compared to approaches emphasizing stakeholder consensus on theories or priorities, realist evaluation might be more time efficient. This approach delves deeper, aiming to identify what works for specific individuals under specific conditions, and how it works (Blamey & Mackenzie, 2007). Realist evaluation goes beyond simply identifying cause-effect relationships. It meticulously explores the intricate interplay between context, the mechanisms driving change, and program outcomes. By iteratively refining theory based on real-world data at the micro level, this approach seeks to pinpoint factors that can enhance or hinder program impact (Marchal et al., 2012). Both realist evaluation and theory of change offer promising avenues for understanding complex social programs, but their relative newness and limitations in methodological clarity require further attention (Blamey & Mackenzie, 2007; Mackenzie & Blamey, 2005). Realist reviews, however, are emerging as a powerful tool for extracting valuable evidence and lessons learned from such programs, particularly in public health and community development settings (Mackenzie & Blamey, 2005; Mack et al., 2013). As a valuable tool for generating evidence and extracting lessons from complex social interventions, realist review is gaining traction, particularly within public health and community development initiatives (Mackenzie & Blamey, 2005; Mack et al., 2013). This makes them the appropriate theories to guide the conceptual framework of this study on an emerging and complex topic like deliberative engagement in the context of genomic research and biobanking.

2.6 Conceptual Framework

The conceptual framework (figure 2) underpinning this study provides a structured representation of how various factors interact to influence the feasibility of implementing

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deliberative engagement (DE) within the context of genomic research and biobanking in rural Ghana. The framework is informed by realist evaluation and the theory of change. These approaches go beyond determining whether an intervention works to interrogate how, why, for whom, and under what circumstances it leads to specific outcomes. The framework was not adopted or adapted from any existing model; rather, it was constructed through an iterative process of critical engagement with literature on deliberative engagement, realist evaluation, and theory of change.

This framework comprises four interrelated domains: (1) the purpose of engagement; (2) procedural and contextual factors; (3) external influences; and (4) expected outcomes. These domains function as a dynamic and interconnected system. The manner in which the engagement is conceptualised and operationalised (procedures), the socio-cultural and infrastructural environment within which it is situated (context), the type and extent of support provided (external influences), and the anticipated results (outcomes) are mutually reinforcing components that lead to the overall success and legitimacy of the engagement process.

The primary objective of DE in this study is to enhance participants' understanding, raise awareness, and empower them to engage meaningfully in dialogues about genomic research and biobanking. This necessitates more than the mere transfer of knowledge; it requires creating an environment in which individuals not only comprehend the scientific content but also feel confident and equipped to express their perspectives, ask questions, and contribute to decision-making processes.

The procedural aspects of DE refer to the design and delivery of the engagement process. These include decisions about participant selection and facilitation, the duration and structure of sessions, the inclusivity and tone of discussions, and whether participants perceive the process to be fair and respectful. However, these procedural components must be responsive to the

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local context. Critical contextual considerations include language accessibility, topic familiarity, prevailing social norms, local belief systems, and the availability of time and resources for engagement. For example, failing to account for literacy levels or cultural practices could inadvertently exclude key voices or generate discomfort among participants. Thus, the alignment between procedures and context is essential to ensure meaningful and inclusive engagement (Shayo et al., 2012; Schlander, 2021).

Given the technical nature of genomics and the unfamiliarity of many community members with such scientific content, additional support is often required to facilitate comprehension and participation. External supports may include simplified communication tools like videos, pre-engagement orientation, translation into the local languages, and the involvement of trusted and experiences local facilitators. These supports function as critical enablers, bridging the gap between the procedural design of engagement activities and the contextual realities of participants. When appropriately tailored, they help foster an environment where participants feel supported, informed, and capable of contributing meaningfully (Lemke et al., 2011; Schlander, 2021).

When procedures are appropriately adapted to the context and supported by adequate external mechanisms, DE can yield several positive outcomes. These include increased knowledge among participants, a sense of being heard and valued within the research process, the development of mutual trust between researchers and community members, and perceptions of legitimacy and fairness in decision-making. These outcomes may be assessed using qualitative and quantitative tools such as interviews, surveys, and feedback sessions (Mercer et al., 2020). Moreover, DE is conceptualised as a cyclical process in which outcomes feed into iterative improvements. Lessons learned from one round of engagement can inform the refinement of future initiatives, creating a feedback loop that enhances practice over time (Oortwijn et al., 2017).

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Importantly, the broader context continues to shape how outcomes are interpreted and whether they translate into tangible change. For instance, in communities with historical mistrust of external actors or where the relevance of genomic research is not immediately apparent, even well-structured engagement efforts may have limited impact (Ryfe, 2005; Stadler et al., 2013; Celi et al., 2014; Lo et al., 2015; Beaton et al., 2017).

This conceptual framework was instrumental in guiding the design, implementation, and evaluation of this study. During the planning phase, it informed the articulation of study goals, the identification of relevant stakeholders, and the anticipation of potential contextual challenges. During implementation, efforts were made to ensure that procedural choices were context-sensitive and that necessary support mechanisms were in place. In the post-engagement phase, the framework informed the analysis of whether the intended outcomes were achieved and what insights could be drawn for future engagement initiatives.

In sum, this framework underscores the importance of a flexible, responsive, and contextually grounded approach to DE. It illustrates that DE cannot be treated as a one-size-fits-all model; rather, each component that is; procedural, contextual, external, and outcome must be carefully integrated and aligned. By employing this framework, the study sought to ensure that the DE processes were ethically sound, culturally appropriate, and practically effective in the Ghanaian context.

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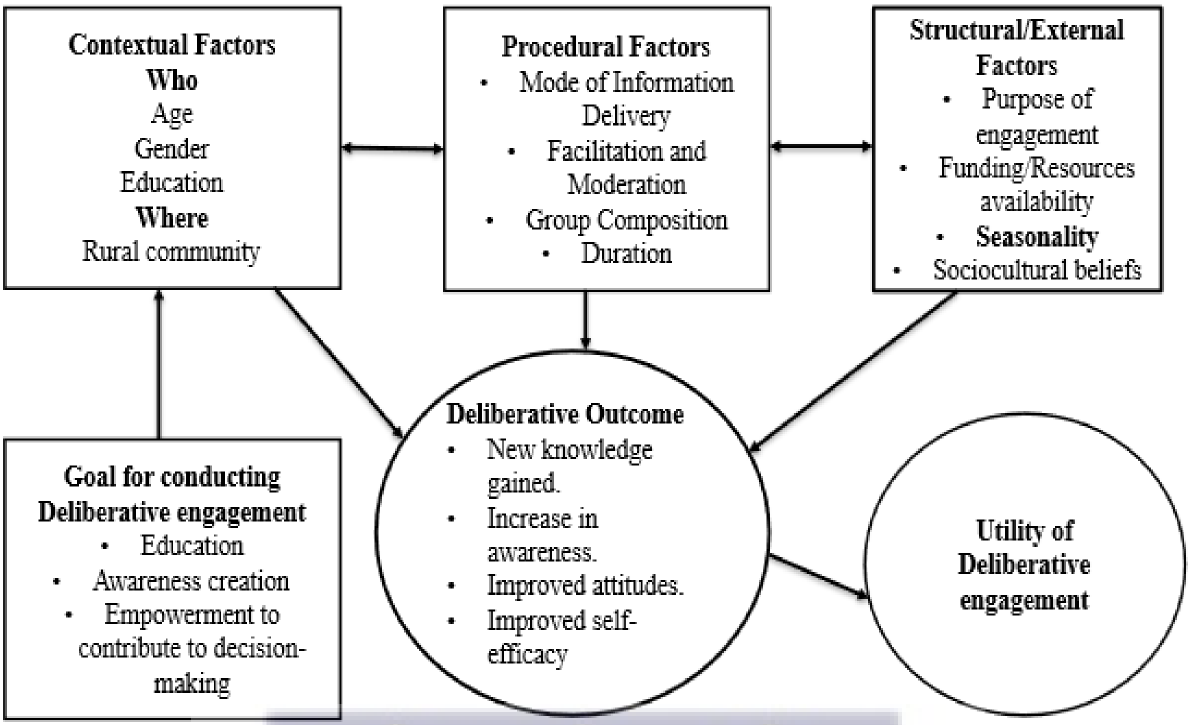

Figure 2:Conceptual framework showing factors that could influence the implementation of deliberative engagement as a model for community engagement (CE) in genomic research and biobanking.

2.7 Chapter summary and outstanding knowledge gaps

The literature review above has shown that deliberative engagement is useful in various contexts including the field of biomedical research. Regarding ethical issues related to genomic research and biobanking especially in sub-Saharan Africa, deliberative engagement as a model for community engagement that incorporates the informed views of potential research participants and communities at large can aid in the drafting of any new harmonization guidelines as well as augment effective and meaningful community engagement. Nonetheless, most evidence supporting the claim of deliberative engagement being a potential CE approach are from high-income settings and most of this empirical evidence show that the focus has

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mainly been on the internal proceedings with less attention on contextual and external factors that could influence implementation. This study therefore sought to contribute to addressing the gap, by planning and implementing a deliberative engagement in a rural community setting, taking into consideration the context and processes factors.

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CHAPTER THREE

METHODS

3.0 Introduction

This chapter provides a description of the methods that were used in the study. The chapter discusses the philosophical underpinnings of the study, the study design, the study setting, the study population as well as the inclusion and exclusion criteria. The chapter further explains the sampling procedures such as sample size estimation and sampling, detailed description of data collection and analysis techniques as well as the ethical issues that were considered in the study.

3.1 Philosophical underpinnings of the study

A key reflection during the research process is the philosophical underpinnings of the study, which lays out the foundation on which the study is conducted. According to Teddlie and Tashakkori, the two primary philosophical issues to consider in study design are ontology and epistemology (Teddlie & Tashakkori, 2010). Ontology is the philosophical field concerned with the nature of reality and the different entities and categories existing within the reality that the researcher investigates while epistemology is the philosophical field that deals with knowledge and how to reach it (Creswell, 2009). Creswell (2009) further refers to epistemology as a philosophical field that examines the relationship between the researcher and what is being studied.

These philosophical principles often influence study design and the technique used to obtain the knowledge. Pragmatism is an epistemological position to knowledge generation that supports the practical use of any of the research methods, either constructivist (which is aligned with qualitative research) or positivist/post-positivist (quantitative) worldviews in addressing a research question. Pragmatism, in this context, emphasizes the practical utility and real-world

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applicability of knowledge. This philosophical stance is particularly appropriate for a study focused on the intricacies of deliberative engagement in genomic research and biobanking within rural communities. By adopting pragmatism, the study recognizes that knowledge must not only be theoretical but also pragmatic and relevant to the specific challenges and contexts encountered in these communities. Specifically, the pragmatist focuses on the nature of the research questions and considers the most appropriate approach to resolving the issue without orienting itself to only one phenomenon or philosophical paradigm (Clark et al., 2008).

Within this pragmatic framework, the study employed a mixed methods approach. This approach harmoniously integrates quantitative and qualitative research methods. From a philosophical standpoint, this aligns with the belief that research should provide both numerical insights and rich, context-specific understanding. In this current study, quantitative methods quantify variables such as awareness and attitudes, offering a broader perspective while qualitative methods delve into the nuanced experiences and perceptions of participants, providing a more comprehensive understanding. The quantitative method specifically examined whether participation in a deliberative engagement session influenced participants' awareness and attitudes towards data sharing in genomic research and biobanking. Meanwhile, the qualitative method explored procedural factors that could influence the implementation of deliberative engagement, contextual factors that could facilitate or hinder its adoption, and participants' perspectives on the potential challenges and opportunities associated with this model.

Since the objectives of the present research consigns most to the use of mixed methods, a pragmatic epistemology was appropriate. As part of its philosophical underpinning, the study draws on the theoretical frameworks of realist evaluation and the theory of change. These frameworks offer a structured lens through which to comprehend the intricacies of how interventions function within complex contexts. From a philosophical perspective, they

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facilitate an understanding of the causal mechanisms driving change or lack thereof. By examining the "how" and "why" behind observed outcomes, these frameworks contribute to an informed and practical approach to recommendations for future implementations. Below is a discussion of the study design for this study.

3.2 Study design

This was an experimental one-group pretest-posttest research design using a sequential embedded mixed-method design. In this study, the qualitative method was the dominant method, with the quantitative method embedded within it (Creswell et al., 2009; Creswell et al., 2003). The quantitative method was embedded in this study because one of the research questions, namely ‘Will participation in a deliberative engagement session affect awareness and attitudes of participants on data sharing in genomic research and biobanking’ could be best answered using a quantitative method (Wright et al., 2014). Figure three (3) is a flowchart that shows the various stages of the study.

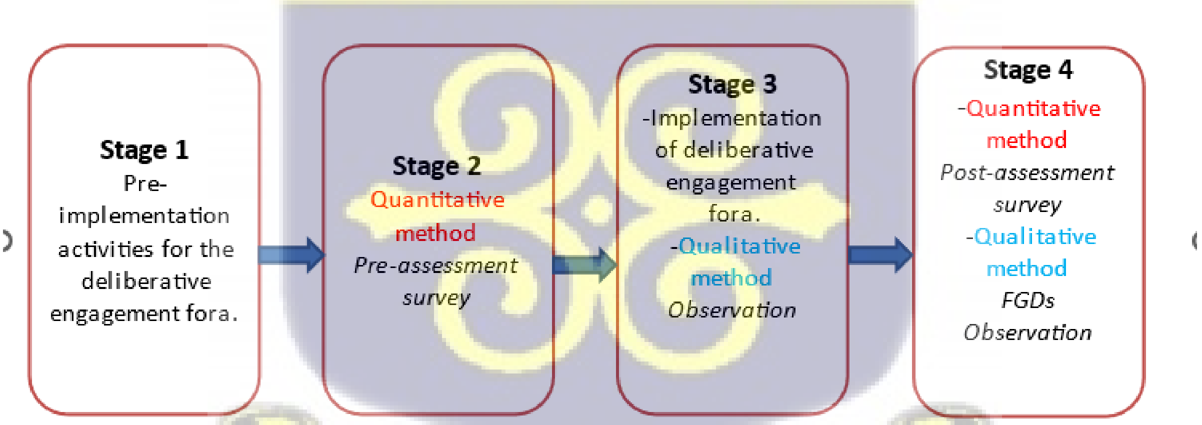

Figure 3: Flow chart of study design

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The study commenced with pre-implementation activities for the deliberative engagement sessions. This involved clearly defining the purpose and objectives of the engagement, tailoring it to the specific rural community context, and handling logistical arrangements, such as identifying and engaging experts for the deliberative engagement session's information session, securing a suitable venue, determining the schedule, arranging catering and transportation, and allocating resources efficiently. Stage two of the study started with the administration of an assessment survey by the lead researcher and trained data collectors. This survey aimed to establish participants' initial levels of awareness and attitudes regarding data sharing and genomic research. This served as a baseline measurement before their involvement in the deliberative engagement. The engagement took the form of a structured deliberative workshop with two main phases. The first phase involved the provision of comprehensive information and education about the purpose of genomic research, as well as the ethical concerns surrounding data sharing. This phase was facilitated by research experts with experience in conducting genomic research and experienced bioethicists who are abreast with the ethical issues and considerations around genomic research and data sharing. In the second phase, participants engaged in small group deliberations of an average of seven participants per group. These discussions aimed to gather the informed views and decisions of participants on the ethical issues related to data sharing in genomic research. Immediately following their participation in the deliberative engagement event, participants were once again administered the same survey questionnaire that they had completed before their involvement. This post-deliberation assessment aimed to determine if the deliberative engagement had resulted in any notable changes in participants' levels of awareness and attitudes. To gain a deeper understanding of participants' perspectives, focus group discussions were conducted with participants.

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3.3 Study setting

This study was conducted in the two Kassena-Nankana districts in the Upper Eastern part of Ghana. Ghana is a lower-middle income country located on the west coast of West Africa and shares boundaries with Togo to the east, La Cote d'Ivoire to the west, Burkina Faso to the north and the Gulf of Guinea to the south. The country's economy is dominated by agriculture, which employs about 58% of the working population (2020 Population and Housing Census) and covers an area of 238,500 square kilometres. Data from the 2020 Population and Housing Census estimate the population of Ghana to be about 31,071,609 (GSS, 2022).

The Kassena -Nankana district border Burkina Faso in the northeast and have a total land area of 1675km2 with a population density of 91.5 km2 (Figure 4) (Binka et al., 1999). The current rate of employment in agriculture for the Kassena Nankana district is 64.9%, according to the 2020 Population and Housing Census ((GSS), 2022). This means that over two-thirds of the working population in the district is engaged in agricultural activities. The district is located in the Upper East Region of Ghana and is predominantly rural, with agriculture being the main source of livelihood for the majority of the population. The districts form the coverage area of the Navrongo Health and Demographic Surveillance System (NHDSS) of the Navrongo Health Research Centre (NHRC), an INDEPTH Network member site (Binka et al., 1999). The NHDSS carries out surveillance on 165,000 individuals (52.3% females) in 32,000 households (Oduro et al., 2012).

Founded in 1989, the NHRC's main mission is to drive health policy and practices through rigorous demographic and health research (Oduro et al., 2012). Throughout the years, the Centre has conducted many community-based research including a genomic study, nested in the H3Africa AWI-Gen project (Ramsay et al., 2016). Targeting older Africans (40-60 years old) across rural and urban environments, the AWI-Gen study investigated how genes, physical traits, and living conditions contribute to body mass index (BMI), body fat distribution, and

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potential risk factors for cardiometabolic diseases (Ramsay et al., 2016). It is from the AWI-Gen study that participants from the current study were drawn.

The AWI-Gen study was chosen because it is one of the few genomic studies being carried out in Ghana, and within a rural community. According to the required standards or principles for conducting deliberative engagement, inclusivity is key when selecting participants. It is recommended that participants who are more likely to be affected by a decision or policy should be included to give them the opportunity to contribute their informed views. In the context of this study, participants from the AWI-Gen study have their biological samples and data taken for genomic research and stored in a biobank in South Africa. As such, they have a stake in policy or decisions around genomic research and biobanking and especially the utility of their samples and the associated data. This is especially important because of the controversies and complexities around the subject area (Chalmers et al., 2014; McWhirter et al., 2014). To broaden representation and ensure inclusivity, the study included participants from rural communities, who often experience a constellation of marginalization, including economic, political, social, and cultural challenges. For example, these communities have limited access to technological development, inadequate transport services and bad road networks, lack information and communication technology, energy (power stations), and suffer from health and social exclusion. The likelihood of these individuals being cut off from the policy development and decision-making processes is therefore real.

