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Community Insights in Phylogenetic HIV Research: The CIPHR Project Protocol

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ABSTRACT

Inferring HIV transmission networks from HIV sequences is gaining popularity in the field of HIV molecular epidemiology. However, HIV sequences are often analyzed at distance from those affected by HIV epidemics, namely without the involvement of communities most affected by HIV. These remote analyses often mean that knowledge is generated in absence of lived experiences and socio-economic realities that could inform the ethical application of network-derived information in 'real world' programmes. Procedures to engage communities are noticeably absent from the HIV molecular epidemiology literature. Here we present our team's protocol for engaging community activists living in Nairobi, Kenya in a knowledge exchange process – The CIPHR Project (Community Insights in Phylogenetic HIV Research). Drawing upon a community-based participatory approach, our team will (1) explore the possibilities and

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limitations of HIV molecular epidemiology for key population programmes, (2) pilot a community-based HIV molecular study, and (3) co-develop policy guidelines on conducting ethically safe HIV molecular epidemiology. Critical dialogue with activist communities will offer insight into the potential uses and abuses of using such information to sharpen HIV prevention programmes. The outcome of this process holds importance to the development of policy frameworks that will guide the next generation of the global response.

Background

HIV genomic sequencing is now a routine standard of clinical care to detect anti-retroviral drug resistance mutations (Wensing et al., 2019), but recent advances in computational biology and phylogenetics offer novel approaches to understanding HIV transmission (Brenner et al., 2021; McLaughlin et al., 2021; Nduva et al., 2021; Ratmann et al., 2019). While this provides new opportunities for 'precision public health' (Arnold, 2022; Buckeridge, 2020; Khoury et al., 2018; Miller et al., 2022; Rasmussen et al., 2020), reconstructing the genetic relationship of HIV sequences and, by extension, links between individual people holds major implications for marginalised populations who already disproportionately experience stigma and criminalisation globally (Molldrem & Smith, 2020).

In an African context, where gay, bisexual and other men who have sex with men [gbMSM; including male sex workers (MSW)] and female sex workers (FSW) endure regular forms of discrimination (Risher et al., 2013; Wanjiru et al., 2022), attending to unintended consequences of phylogenetic analyses is especially salient. Many African countries continue to uphold colonial-era sodomy laws criminalising consensual sex between men (Matetoa-Mohapi, 2021), while FSW face criminalisation and regular harassment at the hands of police throughout the continent (Mbote et al., 2022). Therefore, *how* research findings portray these groups of people when describing trends in HIV transmission raises critical issues that go well beyond 'the molecular', given that outputs from phylogenetic analyses (for example, quantifying rates of HIV flow between places or populations) can perpetuate harm to these and other marginalised communities (Hoppe et al., 2022; Park et al., 2021). This can be especially damaging when the findings from phylogenetic studies reach the public domain and are misinterpreted by law enforcement, journalists, and lay audiences.

For instance, a recent article in the UK-based newspaper The Star (21 April 2022, Nairobi) entitled 'Worrying Trend: HIV Infections Among Gays are From the Coast – Scientists (*sic*)' was based on findings from a phylogenetic analysis by Nduva et al., with members of our team, François Cholette, Paul Sandstrom, and Lyle McKinnon, as co-authors on the study (Muchangi, 2022; Nduva et al., 2022a). The Star article strongly implied that MSM were responsible for spreading HIV from Nyanza to Nairobi since '*MSM from Nairobi visit the Coast for domestic and sex tourism, pick [up] the virus, and spread it upon return*'. Such a portrayal reinforces and perpetuates reductive stereotypes of gay men as 'vectors of disease' that are highly stigmatising against the wider backdrop of anti-homosexuality laws, religious and political vilification, and the criminalisation of HIV transmission in the region (Eba, 2015; Parsitau, 2021). While journalists may occasionally make erroneous and over-simplified claims about scientific studies, it is equally important for scientists to acknowledge their responsibility in reflecting on how data is presented and how it could potentially be misrepresented. As members of the CIPHR Project (Community Insights in Phylogenetic HIV Research) – a team comprised of natural scientists, public health specialists, social scientists, and Kenyan community activists – we aim to highlight a critical dialogue and knowledge exchange process we began around our involvement in phylogenetic studies, while reflecting on the broader benefits and pitfalls of deploying HIV molecular epidemiology for key population prevention programmes in Nairobi, Kenya. These conversations are both timely and relevant since many of the

issues raised concerning HIV molecular epidemiology risk being repeated while responding to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic and more recent Monkeypox virus (Mpox) outbreaks (Molldrem et al., 2021).

