BMC Medical Ethics

RESEARCH Open Access

Developing a contextually and culturally relevant benefit-sharing framework for pathogen genomic research and biobanking in africa: a deliberative expert approach

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Abstract

Background Globally, researchers are struggling to implement benefit-sharing plans in genomics research and biobanking. In the African context, there are currently limited benefit-sharing frameworks to guide researchers, and some often rely on personal relationships and judgments in making decisions. Consequently, there have been calls for the development of contextually and culturally relevant benefit-sharing frameworks for pathogenic research and biobanking in Africa. This study responds to that call by using a deliberative experts approach to propose and develop a benefit-sharing framework for pathogen genomic research and biobanking.

Methods Data were collected through deliberative expert key informant interviews. A total of 25 participants, comprising genomics researchers, policymakers, Nagoya Protocol Focal persons, members of institutional review boards, Sponsors and Experts in the field of genomics and biobanking were purposively sampled from 12 countries. Open-ended topic guides were designed and used to facilitate the interviews. The interviews explored issues such as the need for a benefit-sharing framework, the principles underpinning the practice of benefit-sharing, and key features of a possible benefit-sharing framework. Interviews were conducted in English, audio-recorded, and transcribed. Transcripts were imported into Nvivo 14 software, coded and analysed using the framework approach for qualitative data analysis.

Results The participants reported on the key issues to consider in the development of a benefit-sharing framework. These included motivations for sharing benefits, key elements of a benefit-sharing framework and suggestions for monitoring the implementation of the framework. Based on these expert responses, we proposed and developed a three-phase framework. The first phase presents the contextual benefit-sharing process, which includes the benefit-sharing process, iterative benefit-sharing cycles and post-benefit-sharing responsibilities. The second phase comprises

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the implementation phase with templates on a step-by-step approach to achieving the three areas in phase 1 and the third concentrates on workplans to accommodate future emerging issues such as designing strategies to map out best practices on benefit-sharing, making efforts to publish the selected strategy and implementing the selected benefit-sharing.

Conclusions The deliberative approach used in this study allowed for not only contextually and culturally relevant factors to be identified but also enabled reflexive decision-making. The framework developed has the potential to provide practical guidance to pathogen genomic stakeholders in the identification and implementation of benefit-sharing opportunities in their research programmes. More empirical studies are however required to test and evaluate the framework.

Clinical trial number Not applicable.

Keywords Benefit sharing framework, Deliberative approach, Pathogen genomic research, Biobanking, Africa

Background

Benefit-sharing is broadly defined as the action of giving a portion of the advantage/profit that is derived from the use of genetic resources to the providers of the resources [1]. This benefit may be intrinsic to research, such as improved health outcomes for participants, as well as extrinsic to research, including monetary rewards, ancillary care provisions or community projects) [2]. Access to pathogens and their associated benefits has been a central consideration for global health, especially for pathogens of pandemic potential [3]. The discussion surrounding benefit-sharing in pathogen genomic research has two key aspects: during emergencies, such as outbreaks or in the context of routine practice [3, 4]. The governance of benefit sharing in pathogen genomic research is currently regulated by the Nagoya Protocol [3, 5]. The Nagoya Protocol is a framework that sets out broad principles, such as "prior informed consent" and "mutually agreed terms" for accessing genetic resources to ensure fair and equitable sharing of the benefits that result from their use [6–9]. The objectives of the Nagoya Protocol are to foster a fair and transparent resource-sharing mechanism, and are originally directed towards the conservation of indigenous knowledge [6]. Furthermore, it lists many benefits that could be provided, such as monetary (including sharing of royalties) and non-monetary (such as development of skills and knowledge).

Article 8(b) of the Nagoya Protocol provides some degree of flexibility by allowing waivers or modifications to access and benefit-sharing (ABS) requirements during public health emergencies. This gives countries the discretion to exclude human pathogens from ABS obligations through domestic legislation. While this provision is especially important in situations that require urgent responses, the Protocol does not set out specific mechanisms or procedures for managing such cases. The justification for placing access to pathogens and their benefits under the protocol in general is still a matter of debate, as some scholars believe that pathogens cannot be regarded as traditional knowledge [5, 6]. While some scholars are of the view that this flexibility is good [5], others are concerned that the lack of standardisation leaves room for inconsistencies across regions [5–7, 9]. Another notable weakness of the Nagoya protocol is that access to benefit-sharing provisions was designed to ensure only physical access to genetic resources to facilitate equitable sharing of the benefits obtained from their use with the providers. This neglects the current advancement in science, which permits access to genomic sequence data, which is also crucial for public health surveillance and tracking of new variants. Another limitation of the Nagoya Protocol is that it is only legally binding once it has been ratified by a country. Therefore, there are many researchers who are not bound by the protocol. Some stakeholders believe that placing benefit sharing in pathogen genomics under the Nagoya protocol does not support access to pathogen genomics sequence data [5, 10].

Given the limitations of the Nagoya protocol, the World Health Organisation (WHO) member states developed the Pandemic Influenza Preparedness (PIP) framework to augment its weaknesses [11]. The PIP emerged from two separate empirical studies conducted on researchers, scientists, and member states, which revealed that stakeholders are unhappy about the numerous implementation challenges associated with the Nagoya protocol [3, 5]. While both the Nagoya protocol and PIP have provided useful guidance, researchers across the world are still struggling to implement benefit-sharing plans in genomics research and biobanking. In the African context, in particular, there are currently limited benefit-sharing frameworks to guide researchers, often compelling some to rely on personal relationships and judgments in making decisions. Consequently, there have been calls for the development of contextually and culturally relevant benefit-sharing frameworks for pathogen genomic research and biobanking in Africa. This study responds to that call by using the deliberative approach to propose a benefit-sharing framework for pathogen genomic research and biobanking. Specifically, the study explored stakeholders' views and experiences with approaches to implementing

benefit-sharing, as well as key considerations and expectations of a fair and equitable benefit-sharing framework in pathogen genomics research and biobanking.