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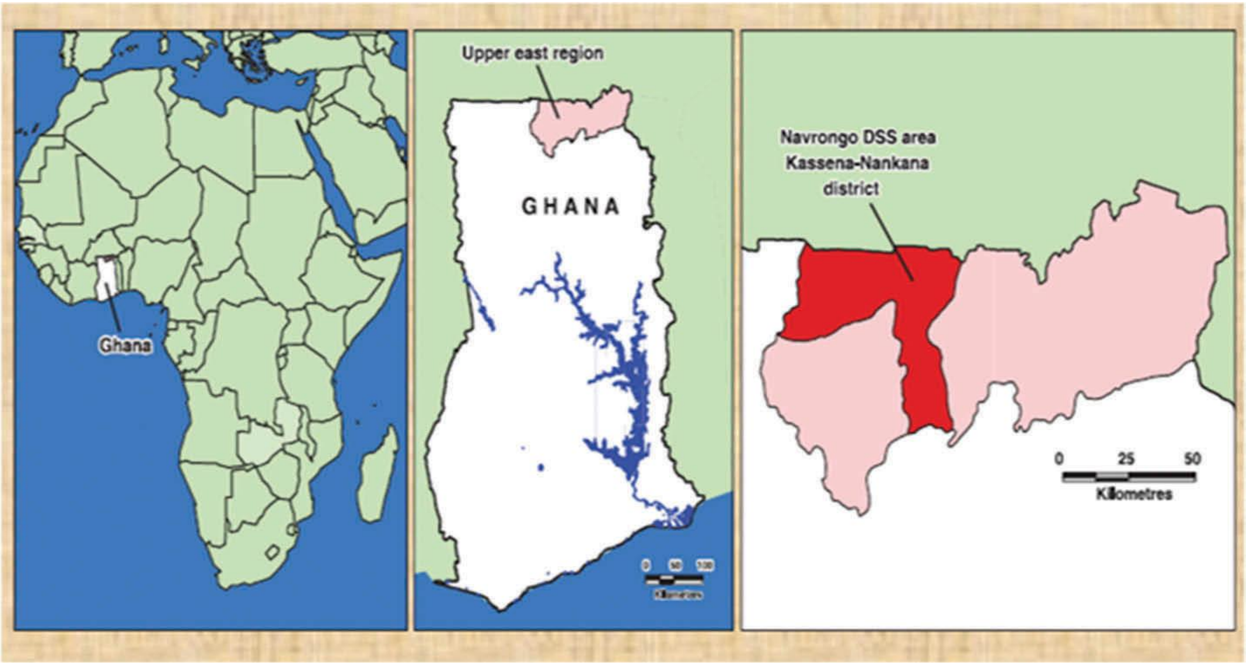

Figure 4: Maps showing Ghana in Africa, Kassena Nankana district in the upper east region and the Navrongo HDSS coverage area (Binka et al., 1999; Nonterah et al., 2018).

3.4 Study Population

The study population comprised individuals who had participated in the AWIGEN study. These were men and women aged above 47 years and who were residents in the study area.

3.4.1 Inclusion Criteria

Participants in the AWIGEN study who had at least primary level of education were eligible for inclusion. In addition, their availability during the implementation of the study as well as their willingness to provide informed consent was a key inclusion requirement.

3.4.2 Exclusion Criteria

Participants who met the specified inclusion criteria but were not available during the period of the study implementation, as well as those with no education/no schooling, were excluded from participation.

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3.4.3 Sampling and sample size for the quantitative study

To determine the sample size for the quantitative study, a census approach was employed. A census entails collecting data from the entire population (Israel, 1992). At the time of this study, the total number of participants in the AWIGEN study was 2,005. After applying the inclusion criteria, only 91 participants were eligible for inclusion in this study. As the number of eligible participants was relatively small, a total census was conducted. However, when the research contacted all the 91 potential participants, only 66 agreed to participate in this study. The other 25 individuals were either not available or were available but declined participation without any reason. Figure 5 illustrates the process of arriving at the sample size.

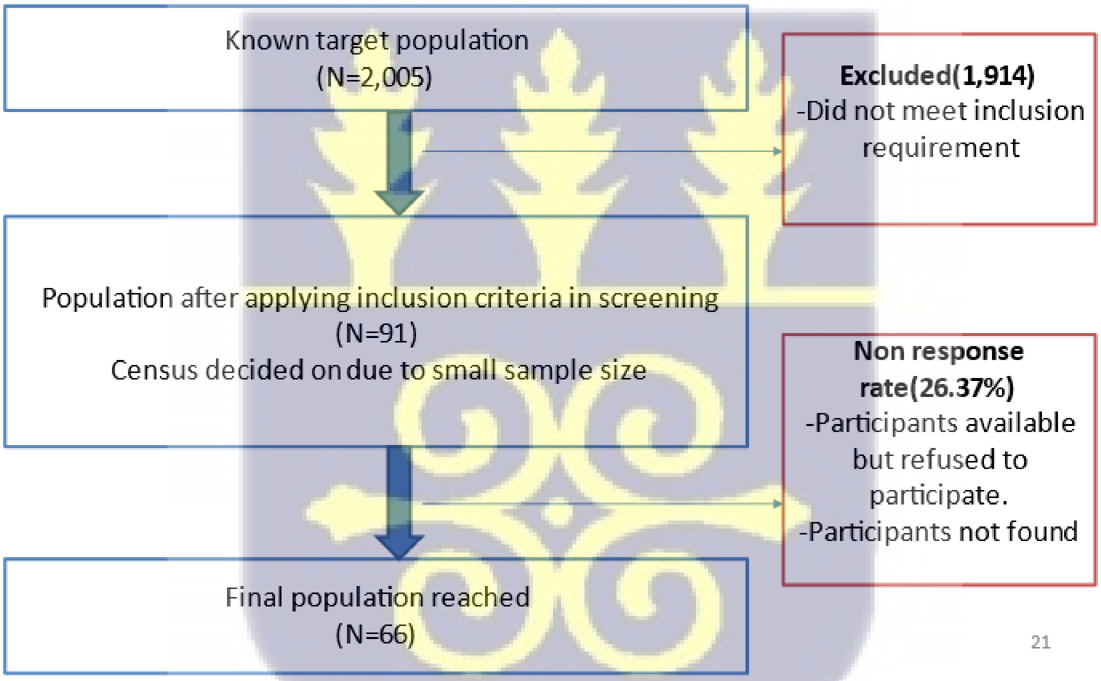

Figure 5: Sampling and sample size

3.4.4 Sampling and sample size for the qualitative research

The qualitative study involved purposive sampling of all 66 participants who had actively engaged in the deliberative engagement session. These participants were initially selected through a census process to ensure a representative sample of the target population. Their

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participation in the deliberative engagement session provided them with direct experience with the intervention, making them well-suited to provide in-depth insights into their perspectives.

The sample size was determined based on the principle of theoretical saturation, which implies that data collection continues until no new themes or insights emerge from the data (Strauss & Corbin, 1998). In this study, saturation was reached at FGD 8, when no new codes or themes relevant to the study objectives emerged, and responses began to repeat earlier insights. This indicates that the sample size was sufficient to provide a comprehensive understanding of the research questions and that no further data collection was necessary.

3.5 Data collection

Below is an overview of the data collection methods and tools for the quantitative and qualitative components of the study.

Table 2: overview of the data collection methods and tools

Study approach	Data collection method	Data collection tools	Data collection
Quantitative study	Survey	• Paper-based questionnaire (Informed by previous literature). • 9 questions with responses on a 3-point Likert scale.	• 66 completed pre-assessment survey • Maximum of 59 completed post assessment survey; the difference due to loss to follow up.
Qualitative study	FGDs	• Discussion guides and voice recorders	• 9 organised FGDs with average of seven on a group.

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3.5.1 Data collection for Quantitative study

Data collection for the quantitative component of the study included a pre- and post-deliberative engagement survey that was administered to all participants prior to participating in the deliberative engagement session and right after participation. All the two-point assessment survey included the same questions on measures of attitude and awareness. The survey was designed to ascertain whether participation in a deliberative engagement would affect awareness and attitudes of the participants regarding data sharing in genomics research.

3.5.2 Development of Survey Tools

The two surveys (pre- and post-deliberation assessment) were developed based on previous literature (Nep & O'Doherty, 2013; O'Doherty et al., 2013; Gornick et al., 2017; Tomlinson et al., 2018; De Vries et al., 2019) alongside consultations with an expert. Based on the goal for implementing the deliberative engagement for this study, the survey was developed to establish if the goal of the deliberative engagement had been achieved. The tool covered questions to examine participants attitudes towards data sharing in general as well as with commercial entities, and whether participants should receive benefits for doing so (Lemke et al., 2010; Shabani et al., 2014). The tool presented a scenario where donated biobank data fuels patent development and profits for commercial companies. The narrative also went on to state that most new drugs used to treat or prevent disease come from commercial companies. Participants were then asked questions on a 3-point scale about their willingness to have their genomic data shared with commercial entities and whether individuals should receive any form of benefit for doing so.

Another section of the tool examined participants awareness about the importance of genomic research as well as regulations and regulatory bodies that ensure protection of privacy and confidentiality in data sharing. These questions were asked to establish baseline awareness using a 3-point scale.

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The final section of questions was to examine participants level of confidence in researchers as well as consent documents in ensuring that their privacy and confidentiality are guaranteed during sample and data sharing. The baseline survey had standard demographic questions such as age, sex, educational status and religion for participants to complete.

3.5.3 Quantitative Data Collection methods and tools

A face-to-face interview was conducted using the structured questionnaire described in section 3.5.2. The tool had 9-items at both baseline and endline. Each question required a response based on a 3-point scale. The responses were graded as follows: The questionnaire was designed in English and administered in English, Kassem and/or Nankam languages. For respondents who could not speak and write English, the questions were translated into Kassem and Nankam languages. The questionnaire was administered to such respondents by trained data collectors who were fluent in both English, Kassem and Nankam.

3.6 Implementation of the Deliberative Engagement Session

3.6.1 Pre-Implementation Phase of the Deliberative Engagement event

To implement deliberative engagement effectively, the process begun with identifying and defining the purpose or goal of the engagement, considering the specific context, and making logistical arrangements, including venue, timing, catering, transport, reimbursement, and resource allocation. Engaging a local team with practical knowledge of the community was also essential. This is because their knowledge ensured that the DE was scheduled at a time that maximized participation, particularly for farmers who would be unavailable on market days. In this study, the primary purpose of the engagement was to inform and educate participants about genomic research and the ethical issues around data sharing and empower them to deliberate in deliberative engagement.

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The planning phase commenced with a meeting involving two senior health researchers and a knowledgeable fieldworker from the NHRC. Together, suitable time and venue for the event was determined. Market days were considered unsuitable for meetings as many participants were anticipated to attend these markets. The deliberations were scheduled in month of December 2022, which was favourable to many participants, particularly teachers, due to the school vacation during that period. Additionally, December aligned with the non-farming season, allowing farmer participants to engage without agricultural obligations. However, some participants faced scheduling conflicts, emphasizing the importance of flexibility. For instance, one participant had to leave for a meeting, while another had prior commitments. These experiences informed adjustments for subsequent events.

3.6.2 Recruitment of participants for the deliberative engagement

For participant selection in deliberative engagement, a small, ideally 13 to 30 participants, is preferred to ensure diversity and minimize bias (Kotrlik & Higgins, 2001; Klautzer et al., 2014; Thaldar et al., 2021). While this sample may not be statistically representative, the focus is on diversity and a wide range of perspectives (Thaldar et al., 2021). This study organized two deliberative events with 66 participants, and the participants were drawn from the H3Africa AWIGEN study as noted earlier. To ensure diversity, participants belonging to various ethnic groups, both men and women, speaking different languages, were represented.

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3.6.3 Implementation of the deliberative engagement event

The deliberative engagement events were implemented in compliance with the key elements and processes required. Figure six (6) is a flowchart of the implemented deliberative engagement.

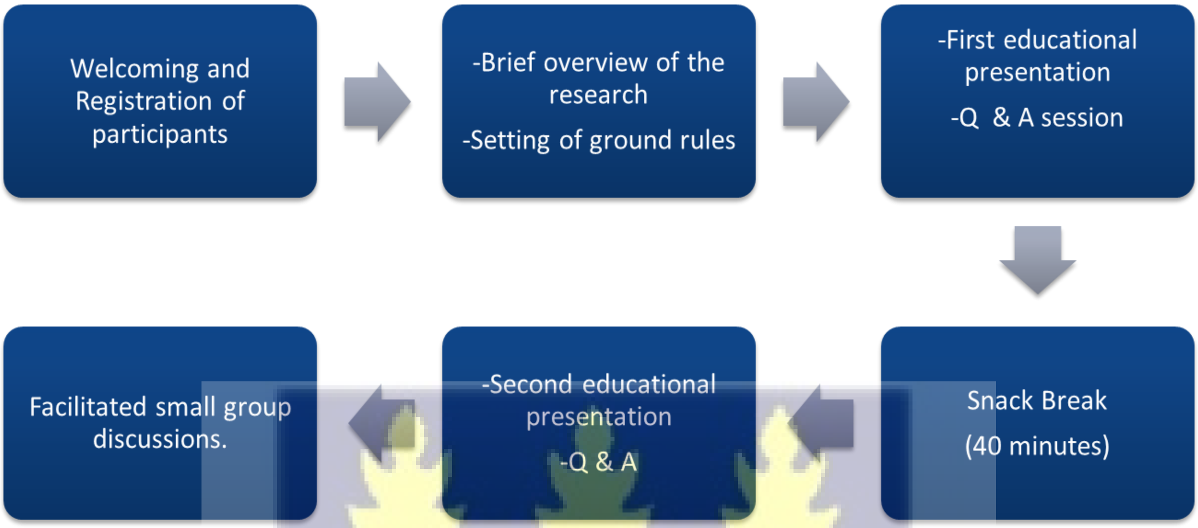

Figure 6: Implemented deliberative engagement

For the purpose of this study, Carman et al. (2015) model was adapted and modified. This model primarily involved recruiting individuals from a wide range of perspectives, information provision, facilitated deliberations among participants, and preparation of a summary of the deliberations. The model was selected due to its structured yet flexible design, which aligns well with the study's objective of engaging diverse lay participants in meaningful dialogue on complex issues such as genomic research. Compared to other models (e.g., IAP2 Spectrum of Public Participation, NICE Citizen Council), the Carman et al. model provided a clearer balance between participant empowerment and guided facilitation, making it particularly suited for the Ghanaian rural context where deliberative engagement on biomedical topics is relatively new.

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The deliberative engagement in this study included two main sessions namely, the information delivery session and the small group deliberations. The information delivery session also included a presentation on the overview of the study as well as the purpose of the deliberative engagement. Participants in this study attended a day session modelled on formats used in previous deliberative engagement events (Kim et al., 2009a; Gornick et al., 2017). The information sharing or expert presentation session started with a welcome of all participants. In this regard, prior engagement with the participants and observation of the sociocultural context proved very useful. The lead researcher wasnot a native of the study location but had observed during the recruitment process, how greetings are exchanged among community members, especially when a younger person is greeting an elderly person or when a woman is greeting a man; and that was the approach was used when welcoming the participants to the venue. This strategy was part of the process to break the ice and make participants feel comfortable. The participants acknowledged this gesture in their assessment of the event. The session continued with a general overview of the study, followed by an introduction of the research team including the experts and the facilitators/moderators for the session. The experts were researchers chosen for their direct involvement in the AWI-Gen project, and bioethicists selected for their breadth of knowledge in ethical issues and considerations around genomic research and biobanking. Their roles extended beyond mere presentation of information; they facilitated discussions, answered questions thoughtfully, and summarized key points, ensuring that all voices were heard and respected. The welcome was done by one of the expert presenters who is a native of the region and has been working in the communities as a social science researcher and bioethicist, and an expert in qualitative research. The general overview was presented in English and interpreted by one of the experts. Thereafter, the remainder of the programme was conducted by the two experts, while the lead researcher observed to avoid introducing bias into the process (Tomlinson et al., 2018).

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Participants were then taken through the agenda for the day and setting of ground rules for the session. The session on expert presentations as well as all subsequent interactions were conducted in the Nankam and Kasem languages. The data collector who is a native of the region interpreted to me in English. The observation allowed me to pick very salient information from participants facial gestures and other body expressions.

After the first video documentary (described under the section on Content of Information shared with Participants), participants were asked to summarize what was presented in the video per their understanding. This interaction continued for about 20 minutes to give as many participants as possible the opportunity to contribute. The purpose was to ensure that the key purpose of the deliberative event was achieved. After this session, the expert reiterated the various aspects of the documentary using PowerPoint presentations and took time to use stories and practical examples and jokes to get the participants to understand the topic. All the participants contributed to the discussion.

The information delivery session was for a duration of an hour and a half. This was followed by short break of thirty minutes and then the second presentation on the "Ethical Issues related to biological sample and data sharing" was given by the second expert, using the same procedure as the first.

The second deliberative event was organized a week from the first one to enable the research team after debriefing, to implement some changes to the approach based on lessons from the first event. For example, participants in the earlier event complained about the duration of the process and not being provided with refreshments on time. In response to participant feedback from the previous DE, refreshments were provided during the first session of the subsequent event. While the long duration remained unavoidable, participants were offered 100 cedis instead of the 50 cedis originally planned as compensation for their time. In addition, it was

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realized that the English-speaking group spent less time in the process compared to those that used the local languages.

As done in most deliberative engagements, participants were given information about the topic of interest, prior to the event (Nep & O'Doherty, 2013; O'Doherty et al., 2013; Tomlinson et al., 2018Thaldar et al., 2021). The original plan was to give participants in this study, handouts and video documentaries via phones or email prior to participation. However, majority of the participants did not have emails or phones, and those who did, did not have smart phones that supported video applications neither did their close relatives have. In other previous studies, the information along with the pre-assessment survey were either emailed or sent by post to the participants (Nep & O'Doherty, 2013; O'Doherty et al., 2013; Tomlinson et al., 2018; Ralefala et al., 2020; Thaldar et al., 2021). To address this limitation, the various information and presentations were reiterated severally with practical examples for them to understand. For example, the two video documentaries used for the deliberative engagement were played several times during the session.

These audio-visuals were developed by the H3Africa CEBioGen project after series of consultation with senior genetic researchers, qualitative research experts, bioethicists, and communication experts. The documentaries were piloted and further refined after series of reviews by external experts in both genetic research and bioethics. Other audio visuals used were PowerPoint video narrations. The content of the PowerPoint video narration was developed based on a story line titled "what is a gene" from a manual used by Ralefala et al. (2020) for deliberative focus group discussion in Botswana. The PowerPoint presentation was on data sharing, including all the advantages and disadvantages surrounding data sharing. Based on previous literature, a manual (Ralefala et al., 2020) was developed to guide the step-by-step implementation of the deliberative engagements.