Understanding patterns of HIV transmission

Molecular epidemiology represents the unification of pathogen sequence analysis (i.e. phylogenetics) and sociodemographic, behavioural, and geographical information (Riley & Blanton, 2018). Increasingly it is being used in precision public health to better understand transmission dynamics and target interventions for populations (Han et al., 2020; Isidro et al., 2022; Poon et al., 2016; Wang et al., 2015; Worobey et al., 2016; Worobey et al., 2020). Molecular epidemiology is particularly impactful in contributing to our understanding of HIV transmission dynamics due to the virus' rapid rate of evolution, resulting in viral progeny virtually unique to the host (Holmes, 2009; Zanini et al., 2015). A high degree of similarity between two or more HIV sequences would therefore suggest that they originate from the same transmission network (Poon et al., 2015). Recent methods in computational biology provide more reliable estimates of the timing and directionality of transmission (i.e. '*who infected who and when*') by exploiting next generation sequencing (NGS) data (Puller et al., 2017; Ratmann et al., 2019; Ratmann et al., 2020; Wymant et al., 2018). This could be used to shed light on HIV transmission patterns which may be otherwise difficult to ascertain using standard survey-based approaches, especially if we consider that many individuals may be reluctant to reveal personal information such as past sexual and drug injecting behaviours (Gnambs & Kaspar, 2014). For example, phylogenetics played a significant role in the Undetectable Equals Untransmissible (U = U) movement by showing that sexual transmission of HIV in sero-discordant couples did not occur when the partner living with HIV was virally suppressed (Cohen et al., 2011; Rodger et al., 2016; Rodger et al., 2019; Zhang et al., 2021). The U = U movement has several significant implications such as: (1) promoting the use of HIV treatment as a prevention strategy and encouraging people living with HIV to engage in and adhere to treatment (Okoli et al., 2021); (2) reducing HIV-related stigma by affirming that people living with HIV, who are virally suppressed, cannot transmit the virus (Ford et al., 2022); (3) empowering individuals living with HIV by emphasising that they have control over their sexual health and can make informed choices without the fear of transmitting the virus to their partners (Calabrese et al., 2021); and (4) influencing public health policies and guidelines worldwide. Many countries and organisations, including UNAIDS, have officially endorsed the U = U message (UNAIDS, 2018, 2020). Despite this, whether or not molecular epidemiology has led to a significant improvement in HIV prevention efforts remains controversial (Mehta et al., 2019).

In terms of public health practice, molecular epidemiology has been used routinely in North America and Europe to identify local patterns of active transmission, which have supported focused HIV prevention programmes and interventions (Bachmann et al., 2021; Brenner et al., 2021; Nguyen et al., 2022; Oster et al., 2021; Poon et al., 2015; Poon et al., 2016; Ragonnet-Cronin et al., 2018; Ragonnet-Cronin et al., 2022; Salazar-Vizcaya et al., 2022; Schneider et al., 2022; Tumpney et al., 2020; Wilbourn et al., 2021). Recently, HIV molecular epidemiology in Eastern and Southern Africa has been thrust into the spotlight. The Kenyan Medical Research Institute (KEMRI) possesses large repositories of mucosal and blood samples, to which a large cadre of international (and mostly Western-based) scientists hold access (Nduva et al., 2022b; Voller et al., 2022). Additionally, a consortium of American, British, and African institutions currently run the Bill & Melinda Gates Foundation-funded Phylogenetics And Networks for Generalised Epidemics in Africa (PANGEA) project, which has gathered >30,000 HIV NGS files from Botswana, Kenya, South Africa, Tanzania, Uganda, and Zambia (Fraser et al., 2018; Pillay et al., 2015; Ratmann et al., 2017; Ratmann et al., 2019).

Some findings from PANGEA have begun to emerge. Most notably, in Rakai, Uganda, HIV deep sequencing revealed that transmission between Lake Victoria hotspots and surrounding inland

