



Stakeholders' attitudes and perceived ethical challenges of returning individual pharmacogenomics research results among people living with HIV (PLHIV)

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Introduction

- There is an increase in pharmacogenomic (PGx) research to improve HIV treatment in Sub-Saharan Africa (Calcagno et al., 2019)
PGx involves studying how an individual's genes response to a given medication.
- PGx analyses can generate a vast amount of information including incidental findings from a single gene.
- However, the process of returning results encounters several debates and ethical challenges especially in a low-income setting.

Introduction

- ❖ Various stakeholders agree to return individual PGx research results to participants in respect of individuals' rights to information and researchers' duty of care.

- ❖ Returning individual results to participants respects
 - The principle of reciprocity
 - Solidarity
 - Accountability
 - Responsibility
 - Impartiality



Study objective

We examined stakeholders' attitudes and perceived challenges of returning individual pharmacogenomics research results to people living with HIV.

Methods

- **Study design:** Cross sectional study employing qualitative data collection methods between September 2021 and February 2022.
- **Study setting:** College of Health Sciences, Makerere University and 5 affiliated research intensive institutions.
- **Study procedure:** KII - 12 researchers,
IDIs- 12 REC members and
dFGDs (five) - 30 community representatives
- **Analysis:** Thematic analysis

Results: Social demographics characteristics

Participants	Researchers	REC members	Community Representatives
N = 54	12	12	30
Age			
< 35 years	06	02	13
>35 years	06	10	17
Sex			
Men	07	05	16
Women	05	07	14
Highest level of Education			
Primary			02
Secondary			07
Diploma			13
Bachelor	02		07
Master	08	07	01
PhD	02	05	-
*Research Experience in PGx research and HIV treatment and care.			
< 5 years	02	02	07
5 -10 years	06	04	11
>10 years	04	06	12

Theme 1: Attitudes towards returning individual pharmacogenomics results to people living with HIV (PLHIV)

- Uphold the principle of reciprocity
- Source of hope to PLHIV
- Uphold the principle of equity
- Uphold the principle of epistemic justice
- It is an ethical requirement as stipulated in the UNCST guidelines

Research participants play a very important role in research and their opinions should be fairly respected. I know we sometime fear that because participants are not very educated, they might not understand these results, so we are hesitant to give them their results.... But, we can empower these people and simplify this information for them to understand. We should treat them fairly as partners in research... (REC 10)

Theme 2: Social and ethical implications of returning individual PGx results

- Building a lasting relationship between the researcher and participants
- Improves quality of care by providing more effective drugs to PLHIV
- Helps participants plan better for their future
- It is a step of translation of pharmacogenomics into clinical care.
- Risks of breach of confidentiality thus increasing stigma and discrimination
- Risk of domestic violence

We always try to build a friendly relationship with our participants so that they can freely share any information they want us to know....and so returning these results could help strengthen our bond and trust....(R 10)

Theme 3: Perceived challenges

Participants' level

- Low literacy levels
- Misconceptions about the role of genes to only determining paternity
- Inability to afford or access more efficacious drugs
- Difficulties in navigating the procedures at new health facility environments.

Researcher's level

- Difficulty in determining the appropriate language to communicate the results
- Limited or no experience in returning individual results to participants
- Tracing and updating participants' contact information

Study specific

- A lot of resources, yet many studies do not budget for this activity
- Numerous consent forms participants

Institutional level

- Absence of policies and SOPs
- Research staff's contracts often expire and move to other opportunities before the study results are ready to be returned.
- Absence of genetic counsellors in Uganda

National level

- Limited and inadequate infrastructure for genomic and genetic research
- Inadequate national guidelines on returning individual results from genomics and genetics research
- Limited sensitization programs about genomics and genetics research in communities

Theme 4: Proposed recommendations to overcome the challenges

- Community sensitization and engagement to improve genetic literacy.
- Capacity building
- Developing ethical and legal frameworks, policies and SOPs

Many people in our communities do not know that genes play several roles in our bodies beyond just informing us about one's paternity lineage. The MoH [Ministry of Health] could come up with some programs to educate people about the functions of genes in one's body.. (CR 15)

Conclusion and recommendations

- It is important to return individual pharmacogenomic research results to vulnerable groups of people such as PLHIV.
- However, there is need for caution when returning such results whose implications do not only affect an individual but might extend to their families and communities.
- Therefore, there is need to develop institutional procedures and national guidelines on how results from genetic and genomic research studies can be safely returned to participants.

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