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These were presented and interpreted by expert social scientists and bioethicists who were also part of the CEBioGen project and the AWIGEN study.

3.6.4 Content of Information shared with Participants

Two 15minutes educational video presentations in two local languages were used. The first video was titled "Basic Genetics" and described genes, genetics, inheritance, and the importance of genomic research. The second video documentary was titled, "The journey of my sample" which describes and explains the various processes involved when study participants samples are drawn for genomic research purposes. The documentary also talks about the various ethical regulations and steps that are taken to ensure privacy and confidentiality. There were also presentations titled "Ethical issues in data sharing" which highlighted the primary bioethical issues related to sample and data sharing and efforts being put in place towards addressing the issues.

3.6.5 The small group deliberations

Following the information sharing meetings, participants were assigned to one of nine groups, each comprised of an average of seven participants (Tomlinson et al., 2018). The groups were organized into 2 categories: participants who can speak and understand English language (3 groups), participants who speak and understand Nankam (3 groups), participants who speak and understand Kasem (3 groups), and participants who speak Twi (1 group). Participants joined the groups based on the language they were comfortable with. There was no intention to group based on gender; however, there were only males in the English groups. This could be because, considering the age category of participants, education of the girl child especially in the rural setting in the Northern regions was not common when they were growing up. Apart from the English groups, the other groups had a mixture of both genders although men were more. A trained facilitator moderated the discussion for each group and participants and the

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moderator sat in a circle. Each facilitator had a background in qualitative research, genomic research and had previously moderated focus group discussions. The deliberations were respectful, without any conflicts even when participants had opposing views. Respectful deliberations created an atmosphere where participants were comfortable to share views, disagree with experts' views, and enthusiastically participated without fear (Longstaff & Burgess, 2010). Throughout the deliberative engagements, experts and members of the study team were available to answer questions that came from participants.

3.7 Data collection for the qualitative study

3.7.1 Development of the FGD Guides

Based on literature and the objectives of the study, a thematic discussion guide was developed on indicators of quality deliberative engagement process as well as questions on external factors that could influence the implementation of deliberative engagement. The guide covered a wide range of issues including participants' general view about the deliberative process and how the event was of benefit to them. Other issues covered in the guide included participants' views about the duration, venue, group composition, information delivery session as well as why they will be willing or unwilling to participate in future deliberative engagements. Each FGD took averagely 60 minutes with the attainment of data saturation on all key themes being the reason for ending a discussion. Data saturation was achieved after conducting nine FGDs.

3.7.2 Qualitative Data collection methods and tools

Focus Group Discussions (FGDs) was the data collection method used. Creswell & Creswell (2017) suggest, FGDs should include a range of 6 to 12 participants for FGDs, although the optimal number may vary based on the specific research objectives and the characteristics of the target population. FGDs were used because they are useful for gathering information on how a group of people collectively make sense of a topic. A total of nine FGDs were conducted,

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each with an average of seven members. This was to provide enough diversity of perspectives while still allowing for manageable discussions. To ensure participants felt comfortable and engaged, groups were formed based on their preferred language among English, Twi, Kasem and Nankam. This resulted in two men-only groups and six mixed-gender groups.

Field notes were taken throughout the discussions to capture the interactions in the groups including non-verbal cues.

Each FGD took averagely 60 minutes, and discussions continued until topic saturation was reached on all key themes relevant to the research questions. The FGDs were conducted by the same moderators for the small deliberative group discussions. Their expertise in FGD moderation and fluency in both English and local languages guaranteed consistent quality across all sessions. Importantly, their gender did not affect the quality of their facilitation. Permission was obtained from participants and all discussions were audio-recorded with a digital voice recorder. and fieldnotes taken in addition. Additionally, detailed field notes were taken to capture the full richness of the discussions. This combination of audio and written records provided a robust foundation for thorough analysis.

3.8 Data Management and Analysis

3.8.1 Qualitative Data Management and Analysis

Towards preparations for data analysis, all audio recordings of the FGDs were transcribed verbatim. Discussions that were done in the local languages (Kasem, Nankani and Twi) were directly transcribed into English.

Whilst the audio recordings for the discussions done in English were only transcribed. Data for the FGDs in Nankam and Kasem were transcribed with the assistance of two data collectors who spoke the two main local languages, Kasem and Nankani, and were fluent in English. With the lead researcher's ability to speak and write the Twi language I transcribed the audio FGDs

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that were done in Twi. The transcriptions were double-checked for correction and validation by reading each of them alongside listening to the audios. The transcripts underwent meticulous cleaning and verification, with inaccurate quotations and typos rectified. Once finalized, they were imported into NVivo 12 (QSR International Pty Ltd, 2012) for systematic organisation and analysis. The framework method for data analysis was used to guide the data analysis in this study. The framework method is a qualitative data analysis approach that is systematic and flexible (Gale, Heath, Cameron, Rashid, & Redwood, 2013) given that it is not limited to any philosophical or epistemological stance. This gives it the room to integrate with specific aims of any aspect of research (Bryman, & Burgess, 1994).This approach falls within a vast family of qualitative sociological data analysis approaches commonly referred to as thematic analysis. These methods ascertain general issues as well as dissimilarities in qualitative data, prior to focusing on how varying parts of the data are linked with each other and aims to elicit descriptive and/or explanatory conclusions arrived at around themes (Gale et al., 2013). As shown in Table 3 below, the framework analysis draws themes from both pre- determined issues and emerging data. Consequently, I had pre-defined areas of interest which were informed by the study objectives, albeit I also stayed open to finding new information shared by the participants (Stapley, & Midgley, 2016). The analysis framework, built upon research objectives and existing literature on DE evaluation, focused on: (1) procedural factors that could influence implementation, (2) contextual factors that could facilitate or hinder implementation, and (3) participants' perspectives on challenges and opportunities associated with DE. Analysis began with careful reading of all transcripts while listening to the audio to familiarise with the data. A coding framework matrix was created prior to coding, based on the study objectives and relevant literature. As coding progressed, additional codes were added to reflect new and important ideas emerging from the data. The combined set of predetermined and emergent codes formed the working analytical framework, which was applied consistently

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across all transcripts. NVivo was used to manage and group codes into broader categories, which were then synthesised into themes. The decision to include a theme was based on its relevance to the study objectives, rather than on frequency alone. Although much of the coding was conducted individually, additional data collector independently coded transcripts to enhance regour and support intercoder reliability. We held informal consensus discussions to compare interpretations, resolve any differences, and refine the coding framework. This collaborative and iterative process enhanced the reliability of coding and allowed for the emergence of nuanced insights that might otherwise have been overlooked. By the end of the process, the framework incorporated both the predetermined issues central to the research questions and the novel perspectives shared by participants, resulting in a comprehensive thematic account of the data.

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Table 3: key pre-determined themes and evolving themes

Pre-determined themes	**Evolving themes**
Theme: Information delivery • Subtheme: Facilitator's Experience and Skills • Subtheme: Video Presentation • Subtheme: Language Used	Theme: Seasonality in Timing of Deliberative Engagement (DE) • Subtheme: Considerations for Timing DE
Theme: Moderation in DE Discussion • Subtheme: Fairness in Moderation • Subtheme: Respect for Views	Theme: Tailoring Group Composition to Topic
Theme: Group Composition • Subtheme: Gender • Subtheme: Group Size	
Theme: Venue for DE • Subtheme: Satisfaction with the Venue	
Theme: Duration and Compensation • Subtheme: Satisfaction with Time Spent	
Theme: Challenges and Opportunities for Future DE	

3.8.2 Quantitative Data Management and Analysis

Quantitative data were collected through structured survey questionnaires. The data management process began with data entry and cleaning. All completed paper-based data from the questionnaire administered were entered into a CSPro 7.7 database and exported into Excel for further consistency checks and data cleaning. The final dataset was then exported into

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STATA version 13.1 MP (College Station, Texas 77845 USA) where all analyses were performed.

Analysis started with descriptive statistics to describe essential demographic characteristics of the respondents and provide an overall summary of the data. Frequency distribution and proportions were estimated and presented in tables and charts. Furthermore, statistical differences in awareness about, and attitude towards, data sharing in genomics research before and after the deliberative engagement were assessed using chi square test and Fisher's exact test (in cases where observations for any variable were less than 5).

3.9 Data Quality Assurance

3.9.1 Training of Data collectors

All the research assistants who assisted with the data collection process were trained. The data collectors also have several years of experience in working in health research at the community level with practical experience in conducting qualitative and quantitative research. Prior to data collection, a one-week training session was conducted for all the expert presenters and the data collectors with additional two hours training on key pointers for moderating deliberative engagement discussions which is different from the standard FGD. The training session included explanation of the objectives of the study, data collection procedures, practice sessions with the tools as well as ethical considerations. The training paid special attention to facilitation of deliberative engagement because it was new to the research assistants. The training on moderating small group deliberations focused on the ability to listen to participants whilst being observant of communication cues from the participants. The training also highlighted the need to be fair and allow all participants to contribute to the discussions with reasons to back their arguments. They were also trained not to force consensus from the participants and to allow divergent views. Prior to the data collection, I had participated in a

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one-month workshop in "Deliberation and participation in healthcare" with topics including "moderation and facilitation of deliberative events. This was organised by the department of Medical Ethics and History of Medicine of the University Medical Center, Gottingen, Germany. The knowledge and skills I gained from the workshop further informed the content of the training for the data collectors. Training was also based on empirical literature where facilitators of small group discussions for deliberative engagement attended two hours training session on qualitative research and deliberative discussions (Kim et al., 2009b; Tomlinson et al., 2018). Training was also provided on notes taking and verbatim transcription, including the importance of including silences and the way in which things are said.

3.9.2 Safeguarding Reliability and credibility of data

To safeguard the reliability and validity of the data, all the data collection tools were pre-tested with study participants during the initial DE implementation. This crucial step allowed for identification and rectification of potential biases or ambiguities in the tools, ultimately improving the accuracy and consistency of collected data. Additionally, debriefing sessions held after the first focus group facilitated continuous improvement by pinpointing gaps in data collection and prompting revisions to ensure the tools captured the intended information. For example, debriefing revealed that some of the questions in the guide triggered the same response, leading to redundancy in the data collected. These redundant questions were identified and deleted to improve the efficiency of data collection and ensure that diverse perspectives were captured. During the discussions in the various FGD groups, research team members who took notes passed on notes to the moderators to probe further where necessary. These steps aligned perfectly with Patton's (1999) principles for safeguarding reliability during data collection and analysis.

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To safeguard the quality of a qualitative research the primary ethics of rigour was observed. This implies that results of any research that does not apply rigour in ensuring quality fails to be reliable and the phenomenon under study becomes biased (Cho & Trent, 2006). In this study, the principles for safeguarding reliability during data collection and analysis according to Patton (1999) were followed. The key principles of rigour in qualitative research are authenticity in making sure that findings can be trusted; making sure that findings can be compared with a similar context as required by the principle of transferability; dependability and confirmability by making sure that same results can be obtained when the study is repeated and ensuring the possibility of result validation by others respectively (Talbot, 1995; De Vos et al., 2013).

Ensuring rigour in qualitative data collection involved addressing key issues of credibility, transferability, dependability, and confirmability. Firstly, I employed multiple data collection methods, including focus group discussions and surveys. This triangulation of perspectives not only enriched the data by providing diverse viewpoints but also enhanced the credibility of the findings by showcasing their consistency across different methods (Creswell, 1998; Mason, 2006).

To further strengthen credibility, the lead researcher and data collectors collaboratively reviewed and coded the data, discussing and resolving any variations in coding decisions. This collaborative approach effectively minimized subjectivity and bias, leading to a more trustworthy coding process. Finally, the data collectors underwent a week-long intensive training workshop where they sharpened their skills in asking appropriate questions and taking informed consent, further solidifying the research's credibility. Addressing transferability involved meticulously describing the study context, including demographics, setting, and DE implementation procedures. This level of detail allows readers to assess the potential transferability of the findings to their own contexts (Talbot, 1995). Additionally, the findings

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were discussed in the context of existing DE research, highlighting how this study complements or contrasts with previous knowledge, further informing transferability judgments.

Guaranteeing dependability and confirmability was also paramount. Interview recordings, field notes, and documented coding decisions, was maintained. This meticulous record-keeping allows for replication of the research process and data analysis by others, strengthening dependability (De Vos et al., 2013). Finally, transcripts were translated, with two transcripts back translated for quality assurance.

3.10 Ethical considerations

3.10.1 Ethical approval

Approval for the study was obtained from the Ghana Health Service Ethics Review Committee (Number GHSERC:032/07/22).

3.10.2 Administrative Approval

Following the approval by the Ghana Health Service Ethics Review Committee, introductory letters were sent to the selected facility (NHRC) in the study district to seek permission before the commencement of the study.

3.10.3 Informed consent

The study followed ethical principles to respect and protect the rights of participants. The participants were informed about the purpose, procedures, risks, and benefits of the study in their local languages (Nankam or Kasem) and English. They were also informed about their right to withdraw from the study at any time without any consequences. The participants who agreed to take part in the study signed or thumb-printed an informed consent form, which was also read to them in their local languages by a designated member of the research team if they could not read or understand English. Witnesses were present to observe and confirm the

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process for these participants. Each participant received a copy of the signed consent form. The participants were encouraged to ask questions before and during the study.

3.10.4 Confidentiality and Privacy

To protect participants' privacy and keep their data confidential, names and other identifying information were not recorded on any data collection instrument. Instead, each participant was allocated a unique identifier which was recorded on the demographic information sheet and the informed consent form. Any printed documents linking participants' names with their unique identifiers were kept in separate locked file cabinets from those containing data.

To reduce potential risks regarding breaches of confidentiality, the importance of keeping the discussion confidential was emphasized to participants. Participants were given numbers to identify them during the focus group discussions to protect their identity. Any identifying information that was inadvertently disclosed during data collection was cleaned from the transcripts before importing into NVivo software for data analysis. The only personal identifiers collected from participants were their names and a telephone number. This information was accessible only to me and the research assistant for the purposes of follow up surveys, as well as reminding participants of scheduled meetings. The information was contained in one contact list that was kept in a locked filing cabinet, separate from any data collected.

All digital voice recordings from the deliberative engagements and FGDs will be destroyed after publication of the study's main findings. Electronic copies of all data will be stored securely at the University of Ghana for up to 5 years after the completion of the study or if necessary to complete all publications.

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3.10.5 Right of withdrawal

It was made clear to participants that they were free to withdraw from the study at any stage without risk of any negative consequences to them. A few participants withdrew during the follow-up period.

3.10.6 Risks and Benefits

There were no direct benefits for participating in this study. It was explained to participants that their views and responses could however inform decision and policymaking around implementation of deliberative engagement in genomic research and biobanking in Africa. The identified risk in this study was economic risk as participants spent the whole day and could have lost their daily incomes or subsistence. This was mitigated by compensating them for their time.

3.11 Reflexivity and positionality

Bryman (2012) suggests that our relationship with a given context significantly shapes our unique perspectives. In the context of this research, it is vital to acknowledge how my background and my position as a researcher may have influenced various aspects of the study, including participant responses to the study intervention (deliberative engagement), focus group discussions (FGDs), and survey questions. Moreover, my own interpretation of the study findings is inherently informed by these factors.

Firstly, I introduce my identity to this study as a young Ghanaian woman. I was born in a rural community and subsequently transitioned to urban life during my childhood and adulthood. Notably, my family history underscores the rural-urban dynamic: my parents initially hailed from a rural background but migrated to the city in their early twenties, where they have resided ever since.

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Although my siblings and I are all females, I occupied a unique position among my siblings, being the most assertive and inquisitive. This disposition led to engaging conversations with my father, who, despite living in the city, maintained a deep connection to our rural roots. These family ties also meant that I accompanied my parents on their annual trips to our village during Easter and Christmas holidays. During these visits, I keenly observed community meetings convened for discussions on development. It was evident that these gatherings predominantly comprised male participants.

In 2009, my journey as a social scientist in the field of health led me to a Health Research Centre in a peri-urban community in the Greater Accra region. Here, I delved into extensive implementation research related to Neglected Tropical Diseases (NTDs). This experience exposed me to a range of participatory research approaches, including Photovoice, Vignettes, and seasonal calendars. I also took on the role of moderating numerous FGDs and IDIs in remote rural communities across all regions of Ghana. Through these endeavours, I witnessed the repercussions of policies failing due to insufficient community engagement. I observed how geographic remoteness marginalized certain communities. Yet, in these very communities, women played pivotal roles in seeking solutions to these issues, often going above and beyond to provide essential services. Despite their invaluable contributions, these women, including community health volunteers and nurses, remained excluded from decision-making processes.

These formative experiences have deeply influenced my choice of research topic and my perspective as a researcher. During the implementation of this study, I viewed the study participants as capable contributors to the research topic, and this perspective likely encouraged their active engagement during discussions.

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Secondly, my capacity to interpret the study findings draws heavily from my understanding of rural community dynamics, sociocultural contexts, and their significance in the context of deliberative engagement. My academic background and professional practice in bioethics further shaped my analysis. Before commencing data collection, I underwent training in "Deliberation and Participation in Healthcare," an experience that broadened my understanding of engaging stakeholders in participatory and deliberative research. This training provided me with insights from diverse worldviews and contexts, encompassing both African and Western settings.

My academic journey includes fellowship at the Johns Hopkins University Berman Institute Bioethics programme, a master's degree in social sciences in Health Research Ethics from the University of Kwa Zulu Natal in South Africa, and over a decade of experience in research ethics administration and capacity-building for health professionals and researchers. I have also served as a social science researcher in the field of implementation research at the Dodowa Health Research Centre of the Ghana Health Service.

These cumulative experiences in bioethics and health research have empowered me to provide well-considered and balanced interpretations of the study findings. Furthermore, my supervisory team, comprising experts with diverse educational backgrounds, experiences, ages, and genders, enriched the research process. The mixed-methods approach demanded proficiency in both quantitative and qualitative research methodologies. Consequently, I dedicated myself to acquiring the necessary skills for data collection, analysis, and reporting, as prescribed by a mixed-methods approach.

This pursuit of expertise was marked by an extensive review of relevant literature on mixed-methods research (Johnson, Onwuegbuzie & Turner, 2007; Creswell & Clark, 2011; Bryman, 2012). Frequent discussions with my primary data collector, who possesses a strong

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background in quantitative research, and consultations with a seasoned expert in the field of quantitative research, enhanced my methodological capabilities. These collaborative efforts, combined with an earnest engagement with the literature, not only improved my proficiency but also enabled a thoughtful and theoretically grounded application of the mixed methods approach throughout the study.