communities was uncommon (Ratmann et al., 2020). Furthermore, it was found that HIV migration occurred more commonly from inland communities to hotspots surrounding Lake Victoria, contrasting the common belief that hotspots sustain the epidemic inland. This suggests that geographical targeting of HIV prevention would not be effective for broader epidemic control in contrast to the current mantra of focused HIV prevention programmes and interventions in HIV prevalence hotspots (Ratmann et al., 2020). Although the PANGEA-HIV Consortium has recognised the ethical implications in HIV phylogenetic research (Coltart et al., 2018), how communities could be meaningfully empowered to guide the ethical course of these studies and the potential use of the findings has not been documented by this group. In Kenya specifically, the collection and stockpiling of biological samples from research cohorts of people living with HIV has been underway for a number of years (Fowke et al., 1996; Plourde et al., 1992). As members of multidisciplinary research teams at the University of Manitoba, we have been part of several studies engaging these research cohorts (Gebrebrhan et al., 2021; Nduva et al., 2022a; Nduva et al., 2022b; Sivro et al., 2020). Additionally, our team has longstanding relationships and collaborations with community-led activist organisations in Nairobi (Becker et al., 2018; Bhattacharjee et al., 2020; Cheuk et al., 2020; Kimani et al., 2020; Lazarus et al., 2022; Lorway, 2020; Macharia et al., 2020; Ma et al., 2020) and, therefore, is particularly well-situated to both interrogate and attempt to collaboratively adapt current approaches to phylogenetic investigations. Our study is also timely because unlike the heated controversy that has appeared in Western activist circles (Bernard et al., 2020; McClelland et al., 2019), phylogenetic studies in African contexts, despite major developments like the PANGEA project, have mostly flown under the radar of bioethicists and HIV activists alike with a few notable exceptions (Mutenherwa et al., 2019a, 2019b, 2019c; Mutenherwa et al., 2020).

Ethical implications of current phylogenetic research

The ethical implications that underlie these technical advances have culminated in a firestorm of criticism in Western contexts. A recent issue of the American Journal of Bioethics recently devoted a special section on HIV molecular epidemiology, raising an array of such criticisms (Guta et al., 2020; Haire, 2020; Molldrem & Smith, 2020; Mutenherwa et al., 2020; Rennie et al., 2020). In a foundational essay, Molldrem and Smith (2020) outline the myriad ethical problems presented when molecular data is reported to surveillance systems, taking the example of the United States (Molldrem & Smith, 2020). In 2018, HIV sequence data for detecting anti-retroviral resistance began being used to identify clusters of people living with HIV using an approach that re-used their personal molecular data without individual consent, so as to establish a new facet of the US national HIV surveillance system (Dawson et al., 2020). In brief, bioethical critiques have been well-documented and focus on the: (1) contribution to intrusive and enhanced surveillance and the inevitable intensified targeting of vulnerable groups (Bernard et al., 2020; Mutenherwa et al., 2020; Sandset, 2020); (2) violation of consent and questions of de-identification with respect to the re-purposing of individuals' biomaterials (Molldrem & Smith, 2020); (3) potential re-stigmatisation of specific communities, erosion of trust in health systems, and the resultant unwillingness to access services (Dawson et al., 2020; Mutenherwa et al., 2020); and (4) how molecular surveillance could intersect with forms of criminalisation that characterise contemporary policing of HIV transmission in many countries, including Kenya (Bernard et al., 2020; Chung et al., 2019). At the heart of these critiques lie broader social justice concerns for communities who continue to face significant stigmatisation and criminalisation, such as gay, trans, bisexual, and other men who have sex with men, sex workers, immigrants, people who use substances, and people living with HIV. These '*high risk*' and often-targeted groups of HIV surveillance and intervention scale-up can be expected to bear the burden of intensified state regulation, control, and punishment (Bernard et al., 2020). Despite these ethical implications, some benefits of HIV molecular epidemiology have been identified by experts in the field, public health officials, and people with lived experiences. However, from the

perspectives of members of key population groups, qualitative research by Shook et al. (2022) has highlighted the importance of integrating community voices into this work in order to expand upon the accessibility and use of molecular data.

