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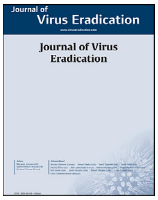

Original research

Time for revolution? Enhancing meaningful involvement of people living with HIV and affected communities in HIV cure-focused science

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ABSTRACT

Introduction: Involving affected communities and people living with HIV (PLHIV) in HIV cure-focused clinical trials has ethical and practical benefits. However, there can be barriers to meaningful involvement of ‘lay people’ in scientific research meaning community consultation is often limited or tokenistic. This paper reports on an Australian project, the INSPIRE project (**I**mprove, **N**urture and **S**trengthen education, collaboration, and communication between **PLHIV** and **Re**searchers), which aimed to explore barriers and enablers to enactment of the principles of meaningful involvement of PLHIV (MIPA) and affected communities in HIV cure-focused research.

Methods: The project involved a workshop attended by 40 stakeholders involved in HIV care, research or advocacy including PLHIV, community organizations, basic scientists, and clinicians. The workshop involved a facilitated discussion about community involvement in a hypothetical HIV cure-focused clinical trial. Data were collected through notetaking and video recordings. Qualitative, thematic analysis was undertaken to organize the data and identify core themes related to MIPA.

Results: Workshop discussions revealed community stakeholders often feel their involvement in HIV clinical research is undervalued, evidenced by limited financial remuneration and minimal capacity to influence the research design or processes. Building long-term, formal and informal relationships between community organizations, PLHIV, researchers and research teams or laboratories was identified as a strategy to support MIPA at all stages of a clinical trial, from design to dissemination of findings.

Conclusions: Enacting MIPA principles in HIV cure-focused research requires a better understanding of the potential to improve research outcomes and ensure quality in the research process.

Introduction

Since the early 1980s, people living with HIV (PLHIV) have been strong advocates for community education and consultation about HIV-related clinical research.[1,2] The principles of PLHIV involvement in clinical research were first articulated in the 1983 Denver Principles and more recently adopted in the United Nations endorsed principles of Meaningful Involvement of PLHIV and Affected Communities (MIPA).[3] While there are no standard criteria to determine whether or not community involvement is ‘meaningful’, the MIPA principles imply a definition of meaningfulness in which community stakeholders hold some level of influence over the design, process and outcomes of HIV-related research.[1,4] Involvement of PLHIV in decisions about clinical research had particular salience in the 1980s and early 1990s when PLHIV were seeking to expedite access to life-saving treatment.[2] However, even today, where most PLHIV in high-income countries have access to antiretroviral treatment (ART) enabling normal life expectancy, the outcomes of clinical research are significant in the lives of PLHIV and

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many PLHIV are trial participants.[11] As such, MIPA principles have been applied to scientific and medical research protocols in documents such as the UNAIDS/AIDS Vaccine Advocacy Coalition (AVAC) Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials.[37] These guidelines recommend comprehensive community involvement throughout the life cycle of a clinical trial, from the formative stages through to reporting and dissemination of results.[3,5,6,37]

Despite widespread support for MIPA principles, meaningful involvement of PLHIV and other community stakeholders can be challenging to achieve and is not applied consistently in all areas of HIV-related clinical research. A recent systematic review found that community stakeholder involvement predominantly occurs in the early stages of a trial, often to support participant recruitment, but is limited in later trial stages.[6] Methods used to engage with communities are also often researcher driven and utilize formal consultation methods, such as interviews or focus groups, that do not afford PLHIV any power to influence the research process.[6] Other barriers to effective community involvement in HIV trials include limited understanding or awareness among researchers or community members about what community involvement requires,[7] poor communication between researchers and

Table 1

Enhancing meaningful community involvement in HIV cure-focused research workshop plan (INSPIRE simulation workshop, 2019).

Workshop plan

•40 participants from a range of sectors: basic scientists, clinicians, PLHIV, community advocates, social scientists and industry/funding body representatives.
•4-hour workshop inclusive of: 1) introduction to HIV cure-focused science and introduction to community engagement in HIV cure-focused science 2) simulation exercise (described below) and 3) post-simulation group discussion.
Simulation exercise:
1)A mock clinical trial related to HIV cure-focused research is described to participants.
2)Participants are allocated small groups (6–8 people), the groups are arranged to ensure a diversity of stakeholders are in each group.
3)Participants are provided with a ‘character card’ which gives them a role to play in the discussion that is different to their real-life role. Participants are encouraged to consider the issues raised in the workshop through the lens of their character. Asking participants to adopt characters for the workshop is intended to encourage creative thinking as well as empathy for other positions. It is also designed to make the activity more engaging and fun for participants. Character roles include: funding body representative, head of laboratory, basic scientist, person living with HIV, community advocacy group representative, bioethicist, HIV clinician.
4)Two facilitators talk participants through the mock trial in stages, from planning to dissemination of findings. At each stage, participants are asked to consider whether and how community members may be involved in the trial and to respond to critical incidents or problems with community involvement in mind. Each group is given just one problem or incident to consider, which is randomly selected.
5)Following the simulation, facilitators run a debrief discussion with the whole workshop with the aim of identifying key barriers to or concerns about community engagement that were identified in the simulation.

Simulation exercise: stages, discussion points and critical hypothetical incidents

Phases of trial	Discussion points	Critical hypothetical incidents/problems
Part 1: Trial planning and protocol development	• Who are the stakeholders? • What differentiates a community stakeholder from other stakeholders? • Who has the most power in this list of stakeholders? • Which stakeholders are likely to be the most difficult to engage? • What is the purpose of stakeholder/community engagement?	• The key local community-based advocacy organisation has agreed to be involved in a CAB, but they have minimal funding and no paid staff members. • At the first CAB meeting, community representatives explain that they want to seek feedback from a wide range of PLHIV about the study design and ethics. This will likely delay the trial timeline. • Local CAB representatives are not happy because they feel the trial does not accommodate a diverse range of participants with respect to gender or cultural background.
Part 2: Community engagement plan	• Identify key strategies for engaging community. • When will engagement begin? • How stakeholders will be approached? • What each stakeholder needs to participate equally? • How community stakeholders can learn about clinical research? • How can scientists learn about community concerns? • What will be needed to establish respect and mutual understanding? • What is the purpose of stakeholder/community engagement at this phase?	• Community members insist on being paid for their time at professional rates. This has not been budgeted for.
Part 3: Trial recruitment	• Identify key strategies for engaging with community. • What is the purpose of stakeholder/community engagement at this phase?	• No women have volunteered for the trial. • Recruitment has begun when criticisms are raised about the lack of community ethics approval for the study though institutional ethics approval has been granted.
Part 4: Trial implementation	• Identify key strategies for generating robust and meaningful participation during the implementation phase. • What is the purpose of stakeholder/community engagement at this phase?	• One trial participant becomes unwell during the trial. While the reasons for this are not clear it is considered an adverse event. The participant is being well cared for. The research team needs to consider how to communicate to stakeholders and the public about the event. • A conspiracy theory is circulating on social media about the influence of ‘Big Pharma’ (including the study drug manufacturer) on perpetuating the HIV epidemic. • The principal investigator struggles to engage with community stakeholders. In meetings they find it hard to avoid using non-scientific language to explain core concepts, and generally seem unwilling to answer questions or consider issues raised by community stakeholders. This is creating tensions.
Part 5: Findings and dissemination	• What are the aims of the project with respect to dissemination? • What is the purpose of stakeholder/community engagement at this phase?	• No funding has been allocated to dissemination beyond production of scientific papers. Participants and community agencies are furious. • Research findings have been prepared for scientific journals, but the language of this is inaccessible to a wider readership. • The trial is early phase and it is not clear if progress will eventually lead to a cure. It is not clear how best to explain this to the public. • Posts about the study on social media are the target of a lot of spam about herbal cures and miraculous interventions. • An article written about the study for a community audience is picked up and misquoted by an AIDS conspiracy website. It’s spreading quickly and discontent is escalating.

communities, or a history of community mistrust in research.[8] In addition, the nature of scientific and medical research as a profession – which by its nature involves access to an exclusive skillset, body of knowledge and terminology – can make it difficult for non-academic or scientifically trained people to engage confidently in the research process.[2,9,10]

This paper reports on a community-engaged study which aimed to identify strategies to enact the MIPA principles in HIV cure-focused research. There is an increasing international body of research aiming to achieve a cure for HIV.[12,13] Early stage clinical trials are underway in several countries seeking to identify therapeutic interventions that achieve long-term virologic control of HIV in the absence of ART or to eliminate HIV from the body.[15–18] However, as HIV cure-focused research remains in its infancy, there may be substantial health risks for PLHIV who participate in clinical trials, and it is unlikely that trial participants will receive therapeutic benefits.[14,17–19] As such, the success of HIV cure-focused research relies heavily on altruistic motivations of PLHIV to participate.[13] For this reason, there is an ethical and practical necessity to involve PLHIV in trial design and implementation. Meaningful involvement of community stakeholders in clinical trials can also enhance the quality of research as it can improve integrity and transparency of trials and strengthen capacity to engage affected communities in the study[1].

This paper reports on the INSPIRE project (**I**mprove, **N**urture and **S**trengthen education, collaboration, and communication between **PLHIV** and **Re**searchers), which aimed to explore barriers, and identify strategies, to enhance enactment of MIPA principles in HIV cure-focused research in Australia.

Methods

Data for this paper were gathered through a half-day workshop held in Melbourne, Australia in March 2019 (Table 1). Workshop attendees were tasked with solving the 'problem' of limited community involvement in HIV cure-focused clinical trials. This project was reviewed and approved by the La Trobe University Human Research Ethics Team (HEC19062). All participants signed a written information and consent to participate in research form on attendance.

Recruitment and sample

The workshop was open to anyone involved in the HIV sector in a personal or professional capacity. It was advertised through the membership lists of a local PLHIV advocacy agency as well as HIV researcher e-lists. The project team also directly approached people in their professional networks to ensure a diverse range of people were invited. Due to the size of the venue, a maximum of 40 people could attend the workshop, 20 places were allocated to community stakeholders and 20 to researchers, clinicians and funding body representatives. Advertising was stopped when capacity was reached and all who expressed interest were able to attend. Participants included community activists and advocates, PLHIV, basic scientists, clinical researchers, clinicians, funding body representatives, and social scientists. Participants did not receive remuneration for participation.

Workshop format

The workshop format was modelled on simulation workshops designed to develop strategic responses to critical incidents in public health, such as disease outbreaks.[20,21] Two facilitators guided participants through a simulated HIV cure-focused clinical trial. Workshop participants were placed into small groups (6-8 participants per group), organised to ensure there was a mix of community members, researchers and clinicians in each group. Each participant was allocated a character to play in the workshop that was different to their real-life role (for instance, a clinician may have been allocated the role of a community advocate). Participants were encouraged to consider problems presented in the workshop through the lens of that character rather than their real-life role. This strategy was based loosely on Edward de Bono's six 'thinking hats' approach to problem solving and was designed to encourage creative thinking among participants while also being engaging and fun.[22,23] (See Table 1 for a full list of characters, and the workshop process).

Each small group was asked to list ideas for strategies to enhance community involvement at each stage of the clinical trial, from design through to dissemination of findings. At each stage of the trial, groups were presented with a critical incident or problem scenario. Groups were asked to consider how community stakeholders could help respond to the problem and factor this into their ideas. (See Table 1 for details of problems posed). Following the simulation activity, a facilitated discussion was held in which participants were asked to reflect on what they had learned about barriers to MIPA in HIV cure focused research and strategies to enhance community involvement.

Data collection and analysis

Data from the workshop were collected in two ways 1) members of the research team recorded detailed notes 2) the final workshop group discussion was recorded using a digital video which was transcribed. Workshop data were analyzed qualitatively using a combination of deductive and inductive thematic analysis.[24] Firstly, the research team met immediately after the workshop to record their observations of the workshop, review the workshop notes and identify emergent themes and ideas that came from the workshop. Detailed notes were taken at this meeting which then became the basis for analytical memos that informed the next stage of analysis. In the next stage, one researcher organised the data (deductively) into themes relating to 1) barriers to community involvement and 2) strategies for enhancing meaningful involvement in the early, mid and late stages of a clinical trial. Within each of these broad groupings, inductive analysis was employed to identify themes and ideas raised by workshop participants. Researchers paid attention to tensions within group discussions as a strategy to identify potential barriers or challenges to community involvement in research [25] All analyses were done manually using standard word processing software. The analysis process involved the whole project team (all authors on this paper) in data gathering and in subsequent discussions and reporting of themes. The aim of this method, in which the data were analyzed through the 'lenses' of multiple researchers, was to ensure rigor and that a broad scope of themes were identified. However, the nature of the workshop method, where we did not have opportunities to follow up or crosscheck themes with workshop participants, means we do not claim to have achieved thematic saturation of the data.[26] The workshop format also made it difficult to identify individual participants in the notes and transcriptions. Quotations presented below are therefore not ascribed to individual participants.

Results

Workshop discussions showed that barriers to enactment of MIPA principles in HIV cure-focused research may emerge through informal cultural processes that tend to undervalue community or non-scientific input in research settings or make it difficult for people who are less confident and resourced or who have lower levels of education to participate.

Gaps in stakeholder representation

At the commencement of the workshop, participants were asked to identify key stakeholders in HIV cure-focused research. The list of identified stakeholders (Table 2) included people who had a direct interest in the outcomes of HIV cure-focused research – PLHIV, affected communities, researchers, funding bodies – as well as people who hold influence over the success of clinical trials including trial nurses (who

Table 2
List of stakeholders in HIV cure-focused research.

Stakeholders		Description
Community members/ people living with HIV	• People living with HIV (PLHIV) • PLHIV advocates • Community members affected by HIV • People at risk of acquiring HIV • Community advisory boards	• Have an interest in the process and outcomes of HIV cure-focused research • Play an important role in design and implementation of trial • May be potential trial participants or refer others
Trial participants	• PLHIV participating in trials • Where relevant, control groups not living with HIV	• PLHIV who may or may not have had previous experience participating in a clinical trial • Voluntary and can withdraw at any time • Must have capacity to give informed consent
Researchers	• Basic scientists • Clinical researchers • Social researchers	• Seek to answer a scientific question • Have a personal and professional interest in the process and outcome of the study • Accountable to funding body to deliver agreed objective for the study
Funding bodies	• National or local government • Educational institutions • Industry • Philanthropic funds/ trusts	• Have an interest in the purpose and outcomes of the study • Wants funds to be spent efficiently, effectively and ethically
Clinicians	• Providers of day to day care and management for PLHIV • Referral of participants to trials • Care for participants during trials • Provision of information to potential trial participants	• Often the key contact between researchers and potential trial participants • Can be influential in recruitment • May have considerable or no experience with HIV cure-focused research
Trial nurses and coordinators	• Support, monitor and ensure safety of participants during trials • Provision of information to potential trial participants	• Usually first and most frequent point of contact for trial participants • Play an important role in looking after trial participants and coordinating study visits • Vital in ensuring participants have a good and safe study experience
Ethics committees	• Local and institutional committees for ethics in human research	• Provide oversight into trial process • Can play an important role in advising and supporting meaningful involvement of PLHIV and other stakeholders

have the most direct contact with trial participants) and HIV clinicians (who refer patients into trials). Workshop participants noted the need to take a critical approach to inclusion as not all stakeholders have equal capacity to participate in research. Within communities, it is generally people who are well educated, well resourced and have more time who are invited to – or in a position to – represent PLHIV or other community stakeholders on research advisory boards or committees. For these reasons, often the most marginalized people are not included. This can be problematic for the research process, including recruitment, as one participant explained:

> The earlier you involve community support, the more chances you have of understanding some of the barriers and putting in place strategies to address these, like considering transport and childcare in the budget.

Further, participants pointed out that if PLHIV/community members do not have capacity to understand the fundamentals of clinical research or confidently engage with researchers, communication between community members and researchers can break down. It was noted that well-resourced PLHIV advocacy agencies can support involvement in research by providing trained staff, but smaller agencies will have less capacity.

Conflating community involvement, engagement, recruitment and trial participation

The process of identifying stakeholders led to discussions within the workshop which revealed how conceptual and practical differences between community 'involvement', 'engagement', 'recruitment' and 'participation' in clinical trials can mask a lack of meaningful involvement in HIV cure-focused research. Workshop participants agreed that meaningful involvement required PLHIV/community stakeholders to have capacity to influence decisions about research design and implementation. By contrast, community engagement was defined as communities being educated about HIV cure-focused research so they could input as requested. Different again, were community engagement strategies which aim to recruit trial participants, as noted by a workshop participant: *engagement and recruitment are separate issues*. Workshop participants felt that the assumption that provision of 'community education' about a trial equaled 'meaningful involvement' risked inadequate involvement of PLHIV. Researchers need to understand what meaningful involvement looks like.

Undervaluing community expertise and knowledge

Following the above discussion, workshop participants emphasized that community input into research is often undervalued by researchers and research institutions – both financially and with respect to how advice is received and acted upon. It was noted that community advisory boards (CABs) are often formed after a trial protocol is established and funded, meaning they have little influence over the study design and no real *seat at the table* (quote from workshop participant). Without capacity to influence the research process, including capacity to veto research protocols deemed unacceptable, there is limited value that community members can add to the study, as one participant described:

> There are issues around how much impact [the] community has on decision-making. [Researchers] need to define what communities are capable of 'impacting' if you ask community members to engage in that study.

Workshop participants felt that, although the perspectives of PLHIV or community stakeholders are often valued, 'lived experience' or community knowledge is not considered professional expertise and so not compensated on professional terms. PLHIV/community members are often unpaid for providing consultation on clinical research. Further, representatives from PLHIV advocacy organizations who attended the workshop explained that this can set up an implicit expectation that community organizations will fund the time provided by their PLHIV members to consult on research. However, many community organizations have minimal funding and cannot afford to pay PLHIV volunteers.

This becomes a major barrier to the enactment of MIPA principles in research. As this gap is rarely acknowledged, research budgets tend not to include provisions to pay community consultants, as one workshop participant explained:

> Community engagement and community participation is never valued [financially] and never budgeted for (or) it's often a tokenistic amount. The research inputs, the clinical inputs, the lab time are all valued but the community engagement, education is never budgeted for and there's no mechanisms for funders to bypass a research proposal and give capacity to community … there's always that end relationship between funders and research team, but not between funders and community.

Enacting MIPA through long-term relationships

Within the workshop, discussions were held about strategies to develop collaborative relationships between researchers and community members (see Table 3 for a summary). Workshop participants felt that MIPA is unlikely to be achieved if it is considered only on a project-by-project basis rather than as a longer-term relationship between PLHIV/community and researchers or research teams/laboratories. This was described by one workshop participant who stated:

> Years and years of collective wisdom that we can draw on [tells us] that these relationships should be built up over years – relationships between labs, individual researchers, community and funders. These take years to build.

Community involvement on one project may not be enough to ensure a culture of collaboration and mutual input. Ongoing relationships foster confidence and collegiality which is required for solid working relationships, particularly when community members may lack experience or confidence in a research environment. Ongoing relationships also facilitate informal networking and sharing of ideas, which are core to the research process. One workshop participant explained this, saying:

> [We] always talk about the importance of broader community engagement prior to the research, but the reality is that research ideas are organic. It starts off as an idea and it grows in someone's mind and they then discuss it with someone else, refine the concept on paper, then it grows into a submission.

Although research ideas often grow organically, workshop participants emphasized the need to adopt a long-term vision for community involvement as this can foster mutual trust in HIV cure-focused research. See Table 3 for details on strategies to enact MIPA principles in HIV cure-focused research. These strategies were identified by workshop participants and through data analysis and observations by the research team.

Discussion

At the heart of meaningful PLHIV/community involvement in HIV cure-focused research is mutual respect and a commitment to achieving genuine collaborative work between researchers and PLHIV/community stakeholders.[3] This goal is often shared by all stakeholders, as evidenced by the range of professional and community representatives who attended our workshop. Researchers, basic scientists and clinicians were eager to learn more about ways to build collaborations with PLHIV and other community stakeholders. Despite these intentions, the workshop highlighted some barriers that may make it difficult to enact MIPA principles in HIV cure-focused research, including cultural barriers within research institutions.

A major theme in our workshop was the ways in which community involvement in research is undervalued, both financially and with regard to limited provision for community stakeholders to influence the research process. Commitment to involving PLHIV/community in

Table 3

Strategies for enacting MIPA in HIV cure-focused clinical studies (INSPIRE simulation workshop, 2019).

Themes	Key Findings	Considerations
Stakeholder roles and relationships	• Meaningful involvement of PLHIV and affected communities is not the same thing as community engagement, attention should be placed on both engagement and involvement. • Community engagement is not only a recruitment strategy, it should involve and engage dialogue that values bi-directional education between community members and researchers. • Decision-making power and authority should be afforded to community stakeholders. • Research teams should provide community education about HIV cure-focused research to encourage MIPA.	• Bidirectional educational strategies in place to ensure community members have a basic understanding of the science and that researchers understand community perspectives. • Community stakeholders must review research protocols, participant information and informed consent documents while they are being developed and again when they are finalized or amended. • Community members who have historically lower rates of participation in trials, and lower representation in advocacy networks should be engaged. • Trial protocols should allow for comments and concerns from CABs to be heard and acted on. • PLHIV/community members involved in research should be aware of the extent to which their advice can influence a trial. • To ensure representation across a diverse cross-section of PLHIV, both community stakeholders and researchers hold responsibility to be cognizant of the 'voices' not represented. This should be acknowledged formally at the outset of the research process.
Valuing community expertise and knowledge	• Involvement on CABs or other forms of PLHIV/community involvement in research can be a significant time commitment that often receives minimal remuneration. • Advice and comment from community members on research protocols and design are often sought too late. • PLHIV/community members feel undervalued if the advice they provide is easily overridden. • Advocates who have previously participated in HIV cure-focused research are a source of information for clinical researchers and potential trial participants.	• Research teams should invest in social research which documents – and produces evidence for – the impact of MIPA on research outcomes. • Funding bodies should be encouraged to insist on collaboration with community as part of research and to adequately fund MIPA strategies. • Researchers should ensure adequate funding for MIPA, including remuneration of PLHIV/community advisors at a rate commensurate with that paid to external consultants for skills and experience or full inclusion as a co-investigator and co-author on research outputs. • Research teams should recognise and appreciate the value of community expertise in supporting the study process. For example, peer navigators can assist with recruitment and guide trial participants through

(*continued on next page*)

Table 3 (*continued*)

Themes	Key Findings	Considerations
		the trial process. They can also assist with incorporating trial participant perspectives into final reports on research findings. • Trial participants should be given the opportunity to speak publicly about their experiences as a community engagement strategy and as a means of demonstrating value placed on their perspective on the research process.
Building the long-term relationship	• Research ideas should be developed through informal as well as formal processes. MIPA will best be supported by ongoing formal and informal networks and relationships between PLHIV, the community sector and the HIV research sectors. • Community involvement is not something taught in a science degree, nor is it something basic scientists will always consider to be part of their job. • Regular workshops (such as the INSPIRE simulation workshop) can bring together researchers and communities allowing for the generation of new research ideas/ collaborative projects and can help participants appreciate each other's perspectives. • Trials can run for a long time, and reports on findings should be presented in the interim to maintain community engagement.	• Community involvement and engagement in HIV cure-focused research could involve initiatives that bring people together and create conversations between researchers and PLHIV/community members. These can be informal and not necessarily focused on a particular piece of research. The aim is for people to meet and feel more confident engaging in formal and informal discussions about HIV cure-focused research. Workshops, such as the INSPIRE simulation workshop reported on here, support MIPA in HIV cure-focused focused research, even though they are not part of one particular project or trial. • Senior researchers should mentor younger or early-career researchers and engage them in community partnerships to ensure the value of these partnerships is recognized and fostered over time. • Research teams should empower and acknowledge community members as co-authors in research. • Utilisation of non-academic means of communication to report research findings, including lay summaries on public forums, news media and community websites will improve community knowledge and understanding of research to foster confidence among PLHIV/community members to engage with scientists in conversations about HIV cure-focused research. • HIV clinicians/care providers and community advocates play an important role in bridging a gap between scientific researchers and PLHIV/ community members, and should be appropriately supported to play this role.

PLHIV, People Living with HIV; MIPA, Meaningful Involvement of People Living with HIV and Affected Communities; CAB, Community Advisory Board.

HIV scientific research was achieved via a strategic and politicized approach by activists in the 1980s and early 1990s, who challenged institutional and structural exclusion of 'lay people' from governance of clinical trial protocols, ethics and research funding.[2] As Steven Epstein[2] writes:

> Perhaps the most striking feature on the landscape of AIDS politics is the development of an "AIDS movement" that is more than just a "disease constituency" pressuring the government for more funding, but is in fact an alternate basis of expertise (page 8).

This history means that, today, the ethical and political value of MIPA in HIV-related research is supported by key institutions such as the International AIDS Society.[5] Nevertheless, involving PLHIV/community members in research is not necessarily standard practice and MIPA still goes against the cultural grain of academic or scientific institutions.[9] This point has been noted as a barrier to community and peer-based participation in other research settings.[9,29–32] Ensuring community stakeholders have genuine investment in, and oversight of, a study requires a level of power sharing between researchers and community stakeholders.[10] However, researchers based in academic institutions intrinsically hold greater power than lay researchers due to entrenched cultures of hierarchy in universities and institutional processes that often do not allow researchers to share responsibility for research funding with community-based organizations or individuals.[9,10] Challenging such power imbalances requires a high level of reflexivity and conscious effort on behalf of researchers.[10]

Biomedical and scientific researchers generally do not receive training in community engagement or involvement and may not see this as part of their role.[9,10] Enactment of MIPA principles in HIV cure-focused research will therefore require advocacy by community organizations and senior researchers. Relying on research protocols to guide enactment of MIPA will not be effective without such advocacy to support cultural change. We outline strategies for enacting MIPA principles in Table 3. However, we argue that these strategies will be limited in their impact unless all stakeholders are willing to challenge processes that undervalue (financially and in practical terms) the role, expertise and knowledge of PLHIV and community members in scientific research.[10] There needs to be a politicized approach to MIPA, hence the title of this paper: there is a need for a revolution.

Drawing on 'lived experience' or subjective insight is not intrinsic to research methods in the biomedical sciences in the way it is in many social science studies.[27] It can be difficult to envision how community involvement will improve the outcomes of biomedical research, particularly experimental or early phase clinical trials. However, there are studies showing benefits. Community members may identify problems or inconsistencies in trials that may not be evident to researchers, or present a different perspective on ethical issues.[9] For example, recent studies on acceptability of HIV cure-focused trials showed that PLHIV assessed the risks and benefits associated with trial participation in different ways to clinicians and researchers.[13,19,33] The feasibility of embedding community participation into clinical trials has been tested in other settings. For example, Rosenthal and colleagues[28] successfully utilized community participatory research to support implementation of a cardiovascular health education trial. Their recommendations from this study concur with the findings from our workshop. Primarily, they found that effective community involvement in a clinical trial requires a flexible timeframe to allow space for community input. They also found it is important to ensure community members are engaged before the research protocol is finalized so they have capacity to provide genuine input and oversight. Investing in behavioral and social sciences to document the ways in which PLHIV/community perspectives add value to HIV cure-focused research may be a useful strategy to build commitment to MIPA in this field.

One strategy for advancing MIPA principles recommended by our workshop participants was a commitment to building long-term relationships between community stakeholders and researchers. These relationships are different to formal project partnerships. Instead they refer to networks of individuals and organizations (community and research) within the HIV sector through which people come to know each other. Such networks can be built through regular meetings or events at which people have opportunities to meet and talk formally and informally. This can build connections between individuals and between organizations, which may establish the groundwork for partnerships between research laboratories and community organizations. Knowing each other can enhance people's confidence to work together on specific projects and facilitate community engagement. The workshop model used in this project is an example of a strategy for generating discussion between a variety of stakeholders with the aim of build connections rather than planning a specific project.

There are some limitations and contextual issues to consider with respect to these findings. Firstly, the sample was small and may not reflect the views of all people in the HIV sector. We did not have the resources to facilitate more than one workshop. In addition, the Australian HIV sector is unique in that, since the 1980s, funding has been provided by successive state and federal governments to support government, community and research sectors and to build cross-sector collaborations to enact HIV prevention and care initiatives across Australia.[34–36] This 'partnership' approach to public health has been central to the success of the Australian HIV response [36], resulting in a relatively well-resourced HIV community sector who can mobilize to engage with HIV cure-focused science.

Conclusions

Achieving meaningful involvement of PLHIV and affected communities in HIV cure-focused research requires a shift in thinking across the HIV and clinical research sectors to accommodate better understanding of the value of MIPA for scientific research. MIPA will not be achieved by research protocols alone given many barriers to meaningful engagement are culturally embedded and often invisible in formal structures. Challenging these barriers requires high-level commitment from research and community organizations supported by funding that translates commitment to MIPA into investment. Investing in research to build evidence for how MIPA improves the quality of research would support this. As researchers in the field of HIV, with highly engaged community advocacy organizations, we are well positioned to do this readily, and lead the way for other fields of clinical research.

Authorship

The community workshop was designed, developed, and facilitated by all authors (J.S.Y.L, M.Z.S, B.A, A.T.Y, K.D. and J.P.). J.S.Y.L, M.Z.S, A.T.Y, K.D. and J.P. analyzed the data. J.S.Y.L, M.Z.S, and J.P wrote the paper. All authors read and approved the final manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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