3.12 Chapter summary

This chapter outlines the research methods employed in the study, including its philosophical foundation (pragmatism), research design (mixed-methods), setting (rural Ghana), population (AWI-Gen study participants), sampling (census and purposive), data collection methods and instruments (surveys and focus groups), data analysis and ethical considerations. The next chapter presents the results of the qualitative aspect of the study.

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CHAPTER FOUR
RESULTS

PROCEDURAL AND CONTEXTUAL FACTORS THAT INFLUENCE THE IMPLEMENTATION OF DELIBERATIVE ENGAGEMENT

4.0 Introduction

This chapter presents the results from the qualitative component of the study, which sought to address objectives one, two and three of the study. The results cover procedural and contextual factors that influence the implementation of the deliberative engagement. The chapter also presents results on participants perspectives on potential challenges and opportunities or recommendations for future implementation of deliberative engagement.

Table 4: Presents A Summary of The Key Themes and Sub-Themes of the Results

Summary of themes		
Research question	**Themes**	**Sub-themes**
1. What procedural factors could influence the implementation of the deliberative engagement?	Procedural factors that could influence the implementation of deliberative engagement.	▪ **Information delivery and education session** ▪ Experts' experience ▪ Use of audio-visual tools ▪ Languages used ▪ **Deliberative discussion session** ▪ Fairness during discussion ▪ Respect for individual views
2. What are the contextual factors that could hinder or enable the implementation of the deliberative engagement?	Contextual factors that could influence the implementation of deliberative engagement.	▪ **Pre-implementation factors** ▪ Mobilization and recruitment of participants ▪ Planning on logistics ▪ **Implementation factors** ▪ Group composition ○ Composition by age ○ Composition by gender ○ Composition by educational status ○ Group size

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		▪ Venue ▪ Duration
3. What are the challenges and opportunities that could influence the implementation of deliberative engagement?	Potential challenges and opportunities to consider for future deliberative engagement.	▪ Seasonality/Timing ▪ Use of more participatory tools ▪ Duration ▪ Venue ▪ Compensation for time

4.1 Procedural factors that influenced the implementation of deliberative engagement

The procedural factors identified to influence the deliberative engagement included the information delivery and educational session (experts' experience, language used and the use of audio-visual tools) and the deliberative discussion session in terms of fairness during deliberations and respect for individual views. The next section explores these factors.

4.1.1 Information delivery and education session

Participants were asked about the information delivery session regarding the expert presentations, the use of audio-visuals as well as the languages that were used. Generally, participants observed that the session was adequate as time was taken to explain all issues and concepts to their understanding. Participants were also happy about the use of different teaching approaches and tools to cater for the diverse participants background especially language, precisely because not all the participants could read or understand the English language. Participants also observed that the communication was not one way with only the experts doing the talking but that they also contributed to the discussion and felt that they were listened to.

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> *Q: What is your view about the information delivery session?*
>
> *R: It was good because some of us can read but some of us cannot read so the expert helped, we those who could not read to understand the meaning of the video so the facilitation was very good. The way the person was pausing the video and explaining to us was the best thing because he helped us understand much about the video*. **(Male, primary education, FGD).**
>
> *The discussion was a kind of like school because the facilitator had time to explain any question that we asked him and we understood everything about this discussion, what we didn't know about our samples now we know, so, we are very happy with this.* **(Male participant, primary education, FGD).**

In terms of the use of audio visuals during the information delivery sessions, several participants were of the view that the use of the audio-visual teaching tools like video documentaries made it easy to understand the various topics that were presented, since the concept was quite new to them. Specifically, some participants reported that, the content of the video documentary provided them with the information that changed their negative perception about what is done to their blood samples by researchers.

> *I was happy about the videos that were shown to us. It made us see the process our samples go through and how they are shared with others and that is how my mind changed from what we were teased about in the community that our blood is sold to other doctors outside.* **(Female participant, primary education, FGD).**

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> *The one who was doing it (referring to the narrator in the video documentary), he was explaining to our understanding.* **(Female participant, primary education, FGD).**

> *I liked the fact that I clearly saw the process involved when my blood is taken and how it is used.* **(Female participant, primary education, FGD).**

Another aspect of the information delivery was the language used. Participants were asked about their views on the languages that were used during the deliberative engagement session. All the participants who came from the same community and participated in the session where the local language for that community was used were satisfied with the language used.

> *Oh, it was easy for us to understand the discussion because the moderator used local language which we all understand so we didn't find any difficulties in understanding the discussion.* **(Male participant, primary education, FGD).**

> *No, there were no issues because the facilitators spoke three languages: English, Kassem and Nankani. So, I think even if you do not understand one of the languages, there is at least one language you would understand to maximize the benefit of coming here.* **(Male participant, primary education, FGD).**

Nonetheless, there were opposing views from participants from different communities who participated in the same deliberative engagement session with two local languages being used. Whilst some admired the ability of the expert to use the two local languages, others were not happy with that approach because it distracted them from focusing.

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> *To me it was somehow difficult because the moderator was using two different local languages in the discussion; before he finishes using one local language to explain something and coming back to explain the same thing using different local it was bringing confusing so, I suggest they should have separated us and have the discussion with us according to our language so that we can be able to concentrate what they have for us.* **(Male participant, primary education, FGD).**

4.1.2 Deliberative discussions session

Participants were generally happy with the session and observed that the opportunity to share different views and values among themselves helped them to learn from each other. They also added that every individual's voice was respected with all given equal opportunity to freely contribute to the deliberation.

> *The moderator was so lovely, and he is approachable, and he gave us the freedom to contribute what we know. There was no doubt about the question. There was even a question that made us think faster.* **(Male participant, secondary education, FGD).**

> *I think the moderation went on well because when you are many in a discussion and the moderation is not good, there will be misunderstanding among you but since we have finished the discussion without any misunderstanding it means the moderation was good.* **(Male participant, primary education, FGD).**

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They also referred to the moderator's attentiveness in listening to them and having a peaceful session without any fights.

> *The moderator, he also paid attention and listened to each and everyone us that wanted to ask question or wanted to contribute in the discussion so he was paying much attention to us.* **(Female participant, primary education, FGD).**

When asked about specific aspects of the deliberation that they liked, participants spoke about fairness during the deliberative discussion. According to participants, the moderator was fair in ensuring that all participants were given the opportunity to contribute to the deliberations.

> *There was fairness in the discussion because I didn't see anyone that raise his hand to talk and the moderator asked him to put the hands down, so there was respect and fairness in the discussion.* **(Male participant, primary education, FGD).**

Another issue was respect for individual views during the discussion. Participants were also asked about how they felt about their own individual contribution to the discussion, in terms of their self-efficacy as well as how other participants viewed their efficacy. Participants were also asked if they felt disrespected in any way. The findings suggest that even for groups that had a mix of both men and women, the women did not feel disrespected and referred to how they felt comfortable in making their contributions.

> *Q: How do you feel about the contribution you made to the discussion as well as the contribution of the other participants?*
>
> *R: I think my colleagues valued my input and I also valued theirs.* **(Female participant, Primary education, FGD).**

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> *Q: Did you feel disrespected or intimidated in anyway during the deliberations?*
>
> *R: I think that as my husband (referring to a male participant) said… (laughs) because we are not in each other's mind, we may not know the actual thinking of people but left to me alone, I am so excited and I do not think anyone made me sad or less valued.* **(Female participant, primary education, FGD).**

They were also asked if they felt that the moderator respected their views.

> *Q: How do you feel about the moderator's treatment of participants' views in terms of respect?*
>
> *R: Oh, there was respect from you (referring to the team) and you also gave us the opportunity to also express our views or ask questions to clarify ourselves so we are very happy for that.* **(Male participant, primary education, FGD).**

4.2 Contextual Factors that Influenced the Implementation of Deliberative Engagement

Another objective of this study was to explore how contextual factors influenced the implementation of the deliberative engagement events. These have been categorized into pre-implementation and implementation factors and discussed below.

4.2.1 Pre-implementation factors

4.2.1.1 Mobilisation and recruitment of participants

One of the key factors that affected the implementation of the deliberative engagement sessions was the mobilization and recruitment of participants. Participants for the study were recruited from rural communities with scattered settlements, and almost all the participants could not be

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accessible by phone. The implications of that were the need to take several trips to the field to recruit potential participants at their households. Even after recruitment, visits had to be made to remind them about the event. To avoid delays in attendance to the sessions, transportation had to be arranged to pick participants to the research centre where the event took place. From most of the homes of the participants to the central pick-up point was quiet a distance, so fieldworkers had to visit the homes of these participants to pick them to the central place to be picked by a bus to the research Centre. This caused a lot of delays to the commencement of the sessions. While participants might have initially envisioned the sessions held within their communities, they ultimately appreciated the chosen venue. They acknowledged that familiar surroundings would have brought distractions from family and neighbours, disrupting their focus on the discussions. Additionally, the venue offered the necessary technological equipment not easily accessible in their communities, ensuring smooth deliberative engagement session activities. Furthermore, participants valued the spacious layout, which adhered to COVID-19 protocols and fostered a safe and comfortable environment. Ultimately, they viewed the chosen venue as a practical and beneficial choice despite its distance from their immediate communities. Although they were not happy with the various delays, the active participation of the research team especially the primary researcher in the mobilization of participants in the community helped in establishing a good rapport. Also, important observations were made about some common norms and values of the communities such as how greetings are exchanged. This was demonstrated in welcoming participants to the venue, allowing them to have a feeling of respect for their way of life.

> *When the woman first came to pick the people for this study, she met me first. When we agreed and came out and met you in the car, I was happy about how you welcomed us, and I said in my mind that we were in for a very good day.* **(Male participant, primary education, FGD).**

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4.2.2.2 Planning of the deliberative engagement sessions and logistics

Study participants highlighted several logistical issues that affected the program's flow and their overall experience. Firstly, transportation delays affected the deliberative session's start time. This caused frustration and disappointment for participants, and ultimately extended the program's duration. Furthermore, a last-minute change in venue due to unforeseen circumstances forced participants to gather in a small space. This proved to be uncomfortable, especially during group discussions and deliberations due to limited space and lack of privacy. The timing of the planned snack breaks also contributed to participant dissatisfaction. Scheduled based on anticipated arrival times, it conflicted with participants who had not eaten breakfast due to earlier departures. This led to feelings of frustration and a perception that the break was unnecessarily delayed. Late arrivals further disrupted the program's flow. Several participants arrived after the session had already begun, requiring the session to be restarted for their benefit. This caused inconvenience and frustration for those already present who had arrived on time. Additionally, the initial plan to utilize two vehicles was not fulfilled, with access limited to only one. This likely contributed to logistical delays and further impacted the smooth execution of the program.

As participants observed concerning the provision of food, venue and transportation below;

> *R: Yes, the time you came and picked us was not good. Next time you should try and separate us, you shouldn't combine different languages in the events and we will do first come first serve; when the kassem group comes first then you will attend to them first and when the Nankam groups comes first then they will be the first people to attend to but we cannot force you to let the events days be different no, it can be the same day but it will now be depending on the group that comes first.* **(Male participant, primary education, FGD).**

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> *Everything in the events is okay for us but the only thing that we didn't like is the time we were waiting for you to come and pick us; you told us that you will come by 7:00 and pick us but finally you came and picked us at 11:00 so, it is only the time that we didn't like in the event. You were supposed to come and pick us 6:30 so that we will finish everything by 10:00 and get back to our various houses to see what we can get and eat because we will come here and sit with hunger and after all we go home late and will not get anything to eat.* **(Male participant, primary education, FGD).**

4.2.2 Implementation factors

4.2.2.1 Group composition for the deliberative discussions

Participants were asked to share their views on how the groups were composed for the deliberative engagement session, and if they had recommendations on how this should be done. In general, they were of the view that the nature of the topic to be deliberated upon should determine who should participate based mainly on gender and age. They added that for topics that are not sensitive and personal, it is fine to include both men and women in the same group. This is however not appropriate for sensitive topics.

> *This discussion is not in such a way that when we are put together men and women, someone will feel shy to express his or her views because we are not discussion personal health conditions; whereby one will say someone will get to know his health conditions. This discussion is just something we trying to get everybody understanding in the events so, I think putting us together in one group discussion is good.* **(Male, primary education, FGD).**

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They added that having a heterogenous group would allow diverse perspectives that would enrich the deliberations.

> *Woman, man, the younger and the older people are having different views in a discussion so we supposed to put them together so that each of them give their views so we can all make senses out of it. I think this is better than putting only the younger ones in a group and they will be having the same views or you put only women in one group and they bring only women views So, combining different views from different people is the good thing to do.* **(Male, primary education, FGD).**

> *Putting all of them together in one group is the best thing because all of them will bring their personal views; the woman brings her view, the man brings his view, the younger brings their views and the older bring their views as well so putting us together in one group will be better than separating us.* **(Male, tertiary education, FGD).**

There were however opposing views on whether individuals with different age groups and educational level should be grouped together. Whilst some participants were of the view that having both younger and older participants in a group would allow learning across the age categories, others felt that it would not be appropriate because the younger age participants would disrespect the older population.

> *To me I think putting them together will be good because the younger people know somethings that the old people don't know, and the older people also know things that the younger people don't know so when you put them together you will have different views which will help you to get enough information.* **(Male, primary education, FGD).**

> *What I think is that it your programme and it is you who can take that decision. If it is left with me, I think you cannot call children. Children and the adult mind are different. It could be that the child is in school or some trade he is learning if you say you are mixing it. They might think we are out of date with current things, and we might also say they do not respect. So, it will bring a lot of issues. So, as you are dividing us into tribes, that Asante's should be on one side and the others. Because they the young people can speak English, they might not respect those who cannot speak English. So, I think that if you will involve children or young people you should do it separately from us, we cannot mix with them.* **(Male, primary education, FGD).**

As regards composition of groups by education status, participants were asked if an individual's educational level should be a requirement for participating in deliberative engagement sessions. They were of the view that if the issue to be deliberated upon is of concern to both the educated and the un-educated, then all must participate irrespective of their educational level. They also added that wisdom or intelligence must not be defined by a person's educational status.

> *You know when you were taking the blood samples you did not take only those who are educated blood samples and even in the discussion, there were local languages so, those who did not go to school will also understand so the discussion does not matter your educational level.* **(Male, primary education, FGD).**

> *The school is good but it not only the school that matters. Some people did not go to school but they speak intelligently and wisely. They are some*

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> *educated people who go about insulting others.* **(Male, secondary education, FGD).**

Another related issue was the composition of deliberative groups by gender. When an all-male group was asked if the discussion would have been any different if there were women in their group, majority were of the view that women did not have the capacity to deliberate with men at the same level on an issue and that women would normally feel inferior.

> *I am saying that there will be a difference. The difference will be that the women will not like to contribute because we are men. So normally when women sit with men they think that they are inferior to men so whatever idea they have they may look at the men and not feel comfortable. But as it is we are all men and we know the problem we can share. If women are with us, they wont talk but if they are with their equals, the way they will talk, they will even talk more than us.* **(Male, tertiary education, FGD).**

However, some men felt it did not really make a difference in how the deliberation would go with both men and women together. It was added that, in the past, it would have been a problem but not anymore.

> *For me, what I think in relation to whether to separate men and women in future discussions I think there are topics such as "Night discussions" that you may consider separating men from women. I mean if a woman feels the man is weak, she may not be able to say it when in the same group with the man. But this is about health, about the biological samples we donated and what benefits it will bring to us. I have not seen any reason why a man or woman should not be able to express himself or herself because of the presence of the opposite sex to warrant separating men and women for discussions like these that*

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> *bother on health. Please wait so that when you are bringing discussions about sex and marital issues then you separate us but for this, there may no need to separate men from women. (laughs)* **(Female, primary education, FGD).**

Many men however observed that English language would be a barrier because most of the women within their cohort had not gone to school and added that for subsequent sessions, women who are more educated should be targeted. Meanwhile, some of the female participants said they felt no form of intimidation from the presence of the men in sharing their views, and that it did not make a difference to have both men and women together unless the topic was related to sex or other sensitive gender issues. There were other women who went further to say that they would even be comfortable to discuss issues related to sex in the same group with men. However, there were others who felt for discussion like sex, men and women should be in separate groups.

> *Left to me I am a woman, and I don't think there would be anything wrong with discussing sex with men in the same group because he who is sitting there is my father, but he is a man and therefore is my husband. So, if my husband and I sit down to discuss sex, I don't think there is a problem there.* **(Female, primary education, FGD).**

> *I don't think in this kind of discussion men should be separated from women cos we are both learning from one another. What they share we learn from and what we share they also learn from so there may be no need to separate the men from women. But really in some other discussions like the sex and other things, let the men have theirs and we will also have ours (laughs).* **(Female, primary education, FGD).**

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The finale issue related to group composition for the engagement was the size of the group. Participants perceived that smaller groups were better than larger groups because most people would not be comfortable contributing in larger groups. They also added that it is easier to manage smaller groups during deliberations and in teaching as it is easier for individuals to understand topics because they can easily ask questions without fear or intimidation.

> *I think this group is good because when you bring a small group together there is understanding, and contributions go well. Smaller groups understand each other better than larger groups.* **(Male, primary education, FGD).**

> *Smaller groups are better because people may feel shy in big groups and then those who cannot speak in public, even though they may have very important issues that need to be said. Like the woman who asked a very strong question.* **(Male, secondary education, FGD).**

> *The number of participants per group is okay because it helped you to control the participants; when we are many more than this, there will be a lot of noise and we will not hear one another and some of us too don't want where there is noise.* **(Male, primary education, FGD).**

4.2.2.2 Venue for the deliberative engagement sessions

Participants were generally satisfied with the choice of venue for the sessions. They acknowledged the fact that organising the session in their local community would have resulted in several distractions from family members as well as other community members. They also added that, the choice of venue was necessary because of the kinds of electronic devices that had to be used. Participants also commented about how the venue ensured spatial distance as required by COVID-19 protocols.