In developing this framework, we were mindful of the diverse legal landscapes across the African continent. Our approach was informed by the work of Thaldar and Shozi [12], who highlighted that benefit-sharing requirements are not legally uniform and, in some cases, may not be permissible. For example, they note that in South Africa, benefit-sharing with research participants who provide blood samples is considered unlawful and may even constitute a criminal offence under national law. National laws of many other countries across the African continent are, however, silent on the legality of benefit-sharing. Despite these legal variations, we believe that the proposed framework can still serve as a useful guide for thinking about benefit-sharing in African contexts where such practices are legally and ethically permissible.

Methods

Study design

This study is part of a larger mixed-method study that examined benefit-sharing in pathogen genomics research in Africa. The data for this paper specifically come from the qualitative component of the larger study. The qualitative study employed deliberative approaches to explore key considerations and expectations for a fair and equitable benefit-sharing framework in pathogen genomics research and biobanking.

Due to the potential of deliberation to produce new knowledge, an expert deliberative approach was adopted for this study. The production of knowledge occurs through a dialectical process of questioning, justifying, and placing one's opinion in a logical space of reasons, rather than merely letting the interviewee articulate their opinions and preferences [13]. It also requires weighing opinions, reasons, and considerations [14, 15].

This deliberative approach, which included a comprehensive, pre-interview briefing on benefit-sharing, was followed by interactive deliberations. This ensured that all participants and the researcher were actively engaged and on the same level of understanding of the topic. This method, which has been effectively used in previous studies, is highly recommended for strengthening knowledge generation on complex issues [11, 13]. As part of this approach, we developed a two-page background on the topic, which was shared with all participants before the interview. This background information included definitions, an account of the various schools of thought on the subject, its importance, and reported challenges with implementation, among other topics.

Study participants, sampling and recruitment

The participants comprised pathogen genomic researchers, ethics review board members, Nagoya Protocol focal persons, policymakers, sponsors and bioethics experts. All participants were purposively sampled. However, where there were difficulties reaching some groups, such as the Nagoya Protocol focal Person and the policymakers, recruitment was done through snowballing. In this situation, pathogen genomic researchers who had been interviewed were re-contacted to assist in providing basic information on how to reach these individuals. The pathogen genomic researchers were selected from the Pathogen Diversity Network in Africa (PDNA), which has members from about sixteen African countries, including Ghana, Mali, Gambia, Cameroon, Tanzania, Ethiopia, Cote d'Ivoire, Cape Verde, Madagascar, South Africa, Angola, Nigeria, Gabon, Mozambique, Kenya, and the Democratic Republic of Congo. Each scientist has varied expertise in bacteria, fungi, parasites, and viruses in humans and animals, contributing to the shaping of national malaria policies. The other participants were drawn from key stakeholders involved in the governance of pathogen genomic research and thus work closely with the research scientists. A total of 25 individuals were interviewed, which became the sample size since saturation was reached via code and thematic saturation. The inclusion and exclusion criteria are captured in Table 1 below:

Table 1 Participants and criteria for selection

Participants	Inclusion criteria	Exclusion criteria
Pathogen genomics researcher	Research investigators are involved in pathogen genomic research in Africa and are part of the PDNA.	Only the principal research investigators and not the Research assistants/support staff
Policy makers	A senior person at any institution that has the mandate to influence policy or implement results and outcomes of pathogen genomic research.	People at the ministry of health
IRB/REC members	IRBs/RECs that review pathogen genomic studies.	IRBs/RECs that have reviewed pathogen genomic studies for a PDNA member
Nagoya Protocol Focal person	The Nagoya protocol focal person in each country	
Sponsors/Funders	Sponsors/Funding agencies that have supported research into pathogen genomics in Africa.	They should have at least sponsored/funded one malaria research.
Experts in the field of genomic research	Bioethicists who are knowledgeable in genomic research and have contributed to the discussion on benefit sharing.	Only those who have been active in the field for at least 10 years and above.

Data collection instrument

A semi-structured interview guide consisting of several key questions focusing on participants' positions on benefit-sharing frameworks, motivations for benefit-sharing, elements/outlines of benefit-sharing, and other indicators recommended by participants was designed (For detailed information, see additional file 1 under supplementary materials). The tool's wide range of areas covered was based on an extensive literature review. All authors were involved in the development of the semi-structured interview guide, which was in English. However, the first draft was by 2 authors with varied experiences in bioethics, genomic research and biobanking. This was shared with the other team members for their comments and finalisation. Because this study was targeted at individuals with specific expertise, it was challenging to recruit participants from some stakeholder groups to test the interview guides. Given the similarities in the guides and questions being explored, an IRB/REC administrator was used to test the interview guide and the necessary corrections were made to all the guides with similar questions. Feedback received from the pre-test was used to improve the other interview guides. For the other interviews, the initial interviews served as a pre-test of the tools to clarify the questions and to refine them for better clarity. Although there were no major changes made after these first interviews, this process helped to understand the questions very well and identify potential field issues, which were subsequently discussed and addressed. It also helped the research team to finalise the interview guides for the remaining data collection process. The tool was created in English. The study used a particular approach called the Deliberative approach precisely because of the complex nature of the topic being studied. This decision was also informed by two separate studies in Kenya and Nigeria, which showed that awareness of the topic is limited among stakeholders [16, 17]. The idea of using a deliberative approach was to provide a comprehensive pre-interview briefing on the subject matter followed by interactive deliberations to ensure that all participants and the researcher were on the same level of understanding of the topic. This method has been tested and is highly recommended to strengthen knowledge generation for complex issues [14, 18]. As a result, a two-page background information on the topic was developed and shared with all participants ahead of the interview.