Communities as nodes for phylogenetic research

Phylogenetic analyses, methods in computational biology, and the ensuing ethical dilemmas are well-documented in the HIV molecular epidemiology landscape [see for example (McClelland et al., 2019; Molldrem & Smith, 2020; Shook et al., 2022; Worobey et al., 2016; Wymant et al., 2018)], but explicit approaches to community engagement are noticeably absent from the literature despite repeated calls for involvement of people living with HIV (Shook et al., 2022; Trejo & McClelland, 2021; UNAIDS, 2007). Through meaningful collaboration, we intend to pilot a community-driven HIV molecular study in Nairobi, Kenya with gbMSM, MSW, and FSW accessing HIV/STI prevention and treatment programmes at our partner community-based organisations. While we are not directly collaborating with transgender-led organisations, individuals who identify as transgender will also be engaged at these sites. Critical dialogue has begun between gbMSM, MSW, and FSW activists (hereinafter referred to as 'community activists'), community-based organisations, programme managers, and our multidisciplinary research team, which includes medical anthropologists, social workers, microbiologists, and computational biologists. Our overarching aim is to critically examine, unpack, and contextualise the practical, ethical, and policy implications of the use of molecular epidemiology in public health decision-making by directly engaging community activists living in Nairobi. We aim to answer if and how HIV sequencing data can be ethically used to inform existing HIV programme design and delivery in this context. In contrast to some researchers who have suspended phylogenetic studies after facing concerns from affected communities (Tordoff et al., 2023), we have taken a proactive stance. Explicit approaches attempting to strike a balance between ongoing discussions surrounding the ethical, human rights, and public health aspects of molecular HIV surveillance have yet to be reported in the literature to the best of our knowledge.

The CIPHR Project Protocol

Drawing upon a community-based participatory approach employed by feminist and postcolonial scholars that aims to democratise and decolonise research practices while confronting power imbalances in traditional research hierarchies (Janes, 2015; Keikelame & Swartz, 2019), we will co-produce lay technical summaries of molecular methods and existing data to iteratively explore the possibilities and limitations of using findings from molecular analyses to inform network-based interventions. One of the largest ethical hurdles for exploring wider applications of phylogenetic analysis in HIV prevention is the lack of technical knowledge possessed by the public to fully adjudicate its potential uses and misuses (Molldrem & Smith, 2020). We will attempt to overcome this hurdle by drawing insight from 'lay expertization', creating a series of discussion forums in which local community activists can critically apprehend, adjudicate, and reinterpret expert forms of scientific knowledge (Epstein, 1995; Irwin, 2001; Prainsack, 2014). Recognising the time and expertise that communities bring to participatory research approaches, we will pay community activists for their time on the project following standards set by previous research partnerships (Roche et al., 2010). This will take place through a three-phase process:

Discussion forums

The CIPHR Project team will include community activists in the translation of phylogenetic data through an iterative process that takes place via a series of critical discussion workshops. This workshop series will provide the space for community activists to engage in intimate dialogue with

scientists while together enabling them to carefully sift through the key technical concepts and findings from molecular epidemiological studies, drawing out the potential applicability and challenges for ongoing prevention and health services linkage work in Kenya. We will use examples of molecular HIV data from Kenya as case studies. Lay expert knowledge will then be disseminated via presentations and local discussion forums that will afford the larger community of gbMSM, MSW, and FSW in Kenya the opportunity to interrogate and respond to the potential uses of phylogenetic analysis in HIV prevention (Haugerud, 1995; Naanyu et al., 2011). The team will summarise the key concerns, insights, and knowledge translations from previous phases and disseminate these findings in an expanded group discussion forum that brings together community activists, scientists, and health officials, who are well-recognized as allies to sex worker communities. These discussion groups will further critically assess how phylogenetic analysis can be utilised in HIV preventive interventions. The critical feedback generated during these discussion forums will be documented and summarised so that it can shape the development of a community-led HIV molecular pilot study.

Molecular pilot study

Based on our past experience (Becker et al., 2019; Bhattacharjee et al., 2020; Cheuk et al., 2020), we will co-design a community-based HIV study that combines molecular data with community knowledge to identify emergent HIV transmission clusters in a sample of population-dense hotspots. This study will be initially piloted at a relatively small scale under carefully controlled conditions, which will allow us to swiftly identify and address potential harms resulting from the molecular data. The team will facilitate planning sessions with key leaders from activist, scientist, and health policy communities to work with existing mapping data collected to compose a detailed procedural plan for setting up, running, and pilot testing the community-based programme. We will combine geographic hotspot mapping data, which have revealed places where communities gather, to design a small-scale pilot project for HIV molecular surveillance. We will not be implementing a surveillance programme *per se*, but attempting to better understand how to collect and use HIV sequences for meaningful and practical data for HIV programmes, which in turn can guide community advocacy. While we don't anticipate drawing definitive conclusions on the utility of community-based molecular research, our pilot study will yield detailed information on community engagement processes needed for future testing and scale-up.