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> *It good that you brought us here because you might not be able to bring all your tools and equipment to our place. So, it good you bring us here.* **(Male, primary education, FGD).**

> *This venue that you have chosen for the discussion is okay if it were to be in our houses, children will interrupt; the children will come and call you that Dada come home they finished preparing food so the venue here is okay.* **(Male, primary education, FGD).**

> *Oh, I think things were not so difficult like that especially the video show because it was a better place for you to project the video for us to watch and understand the whole thing so because the video presentation was done in the room we find it easy to watch and understand everything in the video, it would have been difficult for us to understand the video when you would have shown it in an open place where there is noise and also a blurred vision or display of the screen so, there was no difficulties we face in the discussion.* **(Male, primary education, FGD).**

4.2.2.3 Duration of the deliberative engagement sessions

Another implementation factor that came out of the data is the duration of the deliberation. Participants were generally unhappy with the duration of the deliberative engagement sessions in this study. Some participants were of the view that the long duration of six hours for the session was necessary because all the processes involved were necessary for them to get the needed understanding. They added that the benefits of participation outweighed the loss they have encountered in terms of time but were quick to add that the issue (long duration) had to be addressed to avoid its negative influence on future participation. Some participants were

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also of the view that the mobilization of participants to the venue added to the long duration of the whole process because of the delay.

> *We are not sad about the duration because if you take your time and learn and understand something, it will stay with you forever. For us who are advanced in age, what other things are there to learn, but you have helped us through these discussions to think about the studies we participate in and what they may really mean for us and our families. So, for me I am ok with the time spent.* **(Male, tertiary education, FGD).**

> *The time. I thought it was two or three hours but we spent the whole day here. What I will like to say is that, the next time you are organizing this type of event you should try and let us start it early so that by 3:00 we can go home.* **(Male, primary education, FGD).**

4.3 Challenges and Opportunities to Consider for Future Deliberative Engagement Sessions

Participants were asked about challenges and facilitators that should be considered for future implementation of deliberative engagement forums. In terms of potential challenges, they were of the view that if the timing of future deliberative engagement sessions coincides with the busy farming season, then attendance would be adversely affected. They were however quick to add that if the stakes are high then irrespective of the season, participants are more likely to participate. They were also of the view that the long duration of the forum could also be a challenge as that would discourage participation. However, they recommended adequate compensation in terms of cash as one approach to addressing the issue with long duration.

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> *To me when you are having this type of event in the subsequent community, you should organize it in the community and involve entertainment in it; you should include drumming and dancing.* **(Male, secondary education, FGD).**

> *I think there were no peculiar challenges ooo. I don't see a problem anywhere. The duration for the workshop was too much so if you could have reduced it for us it would have been better.* **(Male, primary education, FGD).**

> *You will face attendance challenges when you call them to come at the time that they are busy on their farms it will be difficult for you to get them.* **(Male, primary education, FGD).**

> *Oh, I don't see any problem from that angle because we are in the dry season and there is not much work for us even if there is, this is also work and the most important thing. Because even if you have work at home but you are not healthy, can you do the work? You can't. so I don't think there are issues with the time given that we discussed health.* **(Male, secondary education, FGD).**

In terms of facilitators, they opined that the direct benefits of gaining new knowledge as well as the peaceful deliberations is an advantage for the successful future implementation.

> *The discussions were beautiful and that would make me come back in the future. I won't come again if there were arguments and misunderstanding.* **(Male, primary education, FGD).**

> *What they are saying is true. Our husbands are pepper farmers and they called us this morning to come and work on the pepper farms for money but we left that and came here. Because we know the importance of these studies and I am*

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> *happy the approach you used helped us understand all that we have been doing in all these years*.**(Female, primary education, FGD).**

In addition, participants were of the view that the use of audio-visuals with local language translations as well as the expertise on the part of the moderators in ensuring a fair and peaceful deliberations should be maintained. They also added that as much as possible, the forum could be implemented within the communities with dancing and drumming incorporated into the process. They also applauded the teamwork by the research team and the various roles played by individual team members in facilitating the sessions. Participants were also of the view that the perceived individual benefits derived from participation should be one of the motivating factors for future participation in similar engagements.

> *The benefit I got from the deliberative event is the knowledge I acquired from the event; I learned that the blood sample that they normally take is not always much and when they collect our blood, they do not sell the blood; they use it to test and know the diseases in our body to be able to develop new drugs for the treatment of the diseases.* **(Male, primary education, FGD)**.

4.4 Chapter Summary

This chapter presented qualitative findings in response to objectives one, two and three of the study. The first section covered the procedural and contextual factors that influenced the implementation of the deliberative engagement events. The chapter also presented findings on participants perspectives on potential challenges and opportunities as well as recommendations that should be considered for future implementation of deliberative engagement.

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CHAPTER FIVE

RESULTS

HOW DELIBERATIVE ENGAGEMENT AFFECTED PARTICIPANTS' AWARENESS AND ATTITUDES

5.0 Introduction

This chapter presents results from the quantitative component of the study. The first component presents data on the demographic characteristics of the study participants. The second part presents data on the awareness and attitudes of participants before and after they had participated in the deliberative engagement. Participants' awareness and attitudes were examined on the topic of genomic research in general and sharing of participants' genomic data with researchers, biobanks, and commercial pharmaceutical entities.

5.1 Background Characteristics of Participants

Table 5 shows the background characteristics of the 66 participants in the baseline and endline surveys. Out of the 66 participants, 43(65.2%) were male, and 23(34.8%) were female. Majority (65.2%) of the participants were aged 54-60 years. Many participants attained Junior High School 17(25.8%) and Primary education 16(24.2). Many of the participants were Christians (49) 74.1% (Table 5).

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Table 5: Characteristics of study participants

Characteristics	**Frequency (n)**	**Percent (%)**
Age in years		
47-53	10	15.2
54-60	43	65.2
61-67	13	19.7
Total	***66***	***100***
Sex		
Male	43	65.2
Female	23	34.8
Total	***66***	***100***
Highest level of education		
None	10	15.2
Primary	16	24.2
JHS/Middle/JSS	17	25.8
Commercial/Vocational/Technical	5	7.6
SHS/Secondary	5	7.6
Tertiary	11	16.7
Apprenticeship	2	3
Total	***66***	***100***
Religion		
Christian	49	74.2
Traditional	13	19.7
Other	4	6.1
Total	***66***	***100***

5.2 How participation in deliberative engagement affected participants' awareness and attitudes towards Genomics research and Data Sharing

Tables six (6) and seven (7) show the difference in the assessment of participants pre and post deliberative engagement on two main domains (1) awareness ((i) awareness on the purpose of genomic research; (ii) awareness of existing of committees and regulatory bodies for ensuring privacy and confidentiality in data sharing). The Awareness refers to participants'

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understanding the purpose of genomic research and knowledge of the existence of committees and regulatory bodies responsible for ensuring privacy and confidentiality in data sharing; (2) attitudes ((i)likelihood to participate in future genomic research; (ii) acceptable for biological samples and the associated data to be stored outside Ghana; (iii) worried about privacy and confidentiality in keeping my genomic samples outside Ghana; (iv) confident that researchers will ensure that my genomic data will be kept private and confidential; (v) confident that the informed consent that I gave before participating in genomic research can ensure confidentiality and privacy of my data; (vi) willingness to have your data donated for commercial purposes; (vii) individuals should receive any form of benefit when their genomic data from a genomic study is shared with commercial entities like pharmaceutical companies.

The pre and post deliberative engagement assessment varied across the various domains assessed. Prior to participation in the deliberative engagement, 34 respondents (51.5%) reported awareness of the purpose of genomic research but awareness of the purpose of research based on deliberative engagement increased to 52 (89.7%) with a p-value=0.001. Similarly at pre-assessment 13 respondents (19.7%) reported not aware of the existence of committees and regulations dedicated to ensuring privacy and confidentiality in data sharing and this decreased to (4) 6.8% in the endline (Table 6).

The results on the domain of attitude towards deliberative engagement process for genetic research also showed marked differences. Participants' likelihood to participate in future deliberative engagements results showed a slight change in likelihood from 62(94.0%) before engaging in the deliberative process to 55(94.8%) after participation in deliberative engagement (Table 7a).

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Regarding the willingness to have their biological samples and associated data shared or stored in biobanks or institutions outside Ghana, at pre-engagement assessment, 6 (9.1%) thought this was unacceptable but after post-engagement in the deliberative process it reduced slightly to 2 (3.4%). Additionally, 6(9.1%) of participants who were initially neutral at pre deliberative engagement assessment also decreased by percentage to 5 (8.5%) post-engagement, indicating proportionately less people preferred to stay neutral (Table 7a).

Concerning privacy and confidentiality, 18.2% of the participants at the baseline expressed worry about privacy and confidentiality being ensured in the storage of their genomic samples outside Ghana. Post-DE, this concern had reduced to 15.3%. (Table 7a). Also, on privacy and confidentiality, eight participants (12.1%) reported a lack of confidence in researchers' ability to maintain the privacy and confidentiality of their genomic data before DE. However, most (53) respondents expressed confidence in researchers' ability to ensure privacy and confidentiality, with an improved response of 89.8% post-DE and this difference was not statistically significant (Table 7a).

Participants were also asked about their belief in the effectiveness of informed consent forms in ensuring the privacy and confidentiality of their data. At pre deliberative engagement process 80.3% expressed confidence in the informed consent forms however significantly increased with a p-value=0.045 to 94.9% post-engagement (Table 7b).

Participants were informed that biological samples and associated data might be donated to biobanks and used to develop patents and profits by commercial entities. They were subsequently asked about their willingness to have their biological samples and data shared for such purposes. At the pre deliberative engagement, 10 participants (15.2%) expressed unwillingness to donate their samples but through the deliberative engagement their opinions changed with only 4 participants (6.8%) remaining unwilling to donate their data to

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pharmaceutical companies. Similarly, the 9 individuals (13.6%) who were neutral at pre deliberative engagement stage also had a better-informed opinion and thus only 3 individuals (5.1%) remained neutral post-engagement (Table 7b).

On the basis that pharmaceutical companies could offer benefits for donated samples, participants were asked if individuals should receive any form of benefit for sharing biological samples and data with these commercial entities. The results show that at the pre deliberative engagement (baseline) 9 participants (12.1%) disagreed to receiving any benefits for donating biological samples while 7 (10.6%) participants were neutral. Following the deliberative engagement process post-engagement, there was a slight change in opinions with 3(5.1) participants disagreeing with individuals receiving benefits whilst those who were neutral had decreased to 3(5.1%) (Table 7b).

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Table 6: How participation in deliberative engagement affected participants' awareness about genomics research and laws/committees ensuring privacy and confidentiality.

Variable	Pre-Intervention (%)	Post-Intervention (%)	p-value
Awareness about the purpose of genomic research			
Not at all aware	17(25.8)	2(3.4)	
Slightly Aware	15(22.7)	4(6.9)	**0.001
Aware	34(51.5)	52(89.7)	
Total	**66(100)**	**58(100)**	
Aware about committees and laws for ensuring privacy and confidentiality of genomic data sharing			
Not at all aware	13(19.7)	4(6.8)	
Slightly Aware	12(18.2)	10(16.9)	0.084
Aware	41(62.1)	45(76.3)	
Total	**66 (100)**	**59(100)**	

Significant level: *p<0.05; **p< 0.001

This table shows changes in participants' awareness about genomics research and laws/committees ensuring privacy and confidentiality before and after participation in deliberative engagement. Figures represent frequency (percentage). p-values are from Chi-square tests comparing pre-intervention and post-intervention responses. Significant levels: *p<0.05, *p<0.001.

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Table 7a: How participation in deliberative engagement affected participants' attitudes towards data sharing in genomics research.

Variable	**Pre-Intervention (%)**	**Post-Intervention (%)**	**p-value**
Likely to participate in genomic research in future			
Unwilling	2(3.0)	3(5.2)	
Not Sure	2(3.0)	0(0.0)	0.348
Willing	62(94.0)	55(94.8)	
Total	**66(100)**	**58(100)**	
It is acceptable for biological samples and the associated data to be stored outside Ghana.			
Unacceptable	6(9.1)	2(3.4)	
Neutral	6(9.1)	5(8.5)	0.419
Acceptable	54(81.8)	52(88.1)	
Total	**66(100)**	**59(100)**	
Worried about privacy and confidentiality in keeping my genomic samples outside Ghana.			
Not at all worried	39(59.1)	43(72.9)	
Somewhat worried	15(22.7)	7(11.9)	0.207
Worried	12(18.2)	9(15.3)	
Total	**66(100)**	**59(100)**	
Confident that researchers will ensure that my genomic data will be kept private and confidential			
Not confident	8(12.1)	4(6.8)	
Neutral	5(7.6)	2(3.4)	0.327
Confident	53(80.3)	53(89.8)	
Total	**66(100)**	**59(100)**	

This table presents changes in participants' attitudes towards data sharing in genomics research before and after deliberative engagement. Figures represent frequency (percentage). p-values are from Chi-square tests comparing pre-intervention and post-intervention responses. Significant levels: *p<0.05, *p<0.001.

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Table 7b: How participation in deliberative engagement affected participants' attitudes towards data sharing in genomics research.

Confident that the informed consent that I gave before participating in genomic research can ensure confidentiality and privacy of my data.			
Not confident			
Neutral	6(9.1)	1(1.7)	
Confident	7(10.6)	2(3.4)	*0.045
	53(80.3)	56(94.9)	
Total			
	66(100)	**59(100)**	
Genomic data could be donated to biobanks and sometimes given to commercial companies who use them to develop drugs and diagnostic tests for profits. Are you willing to have your data donated for such purposes?			
Unwilling	10(15.2)	4(6.8)	
Neutral	9(13.6)	3(5.1)	0.066
Willing	47(71.2)	52(88.1)	
Total	**66(100)**	**59(100)**	
Individuals should receive any form of benefit when their genomic data from a genomic study is shared with commercial entities like pharmaceutical companies.			
Disagree	8(12.1)	3(5.1)	
Neutral	7(10.6)	5(8.5)	0.242
Agree	51(77.3)	51(86.4)	
Total	**66 (100.0)**	**59(100.0)**	

Significant level: *p<0.05; **p< 0.001

This is the continuation of Table 7a, showing additional items on attitudes towards data sharing in genomics research. Figures represent frequency (percentage). p-values are from Chi-square tests comparing pre-intervention and post-intervention responses. Significant levels: *p<0.05, *p<0.001.

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5.3 Chapter Summary

This chapter presented results from the quantitative component of the study to respond to objective four. The first session presented data on the demographic characteristics of the study participants. The second part presented data on the awareness and attitudes of participants before and after they had participated in the deliberative engagement events. The demographic information showed that 66 participants were involved in the study of which 43 (65.2%) were male and 23 (34.8%) were female. The majority (65.2%) were aged 54-60 years. Most participants had attained Junior High School (17, 25.8%) or Primary (16, 24.2%) education and Christians comprised the largest religious group (49, 74.1%).

This findings on how deliberative engagement affected awareness and attitudes towards genomics research and data sharing showed that, participants' awareness of the purpose of genomic research increased significantly from 51.5% to 89.7% after engaging in the deliberative process (p=0.001). Similarly, awareness of committees and regulations protecting privacy and confidentiality grew from 62.1% to 76.3% (p=0.084). While 94.0% participants were already likely to participate in future genomic research before engagement, this remained high at 94.8% afterwards. The acceptability of storing samples outside Ghana increased slightly, from 81.8% to 88.1%. Concerns about privacy and confidentiality decreased, with the percentage of participants not worried increasing from 59.1% to 72.9%. Confidence in researchers' ability to protect data rose from 80.3% to 89.8%, while confidence in informed consent forms significantly increased from 80.3% to 94.9% (p=0.045). Regarding data sharing for commercial purposes, 71.2% were willing before engagement, increasing to 88.1% afterwards (p=0.066). Furthermore, the percentage who believed individuals should receive benefits from data sharing rose from 77.3% to 86.4%.

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CHAPTER SIX

DISCUSSION

6.1 Introduction

This chapter discusses the findings of the study based on the research objectives, the adapted realist theory, and a proposed conceptual framework. The discussion is structured as follows. First, it examines the procedural factors that facilitated successful implementation. Secondly, it discusses contextual factors, analyses participant preferences for mixed-gender groups while recognizing the need for adult-only settings to ensure respect for elders. Additionally, it addresses logistical challenges specific to rural settings, emphasizing the importance of careful venue selection and transportation planning. Next, the discussion explores the challenges and opportunities associated with DE implementation. Following this, the discussion examines the influence of participation on both awareness and attitudes, revealing a significant increase in awareness of genomic research alongside a shift in attitudes towards privacy and confidentiality in data sharing. Finally, the discussion concludes by addressing the implications of these findings and presents a model framework to guide future implementation.

6.2 Procedural factors that could influence the implementation of deliberative engagement.

This study emphasizes the importance of considering both procedural and contextual factors when implementing deliberative engagement (DE), particularly in rural settings. This aligns with the argument put forth by Fox (2015) that DE is not a one-size-fits-all approach and requires careful consideration of the specific context.

Participants generally provided a positive assessment of the deliberative procedures like the information delivery sessions and small group deliberations. This success could be attributed to factors such as the experts' presentation and facilitation skills, use of local languages and

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audio-visual tools and the size of the group composed for deliberations. For example, participants in the study were appreciative of the clear information and comprehensive responses provided by the experts. However, apart from the technical expertise shown by the experts during facilitation, they also displayed respectful and fair conduct which created a safe space ensuring all participants' voices were heard. The emphasis on respect, particularly for elders, aligned perfectly with Ghanaian cultural values. This was evident in the participants' appreciation for gestures like kneeling in greeting, which helped build trust and facilitate open communication. These findings reveal key insights that could translate into practical action for future implementation of DE in the rural African contexts. For example, facilitators should be equipped with the skills to understand and navigate local cultural norms and expectations to create a respectful and inclusive environment. It is also important to note that apart from the respectful approach of the facilitators, participants also showed respect for their individual views which could be due to the establishment of rules that clearly set the expectations for respectful behaviour. The establishment of ground rules at the start of the programme, emphasizing the importance of respecting each other's opinions, played a pivotal role in fostering this atmosphere of respect. This meant that the respect shown by participants among themselves could have also contributed to the success of the DE and must be encouraged in future implementations of DE.

Other procedural choices highlighted by this study as contributors to the successful implementation of deliberative engagement was the use of local languages and audio-visual tools. This aligns with existing research by Wilcox (2009) and Magaço et al. (2021), emphasizing the importance of catering to different learning styles and addressing potential language barriers. Employing local languages and audio-visual aids ensures that knowledge is accessible and comprehensible to all participants, regardless of their educational background. This was particularly pertinent given the challenging task of translating complex genomics and

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biobanking terms. This approach demonstrates the importance of thorough context analysis and tailoring DE procedures to the specific needs and preferences of the participants. Also pertinent was the use of simplified information presentation which aligns with Wynn's (1992) recommendation for facilitating understanding on unfamiliar topics. For example, the video documentaries used during the DE event were designed for easy comprehension without extensive narration, allowing participants to grasp the information without requiring prior knowledge of genomics or biobanking. This underlines the importance of making information accessible and engaging for participants to actively contribute to discussions and deliberation processes. Towards ensuring diversity of perspectives, inviting multiple stakeholders like experienced researchers and bioethicists as expert presenters conform with practices recommended by Nep & O'Doherty (2013), O'Doherty et al. (2013), Gornick et al. (2017) and Tomlinson et al. (2018). This diverse composition of experts ensures a range of perspectives are represented during leading to richer and more informed deliberations.

