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After the research, it's like we have closed the contract": Transitioning beyond trials and unveiling healthcare perspectives and practices for post-trial participants in HIV clinical trials in Tanzania.

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ABSTRACT

Background: The fight against HIV/AIDS has seen significant progress through rigorous research and clinical trials. However, the post-trial transition from research to routine care remains underexplored, offering unique insights into healthcare practices on transitioning HIV patients from research-controlled environment to standard care.

Methods: To investigate the experiences of healthcare workers responsible for transitioning HIV-positive individuals from clinical trials to standard care, the study employed a phenomenographic qualitative methodology. Healthcare professionals from diverse backgrounds were purposively selected from a referral hospital; Kilimanjaro Christian Medical Center and interviewed. The interviews were tape-recorded and later transcribed verbatim. Data analysis was conducted using NVivo 12, and findings were reported thematically.

Findings: Healthcare workers emphasized the significance of referral letters as essential tools to ensure continuity of care during the transition from research settings to routine healthcare. Emotional challenges, including sadness and worry among participants due to perceived loss of intensive care during trials were reported. Complexities in post-trial care such as societal stigma, disparities in medication between the context of research and standard care medication and adherence issues were revealed, along with coping strategies employed by participants. There was emphasis for effective communication and post-trial engagement between researchers and participants, including access to study results and ongoing support.

Conclusion: The study highlights a gap between clinical research and healthcare practice in transitioning participants from HIV studies to standard care. The study raises ethical concerns regarding equitable treatment and the need for improved integration of research outcomes into healthcare practices. The findings emphasize the need for a more patient centered approach to ensure the ongoing care of HIV-positive individuals both during clinical trials and afterward.

KEYWORDS
HIV Clinical trials; post-trial transition; Patient-centered care; Ethical considerations; Healthcare perspectives

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Introduction

The fight against HIV/AIDS has witnessed significant progress through rigorous clinical trials, leading to advancements in treatment strategies and care (Eaton et al.2012; Apondi et al., 2019; Saag et al., 2018; Zhu et al., 2017; Swindels et al., 2017; Goodreau et al., 2014; Barnighhausen et

al., 2012). However, as these trials conclude, the critical phase of transitioning participants from experimental settings to mainstream healthcare emerges as a critical concern. This transition poses distinct challenges and opportunities, particularly in Tanzania where an exploration of healthcare perspectives and practices for post-trial participants warrant investigation (Mwangi et al., 2023; Reynolds et al., 2013; Crane, 2010); it emphasizes the importance of ethical considerations in clinical research, the ongoing responsibilities in post -trial phase, challenges in maintaining healthcare quality, and the need for improvements in healthcare systems to meet global health goals (Hyder et al., 2013; Tanzania Health Sector Strategic Plan 2015-2020; Kruk et al., 2018; Janet et al., 2013; Mselle et al., 2011).

In the context of HIV, significant strides have been made in developing innovative therapies and preventive measures. For instance, the study conducted by Grant et al. in 2010 demonstrated the efficacy of pre-exposure prophylaxis (PrEP) in reducing the risk of HIV transmission among high-risk populations. However, despite these breakthroughs, there remains a critical oversight in the field, particularly regarding the post-trial phase. This issue has been underscored by Cohen et al. (2016) who pointed out the limited attention given to what unfolds after clinical trials conclude.

The critical role of clinical trials in evaluating the safety and effectiveness of various HIV- related interventions such as antiretroviral drugs and prevention strategies cannot be overstated. Nevertheless, the post-trial phase, which encompasses crucial aspects like implementation, long-term monitoring, and real-world impact, has been overshadowed by

the focus on the scientific outcomes and findings of the trials themselves. This oversight is noteworthy, as it affects the translation of research into practical population health benefits. Addressing this gap and shifting attention toward the post-trial phase is imperative for ensuring that the promising innovations in HIV research reach the communities that need them most.

What happens to participants after trial completion?