Data collection process

Data were collected through face-to-face meetings, Zoom calls, telephone calls, and written interviews, among other methods, depending on the location of the participants. By using different interview mediums, the data collection process was not standardised, and this may have affected the data that was collected. A semi-structured interview guide consisting of several key questions focused on participants' positions on benefit-sharing frameworks, motivations for benefit-sharing, elements/outlines of benefit-sharing, and other indicators recommended by participants. Before the interview commenced, participants were asked if they had read the deliberative document, understood it, or had any questions for clarification. Those who had questions received explanations until they were satisfied before the primary interview began. Participants who had not read the document were briefed using the deliberative information developed as a guide to ensure that the same information was provided to all participants. The deliberative session, as described above, lasted for about 5–15 min before the interview. Participants were very appreciative of the reflective documents, pointing out that they were educational, which opened them up to questioning their practices. All interviews were conducted in English since all participants could speak fluent English. The interviews were audio-recorded to ensure accurate data capture and transcription and to facilitate the data analysis.

Data management and analysis

Data management and analysis were guided by Goldsmith's recommendations on conducting thematic analysis [19]. All interviews were transcribed verbatim from the audio recordings by an independent transcriber. To ensure accuracy and quality, a second transcriber, who is a team member, listened to all the tapes at least twice, transcribed a few of them and compared them with the work of the independent transcriber. All transcripts then went through several revisions between the independent transcriber and the second transcriber. To ensure that the data were accurate for analysis, the transcripts underwent sentence cleaning from verbatim to intelligent verbatim, checking that meaning was not lost and deleting identifiers. All transcripts were imported into the qualitative research software NVivo 14 [20]. A codebook was developed to guide the coding of the transcripts. This codebook was also guided by deductive and inductive reasoning. However, it was refined as the main coding process commenced, as some codes became irrelevant, and new additions were made. The categorization of the codes into main themes and subthemes was achieved through deductive and inductive thematic coding.

Results

A total of twenty-five [25] individuals participated in this qualitative study. Nine [9] participants were female, while fifteen [15] were male. There were ten [10] pathogen genomic researchers, one [1] Nagoya Protocol focal person, one [1] policymaker, two [2] sponsors, three [3] representatives from two [2] ethics review committees, and eight [8] global health and bioethics experts. In total,

the participants came from seven [7] African countries, including Ghana, South Africa, Ethiopia, Mali, Angola, Kenya, Cote d'Ivoire and Uganda and three countries outside Africa (the United States, United Kingdom, and Canada).

Summary of themes

Four main themes and fifteen [15] sub-themes were generated from the data as outlined in Table 2 below:

Need for a benefit-sharing framework

Most participants were familiar with the Nagoya Protocol, which is a global document that guides benefit-sharing practices regarding the use of pathogen genomic resources. However, only a few have attempted to implement it and expressed various reservations regarding its practicality. Below are some quotes from stakeholders reflecting their sentiments:

> *I do not think it is detailed enough. And my problem with Nagoya is that it is not standardized. Countries do different things so if you are in a consortium then you find that what your colleague is doing on Nagoya, they are entirely different things. How do you agree as a consortium on benefit sharing when your approach to Nagoya protocol is different? (GR-002).*
>
> *So, I have a fair idea of the Nagoya protocol; I was even invited to be on the committee looking at Nagoya protocol and it does not capture the kind of pathogens we do genomics on. They are interested in GMOs and major pathogens that may affect agriculture. So, we medical researchers, couldn't find ourselves in the protocol (GR-001).*
>
> *I see the Nagoya protocol as a model to start thinking about issues of benefit sharing. It is more than just for pathogen genomics and human genomics; it does not need a copy-and-paste approach; it needs to be able to say what is different between pathogens and plants because the Nagoya protocol is designed with the thinking of indigenous plants and to be able to say that there are indigenous pathogens, I don't I have the scientific capacity to answer that question (EXP-007).*

Participants spoke about clarity issues and lack of further information on its implementation. Consequently, they strongly advocated for developing a comprehensive framework to guide benefit-sharing practices in Africa. They proposed that this framework could either exist as a standalone or integrated into the Nagoya Protocol:

> *I think it is important, especially now that we know that there should be some benefits and there should be beneficiaries. But I do not think we are doing a good job with it because I think once we ship samples abroad, the mechanism of following up can take a lot of years until the benefits are ready. But once it is ready, you ensure that the benefit comes to the individuals or communities that should benefit from it. We need to make a lot of structures. I think a systematic way of approaching it is a very good framework, and I think it is important to have that framework that every country can contextualise to their reality (EXP-001).*

Some participants cautioned that for such a framework to be widely acceptable, particular attention should be given to the process of developing the framework. They advised that inclusivity should be a key consideration, taking into account all relevant stakeholders.