The use of small group deliberations was identified as a key factor contributing to the success of DE in this study. This aligns with the findings of McWhirter et al. (2014), who also highlight the effectiveness of smaller group settings for promoting participation and inclusivity. Smaller groups provide a comfortable environment for hesitant participants to overcome their inhibitions and actively contribute to the discussions. This is particularly relevant in rural African contexts where cultural norms may emphasize deference to elders or authority figures. Additionally, with fewer voices vying for attention, small groups enable facilitators to ensure equal participation and respectful listening, fostering a sense of fairness and preventing dominant personalities from overshadowing others. In addition, the study observed that participants actively encouraged each other to express their views during deliberations, suggesting that the small group format facilitated this collaborative and supportive environment. This further highlights the importance of small groups in fostering a sense of

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community and ownership in the DE process. This further emphasizes that successful DE in Africa requires more than mere adherence to technical procedures. Participants' narratives indicate that the DE process successfully achieved its goals of informing, educating, and empowering them, evidenced by their acquisition of new knowledge and their active participation. This demonstrates that DE could enhance public understanding and engagement in complex scientific topics like genomics and biobanking. Overall, the procedural choices implemented in this study showcase the importance of careful consideration and adaptation to the specific context and participants. By employing culturally appropriate languages, simplifying information, and ensuring diverse perspectives and representation, DE can be used to empower individuals and communities to participate meaningfully in decision-making processes related to research and biobanking.

6.3 Contextual factors that could influence implementation of deliberative engagement.

This study examined the influence of various contextual factors on the implementation of deliberative engagement (DE) in a rural African community. The context was conceptualized as the individual demographic characteristics such as gender, educational status, as well as the geographical location of the study. These contextual factors were examined in relation to their influence on group composition for the small deliberative discussions and their influence on participation, and the logistical and infrastructural requirements of the rural setting where the study was conducted. These factors exert important influence on the success (Ganuza & Francés, 2012) of DE and require careful consideration for successful implementation.

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A key finding is the constructiveness (Kapiriri et al., 2003) of mixed-gender groups in fostering participation, contrary to expectations in patriarchal societies. This highlights the crucial role of facilitator training in cultural sensitivity and ensuring balanced participation. While

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education initially appeared linked to confidence, the study revealed that women with lower education actively participated in mixed-gender groups. This suggests that factors beyond education, such as shifting gender norms, might be facilitating women's participation (Magaço et al., 2021). Age emerged as another key factor, with participants overwhelmingly preferring adult-only groups due to concerns about respect and deference towards elders. This underscores the importance of tailoring group composition to the specific cultural context for successful DE (McWhirter et al., 2014).

Participants emphasized that educational status should not be a barrier to participation, especially when issues affect all community members regardless of their education level. This highlights the need for inclusive recruitment strategies. To ensure effective participation across diverse literacy levels, the study employed audio-visual tools like video documentaries and storytelling in local languages (Wendler & Emanuel, 2002; Wilcox, 2009). This demonstrates the importance of employing enriching participatory approaches that cater to different learning styles and support inclusivity (Walmsley, 2009, 2011; Nicholls et al., 2016)). The study revealed the importance of considering the geographic context when implementing DE. While participants initially envisioned holding the event within their communities, they acknowledged the impracticality due to potential distractions and logistical challenges. The need for electricity and adequate facilities necessitated choosing a venue outside the community. Participants had also expressed concerns about potential distractions from family and friends if the event were held within their communities. Choosing a venue outside participants' communities however presented transportation logistics challenges, causing delays, and extending the time commitment required from participants. These findings emphasize the need for careful planning and consideration of logistical challenges when selecting a venue and organizing transportation for DE events in rural settings (Ganuza & Francés, 2012). By acknowledging and addressing these contextual factors, researchers and

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practitioners can empower communities to engage meaningfully in decision-making processes related to genomic research and biobanking (Nep & O'Doherty, 2013; O'Doherty et al., 2013; Gornick et al., 2017; Tomlinson et al., 2018). Investing in facilitator training to navigate cultural nuances and power dynamics, promoting inclusivity through active recruitment and participatory approaches, tailoring DE procedures to respect local norms and values, and addressing logistical challenges through efficient transportation and venue selection are crucial steps towards achieving this goal.

In terms of the geographic context, it is important to mention that the study took place in a rural community. The study's rural context affected the implementation of the event. While participants initially envisioned hosting it within their communities, they recognized the practicality concerns of potential distractions and logistical hurdles.

Participants expressed overall satisfaction with the chosen venue for the deliberative event, acknowledging the crucial role of electricity in facilitating presentations and utilizing educational tools. They further noted that beyond the lack of suitable venues in their communities, hosting the event close to families and friends would have inevitably led to distractions. Choosing a venue outside their communities required planning transportation for all participants, ferrying them from their rural communities to the district capital for the event and returning them afterwards. While some participants managed to reach designated pickup points independently, others required motorcycle transport from their homes to join the buses. These efforts, coupled with the poor road network, caused delays, and extended the time commitment for participants.

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6.4 Challenges to, and opportunities for, implementation of deliberative engagement

One of the key objectives of this study was to explore the perspectives of participants regarding the challenges and opportunities that could influence the implementation of deliberative engagement. While participants generally expressed positive feedback, they did express dissatisfaction with the length of the deliberative engagement sessions. They raised concerns that the extended duration of these events could pose potential challenges and act as a deterrent to future implementation. Participants indicated that the prospect of dedicating an entire day to deliberative engagement posed a concern, particularly when it meant sacrificing their livelihoods. Deliberative engagement sessions are acknowledged to be time-intensive, as noted in previous studies (Bolsewicz Alderman et al., 2013; Tugendhaft et al., 2021). Nevertheless, the extended duration is deemed necessary to ensure meaningful and effective outcomes. Given the significance of this extended timeframe, it is essential to explore avenues to adequately compensate participants for the time they invest. Participants, however, mentioned that despite the potential challenge posed by the duration, they would still consider participation if the deliberative engagement topic or purpose directly benefitted them, their families, or their communities. A systematic review of deliberative engagements reported participants' reasons for participation to include; when the issues of concern directly affected them, their families or communities, or because they saw the event as an opportunity to meet and talk with others with common interests (Baek et al., 2012). This underscores the importance of selecting participants who have a vested interest in deliberative engagement to ensure their commitment.

Furthermore, participants highlighted the influence of timing, especially given their predominant occupation as farmers. The season during which a deliberative event is scheduled can significantly affect their ability to participate. For instance, if the event coincided with their busy farming season, they expressed reservations about attending. Nevertheless, some participants indicated that their attendance could be influenced by their direct connection to the

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topic of the deliberative event. Others suggested that adequate compensation could serve as a motivating factor, mitigating the challenge of the extended duration and thereby enhancing willingness to participate and promoting more robust engagement. Notably, in countries such as Canada, Poland, the Netherlands, and England, established governmental policies exist for providing financial compensation to participants (Wranik et al., 2019).

Concerning other potential opportunities that could influence the implementation of deliberative engagement, participants in this study highlighted various direct and indirect benefits that could serve as facilitators for such implementation. These findings shed light on the positive outcomes that participants associated with their involvement in deliberative engagement, which, in turn, may encourage the broader adoption of this approach. Regarding direct benefits, participants expressed that their involvement provided them with valuable insights and knowledge regarding the sharing of biological samples and associated data in genomic research, as well as the significance of genomic research and biobanking. This newfound knowledge challenged and rectified misconceptions they held, making it transformative. This enhanced their capacity for informed decision-making, aligning with the fundamental objectives of deliberative engagement (Gutmann and Thompson 2004, 21).

Additionally, participants emphasized the indirect benefits of their participation, extending beyond mere knowledge acquisition. They spoke of feeling a sense of importance and belonging as they became part of these deliberative engagements. Connecting with fellow community members and participating in peaceful deliberations, even when disagreements arose, were seen as essential aspects of their experience. This underlines the intrinsic value of deliberation, emphasizing mutual respect and recognition among participants (Rostbøll 2009; Gutmann & Thompson 2004). Also reiterated by Festenstein (2002) is that a non-instrumental value for most participants in a deliberative engagement is the ability to participate in a deliberative process and engage with other participants as equals.

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Moreover, a systematic review of deliberative engagements has further corroborated the notion that people participate in such events for a range of reasons, including when issues directly affect them, their families, or communities, or when they perceive the event as an opportunity to connect with like-minded individuals (Baek et al., 2012).

Considering participants' recommendations for future deliberative events, several key insights emerge. First, there is a desire to expand the reach of these events to include a wider segment of the community. Participants indicated that this inclusivity could be achieved through more participatory approaches and the incorporation of entertainment elements to engage a broader audience. Some participants also expressed a preference for holding such events within their own communities, emphasizing the importance of localized engagement.

To facilitate future implementation, participants highlighted the importance of incorporating participatory approaches. They suggested the use of practical educational tools that enhance learning as a valuable addition to future deliberative engagement initiatives. This approach aligns with the overarching goal of empowering participants with the knowledge and skills needed to contribute meaningfully to the decision-making process.

In summary, the insights from this study underscore the potential opportunities and facilitators that can influence the successful implementation of deliberative engagement in genomic research and biobanking. These findings emphasize the importance of providing participants with valuable knowledge and fostering a sense of belonging and mutual respect within the deliberative process. Furthermore, they highlight the need for inclusivity, community involvement, and the use of innovative, participatory approaches in shaping the future of deliberative engagement initiatives.

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6.5 Influence of participation on awareness about the purpose of genomic research

One of the most notable findings of this study is the significant increase in participants' awareness of the purpose of genomic research following their participation in the deliberative engagement process. This observation aligns with findings from previous research, such as a study on biobanking conducted in Australia (Molster et al., 2013). Both studies suggest that deliberative engagement can significantly improve participants' understanding of complex topics by exposing them to diverse perspectives, facilitating in-depth discussions, and providing accurate information.

This increase in awareness is likely due to several factors, including the opportunity to learn from experts, engage in active discussions, and consider a wider range of viewpoints. These factors contribute to a deeper understanding of the objectives and potential benefits of genomic research, empowering individuals to make informed decisions about participation and data sharing. Furthermore, increased awareness can alleviate fear and uncertainty, leading to more positive public attitudes and trust in this rapidly advancing field of genomic research and biobanking. The transformative potential of deliberative engagement extends beyond individual awareness. By fostering constructive dialogue about the ethical and societal implications of genomics, deliberative processes can contribute to improved public discourse and more informed decision-making on important scientific advancements. Overall, these findings underscore the importance of deliberative engagement as a tool for enhancing public understanding of complex scientific topics like genomics.

Furthermore, this study found that participation in deliberative engagement led to a decrease in the number of participants unaware of regulatory bodies like Research Ethics Committees (RECs). This finding aligns with the overall increase in awareness observed after engagement.

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Several factors likely contributed to this shift, including exposure to information about RECs and their role, discussions about regulations during the engagement process, which could have increased participants’ trust in researchers and the research process. This increased awareness of regulatory bodies has several important implications, including reduced anxiety and fear about data privacy, empowered decision-making about research participation, improved public trust in the research enterprise, and the development of more ethical research practices.

Overall, these findings highlight the potential of deliberative engagement as a powerful tool for enhancing public understanding of complex topics like genomic research and the regulatory frameworks that govern them. By increasing awareness and trust, deliberative engagement can contribute to informed decision-making, empower communities, and promote the development of research practices that are more aligned with public values and expectations.

6.6 Influence of participation on attitudes towards data sharing

This study revealed a significant shift in participants' attitudes towards privacy and confidentiality. Participation in deliberative engagement led to a reduction in worry about storing samples and data in biobanks outside Ghana, indicating a growing comfort with international data sharing. This positive change aligns with the overall increase in awareness and trust observed after engagement.

Several factors likely contributed to this shift, including increased trust in researchers, information about data protection procedures, and clarity on the benefits and risks of international collaboration (Wendler & Emanuel, 2002; Parker & Bull, 2009;).

However, despite this positive trend, some participants continued to express reservations about local researchers' capacity to ensure privacy and confidentiality. This finding highlights the need for further exploration into the specific reasons behind these reservations, which may

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include past experiences, lack of awareness, and cultural factors (Wendler & Emanuel, 2002; Parker & Bull, 2009).

Addressing these concerns and building trust in research institutions requires a multi-pronged approach, including increased transparency and communication, community engagement, and capacity building for local researchers and institutions. By fostering an environment of trust and collaboration, researchers can ensure responsible research practices and unlock the potential benefits of genomic research for society.

This research revealed a surprising finding: an increase in participants' likelihood of declining future participation in genomic research after deliberative engagement. This observation, counterintuitive to the overall goal of promoting participation in genomic research, raises crucial questions about the factors contributing to this shift.

Several potential explanations warrant further investigation. Increased awareness of potential risks and uncertainties during deliberative engagement may have led some participants to reconsider their initial willingness to participate. Others may lack clarity on personal benefits despite a better understanding of the research process, leading to decreased motivation. Concerns about data sharing, even with increased understanding of data protection, may also influence participants to opt out. Additionally, unresolved questions or misunderstandings arising during the process could lead to uncertainty and hesitancy towards future participation.

Previous research supports the notion that deliberative engagement can lead to diverse attitude changes, including both positive and negative shifts, and sometimes even no change at all (Nicholls et al., 2016). This underscores the complexity of the process and its variable impact on individuals' perspectives.

To effectively address this unexpected shift and ensure the success of future deliberative engagement efforts, several steps are crucial. Conducting follow-up interviews or surveys with

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participants who decline participation can help identify specific concerns influencing their decisions. Tailoring communication strategies to address these concerns can promote understanding and address misperceptions. Providing a more tangible and personalized understanding of potential benefits can encourage individuals to overcome their initial reservations. Finally, maintaining open communication channels and fostering continuous dialogue can build trust and address concerns as they arise.

By understanding the reasons behind this shift, researchers can adapt their deliberative engagement strategies, optimize communication approaches, and ultimately encourage informed and enthusiastic participation in future genomic research. This will contribute to the success of deliberative engagement as a tool for enhancing public understanding and promoting responsible research practices in the field of genomics.

6.7 Deliberative engagement as a model for Genomic Research and Biobanking: a new framework

Considering the findings from the study, a framework to guide future implementation of deliberative engagement in the context of genomic research and biobanking can be a valuable step. This framework for deliberative engagement draws upon the principles of realist evaluation, a theory-driven approach that emphasizes understanding the mechanisms through which interventions work in specific contexts. By incorporating realist evaluation principles, the framework aims to identify the context-specific factors and mechanisms that influence the effectiveness of deliberative engagement. The framework provides a more robust and evidence-based approach to deliberative engagement. It emphasizes the importance of understanding the context, tailoring the intervention accordingly, and employing rigorous evaluation methods to assess its effectiveness. This approach contributes to the continuous improvement of deliberative engagement practices and ensures they are effective in achieving

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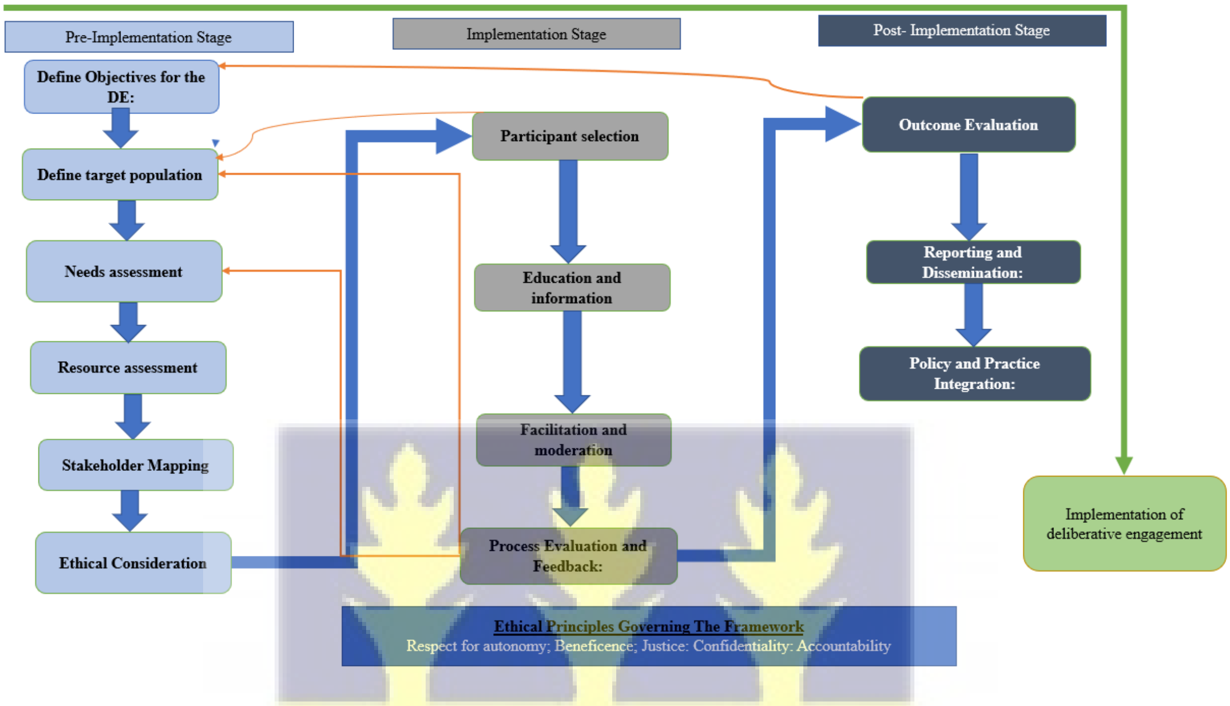
desired outcomes in genomic research and biobanking, and diverse settings. Figure 16 shows a proposed framework to guide future implementation.