The transition of participants from controlled environments to routine care can be an intimidating and challenging experience, requiring adjustments to various aspects of their medical care. In the context of HIV, participants must navigate changes in healthcare providers, treatment regimes, and the complexities of managing a chronic condition like HIV as highlighted by several studies. For instance, Mugavero et al. (2009) conducted a study in which participants who had completed HIV vaccine trials shared their experiences during this transition. Their accounts depicted emotions of anxiety and uncertainty that accompanied the shift from the structured clinical trial setting to the more decentralized landscape of

community healthcare. Moreover, Wallerstein and Duran (2010), Ponce and Schroth (2016), and Emanuel et al. (2008) explored various aspects of the transition processes, challenges, outcomes, and strategies for improving continuity of care for HIV clinical trial participants. These findings indicate the complexity of ensuring a smooth and effective transition from research settings to standard care.

In a similar context, Crane et al. (2007), Mugavero et al. (2013), and Ryscavage (2014) have contributed valuable insights into the intricacies of this transition. Their research shed light on the unique challenges faced by individuals as they navigate the post-trial phase, emphasizing the need for comprehensive support systems and interventions to facilitate a successful transition.

This study explores the critical phase of transitioning beyond HIV clinical trials in Tanzania. Our primary objective is to gain insight into the experiences, perspectives, and practices of healthcare

workers as they engage with HIV post-trial participants. By identifying challenges and opportunities, we aim to strengthen patient-centered care and holistic healthcare approaches for individuals living with HIV. Ultimately, our goal is to bridge the gap between research and practice, offering comprehensive support that empowers participants to lead healthy, fulfilling lives beyond the confines of clinical trials. Through qualitative research, we investigate the roles of healthcare workers in this transition and assess their readiness for the task.

Methods

Study design

This study uses a phenomenographic qualitative methodology to explore healthcare workers' experiences in transitioning HIV-positive individuals from clinical trials to standard care.

Study setting

Between June and August 2023, healthcare workers responsible for the care of HIV-positive patients were purposively selected from the Kilimanjaro Christian Medical Center (KCMC), including the Care and Treatment Centers (CTC) and the Child-Centred Family Care Clinic (CCFCC).

Study participants

Healthcare professionals caring for HIV patients were purposively selected based on their diverse backgrounds and roles within the healthcare system. The inclusion criteria aimed to ensure a varied representation of perspectives, considering factors such as clinical experience, specialization, and involvement in the transition process of HIV-positive individuals from clinical trials to standard care. This purposive sampling approach was chosen to capture a comprehensive range of insights from healthcare professionals with direct experience in the care of HIV patients.

Informed consent was obtained, after which the interviews were conducted at the healthcare workers' office or in a private room within the hospital. The interviews were conducted in the local language, Kiswahili, but the healthcare workers were given freedom to use English. Confidentiality was ensured. The interviews were tape recorded and, on average, took between thirty minutes and one hour.

Data collection

Interviews were guided by a prepared script and continued until data saturation. The first author (RM) and second author (EM) facilitated the interviews using standardized probes.

Data analysis

The data analysis process began with the transcription and translation of recorded interviews, followed by a coding process to identify key concepts, challenges, and experiences. Thematic analysis was based on an inductive coding frame, where a basic unit of an idea was defined as a code. Initially, the team selected a specific idea within each transcript and then discussed the ideas to ensure appropriate coding of each subsequent transcript. Finally, the codes associated with a particular major theme were grouped together into an overarching theme. Categories were then refined into core themes, which served as the foundational structure for analysis. RM, EM, DK, and REM reviewed the transcripts for consensus. Data analysis was facilitated by using

NVivo 12, and findings were reported in accordance with qualitative research reporting guidelines described by Miles and Herbman (1994).

Data interpretation

Recurring patterns and unique experiences were identified. Contextual factors were considered, and narratives were developed to illustrate healthcare workers' experiences, challenges and emotions they encountered from participants during the transition. Peer debriefing was done to enhance the credibility of the findings.

Ethical considerations

All participants provided written informed consent, which was thoroughly documented and witnessed. The study received approval from the College Research Ethics Review Committee (CRERC) of the Kilimanjaro Christian Medical University College with a reference number of 2506.