Throughout this collaborative endeavour, we will critically assess and identify emergent ethical issues, advantages, and disadvantages of the community-based phylogenetic project. Rather than identify ethical issues in a post-mortem assessment, we aim to conduct a critical ethnography to track ethical issues and other tensions, *in situ*, during our ongoing phylogenetic project and pilot planning. More specifically, we will pursue a "project ethnography" approach that will also draw upon participatory techniques of collecting and analyzing data (Evans & Lambert, 2008). In other words, our approach will remove the problems of surveillance from the abstract world of bioethics and, instead, firmly ground ethical issues in programme contexts as well as in the lived realities of those who rely on programmes for their well-being. Our team will train community researchers to perform "participant observation" and keep ethnographic field notes, in close collaboration with our team's social scientists [see for example: (Baba et al., 2019; Lorway et al., 2011; Lorway et al., 2018; Thomann et al., 2022)]. This will enable us to go beyond what Michelle Brear refers to as "dialogic member checking", as the community is not only consulted with but is integrally a part of the critical ethnographic knowledge production process (Brear, 2019).

Policy development

We will co-develop lay-friendly policy guidelines on how to establish an ethically safer, community-owned, and regulated molecular sequencing database and repository of biomaterials. To achieve our

goal of greater 'data justice', of more democratised and de-monopolized control over biodata, we build on approaches developed with Indigenous First Nations leaders. For instance, working in close collaboration with the Māori, the original inhabitants of New Zealand, scientists interested in genetic research developed an important community engagement model that incorporated cultural values, understandings, and practices with respect to specimen collection and overall governance of the project, a model that informed the resultant establishment of a biobank (Beaton et al., 2017). A similarly effective Canadian example comes from the First Nations principles of ownership, control, access, and possession (OCAP®), that include a strong component of data ownership for studies that are done with First Nations communities (FNIGC, 2014). We expect our resultant model will stand as a vital exemplar of best practices and standards for ethical molecular sequencing and knowledge mobilisation and translational work occurring throughout Africa, such as the PANGEA project. Given the criminalisation that surrounds sex work and especially male sex work, following anti-gay legislation passed in Kenya in May 2019, our wider goal of strengthening community health infrastructures to regulate the flow of molecular data is crucial to achieving the greater vision of data justice (Taylor et al., 2020). The findings from our study will culminate in the co-design and development of the technical report and policy guidelines that will be disseminated at a community forum attended by scientists, policy makers, and community activists (Isac et al., 2021; Lazarus et al., 2021; Lorway et al., 2021).

High risk or high reward?

This ambitious community collaboration has been conceptualised as a study that could unveil high risk or reap high rewards for those involved. After pursuing a collaboration that centres community control and ownership, we may find that HIV phylogenetics would undermine hard-built relationships between local community activists and the scientific community, potentially resulting in its abandonment altogether. Using these techniques to focus on and respond to HIV transmission outbreak clusters, even when mediated by meaningful community engagement processes, might not be feasible in terms of the ethical, political, cultural, and legal disruptions it sets in motion and the vulnerabilities it exposes. However, if we discover a process in which this technique can be used effectively from an HIV preventive and ethical perspective, this process would be the first of its kind to demonstrate the applicability of HIV phylogenetic methods in the context of HIV prevention programmes, with meaningful involvement of participants who stand to benefit most from any tangible outcomes of the research. By democratising HIV molecular epidemiological studies among key populations in Kenya we hope to establish a sense of community ownership and data justice. Ideally these activities should fit within a wider de-stigmatisation of HIV as being more treatable and preventable, such that interventions can be made available to those most in need. This is necessary as HIV incidence decreases, and global HIV funding allocations continue to flat-line or decrease (Kenworthy et al., 2018). Whether a success or failure, understanding the viability of this technique for more precise HIV prevention will produce global guidance to policy makers on the strengths and limitations of its employment.

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Ethics approval and consent to participate

Ethical approval will be obtained from the Human Research Ethics Board at the University of Manitoba, Canada and AmREF Health Africa, Kenya for the molecular pilot study. Written informed consent will be obtained from all participants for the behavioural and biological sampling component of this study. All experiments will be carried out in accordance with relevant guidelines and regulations. All experimental protocols will be approved by the relevant ethics research boards ahead of implementing our community-based molecular pilot study.

Author's contributions

LM and RL conceived the study described in this publication. FC, LHT, and LL contributed to writing the initial draft. PM, SG, JM, JW, IK, SO, SW, HA, PM, JA, RK, EJ, PB, JK, PS, AFAM, JBJ, MT, PJM, SS, SM, MLB, and LM reviewed and edited all subsequent versions of the manuscript. FC, LL, PM, JM, PW, PB, SS, MLB, LM, and RL made contributions to the acquisition of financial support leading to this publication. RL provided supervision and critical review of all iterations of the manuscript.

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