Figure 7: Proposed Framework to Guide Future Implementation



This framework outlines three phases for effective deliberative engagement: pre-implementation, implementation, and post -implementation phase. Before embarking on the journey of implementing deliberative engagement (DE), it is important to define objectives for which the DE is being implemented. This is the first activity of the pre-implementation stage. This involves a clear articulation of the desired outcomes of the DE process, specifying the intended goal such as education, empowerment, and attitude change. This ensures that the DE process involves the right people and aligns with the desired outcomes. It is important to note that identifying the right people or stakeholders increases their commitment level as participants because the issues for the engagement would be of importance to them and their wider community. The second activity in this stage is to define the target population. This

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includes gaining thorough understanding of the target population's cultural context, existing knowledge, values, and seasonal factors (especially for farming communities) which informs all subsequent stages. For example, knowing the target population and their needs informs tailoring the information and education sessions, including language used, and overall approach to the deliberative engagement process. This means it is important to conduct a comprehensive needs assessment to identify participants' specific needs, expectations, and concerns to ensure the engagement process is relevant and responsive. The outputs of this assessment form a needs assessment report and a stakeholder map, which provide valuable insights for further planning. Analysing community demographics as part of defining the target population implies gaining understanding of the population’s age, gender, educational level, as well as type of community. It is also important to understand that a community could be based on shared location or values or interests. In the context of genomic research, it includes the multiple stakeholders affected by, or interested in, biobanking and genetic research. This is necessary to tailor the engagement process for the relevant stakeholders. To assess the stakeholder interests includes the identification of key individuals and groups who have a stake in the issue at hand and understand their perspectives and expectations. This is done through stakeholder mapping. Stakeholder mapping is another crucial step under the pre-implementation phase. This involves identifying key community leaders, mapping decision-makers and experts, and engaging all relevant stakeholders through a well-defined engagement plan and communication strategy. It is important to engage with influential individuals who can advocate for the DE process and mobilize community participation. Also important is to identify individuals with relevant expertise and authority who can contribute to informed decision-making. Another key element of the pre-implementation stage is to conduct needs assessment. This involves identification of cultural factors that could influence engagement. These could be cultural norms, values, and traditions that might affect participation and communication. It also involves evaluating the

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knowledge level of the target community's existing knowledge and understanding of the issue to determine the level of information required for example, during the implementation stage. The next phase of the pre-implementation phase is to conduct a resource assessment. A comprehensive resource assessment identifies the logistical and human resources needed (facilitators, language interpreters, venues, training materials, transportation, compensation) to effectively implement the engagement process. This involves identifying required facilitators, assessing venue needs, determining interpreter requirements, and evaluating material needs. A well-developed resource inventory and allocated budget ensure the successful execution of the DE process. It is important to identify required facilitators by recruiting and training individuals skilled in facilitating productive and inclusive discussions. Additionally, to assess venue needs requires securing a suitable space that can accommodate the desired number of participants and facilitate comfortable and accessible discussions. Determining interpreter requirements is to ensure language accessibility by arranging for interpretation services if the necessary. Lastly are the evaluation of material needs which includes the development or gathering of materials such as presentations and handouts that are culturally relevant and easy to understand.

The last step under the pre-implementation phase is the establishment of clear ethical guidelines for the engagement to protects participants' rights and privacy, fostering trust and participation. Ethical considerations are paramount in any DE process. Establishing clear guidelines for participant rights protection, data privacy and security, and conflict resolution mechanisms ensures that the process is conducted in an ethical and responsible manner. This stage results in an ethical guidelines document and training materials for facilitators and participants. For example, it is important to ensure informed consent, data privacy, and respect for participant confidentiality. The development of conflict resolution mechanisms is to establish clear guidelines for addressing potential disagreements or conflicts that may arise during the discussions.

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Moving into the implementation phase, participant selection is key. Defining criteria and processes for selecting participants that ensure diversity and representation of different perspectives strengthens the deliberative process and its outcomes. To ensure diversity and representation. Factors to consider could be age, gender, education, and cultural backgrounds.

The second element of this stage is information and education delivery. Planning the presentation of information and educational materials to participants in an accessible and understandable manner is crucial for informed deliberation. The pre-implementation stage also involves the creation of tangible outcomes, such as information materials, training modules, and presentation slides which serve as vital tools for the education and information delivery phase of the implementation stage. However, it is crucial to conduct thorough needs and resource assessments beforehand to avoid errors that could negatively impact implementation and program outcomes. Should errors occur during this stage, returning to the pre-implementation phase and conducting a revised needs and resource assessment may be necessary. This ensures that program activities and materials are adequately tailored to the target population and their context, ultimately leading to a more effective and successful DE implementation.

The third element of the implementation stage is facilitation and moderation of the small group deliberations. Effective facilitation and moderation are critical for fostering productive and inclusive discussions. Training facilitators in effective techniques, implementing strategies for respectful discussions, and addressing potential power imbalances and biases create a safe and inclusive space for diverse perspectives to be heard. Facilitator training materials, a moderation plan, and conflict resolution protocols are the key outputs of this stage. Training facilitators in effective techniques means to equip facilitators with skills to manage discussions, encourage participation, and build consensus where necessary. Element just like the education and information stage is critical for successful DE implementation.

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Logistics and coordination are vital for ensuring the smooth running of the DE process. Securing venues, managing logistics, and establishing clear communication with participants are essential for a well-organized and successful event. An event logistics plan, communication materials, and participant handbooks facilitate smooth implementation. It is important to secure appropriate venues and arrange necessary logistics, such as catering, equipment, and transportation. Also important is to provide clear instructions, timelines, and updates to participants throughout the process. Finally, it is important to develop materials, such as agendas, participant handbooks, and name tags, to facilitate smooth implementation. All these should have been done during the needs and resource assessment. Lastly, implementing mechanisms for ongoing evaluation and feedback collection allows for adjustments and improvements during the process, enhancing its effectiveness. This stage also determines whether the process was successful or not and is strongly dependent on adequate needs assessment. If the process evaluation and feedback are not satisfactory, it is necessary to revisit the pre-implementation stage to do needs assessment based on the evaluation report and feedback. This stage includes evaluation and learning, essential for continuous improvement.

The post-implementation phase is the third and last stage of the framework. This stage includes outcome evaluation, reporting and dissemination, and policy and practice integration. Defining clear criteria and indicators for evaluating the outcomes of the deliberative engagement, including changes in attitudes and decisions, allows for measuring its impact. Evaluation reports, recommendations for improvement, and a lesson learned report with best practices and challenges identified are the key outcomes of this stage. Data collection and analysis are crucial for assessing the effectiveness of the DE process. Implementing appropriate data collection methods, analysing the data to measure outcomes, and identifying key trends and insights provide valuable information for improvement and future initiatives. Data collection instruments, analysis reports, and findings summaries are the key outputs of this stage. It is

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important to choose appropriate methods for collecting data on participant engagement, attitudes, and knowledge, such as surveys, interviews, and focus groups. Also relevant is to assess the effectiveness of the DE process, identify its impact, and measure changes in participant attitudes and behaviours. Drawing key insights and learnings from the data analysis to inform future initiatives and improve DE practices should be paramount. It is important to note that the outcome of the outcome evaluation directly or indirectly measures whether the objectives defined at the first phase of the pre-implementation stage have been achieved. If not, there would be a need to either check if the objectives were measurable or there was an issue during the implementation stage.

Another critical phase of the post-assessment stage is reporting, and dissemination ensure that the findings and learnings reach a wider audience. Compiling a comprehensive report outlining the process, key findings, and recommendations ensures transparency and facilitates knowledge sharing with the broader community, stakeholders, and policymakers. The last and most critical phase of the post-implementation stage is policy integration and research. Advocating for the integration of deliberative engagement outcomes into policy development and research practices ensures the process has a tangible impact and informs future efforts. Fostering collaboration between policymakers, researchers, and the public promotes long-term sustainability and ensures the deliberative engagement process continues to evolve and adapt to changing contexts.

By following these steps and continually evaluating and learning, we can effectively implement DE processes that empower communities, inform decision-making, and lead to positive outcomes for all in the context of genomic research and beyond.

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6.7.1 Foundational ethical principles for the framework

Deliberative engagement (DE) is a powerful tool for engaging diverse communities in dialogue and decision-making. However, its effectiveness hinges on ensuring a fair and inclusive process that respects all participants and protects their rights. This is where ethical principles come into play. Ethical principles provide benchmarks for conducting DE in a responsible and trustworthy manner. They guide the planning, implementation, and evaluation of the process, ensuring that power imbalances are addressed, individual rights are protected, and data is handled responsibly.

Without clear ethical principles, DE can be vulnerable to manipulation, bias, and exploitation. This can erode trust in the process and ultimately undermine its potential for meaningful engagement and positive outcomes. Therefore, incorporating robust ethical principles into the proposed DE framework is crucial. This will ensure that the process remains fair, inclusive, and respectful, fostering trust and building a foundation for successful and impactful engagement. Specifically, this framework is founded on five ethical principles namely, respect for autonomy, beneficence, justice, confidentiality and privacy, and accountability. The principle of respect for autonomy emphasizes the right of individuals to make their own informed decisions about their participation in the deliberative engagement process. It requires ensuring voluntary participation, informed consent, and the right to withdraw. Further, ensuring respect for autonomy should ensure accommodation of diverse needs. This calls for flexibility and adaptability to accommodate different abilities, cultural backgrounds, and communication styles. Next is the principle of beneficence. This principle emphasizes the responsibility to promote the well-being and interests of not only participants but the entire community. The framework is designed to maximize the potential benefits of participation for individuals and the community. The principle of justice emphasizes the need for fairness and equity in the deliberative engagement process. It requires fair selection of participants and must

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ensure that power imbalances are addressed. The fourth principle is the principle of confidentiality and privacy. This principle emphasizes the importance of protecting the privacy and confidentiality of participants' information. Lastly, is the principle of accountability which emphasizes the responsibility to be accountable for the ethical conduct of the deliberative engagement process. Transparency and reporting are required in the framework with regular reporting on its activities and outcomes. This ensures accountability to the public and other key stakeholders.

6.7.2 Limitations of the Framework

While this framework provides a valuable guide for deliberative engagement, it is important to acknowledge its limitations. First, the framework is designed to be adaptable, but its effectiveness may depend on the specific context of the engagement, including the cultural background, existing knowledge, and power dynamics within the target population. Tailoring the framework to different contexts may require adjustments to the approaches employed. Secondly, implementing the framework effectively requires substantial resources, including trained facilitators, translators, transportation, and venue rentals. This may limit its applicability in resource-constrained settings. Thirdly, conducting a thorough needs assessment, stakeholder mapping, and resource assessment can be time-consuming, potentially delaying the implementation of the engagement process. Fourthly, ensuring effective participation and meaningful deliberation may require multiple sessions or extended discussion periods. Fifthly, despite best efforts, unconscious biases can influence the selection of participants, the framing of information, and the facilitation of discussions. Careful consideration of potential biases and strategies to mitigate them are therefore crucial to ensure inclusive and equitable deliberation. Lastly, whilst this framework aims to promote informed decision-making and positive outcomes, there is no guarantee that participants will reach consensus or that policymakers will implement their recommendations. Moreover, evaluating

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the long-term impact of the engagement process can be challenging and require additional resources.

6.8 Strength and Limitations of the study

Overall, the study's innovative deliberative engagement approach is a key strength. The approach allowed for in-depth exploration of complex issues from a variety of perspectives. This approach also helped to ensure that all participants had an equal voice in the discussions and that their opinions were valued. The study's participants were well-informed about the issues at hand, which allowed for rich and productive discussions. This was likely due to the study's use of local languages and audio-visual tools to communicate complex information in a clear and accessible way.

However, it is important to be aware of the limitations of the study such as the lack of representativeness, context-specificity, limited stakeholder engagement, translation challenges, and limited generalizability. For example, the study's participant group was not fully representative of the broader community in terms of age and education. This means that the findings may not be generalizable to the entire community. Also, the study's findings may not apply universally, especially in urban or different cultural settings. This is because the study was conducted in a specific rural African community with its own unique context. Additionally, the study primarily captured the perspectives of community members, potentially overlooking other key stakeholders, such as policymakers and researchers. This could have limited the study's ability to identify and address all relevant perspectives.

Translating local language interviews into English may have resulted in some loss of original meaning.

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However, the interviews were transcribed by people who were native speakers with experience in transcribing qualitative interviews. Any loss of meaning during the translation was thus minimized and therefore did not affect the findings of the study. While valuable insights were gained from the study, not all findings may fit different contexts. This is due to the context specific nature of the study and the limited range of participants. However, for similar contexts, the findings can offer valuable guidance and a starting point for further research and adaptation.

6.9 Chapter Summary

In line with the research objectives, adapted realist theory, and a proposed conceptual framework, the chapter provided valuable insights into the successful implementation of DE in rural African communities. The chapter highlighted the importance of considering procedural and contextual factors, adapting approaches to address cultural sensitivities, and developing strategies to overcome logistical challenges. The chapter also emphasized the potential of DE to increase awareness of complex topics, shift attitudes, and empower individuals to participate in decision-making processes. Additionally, a model framework was presented to guide future implementation of DE in similar settings. In the next chapter, specific conclusions are drawn.

INTEGRI PROCEDAMUS

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CHAPTER SEVEN

CONCLUSION

7.1 Introduction

This chapter presents a summary of the key findings and relevant conclusions in line with the objectives of the study. It further highlights contributions of the study to knowledge and concludes by providing recommendations for policy, practice, and further research.

7.2 Summary of findings

This study aimed to investigate the procedural and contextual factors that influence its implementation, as well as to explore the challenges, opportunities, and the effect of participation on attitudes and awareness of participants. To achieve these objectives, an experimental one-group pretest-posttest research design using a sequential embedded mixed-method design was followed, involving a total of 66 participants recruited from the Africa-Wits Genomics Network under the Human Heredity and Health in Africa Initiative in the Kassena-Nankana district of the Upper East region of Ghana. A baseline survey assessed participants' awareness and attitudes, followed by a structured deliberative workshop with comprehensive information and small group discussions. Post-engagement surveys measured changes in awareness and attitudes and focus group discussions provided deeper insights into participants' perspectives. Qualitative focus group discussions were then conducted to further understand procedural and contextual factors that affect the implementation of deliberative engagement.

INTEGRI PROCEDAMUS

The key findings from this research, as detailed in chapters 4 and 5, are as follows:

1. Factors that affected the implementation of the deliberative engagement included the expertise of the individual’s delivering information and facilitating the sessions, the use

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of audio-visual to aid comprehension, and the use of participants' preferred languages for discussions.

2. Ensuring fairness and respect for all participants and their viewpoints during small group discussions emerged as a crucial aspect of the deliberative events.
3. Preparatory activities, such as selecting the right time, season, and venue, as well as logistical preparations, were identified as essential for successful implementation.
4. Contextual factors such as the composition of the groups, especially in terms of gender and educational status, played a key role in the implementation of the deliberative engagement. Smaller group sizes were favoured as they encouraged contributions, especially from shy participants.
5. The extended duration of the deliberative engagement process was identified as a potential challenge for future implementation.
6. Participants recommended the use of more participatory tools and approaches in future deliberative engagement activities.
7. Overall, participation in deliberative engagement sessions was found to influence participants' attitudes and increase their awareness on the topics discussed.

Together, these findings provide valuable insights into the practical aspects of implementing deliberative engagement in the context of genomic research and biobanking. They underscore the importance of careful consideration of procedural and contextual factors, as well as the need for fair and respectful dialogue among participants. While challenges exist, the potential for informed and empowered community engagement in genomics research is evident. These findings serve as a foundation for improving the use of deliberative engagement as a model for inclusive and ethical decision-making in the evolving field of genomics and biobanking in Sub-Saharan Africa and similar contexts worldwide.

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7.3 Conclusion

In conclusion, genomic research presents a unique set of ethical and social challenges which are beyond the scope of traditional healthcare research. These challenges exceed the capacities of individual researchers, specific fields of study, or the public to completely address. Importantly, many of these challenges are not unique to the African context but require a multifaceted approach to grasp the contextual differences within African settings. Additionally, there are region-specific issues, such as trust and fairness in research collaborations, the vulnerability of research participants due to lower socio-economic status, a history of exploitation of local populations and researchers, and cultural factors.

Furthermore, there are language and literacy barriers, as indigenous African languages may lack terminology for various concepts related to genomic research and biobanking. The absence of effective and ethically sound community engagement to tackle these multifaceted issues could hinder the successful implementation of genomic research and biobanking, which are gaining momentum in Africa.

The findings of this study emphasize the potential of deliberative engagement as a feasible and effective approach for implementation. This method enables iterative dialogues that result in well-informed perspectives from participating community members, a crucial aspect in the field of genomic research. Deliberative engagement complements traditional community engagement approaches and offers a unique platform for addressing complex ethical and social concerns.

However, for deliberative engagement to yield successful outcomes, where participants are educated on pertinent issues, empowered to make informed attitudinal changes, and contribute to addressing challenges related to genomic research and biobanking, both contextual and procedural factors must be meticulously considered during implementation.

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While the focus of this study was on a rural community in Ghana, the insights gained can serve as a valuable guide for implementing deliberative engagement in similar contexts across Africa and beyond. Ultimately, this research underscores the significance of adopting innovative approaches like deliberative engagement to foster inclusivity, transparency, and ethical integrity in the evolving landscape of genomic research and biobanking in Africa and other regions.

7.4 Recommendations

7.4.1 Recommendations for Policy and Practice

1. Genomic researchers in the field of genomic research and biobanking should consider adopting deliberative engagement as a valuable approach for community involvement. This approach, as demonstrated in this study, enhances participant education and empowerment, leading to more informed attitudes and decisions.
2. Researchers should advocate for funding organisations to encourage and support the use of DE in research projects by allocating resources and offering guidance on implementation.
3. Researchers should collaborate with Research Ethics Committees to promote the integration of DE requirements into ethical guidelines and regulations governing genomic research and biobanking.
4. Genomic researchers should actively seek training opportunities and workshops to develop their skills and knowledge in conducting effective DE processes.
5. Genomic researchers considering adopting DE should ensure that deliberative engagement sessions are conducted in participants' preferred languages and that cultural factors are considered in the planning and execution of these sessions. This will facilitate more inclusive and productive discussions.

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6. Researchers and other community engagement practitioners should when considering the composition of deliberative engagement groups, should focus on participants' language proficiency rather than educational status. Additionally, mixed-gender groups can be encouraged to promote diverse perspectives and inclusivity.
7. Researchers and other community engagement practitioners should prioritize adequate pre-implementation activities, including careful selection of timing, venue, and logistical arrangements, should be prioritized to ensure smooth and successful deliberative engagement events.
8. Genomic researchers considering adopting DE as a valuable approach to community engagement should be mindful of the duration of deliberative engagement processes. Efforts should be made to strike a balance between comprehensive discussions and participant fatigue, possibly through more efficient facilitation techniques.
9. Researchers and community engagement practitioners should incorporate more participatory tools and approaches into future deliberative engagement efforts should incorporate more participatory tools and approaches, as recommended by participants. These tools and approaches could include visual and participatory activities like storytelling and music, community theatres, seasonal calendars, photovoice and mapping exercises. These methods can enhance engagement and knowledge dissemination among participants.