Results

A cohort of eight healthcare workers representing diverse professions participated in the interviews, with nurses and nurse midwives predominantly represented. The age distribution of the healthcare workers (HWs) exhibited variability with the youngest individual being 27 years and the oldest being 56 years. All the HWs were in a married relationship with 2-4 children, acknowledging the potential impact on various aspects of their professional lives and well-being allowing for a more comprehensive exploration of the

challenges and support systems they may encounter in both their personal and professional lives. The range of professional service years for health workers spanned from 5-20 years.

Table 1: Demographic characteristics for Health care workers

IDI	Profession	Age	Marital status	Years of service
1	Research Nurse	45	Married with 2 children	10
2	Pharmacist	48	Married with 4 children	8
3	Nurse Midwife	36	Married with 3 children	11
4	Medical Officer	47	Married with 4 children	17
5	Resident – Pediatrics	27	Married with 2 children	5
6	Emergency Nurse	39	Married with 2 children	7
7	Research Nurse	58	Single mother of one	Over 20 years
8	Nurse Midwife	56	Married with 2 children	Over 20 years

Generally, the healthcare professionals exhibited a substantial breadth of experience in across diverse research endeavors, including HIV studies with durations spanning from 5 to over two decades. In this study, we identified four major themes that capture the complex nature of transition from clinical trials to standard care in the context of HIV research, including practical, emotional, ethical and logistical aspects.

Theme 1: Experience in HIV care transition process to regular care

This theme explores how participants in HIV clinical trials transition to regular healthcare and the role of guidelines in ensuring a smooth transition.

Referral letters as information repositories

Structures for exiting participants from the study exist through the provision of referral letters to participants. The letters serve as a repository of essential information summarizing their previous treatment, medication regimes, diagnostic results, and overall health status.

Additionally, the inclusion of contact details ensures a supportive avenue for participants to access further assistance, if needed. This systematic approach is meant to enhance continuity of care as individuals move from research involvement to routine medical management as this healthcare worker indicated:

"The guidelines are like referral letters, everyone who leaves will be given a letter to return to their clinics and even when we take them to their sites, we tell the [regular] staff there that they [participants] will go to participate in the research [from the original facility], and that they will stay for a certain period of time, but when they come back, they will come with a letter that explains all the things [that happened] in the research and that when he/she comes out of the study, what drugs they took from the study and the ones he/she should continue to take, and their condition in general. If there are any tests that were done on them [in the study], that they have in their files." (IDI-3)

Supportive avenues for participant-centered research closure and the role of guidelines in transition

In the context of a research study focused on HIV, the process begins with participants receiving an identification card specifically designed for HIV-related purposes. This card serves as a crucial initial step, providing individuals with a unique number that links them to the study. As they progress through the research, this number becomes an integral identifier that ensures accurate tracking of their involvement and interactions within the study.

Healthcare workers described an approach centered on the well-being of participants during research closure aligning with established guidelines. According to them, this transition signifies the researcher's commitment to ensuring that individuals return to their original treatment regimen, prioritizing their health and maintaining consistency in their established healthcare routine. Upon completing their involvement in the study, participants return the assigned number, effectively marking the conclusion of their active engagement in the research. At this juncture, it is assumed that participants smoothly transition back to following their initial treatment plan in their respective health facilities. One of the healthcare workers summarized this succinctly:

"For Step one, they get a card for HIV when they get into the study…. then after the study they give back the card number and continue with the original treatment." (IDI-7)

In the context of support avenues, a successful modification not only influences the specific study at hand but also holds the potential to shape future development and prescription practices. In contrast to the conventional tablet form found in standard care, participants making transition back to regular care receive guidance on preparing a syrup for the medications. This

approach ensures a smooth continuation of the modified administration method promoting continuity and enhancing overall effectiveness:

"After the mother accepts the consent form, and she has said that she has understood and signed, we give her our medicines, different from the standard of care as we know they are in the form of tablets, but now we are making a solution or syrup system. The goal [in the study] is to make it easier for the mother to give the child to use the study drug which is retrogravir, which is the drug we are currently testing. When they are going back [to regular care], we teach them how to make the syrup." (IDI-8)

Theme 2: Challenges within transitioning from clinical trial to regular care

This theme explores the difficulties faced by participants when moving from clinical trials to regular care and addresses the emotional impact of this transition, challenges such as stigma and medication adherence. It highlights the implications of these challenges to the well-being of patients.

Emotional impact of transition

According to the healthcare workers, transitioning from a clinical trial environment to regular care can pose significant challenges for participants. The sentiments expressed by these healthcare professionals highlight the emotional intricacies inherent in this transition.

Healthcare workers emphasized that individuals who have been part of a clinical trial often feel sad and/or worried from the realization that the intensive level of care they had been accustomed to within the confines of the trial may no longer be readily accessible; mirroring the underlying emotional journey that participants undergo during this pivotal phase of their healthcare experience.

A dedicated nurse, who had passionately cared for HIV-positive children for nearly 6 years as part of an HIV study shared her thoughts as she compassionately guided these children through the transition to routine medical care:

"Usually, they are sad because they feel that when they go there [regular care] they will not get the care they used to get from the study. we always give them a referral letter because the clinic they choose is near their home, but we give them information to prepare for two visits before that and they have that information. We also give them phone numbers in case it happens they need to be informed about the treatment they were getting before, and there is a letter that usually explains what medicine they were taking and for what reason, or also the tests they underwent and the results we document well in the referral letter which is available. Those who are there [in the study] continue with services as usual." (IDI-1)

Navigating the complexities of post-trial healthcare

According to healthcare professionals, individuals who transition from clinical trials to standard medical care may encounter a multitude of challenges and complexities. These hurdles encompass a broad range of experiences, ranging from facing societal stigma to struggling with medication adherence issues. In some instances, participants may even discontinue with treatment altogether. The spectrum of responses to these challenges is remarkably diverse, with some individuals seeking alternative solace in prayer for healing, reflecting the myriad coping strategies adopted during the transition from the structured environment to the demands of conventional medical care. According to healthcare workers, this transition period presents a

complex landscape that warrants attention and support to ensure the well-being of those involved.

In the perspective of a medical officer,

"Yes, the challenges are there, most of them are very sad because they see that they will not get good services out there [regular care], so many of them are worried, but we always encourage them that there are other people who are receiving services there, so the basic thing is to cope with the situation there, and understand that this was for research only and for a short time, and at the moment the study's time is over that is all." (IDI-4)

Healthcare workers further highlighted complexities they face in their mission to ensure patient compliance and overall well-being following transition to standard care. As this healthcare worker illustrates, for individual patients, once the study or treatment regimen was completed, they exhibited behaviors that lead to non-compliance with prescribed medical treatments:

"There are others who were completely lost from those other clinics and did not go to use medicine at all…when they finish the research, they no longer pay attention to the medicine as required or others enter into the belief that being prayed for that a certain pastor is healing and that there are people who have given testimony that they have been healed then they end up there and there are those who go there and stop taking medicine and when their conditions worsens, they come back [to study site] to ask for advice but they don't want to go to the original clinic, they want to go to another clinic, so challenges like those are there." (IDI-6)

Implications related to transition challenges

The challenges associated with the transitioning can have significant implications for both physical and mental well-being of patients. Healthcare workers have pointed out that the sense of disconnection from their regular healthcare providers during the study period can result in a loss of follow-up. Patients may not have an immediate and direct channel to discuss their health concerns or deal with challenges when transitioning away from their usual

support network in regular care. Furthermore, healthcare workers have observed a systematic gap that fails to indicate whether a patient is transitioning from a study or not. This gap in information can create additional challenges in providing smooth care and support to patients during this critical phase.

A 36 years nurse midwife with 10 years' experience in HIV studies provides useful details on how lack of clarity and proper transitioning can create confusion among healthcare providers and potentially result in suboptimal care for transitioning study participants:

"On exit, under normal circumstances, the study nurse is supposed to be in communication with the original clinic following up on how the patient in the study is doing. However, there is no link between the patient during the period of the study. Some do not go back to the original clinic and get lost in the process. Their mental health is affected as some have not disclosed their status and would come as far as Arusha [80Km] to participate in the study." (IDI-3)

In the course of conducting the in-depth interviews with healthcare workers, a recurring theme emerged regarding the uncertainty and potential lack of clarity surrounding the protocols for follow-up care beyond the conclusion of research periods. Healthcare workers feel that this issue poses a significant challenge in the effort to ensure the uninterrupted and sustained well-being of patients during their transition from a research phase to regular care.

One healthcare worker summarized this concern by pointing out a specific deficiency in the current healthcare system. Unlike in the past, where patient files clearly indicated whether an individual was part of a research or not, the present system fails to provide such critical information. As a result, the professionals face difficulty discerning a patient's research involvement status, adding an extra layer of complexity to their efforts to provide appropriate care and follow-up:

"The system also does not indicate whether the patient is coming from a study or not unlike in the past where the files indicated whether they were on the study or not. These days it is not easy to know." (IDI-8)

Theme 3: Ethical and practical implications of post-trial care

This theme focuses on the ethical and practical considerations involved in post-trial care. It discusses how participants are responsible for treatment costs after the trial, variability in drug responses, dosing discrepancies, and the benefits of participating in clinical trials.

Balancing patient safety and practical challenges in post-trial care

Within the context of transition of patients from research to regular care, healthcare workers view the end of the research period as a conclusive endpoint, assuming that any additional care or follow up might not be necessary. However, the provision of post-trial care depends on the specific protocol in place leading to uncertainty among healthcare workers regarding the existence of any supplementary measures beyond the research period.

A healthcare worker emphasizes the importance of adhering to established protocols, as they dictate the course of action after the research period ends:

"It depends on the existing protocol, and what it says because when the research period ends, it is over, so I don't think I need it or there is no extra follow up, [thinking] I wonder if there is anything extra." (IDI-4)

For other healthcare workers, the primary concern for any research is to ensuring patient safety and preventing harm. These healthcare professionals recognize the importance of follow-up in aligning with good clinical practice (GCP) guidelines. However, when it comes to post-trial patients' follow-up, they express apprehension about maintaining the benefits gained during the research period because this poses challenges including the costs associated with tests like viral load:

"In doing no harm it must have follow-up and it is a GCP requirement…. and if something bad happens and related to the study it must be reported. We have stopped people from the study. You cannot[report/follow-up] someone after the study. Viral load alone is almost 100USD." (IDI-4)

Informed consent and participant responsibility in transitional care

In the context of healthcare research, the transition from experimental interventions within a research study to regular care can raise a complex interplay of ethical and practical considerations. Healthcare professionals emphasize that participants typically have a limited role, mainly involving the signing of consent forms prior to joining the study. However, once the study concludes, any subsequent issues or costs associated with treatment often shift onto the shoulders of the participants themselves, even in cases where adverse effects arise.

There was an emphasis that participants should not harbor unrealistic beliefs that the study will continue to provide ongoing care or treatment for an extended period beyond its conclusion. As one healthcare worker explains, participants should be reminded that their involvement in the study is limited to the consent they signed:

"They [Participants] should not leave thinking that the study will take care of them all their lives. We remind them on the consent part that they signed..." (IDI-5)

In specific instances, however, healthcare workers find themselves involved in acts of charity actions aimed at supporting treatment of a child associated with the research project. Importantly, this charitable involvement is not an ongoing commitment but rather a gesture of goodwill towards the community. It serves as a means to reciprocate the support received from the community and to potentially cultivate a positive relationship with participants for future research endeavors conducted at the same site as alluded by one healthcare worker:

"Sometimes on humanitarian grounds you may find that a mother has delivered a baby and it needs some tests done so as a team we find ourselves coming together and as an act of charity we raise contributions to assist. Then when you look at it, we shall need the baby for future studies." (IDI-6)

Variability in drug responses during transition to regular care

According to healthcare workers, the transition of participants from research to regular care can be associated with an increased risk of drug toxicity and the emergence of side-effects. As highlighted by this healthcare professional; variations in patient responses to drugs can become apparent when comparing their experiences in research settings to those in regular care arrangements. This discrepancy can often be attributed to differences in treatment protocols between the two contexts:

"In terms of treatment, difference maybe there if the protocol is different from the guidelines in standard care. We had one drug under trial (Detonavir) that you use alone in the study as one single dose but the guideline in standard care says you use three doses and they add [the dose] to him/her." (IDI-4)

However, healthcare workers have limited options in intervening in the dosing discrepancies, indicating that not much can be done when a patient experiences side-effects or complications from a drug that was initially accepted in the research context. In some cases, healthcare providers in regular care might not have an authority to change the treatment plan or dosage, even if it leads to negative outcomes for the patient, emphasizing the outlined dosage in the consent form.

"If he/she says that they're using one drug, he/she should not have it changed, we tell them [in the study] it is because they signed a consent. When they go back, they must go by the national guidelines even if they are given 3 doses." (IDI-5)

This healthcare professional highlights the inherent challenges and complexities in drug research, including the potential toxicity, emphasizing importance of studying and understanding these variables in research settings:

"Yes, such things exist because drugs are being researched, for example, other drugs can cause toxicity, so you may encounter the problem of patients getting toxicity, so you can see that the research drugs have caused problems, for example, one day we were doing research on TB

drugs and some were starting drugs after giving birth, and others before giving birth, but the results were different." (IDI-2)

Another stated:

"Sometimes the drug in the research has accepted him but in standard care arrangement it rejects him, he encounters side-effects." (IDI-8)

The observations from this healthcare professional reflects a broader discussion within medical research in the medical field; one that encompasses critical topics such as, patient autonomy, and the moral obligation to safeguard the well-being of individuals beyond the confines of a study.

"There is nothing that can be done. Remember, this one came out of (Exited) the study with a single dose and left with it, but there are 3 doses in the standard care and we are not advised to change it……. If it costs him, whose problem will it be? They signed consent and the contract ends there [on exit]." (IDI-4)

Benefits of participating in clinical trials

Participating in the trials offers a unique and enhanced healthcare experience through frequent and close follow-ups, providing a clear-cut contrast to standard care practices. Additionally, the acknowledgement of the financial needs emphasizes the importance of continued investment in research for sustained improvements in medical care as indicated by this health professional:

"There are follow ups done closely [in the study] These are the benefits. In standard care, a follow-up can be after 6 months but we do it monthly here in the study. That is why I tell you that research needs money." (IDI- 7)

Theme 4: Perspectives on what should happen after the trial

This theme examines the perspectives of healthcare workers on the broader implications of post-trial participants' lives and what should happen after the trial. It emphasizes the ethical commitment of researchers to provide meaningful outcomes to participants including sharing research results and maintaining communication with them after the trial.

Healthcare workers, shared a complex viewpoint on the management of how to handle post-trial participants, emphasizing the significance of expressing gratitude, providing ongoing support, and upholding ethical principles in their care. Nevertheless, the hesitancy expressed by this healthcare worker suggests that post-trial procedures may not be a widespread or established practice:

Interviewer: What should happen to post trial participants on exit?

Interviewee:" Silence… laughs I don't think there's anything else apart from thanking them. Even if you say for example maybe they can organize workshops for training. You tell them that give education on how they can stay healthy even if they are living with HIV as an offer; nothing more. If you say pay, that can be seen as a coercion." (IDI- 5)

Participant communication, post-trial engagement and expectations

In the context of research dynamics, maintaining a balance is crucial to ensure participants are not driven solely by research outcomes while researchers have an ethical commitment to

provide meaningful outcomes to participants. The sentiment of this healthcare worker when asked about potential post-trial considerations for participants draws attention to the researchers' ethical commitment to offer meaningful outcomes to participants who voluntarily chose to be part of a study.

"Mmmm not much or there would be a possibility to get the results instead of participating; they get the results that they do not know anything about. I [researcher] have committed something to him/her to bring results. Because he/she is not forced to participate. At the end of the day, he/she has committed himself/herself; so, it would be very good to get the results because they have their contacts. They can even call them. I have not seen that happening." (IDI -6)

Some healthcare workers suggest that as a post-trial support, since the patient had already established a familiarity and comfort level with healthcare workers and environment at the trial site environment, it maybe the patient's best interest to maintain continuity of care at the site facility.

"Maybe if the patient is living nearby KCMC [trial site] they should be allowed to continue with their clinic at KCMC because they are already used to the health workers and the [research] environment rather than going back to the original facility." (IDI-3)

Discussion and implications

The use of referral letters as information repositories is a systematic approach to enhance regular care in the context of HIV research. The letters serve as a means of transferring essential patient information and medical history. To optimize the use of these letters and improve continuity of care, health systems can implement strategies and technologies such as electronic records (Schctman et al., 2003; Adler et al., 2014; Irizarry et al., 2015).

Utilizing technology in transitions

Our study reveals challenges in the transition related to the use of identification cards. Recent literature and technological advancement offer valuable insights into how technology can be leveraged to enhance communication and support such transitions (Patel et al., 2014; Marcolino et al., 2018; Topol et al., 2019).

Emotional impact of transition

The transition from clinical trial to regular care presents emotional challenges for participants, including societal stigma and medication adherence issues. Psychosocial support and referral to mental health professionals are recommended (Appelbaum et al., 2001). Open conversations about trials can help reduce societal bias (Corrigan & Watson, 2002).

Medication adherence post-trial

Our study finds out that some participants are likely to default from medication post-trial due to fear, indicating the need for post-trial support. Patient advocacy and peer support (Davidson et al., 2012) and policy initiatives are suggested interventions.

Treatment variability and dosing discrepancies

Issues related to treatment variability and dosing discrepancies during the transition phase are significant. Further research is needed to understand the extent and impact of these disparities,

leading to the development of guidelines and interventions for optimal patient care (Smith et al., 2020; Garcia et al., 2021; Williams et al., 2018; Carter et al., 2022).

Enhancing medication transition: key findings and recommendations

Participants receiving closer follow- up care highlight the need to align post-trial engagement with standard healthcare practices. clear communication and continuity of care which are crucial to prevent patient disengagement (Emanuel, Wendler & Grady, 2008). Healthcare systems should prioritize improving communication between research and regular healthcare providers.

Ethical dimensions and financial limitations

'After the research, it's like we have closed the contract': balancing ethical dimensions against financial limitations"

In the context of HIV research, addressing ethical concerns related to informed consent, participant responsibilities, and financial aspects of post-trial treatment is of paramount. Guidelines provided by UNAIDS (2019) and WHO (2019) offer a foundational framework, but further research is essential to deepen our understanding of the ethical dimensions of post-trial care. This will contribute to development of more effective and ethically sound guidelines and practices in medical research. Balancing ethical dimensions against financial limitations remains a critical consideration (Dal-Re & Rid, 2016).

Conclusion

Our study highlights the crucial role of patient-centered care for post-trial HIV patients. We propose practical steps to enhance their transition, emphasizing optimized referral letters, technology integration, and transparent communication. To tackle emotional challenges, we recommend promoting psychosocial support, open conversations, and initiatives for medication adherence like patient advocacy and peer support. Ongoing research is necessary to address treatment variability and dosing discrepancies, guiding the development of essential guidelines. For a smoother medication transition, aligning post-trial engagement with standard healthcare practices providing study results, and improving communication are essential. Ethical considerations, including informed consent and financial constraints, should be carefully balanced to uphold ethical standards in HIV research. Implementing these recommendations will mean a more efficient and ethical transition process nurturing public trust and ensuring better outcomes for participants in HIV studies.

Study limitations

The study, conducted at a specific referral hospital, may not fully represent healthcare practices in other settings, regions, or countries. While valuable insights were gained from health workers' experiences, the study does not provide perspectives from HIV-positive individuals transitioning from clinical trials to standard care. Furthermore, although ethical concerns were touched upon, a more in-depth exploration of these considerations could enhance the understanding of the transition process. Future research efforts should aim for a more comprehensive approach to include diverse settings, patients' perspectives, and a detailed exploration of ethical considerations to contribute to a more robust understanding of the complexities involved in the transitions from clinical trials to standard care in the context of HIV care.

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Conflict of interest
The authors declare that they have no conflict of interest

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