> *It will be critical to include diverse professionals in the review, such as environmental scientists, biologists, botanists, and so on, as one health approach so that different sectors of big professionals will*

Table 2 Summary of main themes and sub-themes

Main Themes	Sub-themes
Position on benefit-sharing framework	• A call for a new framework • Inclusivity of process
Motivation for benefit-sharing provision	• Principles
Elements/Outline of framework	• General Statement • Types of potential benefits • Responsibility/obligations of key stakeholders • Ethical issues • Conflict resolution and management • Enforcement plan/monitoring plan • Community engagement plan
Indicators for monitoring	• Independent Board • Penalties • Institutional buy-in • Submission of progress reports • Solicit feedback

be involved in this and have to consent before the development of this protocol so that it will be very inclusive and represent a wide range of disciplines to ensure you do not overlook any important point from any of the various perspectives. So, I believe it will be beneficial if you invite experts from various fields to note down what should be included in the framework (GR-009).

Key ethical principles to guide the benefit-sharing framework

Based on the general support for developing a benefit-sharing framework, participants were asked to identify the key ethical principles that should guide the framework. The majority of participants agreed that a set of principles, including *fairness*, *justice*, *reciprocity*, *solidarity*, *transparency*, *accountability*, *trust*, *inclusivity*, *proportionality*, and *integrity*, should be key principles informing or promoting the provision of benefits in pathogen genomics research in Africa. Among these principles, justice, solidarity, reciprocity, fairness, and inclusivity were rated as highly important by all the key stakeholders interviewed. Bioethicists who were interviewed particularly recommended additional safeguards, including the principles of *accountability*, *proportionality* and t*ransparency*:

When you talk about genomics, several moral principles are at play, but for me, equity and fairness in the distribution of this kind of thing are important. When you talk about sharing benefits, not only north-south, equity and fairness will be very important for me (EXP-001).

If we are to look at the principles, we have transparency, accountability, reciprocity, and solidarity whereby you… make sure that all of you benefit and nobody is exploited (EXP-002).

Key elements of a benefit-sharing framework for Africa

Most participants reported that a clear statement of the framework's objectives is necessary because it will set the precedent for everyone to understand what the framework stands for. The quote below illustrates the view of a genomic researcher;

What is termed as benefit sharing and also a much clearer guide on what a benefit is. Does it have to be directly to the person, can it be at a community level, does it have to be needed and how can you say you want to see the impact in 20 years? I would like to see things like that in how you categorize benefits and beneficiaries. How you inform them, how long do you have to inform them, the feedback you need to give, how do you access that the benefit you assume is going to happen as truly happened (GR-005).

In addition to outlining the various benefits that can be obtained from pathogen genomic research and biobanking, the participants suggested that the framework should also address the duties and obligations of important stakeholders, potential ethical concerns with pathogen genomic research, ways to resolve conflicts, management plans, enforcement and monitoring plans, and a clear strategy for community engagement. The following quotes reflect how participants expressed their sentiments:

What are the objectives of genotyping, what could be the use of the resources? We have also a set of obligations that ask the scientist to share the data with the community, also to show clearly what could be the benefit to the community and different ethical issues should be mentioned in this guideline (GR-010). I think one of the things that will be important to emphasize is the benefit of doing the research in the first place even if it is not immediate; it is only through research that we can improve health whether at the public level or individual level. So, one element of thinking about research is to think about the benefits (Sponsor-001).

While all these elements are important to stakeholders, community engagement emerged as a priority for most. They believed it would facilitate a clear understanding of the community's expectations and address them from the outset. Participants emphasised the importance of community engagement because they felt it could provide valuable insight into public expectations and enable them to address issues proactively.

The other thing that we have found very helpful is what we call community engagement or community involvement, where the people doing the research interact or even employ people in the communities being researched. So, they feel involved in the process and can even have input in the process compared to just having researchers take their samples and then be out of there. The other thing that is even more important going forward is that just having someone's DNA sequence is not enough to understand everything; it also requires learning more about their medical history, what we call phenotypes and more information. This requires more engagement with individuals and communities when asking about health conditions or health habits, so more engagement is necessary (Sponsor-001).

Indicators for monitoring adherence/compliance to the framework

Monitoring the framework was a major concern for all participants. They believed that monitoring was important to ensure the correct implementation of the framework and to establish a plan for consequences in cases of non-compliance. Regarding potential measures, the participants suggested the following:

1. Set up a Board (inclusive) that will be tasked to perform monitoring and evaluation of compliance.

I think that maybe we can set up a board including different stakeholders, scientists that are also decision makers as well as community leaders in order to monitor the different decision and implementation to be sure if it will fit the objectives and will reach the goal of our activities. So that could be a way to monitor and evaluate our different strategies (GR-010).

2. Set penalties for defaulting or non-compliance.

I think we have to be limit what can be done and what cannot be done and apply a strong penalty when people do not commit and follow those strategies (GR-006).

3. Ensure proper institutional buy-ins and task institutions to monitor their employees.

This is actually when institutions accept this protocol and this framework into respective ethical bodies, and this could be one of the indicators that everybody at least every institute engages in genomic research if they involve all these documents in their studies so this can be used as an indicator. You are asking me if I have read any written documents about this, so if every institution will make institutions develop and accept these regulatory bodies that could be an indicator that at least countries, universities or research centers will accept these to be implemented (GR-009).

4. Submission of progress reports.

I think undercover policing. One thing is you want transparency so you want an annual report and by the way, I will say the same thing for the global North not just for the global South I think everywhere. We should have all the time undercover policing. What I mean by undercover policing is you go basically or somebody your research assistant goes into one of these villages, one of these clinics, and is just eligible for the program and see how I am being approached, do they follow the process. We should pay people to test the system all the time. And I will say the same time for our part of the world. It has nothing to do with Africa. So, I will never say we should take people's word for it that will do everything right. You can even hire local people to do it (EXP-004).

5. Solicit feedback.

Something you can use to monitor is tracking output that makes reference to specific genomic information and seeing what that output is influencing. An example, if we are using a particular genetic we say we are going to use it to develop a particular testing platform, just being able to follow on because nowadays as you publish you are required to refer to whichever research or protocol, your work comes from so just being able to track if it is a particular protocol and we know that particular products have been produced (GR-008).

A proposed benefit-sharing framework for pathogen genomics research in Africa

Based on the evidence presented above, we propose and develop a new framework to guide benefit-sharing in pathogen genomic research in Africa. We drew on the reflective equilibrium model based on the belief that ethical theories and frameworks arise from the problems, contexts, and dilemmas we encounter; thus, practice can inform theory just as theory can inform practice; highlighting their symbiotic relationship [21]. Furthermore, we align with the idea that moderate pragmatic naturalism in bioethics acknowledges that empirical knowledge is useful to shed light on meta-ethical issues [22]. Lastly, ethical principles and theories were also used to analyse and clarify the data, identify areas of agreement, define terms, and reveal ambiguities. The insights gained from the examination of the delicate interplay between empirical data (actual practice) and the prescriptive principles and the refinement of these principles were instrumental in developing the benefit-sharing framework. Figure 1 shows the process of reflective equilibrium that was adopted [23].

The framework as outlined in Fig. 2 involves three stages: the conceptual benefit-sharing process, which involves three steps (the benefit-sharing process, iterative benefit-sharing cycles and the post-benefit-sharing review); the implementation plans (templates) which provide a step-by-step guide to how to effectively achieve the three steps mentioned under the conceptual benefit-sharing process, and the work plan which also involves three steps including designing strategies to map out best practices, designing meta-data strategies to publish

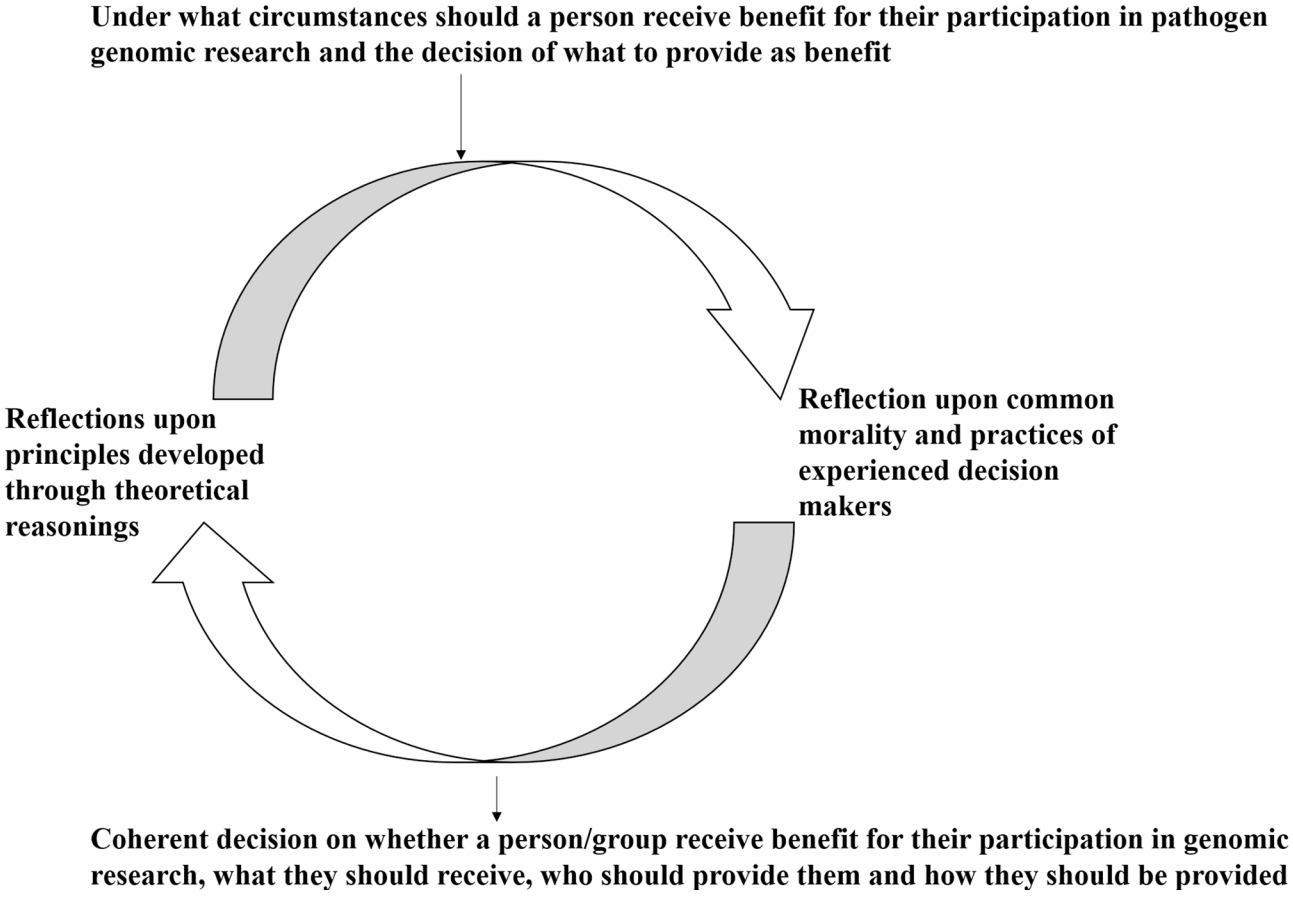

Fig. 1 Reflective equilibrium model adapted for developing the proposed framework

agreed processes and sharing of benefits with prospective beneficiaries. Each of these phases are sequentially dependent on each other and can involve three groups:

1. The first group is the project owner or the principal project coordinator, who plays a major role in defining the goals and reviewing their impacts.
2. The second group can be the research assistant and key stakeholders who assist the principal project coordinator in implementing the goals successfully. However, a clear distinction should be made in terms of responsibility setting to attain results efficiently.
3. The third group can still be research assistants specialized in monitoring and evaluation who play the role of aligning benefit-sharing goals with outcomes.

Phase 1 and 2: conceptual benefit-sharing process and its implementation plan (templates)

As described above, phase 1 comprises three major steps: the benefit-sharing process, the iterative benefit-sharing cycle, and the post-benefit-sharing review. These three steps are the main backbone of the proposed benefit-sharing framework. Phase 2 provides detailed step-by-step guidance to effectively implement each of the steps in Phase 1. Below is a description of each step and how best to achieve them;

Benefit-sharing process

This process focuses on the preparations that a researcher or research team should undertake during the conceptualisation stage of the research. This brainstorming phase facilitates critical reflection of the concept of benefit-sharing as an integral part of their research programme. To achieve this, we propose six key steps.

The first step clearly defines the benefit-sharing goals of the project. This statement should articulate the rationale behind the need to appropriately share benefits arising from the research. Next, the principles underpinning or motivating this decision to provide benefits should be outlined.

The next step is to list all anticipated benefits that are likely to result from the research, as well as defining the beneficiaries. It is also important to acknowledge that genomic research may yield other unanticipated benefits; therefore, researchers should provide a clear statement on how these will be handled if they arise.

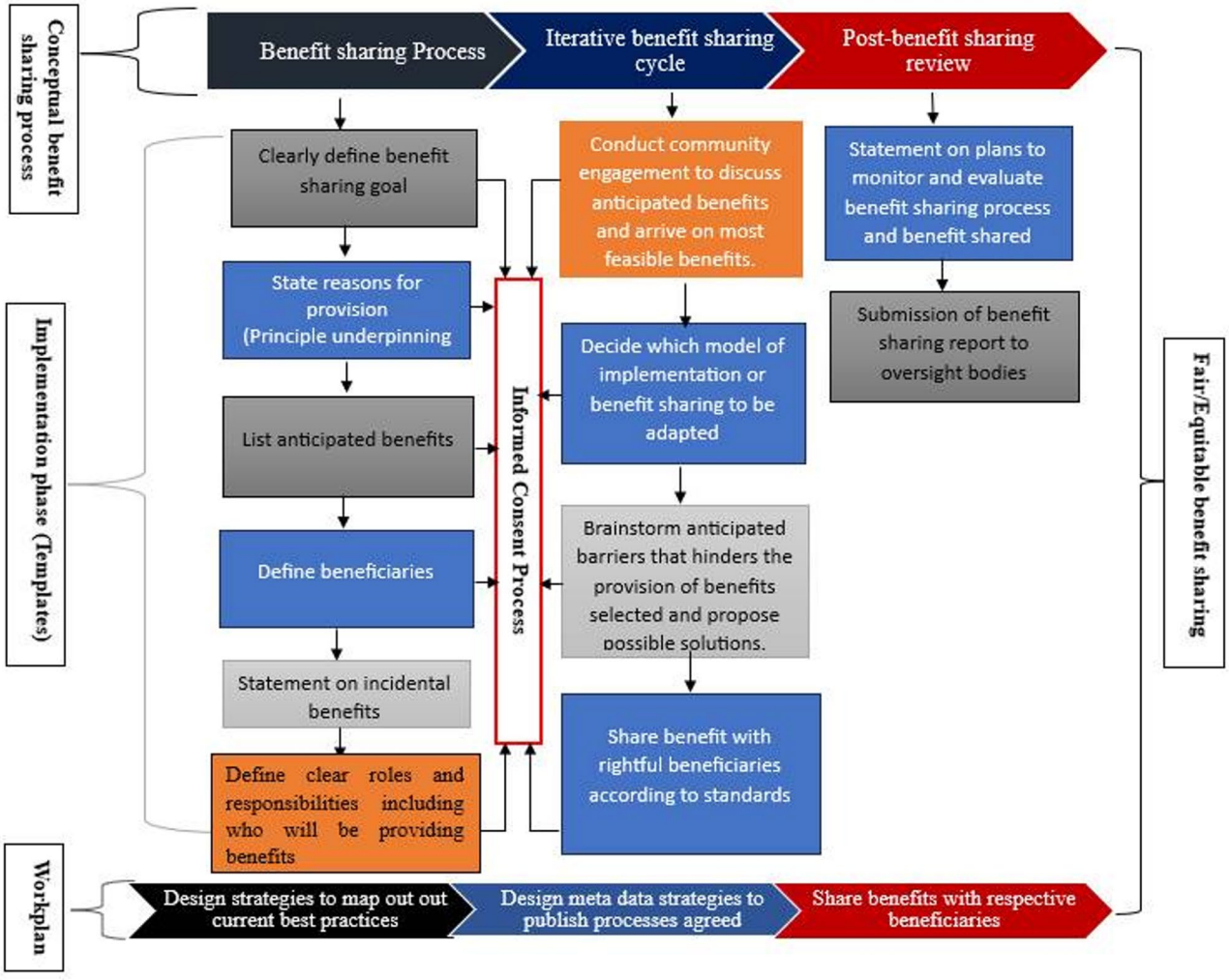

Fig. 2 Proposed flexible benefit-sharing framework for genomic research in Africa

The final step involves assigning roles and responsibilities regarding who will be responsible for providing the benefits, including funding sources and the implementation of those benefits.

Iterative benefit-sharing cycle

This step also provides information on the preparations to consider before the actual benefit-sharing process takes place fairly or equitably. It is referred to as the cycle of sharing benefits because we believe that benefit-sharing is relational and thus can be likened to a life cycle, which starts from a point and ends at a point for the cycle to repeat itself. Based on what participants have said, as captured earlier on the need for engagement and inclusivity, we proposed that after setting the grounds in step 1 above, there is a need for community engagement. At this stage, the researcher is expected to engage with the prospective community on their proposed research agenda, the possible benefits or justifying the need for such research in the community and how the community stands to benefit from the research. Where community can be defined by the research participants or the appropriate beneficiaries, or key stakeholders. We believe that this consultation will empower stakeholders and allow for the collection and incorporation of their views and perspectives. It will also help researchers or research teams arrive at feasible conclusions, making their research and proposed benefit-sharing plans more accepted.

We also advise that at these consultative fora, there should be a consensus or near consensus on what to provide as a benefit. We are emphasising strongly the need for community consultation because we also acknowledge that not all listed anticipated benefits of that research can be provided by the researcher, considering the fact that some could be capital intensive, which research budgets may not be able to support immediately, however, could be transferred to policymakers for consideration. Thus, together, the researcher and the stakeholders can agree on a more feasible benefit-sharing plan. After this, decisions should also be taken on which

implementation mode or benefit-sharing strategy will be adopted, with clear justification. At this consultation, we also advise that interested stakeholders should brainstorm on possible or foreseeable barriers that can hinder the provision of selected benefits and propose possible solutions. After this, benefit sharing can now occur according to standards or key regulations.

It is important to note that steps 1 and 2 must be addressed for an effective informed consent process to take place. All this information will feed into designing a comprehensive and well-informed consent form.

Post-benefit sharing review

Lastly, we proposed that benefit sharing should not just end at the iterative benefit-sharing cycle, but rather, efforts should be made to monitor the process to a successful implementation. Hence, we are recommending that there is a need for a clear statement on plans to monitor the process to ensure maximum compliance by all parties. At this stage, there should also be provision for conflict resolution should the need arise. To encourage transparency and proper oversight, we also recommend that benefit-sharing reports be submitted to appropriate oversight bodies such as Institutional Review Boards (IRBs) or Ethics Review Boards (ERCs) for independent scrutiny.

Phase 3: Benefit-sharing workplan

We also acknowledge that genomic research is still evolving, therefore, there is a need for a flexible benefit-sharing framework which can accommodate future transformations. Based on this, we proposed a work plan to provide a specific design and implementation plan for future projects based on the goals set for phases 1 and 2. This work plan includes three steps; it recommends that researchers design strategies to map out current best practices around benefit-sharing in genomic research. This information could be gathered from the literature. This will also help researchers to agree on the best strategies to adopt or adapt for their work, learning from others. Next, we proposed or encouraged researchers to publish their decisions on benefit-sharing regarding their work before they proceed with implementing benefit-sharing as part of their research programme. In summary, this benefit-sharing framework encourages the publishing of metadata on benefit-sharing practices in genomic research and biobanking, since this can go a long way to help provide a catalogue of best practices on the subject.

Stakeholders/Audiences

This proposed benefit-sharing framework provides step-by-step guidance for stakeholders such as genomic researchers, research assistants, IRB/RECs, sponsors, and policymakers on decision-making regarding benefit sharing. However, for this framework to realise its full potential, it should be contextualized.

Practical considerations

For practical considerations of this framework, special attention should be paid to inclusive consultations and community engagement. This will help expand on the different levels of the framework and improve its implementation and acceptance among a wide range of stakeholders. Failure to critically consider every aspect of the framework may limit the successful implementation of the framework. Critical attention should also be given to contextual factors.

Strength of the proposed framework

This framework is comprehensive, flexible and acknowledges the fact that genomic research is still evolving and makes room for nuances in the field. It also provides a step-by-step approach to conceptualizing benefit sharing and a workplan that can be followed by any genomic research.

Limitations of the proposed framework

A key limitation of this framework is that it does not take into account the expectations, perspectives and preferences of research participants who are also key stakeholders in genomic research. Another key stakeholder whose perspective was not included in the development of this framework is the legal expert. Including legal expertise could have contributed to a more balanced and comprehensive analysis of the ethical, legal, and practical dimensions of benefit-sharing. We recommend that future deliberations actively involve legal experts to strengthen the robustness and applicability of such frameworks. Additionally, the framework has not been tested and evaluated to confirm its practicability and acceptance for a successful implementation. As a result, it can be concluded that this framework is a work in progress and requires fine-tuning and testing in future studies.

Discussion

This qualitative study explored stakeholders' experiences and perspectives on benefit sharing in pathogen genomic research in Africa as well as key considerations and expectations for developing a fair and equitable benefit-sharing framework. The findings suggested that stakeholders face challenges implementing current ethical guidelines and policies related to benefit sharing. These challenges have prompted calls for the development of a robust framework to guide benefit-sharing practices in pathogen genomic research and biobanking. This call aligns with findings from previous research in both human and pathogen genomics [3, 5, 16, 24–28].

Most participants reported that they do not rely on formal documents or guidelines to implement their benefit-sharing activities in their projects. Instead, they heavily rely on personal relationships when making decisions about benefit sharing. This finding is surprising, as one would expect stakeholders to engage with the few existing frameworks like HUGO, or the Nagoya protocol or draw insights from other fields when needed. However, this overreliance on personal relationships can be both a potential weakness and a strength in the implementation of benefit sharing. While it fosters personal connections, particularly with international collaborators and local communities, it also leads to inconsistencies, a lack of accountability and the potential risk of exploitation. Therefore, there is a need for formalized governance approaches to complement the informal approaches currently in use.

Participants also noted that this formalized governance could take the form of a standalone document or a supplementary resource that reinforces existing frameworks such as the Nagoya protocol [3]. A key challenge reported in the current guidelines relates to compliance and the mechanisms for enforcement [3, 5, 29]. Consequently, participants in this study emphasized a need for indicators for monitoring to promote adherence.

In developing a framework to guide benefit-sharing in pathogen genomics and biobanking in Africa, participants highlighted the importance of the principles of reciprocity and solidarity. They expressed a desire for benefit-sharing practices in Africa to be grounded on these principles, reflecting the African way of life exemplified in African philosophical concepts, which emphasises the interconnectedness of all life forms, including humans, animals and nature and the principles of communalism and mutual support [30, 31]. For African communities, acknowledging that researchers exist because individuals are willing to voluntarily participate in research for various reasons and vice versa, implies that we honour such gestures with rewards when appropriate. Therefore, any framework on benefit-sharing tailored to Africa should prioritise these principles before other considerations, such as justice or transparency.

The processes involved in the development of a framework for benefit sharing were a major concern for the participants interviewed in this study. To address some of the documented challenges and weaknesses of existing frameworks, participants emphasised the importance of inclusivity and community engagement as key ways to eliminate or mitigate these challenges.

As indicated earlier, informal approaches to benefit-sharing based on key principles of reciprocity, solidarity and justice are integral to the implementation of the concept. The findings support recommendations from other studies advocating for an independent body to perform oversight responsibilities to ensure compliance with benefit-sharing frameworks during implementation, monitoring, and setting penalties for non-compliance [5].

Another key element participants suggested to be considered during the development of any future framework is institutional buy-in. This includes, but is not limited to, public and private research organizations, policy makers, sponsors/funders, policy implementers, global organizations, and governments. The results from the qualitative interviews on the expectations of stakeholders have been incorporated into a flexible benefit-sharing framework for pathogen genomic research. Given that genomic research is still evolving and many questions remain unanswered, any future benefit-sharing framework should not be static but rather flexible and easy for stakeholders to follow and implement.

The desire for a framework that is actionable contrasts with other prominent frameworks, such as the HUGO or the Nagoya protocol, which make broad statements without detailed guidance on how to achieve those goals. This proposed framework provides a step-by-step actionable plan which encourages researchers to consider benefit-sharing at the conceptualisation stage of their projects. Similar to how community engagement has gained recognition as a key consideration to the success of research, this framework advocates for the appreciation of benefit-sharing as a key indicator to the successful completion of any research and the continuity of scientific advancements. Although this framework was developed from stakeholder engagement in the pathogen genomic research and biobanking space, it is applicable across all areas of genomic research and biobanking, including human genomic research. It also allows for contextualisation of the various steps recommended.

Conclusions

Benefit sharing is a fundamental ethical principle aimed at preventing exploitation, fostering trust and ensuring the ethical and equitable sharing of the benefits generated from pathogen genomics research. However, the practice presents challenges to many stakeholders. The proposed framework is flexible and has the potential to provide practical guidance to stakeholders involved in pathogen genomic research as well as genomic research stakeholders (human and pathogen), in the identification and implementation of benefit-sharing opportunities in their research programmes. We encourage other networks and further empirical studies to test and evaluate the framework.

Abbreviations

dKIIs	Deliberative Key Informant Interviews
CBD	Convention on Biological Diversity
GSD	Genomic sequence data
PIP	Pandemic Influenza Preparedness

IRB Institutional Review Board
REC Research Ethics Committee
GHS Ghana Health Service

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-025-01238-w.

Supplementary Material 1

Supplementary Material 2

Acknowledgements
The authors would like to thank the Pathogen Genomic Diversity Network Africa (PDNA) and all the individual bioethics experts and funding agencies who participated in this study for their insightful contributions to the data that informed this study. A special thanks goes to Prof. Jantina de Vries for her empathetic, kind, inspirational leadership and immense knowledge in providing insightful and constructive feedback during this research work.

Author contributions
P.E.S. and P.T. conceived and designed the research. P.E.S., I.T., P.T., J.G. and P.A. developed and contributed to the methods. P.E.S. and I.T. conducted literature search and review. P.E.S. conducted the qualitative interviews and initial analysis of the data. P.E.S., I.T., P.T., J.G., and P.A. contributed to the data analysis. P.E.S. wrote the first draft of the manuscript with substantive comments and inputs from I.T., P.T., J.G. and P.A. All authors approved the final manuscript.

Funding
The study was supported by the Community Engagement in Genomics and Biobanking (CEBioGen) project with funding from the National Institutes of Health (NIH)– (USA)– under the Human Heredity and Health in Africa (H3A) Initiative, Grant No. 5U54HG010275. NIH-USA had no role in the study design, data collection, analysis, or decision to publish or prepare the manuscript.

Data availability
The data generated during the current study are based on qualitative interviews with key stakeholders and not publicly available. However, they are available from the corresponding authors on reasonable request.

Declarations

Ethics approval and consent to participate
The Ghana Health Service Ethics Review Committee (GHS-REC:031/07/22) reviewed and approved the study protocol. Written informed consent was obtained from all study participants, and permission to record the audio was also obtained from all participants. All these were done in compliance with the Helsinki Declaration (https://www.wma.net/policies-post/wma-declaration-of-helsinki/).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 1 November 2024 / Accepted: 6 June 2025
Published online: 03 July 2025

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