7.4.2 Recommendation for Future Research

1. Future research should explore the contextual variations in the utility of deliberative engagement in diverse settings within Sub-Saharan Africa and beyond. This can help identify region-specific factors that influence the effectiveness of this approach.
2. Comparative studies could be conducted to assess the impact of deliberative engagement against other community engagement methods in genomic research and

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biobanking. Such studies can provide insights into the relative effectiveness of different approaches.

3. Investigating the long-term impact of deliberative engagement on participants' attitudes and behaviours is essential. This can shed light on the sustainability of attitude changes and informed decision-making over time.

7.5 Contribution to knowledge

The findings of this research make important contributions to the field of genomic research, biobanking, and community engagement in several ways:

1. The study has contributed to understanding the key role of procedural and contextual factors in the implementation of deliberative engagement in genomic research and biobanking. Key elements identified such as use of audio-visual tools, group composition and size, and logistical preparation could influence the success of deliberative engagement, providing actionable recommendations for future implementations.
2. The study demonstrates the potential of DE to increase awareness of complex topics like genomic research, shift attitudes, and empower individuals to participate in decision-making processes.
3. The study has proposed a conceptual framework that could be used to guide future organization and implementation deliberative engagement. This framework, when successfully validated, could serve as a valuable tool for future implementations, particularly in resource-poor settings like rural Ghana.

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APPENDICES

APPENDIX A: Baseline Survey questionnaire for research participants.

Study Title: Exploring Deliberative Engagement for Genomic Research and Biobanking in Africa: Procedural Considerations, Contextual Influences, and Associated Outcomes.

Section A

Demographic Information

1. Age

i. 47-53 [ ]

ii. 54-60 [ ]

iii. 61-67 [ ]

2. Sex

i. Male [ ]

ii. Female [ ]

3. Highest Level of Education

i. Primary [ ]

ii. JHS/Middle/JSS [ ]

iii. Commercial/Vocational/Technical [ ]

iv. SHS/Secondary [ ]

v. Tertiary [ ]

4. Religion

i. Christian [ ]

ii. Moslem [ ]

iii. Traditional [ ]

iv. Other [ ]

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Section B

5. Are you aware of the purpose of genomic research?

i. not at all aware [ ]

ii. Slightly aware [ ]

iii. Somewhat aware [ ]

6. Are you aware of committees and laws for ensuring privacy and confidentiality in sharing your data from genomic studies?

i. not at all aware [ ]

ii. Slightly aware [ ]

iii. Somewhat aware [ ]

7. How likely are you to participate in genomic research in future?

i. Likely [ ]

ii. Not sure [ ]

iii. Unlikely [ ]

8. How willing are you to have your biological samples and the associated data stored in biobanks and researchers outside Ghana?

i. Unwilling [ ]

ii. Neutral [ ]

iii. Willing [ ]

8. How worried will you be about privacy and confidentiality in keeping your samples and associated data in biobanks outside Ghana?

i. not at all worried [ ]

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ii. Slightly worried [ ]

iii. Somewhat worried [ ]

9. How confident are you that researchers will ensure that your genomic data will be kept private and confidential?

i. Not confident [ ]

ii. Neutral [ ]

iii. Confident [ ]

10. How confident are you that the informed consent that you give before participating in genomic research can ensure confidentiality and privacy in sharing your data with researchers and institutions outside Ghana?

i. Not confident [ ]

ii. Neutral [ ]

iii. Confident [ ]

11. Researchers might use data that is donated to biobanks to develop patents and earn profits for commercial companies. Most new drugs used to treat or prevent disease come from commercial companies. How willing are you to have your genomic data shared with commercial entities like pharmaceutical companies?

i. Unwilling [ ]

ii. Neutral [ ]

iii. Willing [ ]

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12. Do you agree that individuals should receive any form of benefit when their genomic data from a genomic study is shared with commercial entities like pharmaceutical companies?

i. Disagree [ ]
ii. Neither agree nor disagree [ ]
iii. Agree [ ]

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APPENDIX B: Post- Deliberative Engagement Survey questionnaire for research participants.

Study Title: Exploring Deliberative Engagement for Genomic Research and Biobanking in Africa: Procedural Considerations, Contextual Influences, and Associated Outcomes.

1. Are you aware of the purpose of genomic research?

i. not at all aware [ ]
ii. Slightly aware [ ]
iii. Somewhat aware [ ]

2. Are you aware of committees and laws for ensuring privacy and confidentiality in sharing your data from genomic studies?

i. not at all aware [ ]
ii. Slightly aware [ ]
iii. Somewhat aware [ ]

3. How likely are you to participate in genomic research in future?

i. Likely [ ]
ii. Not sure [ ]
iii. Unlikely [ ]

4. How willing are you to have your biological samples and the associated data stored in biobanks and researchers outside Ghana?

i. Unwilling [ ]
ii. Neutral [ ]
iii. Willing [ ]

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5. How worried will you be about privacy and confidentiality in keeping your samples and associated data in biobanks outside Ghana?

i. not at all worried [ ]

ii. Slightly worried [ ]

iii. Somewhat worried [ ]

6. How confident are you that researchers will ensure that your genomic data will be kept private and confidential?

i. Not confident [ ]

ii. Neutral [ ]

iii. Confident [ ]

7. How confident are you that the informed consent that you give before participating in genomic research can ensure confidentiality and privacy in sharing your data with researchers and institutions outside Ghana?

i. Not confident [ ]

ii. Neutral [ ]

iii. Confident [ ]

8. Researchers might use data that is donated to biobanks to develop patents and earn profits for commercial companies. Most new drugs used to treat or prevent disease come from commercial companies. How willing are you to have your genomic data shared with commercial entities like pharmaceutical companies?

i. Unwilling [ ]

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ii. Neutral [ ]

iii. Willing [ ]

9. Do you agree that individuals should receive any form of benefit when their genomic data from a genomic study is shared with commercial entities like pharmaceutical companies?

i. Disagree [ ]

ii. Neither agree nor disagree [ ]

iii. Agree [ ]

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APPENDIX C: FGD Guide for Research Participants.

Study Title: Project Title: Exploring Deliberative Engagement for Genomic Research and Biobanking in Africa: Procedural Considerations, Contextual Influences, and Associated Outcomes.

1. What is your opinion about the deliberative event you just participated in?
2. What are your views about the following?
    - Duration of the workshop
    - Duration of the deliberative discussion
    - Venue
    - Facilitation of the workshop
    - Moderation of the deliberative discussion
    - Language use
    - Group composition
    - Number of participants
    - Information that was given (Adequacy)
3. What are your views about the following?
    - Question and answer interaction with experts
    - Presentations that were given by the experts
    - Discussing the issues with other people in a similar situation as yours
    - The videos documentaries
4. How do you feel about the contributions you made to the discussion? [Probe for respect for individual opinions and why]
5. What is your opinion about the processes that were involved in the event [Probe for fairness on the part of the moderator in allowing all to contribute to the deliberation]?

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6. What aspect of the event changed your views about data sharing in genomic research [Probe whether it was the workshop or the deliberative discussion]?
7. What is your view about using this type of event for subsequent community engagements in genomic research? [Probe for when it should be used]

8. How did you benefit from participating in the deliberative events? [Probe for benefits in terms of learning/understanding/change in perspectives]
9. Is there anything about today's session that changed how you think about data sharing in genomic research and biobanking? [Probe for change in terms of concerns]
10. What should be the requirement for participation [age, gender, socioeconomic status, educational level, individual willingness]
11. What is your opinion about the group composition for the deliberative discussion [Probe whether composition should be by gender and why]
12. What did you like about the deliberative event you just participated in?
13. What did you not like about the deliberative event you just participated in?
14. What are the foreseeable challenges of using deliberative engagement as a community engagement? [Probe for challenges with duration, availability, and accessibility to information such as language translation and mode of information sharing]
15. In your opinion, how can these challenges be addressed?
16. How do you feel about participating in a similar event like this in the future? [Probe for what will make or not make them participate?]

INTEGRI PROCEDAMUS

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APPENDIX D: **Participant Information Sheet**

Study Title: Exploring Deliberative Engagement for Genomic Research and Biobanking in Africa: Procedural Considerations, Contextual Influences, and Associated Outcomes.

Introduction

My name is ----------------------I invite you to participate in a research study that aims to investigate how complex ethical issues in genomics research and biobanking could be addressed using deliberative approaches to community engagement. This study is part of a PhD in Public Health at the Department of Health Policy, Planning and Management, School of Public Health, University of Ghana. This form explains the research study. Kindly, read it carefully and ask any questions about the study before you agree to join.

Background of the Research

Genomic research involves the study of the entire human genetic code, known as the genome **(contains all information needed for an individual to develop and function)** and biobanking involves the collection and storage of biological material, often in the form of blood, saliva, and urine, as well as **demographic such as age, marital status, gender, ethnicity, religion,** and health-related donor information. Although very vital to the provision of health care, genomic research and biobanking are associated with a range of unique ethical issues such as privacy, consent, data management and access, benefit-sharing, feeding back individual results and overall governance oversight. These issues if unresolved will hinder the successful implementation of genomic research and biobanking. Community Engagement has gained recognition as an approach that can help in addressing the issues but there is call for community engagement approaches that will allow informed debate with community members. Deliberative engagement **(a process by which the community members are given the room to learn about a topic, engage others in a debate about the topic, and then come to a mutual agreement on what should be included in policy regarding the topic)** is one

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approach that has been proposed as an approach that will allow informed debate, but it has mainly been used in advanced countries. For this reason, there is a need to explore whether Deliberative engagement style of community engagement will be feasible or useful for addressing the ethical issues related to genomic research and biobanking in Africa.

Research Objective

The main objective of the study is to assess the feasibility of deliberative democracy model of community engagement in genomic research and biobanking in Africa. This could generate empirical data that will inform ongoing debate on best practices for community engagement in addressing the ethical, legal, and social issues associated with genomics research and biobanking in Africa.

Participants Selection

You are being invited to take part in this research because of you are a participant or a caretaker of a participant in genomic research or a member within or outside the geographic community within which genomic research is taking place. As such your participation in this study is vital to its successful implementation.

Study Procedure and participants' involvement

If you agree to participate, you will either join other participants in a Focus Group Discussion (FGD) or a deliberative discussion named Deliberative Focus Group Discussion (DFGD), to your views on the ethical concerns associated with data sharing in genomic research and biobanking. If you are selected to join the FGD group, you will join other participants in a discussion about your views, perspectives as well as your concerns about the ethical issues with sharing data in genomic research and biobanking. The discussion will be for a duration of 1-2 hours in a location around your community. You will also be asked some questions right before and after you have participated in the discussions. The questions will be about your views,

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perspectives, and concerns about the ethical issues with data sharing. You will also answer questions about your views about the discussion event that you participated in. The DFGD event will include presentations and short videos after which you will be asked questions and allowed to ask questions. The duration for the DFGD will be between 2-4 hours. The discussion will be audio recorded with your permission and used for data analysis purposes only. A month after the DFGD event, you will be contacted by phone or face to face to answer some questions about your views, perceptions as well as concerns about the ethical issues around data sharing in genomic research and biobanking. This should be for a duration between 1-2 hours.

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Voluntariness and right to withdraw

Your participation in this research is voluntary. If during the discussion or at any later date, do not wish to continue with your participation, you are free to withdraw from the study.

Risks/Discomforts

There are no physical risks in this study. Nonetheless, you may feel uncomfortable answering some of the questions. To decrease this, please, feel free to choose not to answer 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 debate on best practices for community engagement in complex studies like genomics research and biobanking in Africa.

Compensation

You will receive an amount of GHC200.00 as reimbursement for transportation cost and time loss because the discussion may take the whole day.

Adherence to Covid Protocols

Due to the ongoing COVID-19 pandemic, interacting with other people can increase participants' and research team members' risks of contracting COVID-19, an infectious illness, which can be fatal. To ensure the safety of all participants and the research team, you will be provided with hand sanitizer to clean your hands whenever necessary before, during and after

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interview and deliberative or discussion events. You will also be provided disposable face masks to wear during the interviews, deliberation, or discussion events.

Contact Information

If you will like more information about this research project before/after deciding to participate, please contact Irene Honam Tsey on mobile phone (0208420640) or by email(hirene.tsey@gmail.com). If you have questions with regards to your rights as a participant in the study, you can contact the GHS ERC Administrator, Nana Abena Apatu on 0503539896 or at ethics.research@ghsmail.org on ethical issues only. This proposal has been reviewed and approved by the Ghana Health Service ERC, which is a committee whose task it is to make sure that research participants are protected from harm.

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APPENDIX E: Participant Consent Form

Study Title: Exploring Deliberative Engagement for Genomic Research and Biobanking in Africa: Procedural Considerations, Contextual Influences, and Associated Outcomes.

Consent Form

I have been adequately informed of (or I have read and understood) the purpose, procedures, potential risks, and benefits of this study. I have had the opportunity to ask questions about it. Any questions that I have asked, have been answered to my satisfaction. I know that I can refuse to participate in the study without any loss of benefit to which I will have otherwise been entitled. I understand that if I agree to participate, I can withdraw my consent at any time without any problem. I understand that any information collected will be treated confidentially. I freely agree to participate in the study, after signing below I will receive a copy of this consent form.

Name of Participant

……………………………………………………………………………………………………

Signature or Right Thumb Print (participant/parent/guardian)

…………………………………… Date: ……./……./……..

Name of Witness:

……………………………………………………………………………………………………

Signature or Right Thumb Print ………………………………………………….

Date: …..../……../……….

I have adequately informed the participant of the purpose, procedures, potential risks and benefits of this study. I have answered all questions to the best of my ability.

Name of study personnel

……………………………………………………………………………………..

Signature……………………………… Date: ……./……./…………

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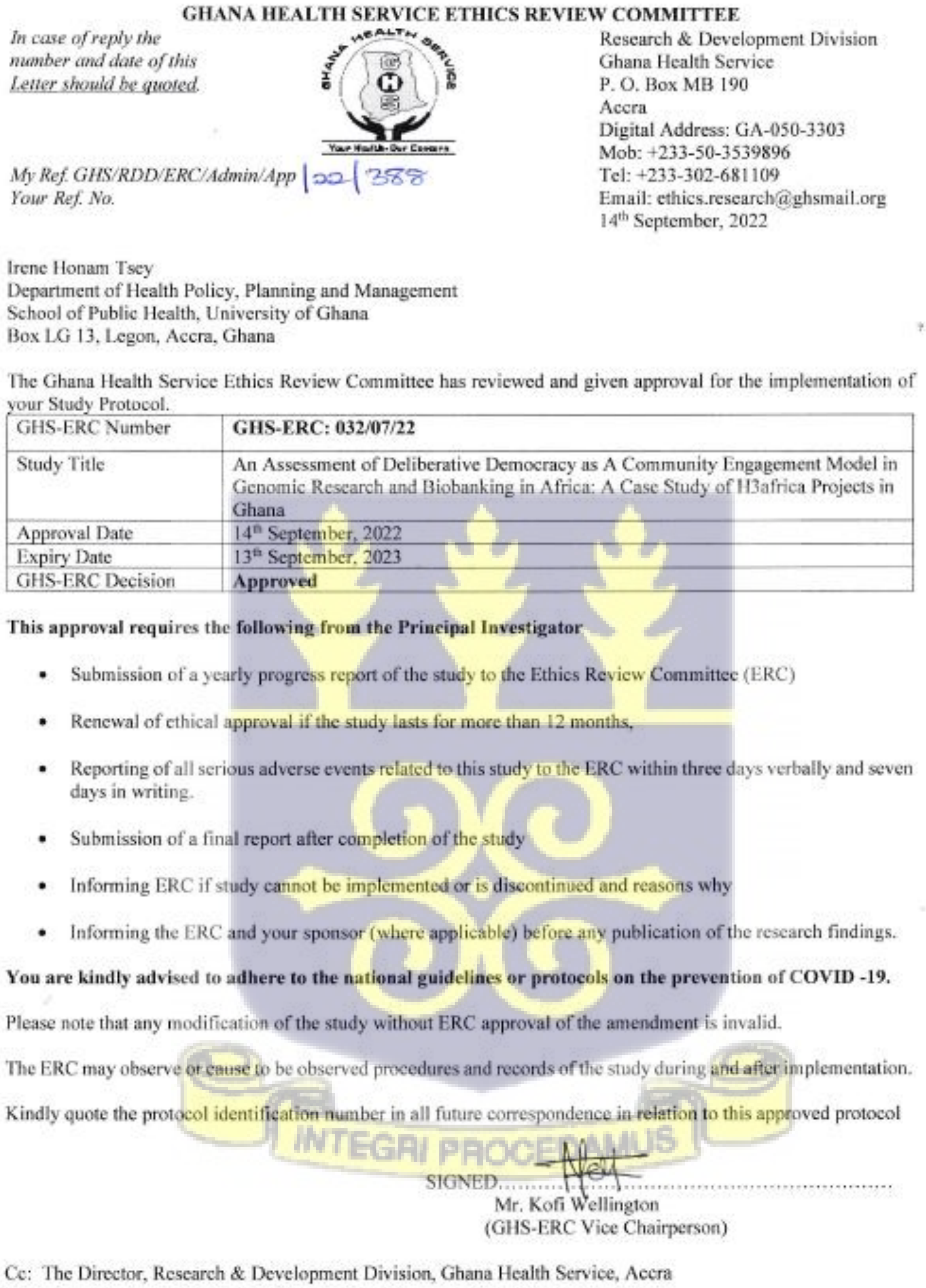
APPENDIX F: Ethical approval letter



GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the
number and date of this
Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Digital Address: GA-050-3303
Mob: +233-50-3539896
Tel: +233-302-681109
Email: ethics.research@ghsmail.org

My Ref. GHS/RDD/ERC/Admin/App /22/388
Your Ref. No.

14th September, 2022

Irene Honam Tsey
Department of Health Policy, Planning and Management
School of Public Health, University of Ghana
Box LG 13, Legon, Accra, Ghana

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 032/07/22**
Study Title	An Assessment of Deliberative Democracy as A Community Engagement Model in Genomic Research and Biobanking in Africa: A Case Study of H3africa Projects in Ghana
Approval Date	14th September, 2022
Expiry Date	13th September, 2023
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

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SIGNED……………………………………………………
Mr. Kofi Wellington
(GHS-ERC Vice Chairperson)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra