DEBATING ETHICS IN HIV RESEARCH: GAPS BETWEEN POLICY AND PRACTICE IN NIGERIA

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ABSTRACT

HIV prevention is a critical health issue in Nigeria; a country that has one of the worst HIV epidemic profiles in the world. With 270,000 new infections in 2012, Nigeria is a prime site for HIV prevention research. One effect of the HIV epidemic has been to revolutionalise ethical norms for the conduct of research: it is now considered unethical to design and implement HIV related studies without community engagement. Unfortunately, there is very little commensurate effort in building the capacity of local persons to engage actively with researchers, and there is no existing platform to facilitate dialogue between researchers and communities engaged in research in Nigeria. In an effort to address this gap, we undertook a series of three community dialogues (Phase One) and two community-researcher interface meetings (Phase Two) in Nigeria. This paper aims to give an empirical account of the dialogue from these community engagement processes and provide a resulting critique of the implementation of research ethics practices in Nigeria. It is anticipated that the outputs will: (i) support researchers in designing community-based research protocols; (ii) inform ethics committees of key considerations during research protocol reviews from a community perspective; and (iii) inform policy makers and research sponsors about issues of primary concern to communities with respect to HIV research.

INTRODUCTION

HIV prevention is a critical health issue in Nigeria. The country is one of the most HIV-affected nations in the world with a burden second only to South Africa.[1] Sexual transmission of HIV accounts for about 80% of HIV infections in Nigeria,[2] and condoms remain the only established, readily available measure for prevention of new infections. Condom use with casual partners is estimated at 98% among female sex workers (FSW), 62% among injection drug users (IDU) and 52% among men who have sex with men (MSM).[3] In the general Nigerian population, condoms are used by less than 40% of sexually active men and women.[4]

With 270,000 new infections in 2012,[5] Nigeria is a prime site for HIV prevention research. Understanding

[1] Joint United Nations Programme on HIV/AIDS (UNAIDS). UNIADS Report on Global AIDS Epidemic. 2012.
[2] National Agency for the Control of AIDS (NACA), Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Bank. Modes of HIV transmission in Nigeria: analysis of the distribution of new infections in Nigeria and recommendations for prevention. 2009, 2010.

[3] Federal Ministry of Health, Nigeria. Integrated Behavioural and Biological Sentinel Survey. 2010.
[4] Federal Ministry of Health, Nigeria. 2012 National HIV and AIDS and Reproductive Health Survey (NARHS Plus). 2013.
[5] Federal Ministry of Health, National Agency for the Control of AIDS, Joint United Nations Programme on HIV. 2012 Nigeria HIV Estimates, Spectrum. 2013.

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Conflict of interest statement: No conflicts declared

sexual practices as linked to national epidemiological profiles is vital to the national HIV prevention response. One important response to the epidemic is to concentrate resources in identifiable populations who carry the heaviest burden of HIV infections. For Nigeria, these populations include MSM, FSWs, and IDUs. Together, these high-risk groups constitute 3.4% of the general Nigerian population, but account for 40% of the HIV burden.[6] At the same time, 80% of new infections occur through heterosexual transmission.[7]

The HIV epidemic has generated a revolution in the field of health research ethics.[8] Specifically it is now considered unethical to design and implement HIV related studies in host communities without in-depth consultation with critical stakeholders such as local authorities, NGOs, advocacy groups, and research participants a process described as community engagement.[9] The

UNAIDS and The Global Advocacy for HIV Prevention (AVAC) developed the Good Participatory Practice guidelines document (GPP) that details expected engagement processes with communities as well as mechanisms that give communities opportunities for input throughout the lifecycle of clinical research.[10] The Nigerian National HIV Research Policy also promotes active engagement with targeted communities in the design, implementation and monitoring of HIV research. Specifically, section 6.2 of the policy notes, as part of its ethical framework for HIV research implementation, that researchers should 'ensure that HIV and AIDS research protocols have well defined formal mechanisms such as a Community Advisory Board (CAB), which engages and consults the community in study design, implementation, monitoring, information and result sharing'.[11]

However, it is likely that only about 10% of the research conducted in Nigeria receives ethics approval. Community members are increasingly interested in being consulted in the design, implementation and monitoring of the growing number of research projects.[12] As of October 15, 2012, there were 45 clinical trials registered in Nigeria on the Clinical Trials.gov website;[13] and it is likely that only about 10% of the research conducted in the country receives ethics approval. In terms of HIV/AIDS research, the country has hosted multiple studies involving populations most at risk for HIV infection (MSM, IDU, FSW) since 2000. These include one phase 1 cellulose sulphate microbicide study, one phase IIb cellulose sulphate microbicide study and one phase IIB SAVVY microbicide study; a phase IIb HIV tenofovir pre-exposure prophylaxis study,[14] two Integrated Biological and Behavioural Sentinel Survey studies,[15] mapping and size estimation of MSM, IDU, FSW and

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[6] NACA/UNAIDS/World Bank. *Op. cit.* note 2.

[7] Ibid.

[8] Major changes in HIV and AIDS health research ethics began in June 1994, when a World Health Organization meeting convened to create a research agenda for perinatal HIV transmission. Scientists concluded that placebo controlled trials offer the best option for treatment assessment. This decision sparked an ethical debate over the use of placebo and established standards of care in international clinical trials. Subsequent trial designs were based on new placebo standards. Lurie and Wolfe (1997) claimed that 15 out of 16 of the new trials were unethical. They argue that decisions on the standard of care were not based on available alternative treatments or previous clinical data, but rather on the policy of governments whose economy makes it difficult for them to afford the prices of drugs (Lurie and Wolfe 1997, 855). Since this claim, a number of researchers have debated ethical standards in clinical research (Angell 1997, 2000; Bayer 1998; Benatar 2001; Botbol-Baum 2000; de Zulueta 2001; Lurie and Wolfe 1999; Shapiro and Meslin 2001; Schuklenk and Ashcroft 2000; Temple 2002; Varmus and Satcher 1997). The Helsinki Declaration updated in 2000 took a stance and set a standard for care equivalent to that of the country conducting the research rather than the host country. Just four years later, Kent et. al. (2004) found that out of all the HIV, tuberculosis and malaria-related clinical trials conducted between January 1998 and November 2003 in Sub-Saharan Africa, only 16% provided care that met recommended ethical guidelines. In October 2013, the Helsinki Declaration was revised again to increase the protections of clinical trial participants. Specifically, research sponsors, research scientists, and host governments share increased responsibility toward research participants' safety and protection.

[9] Community engagement became a critical factor in HIV clinical research after the failure the early tenofovir pre-exposure prophylaxis trials that sparked intense and prolonged community debates and captured widespread attention in the international media and medical literature. See: L. Miller, M.O. Folayan, D. Allman, B. Nkala, L.M. Kasirye, L.R. Mingote, G. Calazans, R. Mburu, F. Ntombela & M. Ditmore. How Ethical is Your Clinical Trial. *International Journal of Clinical Practice* 2010; 64(9): 1179–1182; M.O. Folayan, L. Mutengu-Kasirye & G. Calazans. Participating in Biomedical Research. *JAMA* 2009; 302: 2201–2202; AVAC Community Consultations on Good Participatory Practice Guidelines. Partner Report-Back Meeting 30 April–2 May, 2009, Johannesburg. South Africa. New York: AVAC; 2009; Creating Effective Partnership for HIV Prevention trials: report of a UNAIDS Consultation, Geneva 20–21 June, 2005. AIDS 2006; 20: W1–W11.

[10] Joint United Nations Programme on HIV/AIDS (UNAIDS), AVAC. UNAIDS/07.30E/JC1364E. Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials. Second edition. Geneva: UNAIDS, 2011. Available at: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110629_JC1853_GPP_Guidelines_2011.pdf. [Accessed 5 May 2014].

[11] National Agency for the Control of AIDs, Nigeria. National HIV/AIDS Research Policy. 2010.

[12] Creating Effective Partnership for HIV Prevention trials: report of a UNAIDS Consultation, Geneva 20–21 June, 2005. (2006). AIDS 20: W1–W11.

[13] ClinicalTrials.gov. Clinical Trial Database. Website. Accessed October 15, 2012.

[14] Nigeria HIV Vaccine and Microbicide Advocacy Group. The challenges of developing new HIV technologies for HIV prevention: a situation report on research and development of new HIV prevention technologies in Nigeria. November 2004.

[15] Federal Ministry of Health, Nigeria *Op cit*. note 3; Federal Ministry of Health, Nigeria. Integrated Behavioural and Biological Sentinel Survey. 2007.

male sex workers population surveys[16] among others. Yet, despite the growing interest in conducting large HIV prevention research in the country, there is very little effort expended on building the capacity of local persons to engage actively in the field, and no existing platform to facilitate dialogue between researchers and communities conducting research in Nigeria.

Up until now, the focus on community engagement in research has been on reviewing research protocols in an effort to address community concerns. Such reviews enable ethics committee members or community advisory boards to identify and ultimately minimize culturally specific risks.[17] The place of dialogue has been conscribed to the negotiation of packages for study participants including standard of care for HIV prevention research.[18] However, dialogue that facilitates community engagement in health research however has other utility – it allows researchers and community representatives to gain shared understanding of project-related priority areas for intervention, enables communities to clarify the scope of the research project and project related procedures and terminologies and enables researchers to develop a relationship of mutual trust and understanding with the community in recognition of inequalities and power differences between international researchers and community members.[19] Community dialogue is one aspect of the community engagement process and a process widely used on health programming but less so in health research and clinical trials.[20]

In an effort to address this gap between existing extensive clinical research and a lack of mechanisms that facilitate trial dialogues, we developed and implemented a novel approach to community engagement in order to better understand ethical issues in HIV/AIDS. This included Community Dialogue events in three major cities in Nigeria (Phase One), leading to two community-researcher interface meetings (Phase Two) styled as 'Round Table' discussions. This paper aims to describe these processes and give an account of the main outcomes

so as to provide a linked critique of research ethics practice in general and HIV prevention research ethics practice specifically in Nigeria. It is anticipated that the issues raised in this paper will provide support to research stakeholders in Nigeria and other similar setting in three main ways: (i) it will support researchers in the design of community-based research protocols; (ii) it will inform ethics committees of key considerations to be taken into account during research protocols review from a community perspective; and (iii) it will inform policy makers and research sponsors about issues of primary concern to communities with respect to HIV research.

THE COMMUNITY DIALOGUE AND ROUNDTABLE EVENTS

Background to the Community Engagement Activities

The design of the community engagement activities described in this paper was developed at a one-day stakeholder meeting. Attendees included representatives from several organized communities, including men who have sex with men, female sex workers, people living with HIV/AIDS and injecting drug user. The group identified key gatekeepers and stakeholders working with the community to be engaged in the programme, based on their own and other colleagues' experiences.[21] Key gatekeepers were defined as community members who were often approached for community member recruitment during research or HIV programme activities to facilitate the participation of other community members. The one-day meeting focused on three prominent areas of concern in research ethics: informed consent, community engagement in research, and standard of care in HIV research. The meeting began with a Community Dialogue whose aim was to discuss and develop consensus on key issues within these areas of focus. Following the Community Dialogue was a Round Table meeting. In attendance were HIV/AIDS research stakeholders as well as representatives from the Community Dialogue events. The aim of this second meeting was to discuss the concerns and findings of the Community Dialogue and to incorporate them into ethical research practice. The Round Table events included stakeholders with experience of direct and indirect involvement with the conduct of HIV research among most-at-risk populations in Nigeria. These included policy makers, programmers, programme sponsors, researchers and ethics committee members. An

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[16] Population Council, Nigeria. Estimating the population of male sex Workers (MSW) in Nigeria using capture – recapture method. Available at: http://www.popcouncil.org/pdfs/2012HIV_Evidence-for-Action01.pdf [Accessed 5 May 2014]; Population Council, Nigeria. Formative Assessment and Geo-Mapping of Female Drug Users in Kano, Kaduna, Abeokuta, and Lagos, Nigeria. Available at: http://www.popcouncil.org/pdfs/2012HIV_Evidence-for-Action01.pdf [Accessed 5 May 2014].
[17] J.H. Moore. Native Americans, scientists and the HGDP. *Cult Survival* 1996; 20: 60–62.
[18] Joint United Nations Programme on HIV/AIDS (UNAIDS), AVAC. UNAIDS/07.30E/JC1364E. *Op. cit.* note 9.
[19] A. Vallely, C. Shagi, S. Kasindi, N. Desmond, S. Lees, B. Chiduo, R. Hayes, C. Allen, D. Ross. Microbicides Development Programme. The benefits of participatory methodologies to develop effective community dialogue in the context of a microbicide trial feasibility study in Mwanza, Tanzania. *BMC Public Health* 2007; 7: 133.
[20] Ibid.

[21] The Initiative for Equal Rights (TIER) and International Rectal Microbicide Advocacy (IRMA) works extensively with the LGBTI community; Safehaven and Lifelink works with FSWs; Positive Action for Treatment Access (PATA) works with PLHIV; and Christ Against Drug Abuse Ministry (CADAM) works with IDUs.

Table 1. Summary of participants at the Community Dialogue meetings

Place & Date	Participants
Lagos 28th June 2012	15 total: One community representative from Ibarapa (Oyo State) and Ifon (Ogun State) respectively[22] who are community leaders[23]; 11 representatives of FSW, MSW, MSM, PLHIV, IDU communities; one journalist and one layperson from an ethics committee that handles protocols of multiple national studies involving MARPs.
Osogbo 22nd August 2012	43 total: representatives of non-governmental organisations, programmers and policy makers engaged with HIV programming for MARPs and PLHIV in Osun State.
Abuja 11th September 2012	13 total: Four community representatives from the community hosting the NICCAV[24] project in Nigeria, eight representatives of MSM, FSW and IDU populations; one journalist; and one layperson from an ethics review committee that handles multiple HIV research related protocols that involve MARPs

important underlying aim of these community engagement activities was to develop a research advocacy agenda for partnering organisations in Nigeria, including wide dissemination of the outcomes of the Round Table events in the coming years.

Phase One: Community Dialogue

Table 1 provides a summary of the participants at the one-day Community Dialogue events held in the cities of Lagos, Osogbo and Abuja. These events lasted between 8 and 10 hours, often with evening meetings. Activities included information sharing, group discussions and plenary discussions. The first Community Dialogue meetings were held in Lagos and Abuja, and the findings from these events fed into discussions at the Osogbo meeting.

In all Community Dialogue meetings, the first two hours were used to share general information with participants on basic aspects of clinical research and key information on HIV prevention and treatment research, using a specially developed research literacy training guide. This guide covered the following topics: (i) what is research; (ii) why is research important; (iii) why should we care about research; (iv) payment for participation in research; (v) informed consent; (vi) confidentiality; (vii) HIV prevention: existing tools; (viii) HIV prevention: new tools; and (ix) community involvement in research.

The remainder, and main part, of the one-day dialogue focused on sharing background information and discussing participants' experiences as research participants or recruiters of research participants, and their perceptions on three key areas – informed consent, standard of care for HIV research, and community engagement in research – as three separate sessions. Each session was introduced through a short plenary talk, followed by group discussions in which participants were asked to share their experiences as research participants or recruiters of research participants, identify priority issues and put forward their recommendations. All groups presented the highlights of their discussions in a plenary discussion. Throughout the day, discussions were managed by a facilitator, who was a member of the New HIV Vaccine and Microbicide Advocacy Society

(NHVMAS),[25] and issues discussed were recorded by a note taker. At the end of the community dialogue, the note taker and representatives of the group developed a summary of the consensus reached during the discussions, which was presented to and agreed upon by participants at an evening meeting. The consensus statement was presented at a subsequent Round Table meeting.

Phase Two: Round Table Meetings

Two round table meetings were held immediately after the community dialogue events in Lagos and Abuja. Present at the meetings were all the community representatives who participated in the preceding Community Dialogue and invited researchers, ethicists, academicians, programmers, representatives of government research regulatory agencies, and policy makers and other stakeholders who were directly linked to HIV prevention and treatment research.

At the meeting, community representatives shared the consensus statements reached during the prior day's

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[22] Ibarapa is the research community for medical and dental health projects for the School of Medicine and Dentistry, University of Ibadan and Ifon is the research community for the dental school of the University of Lagos.

[23] Gatekeepers in this context mean local community leaders. These include chiefs and community heads with whom researchers will often meet to take permission to work with the local geographical communities. All communities in Nigeria have such communities. The gatekeepers for the four research communities are to be engaged in this project.

[24] The Nigeria Canadian government funded HIV Vaccine demonstration project titled' Creating a common platform for HIV vaccine research and HIV care and treatment program'. This is popularly called the NICCAV project.

[25] The New HIV Vaccine and Microbicide Advcacy Society (NHVMAS) was established in 2003 by Nigerian scientists and activists to ensure proactive and early involvement of the Nigerian Government and its citizens in the research and development of new HIV prevention technologies. It operates as a non-governmental organisation with a mission to contribute to the prevention of HIV infection by promoting a supportive environment for the conduct of research and development of new HIV prevention technologies.

discussions. All participants extensively discussed the issues raised. Finally, consensus was reached on how best to address the gaps identified with the informed consent process and community engagement in research. The groups also identified key issues to take forward for wider dissemination to national audiences like research institutions, HIV implementing partners, regulatory agencies, academic institutions, teaching hospitals, medical centres, ethics committees, policy makers, CSOs, research funding agencies, and other identified relevant agencies.

OUTCOMES OF THE COMMUNITY DIALOGUE AND ROUND TABLE MEETING

In this section, we describe the most important agreed-upon issues at Community Dialogue events that were then taken up at the Round Table discussions. The three target topics were informed consent, community engagement, and standard of care (Lagos only). We also present the main emerging recommendations from Round Table events in these three topics.

1. Informed Consent

During community dialogue events in all sites, many concerns were raised about the informed consent processes. Across all sites, many community representatives perceived that the current standards of consenting for research participation were low and, in many cases, reported that informed consent might not occur at all, increasing the risks of different forms of research misconduct. Round Table participants felt that research misconduct often disproportionately affected the most vulnerable participants, particularly those who did not understand their rights as participants. For example, it was noted that participants are sometimes asked to pay for research-related investigations. Research participants often agree to making payments because they are unaware they are participating in research; they assume the investigations are part of their health care package, and are not aware of their rights as research participants. Meeting members agreed that such misconduct would be less likely if research participants were made aware of their rights during consenting for research participation. Discussants at the Round Table event in Abuja noted that the tendency for such misconduct could be higher when research is funded by the principal investigator in comparison to research that receives external funding.

In all sites, many of the main issues raised during Community Dialogues were related to situations where recognised national and international policies and guidelines for ethical conduct in research were not fully imple-

mented *in practice*. The main areas taken forward from the Community Dialogues to the Round Table meetings provide illustrations of this perceived shortfall between policy and practice, summarised below:

Lagos:

- Researchers sometimes fail to implement consent processes, even when approved as part of the study protocol.
- Researchers overemphasize benefits and avoid talking about risks when providing information on studies during consent processes.
- Insufficient information is given about the purpose of research during consent.
- Highly technical language is used in consent forms which is difficult for many people to understand.

Osogbo:

- Researchers sometimes fail to implement consent processes.
- Participants are not given enough information about their right to not participate and their right to withdraw from research if they choose to do so.

Abuja:

- Negotiation of compensation often takes place during recruitment of participants rather than prior to protocol approval.

As a result, in all sites a key recommendation from the Round Table events was that Ethics Review Committees should strengthen their capacity to monitor research they approve – including monitoring of informed consent – to reduce the risks of research misconduct, in line with the National Health Research Ethics Code.[26] As noted by a member of staff of a research regulatory agency in Nigeria:

> *The process of informed consent is still challenging in Nigeria. Sometimes during clinical trial monitoring visits, we find irregularities concerning the process of informed consent. Although researchers are required to have the informed consent in the local language, this is not often the case. The adequacy of informed consent is supposed to be addressed by the ethics committee while the National Agency for Food and Drug Administration and Control [NAFDAC] looks at the scientific aspect of the research. We see informed consent forms approved*

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[26] Federal Ministry of Health, Nigeria. The National Code for Health Research Ethics. Version 7.0. Available at: www.nhrec.net [Accessed 5 May 2014].

Table 2. Site specific recommendations for informed consent processes from Round Table Events

Site	Recommendations
Lagos	• Informed consent forms should more clearly contain information on the goal of the research, procedures and schedules, study duration, compensation, confidentiality/anonymity, the risks and benefits associated with study participation, the study product if any, and the voluntary nature of the project.
	• There should be increased efforts to train researchers on the importance of the informed consent, and how to conduct the informed consent process. Particular issues were the rights of participants to withdraw without fear of penalty or discrimination; and ensuring the benefits and risks/burdens of research were accurately described.
	• Training plans for research field workers should be assessed by ethics committee to ascertain their competency to be able to administer consent.
	• Informed consent forms should be available in local languages for ease of understanding; verbal translation of English to local language is not acceptable
	• Communities should have access through simple communication systems to voice their concerns, including requests to withdraw from research.
	• When participants withdraw from studies, there must be assurance that all the data related to the individual is withdrawn.
Abuja	• There is a need to create a regular platform for communities and researcher dialogue. This will also help ethics committee identify community concerns and how to address this when reviewing research protocols.
	• Ethics committees have the responsibility to educate their communities about their role and responsibility in research.
	• Research protocols should include timelines for planned project implementations so as to enable ethics committee assess the adequacy of time allocated for study implementation. This will reduce the tendency to compromise on proper study implementation processes when they are faced with pressure of time for project completion

by ethics committees and wonder if the protocol was critically appraised.

From the subsequent Round Table discussions on informed consent, the main recommendations highlighted the importance of:

i) Strengthening training on informed consent processes for researchers and field workers, including highlighting the importance of voluntariness;

ii) Ensuring that information given during consent is sufficiently comprehensive to support informed choice for research participation, in terms of content and language;

iii) Setting up easily accessible communication mechanisms within study communities through which research participants and other community members could ask questions, discuss issues, and get concerns efficiently communicated to research teams;

iv) More detailed project implementation timelines need to be included in study protocols. Ethics review committees need to check if sufficient time and resources have been invested for study implementation so as to prevent compromising the informed consent process during study participant recruitment.

See Table 2 for a summary on the discussion on informed consent.

2. Community Engagement

Across Community Dialogues and Round Table events, there was much discussion around community engagement[27] in research. During Community Dialogue events at all sites, it was agreed that:

i) There is inadequate community engagement pertaining to the design, implementation, monitoring and evaluation of research that involves them.

ii) One form of inadequate community engagement is based on a common misconception amongst researchers that Civil Society Organisations (CSO) are broadly representative of 'communities' and provide a reasonable means of recruiting and communicating with community members, a practice that should be discouraged.

iii) Research updates and outcomes are poorly disseminated to communities and individuals involved in research.

iv) There is very little effort made to strengthen general research literacy amongst communities who participate in research, so that community members are only able to respond to the information specific researchers share with them.

v) Community engagement is often too heavily focused on gaining access to community members for purposes of recruitment into studies.

[27] In these discussions, the word 'community' referred to the specific 'sub-group' (e.g., men who have sex with men [MSM] or sex workers) and/or geographic community from which trial participants will be drawn (K West Slevin, M Ukpong & L Heise. Community Engagement in HIV Prevention Trials: Evolution of the Field and Opportunities for Growth. Aids2031 Science and Technology Working Group, No 11, November 2008:3). Community engagement means involving these communities hosting research trials in the research decision-making process.

A key underlying theme across these issues related to the extent to which community members' and communities' interests are adequately considered by researchers given 'low levels' of engagement. Speaking to the low investment in promoting general research literacy within communities, a community representative noted:

Researchers must create a level ground to enable them to relate and communicate with the community. They should change the mindset that the community does not know or cannot understand the science of research [and] hence they do not need to be engaged in the research processes.

Similarly, it was seen that community engagement should aim to ensure that research projects address local needs. In the words of community representatives during Community Dialogue:

'Researchers have to advise funders of research projects on issues that are of importance to the Nigerian community and not just implement what is of importance to foreign donors in Nigeria'

'Most of the operational/implementation research in our community is initiated by foreign partners and does not allow for local context. What are we doing about this?'

Specific concerns from each of the Community Dialogue sites that were also discussed at the Round Tables are summarized below:

Lagos:

• Research protocols often show no evidence of community involvement yet ethics committees approve them nonetheless.
• Ethics committees do not monitor research studies they approve to ensure that community engagement happens in the field.

Osogbo:

• Researchers make poor efforts at identifying communities representatives to work with during research programmes.

Abuja:

• Minimum community engagement occurs at the design stage of the research, but extensive engagement during the implementation.
• Police officers should be considered as members of Community Advisory Boards constituted for research involving vulnerable communities.
• Where CSO are formally engaged on projects, Terms of References are not drawn up to guide their work.

The main recommendations made by participants at the Round Table discussions were that:

i) Community engagement should happen throughout the lifecycle of research – from the design to the dissemination stage in line with the requirements of national health research ethics codes and national HIV research policies, and should involve a wide range of community stakeholders.
ii) Both formal and informal ways of engaging with community members are important. An example of a formal approach is for researchers to develop a Memorandum of Understanding (MOU) with representative community members that can be submitted to ethics review committees as part of study protocols.
iii) Study protocols should always include information on how research updates and findings will be communicated to participants and participant communities.
iv) Recruitment of research participants should be done by trained research team members, although other community based groups can be involved in providing information to the community about the research.
v) Although CSO should not be primarily involved in recruitment of participants in studies, these organisations can play a key role in promoting research literacy.
vi) Research regulatory agencies should interact with research communities during their monitoring visits to evaluate level and efficacy of community engagement in the research projects.

3. Standard of Care

The issue of standard of care was only central to discussions by community representatives in Lagos State. In this section, we describe the two main issues emerging from Community Dialogue and Round Table discussions in Lagos.

i) *Differences between national and international standards of care*: Community Dialogue participants raised concerns about differences between national and international standards of care for HIV prevention and treatment research. Standard of care in HIV prevention and treatment research in Nigeria are only required to conform to national research ethics guidelines, which describe standards that are often lower than those in other countries and those obtainable in Nigeria. At the Round Table discussion, it was agreed that national and global standards should both be considered in developing the care package for research participants in Nigeria. A particular importance for this policy was seen in the

ability to 'rachet up' standards of care for HIV/AIDS more generally in the country over time, as research feeds into policy.

ii) *Researchers' responsibilities for participants' health care*: Community Dialogue participants raised concerns that study participants are sometimes asked to bear the costs of managing illnesses that develop during the course of studies with a long duration. They also felt that participants engaged in HIV treatment (antiretroviral therapy) research should have continued access to drug therapy after completing or voluntarily withdrawing from studies. Participants in the Round Table events agreed on the importance of researchers planning in advance to manage all forms of foreseeable research related injuries, including those described in the study protocol and the consent form; researchers should adequately discuss this issue with study participants. Further, Round Table participants considered it morally important that researchers support participants in treating other chronic illnesses occurring during clinical trial participation as much as possible. One reason discussed was the difficulty community members have in distinguishing between 'research-related' and 'non-researcher-related' illnesses, leading to loss of trust and difficulty in conducting studies. This has led to researchers being viewed by participants as unreasonably ignoring their responsibilities.

DISCUSSION

In this paper, we set out to describe a relatively novel process of community engagement undertaken in three major cities in Nigeria that included a range of important research stakeholders for HIV/AIDS research. In doing this, we aimed to highlight the main issues perceived by community groups in the areas of informed consent, community engagement and standard of care; and to describe the outcomes of discussions between community groups, researchers and other HIV/AIDS research stakeholders on these issues. In this discussion, we focus on four related areas emerging from the process overall. Firstly, we underline the importance of perceptions of a gap between policy and practice in relation to 'implementation' of research ethics policies on the ground, and its relationship to risks of different forms of research misconduct. Secondly, we recognise the potential for greater engagement of communities to contribute to closing this gap between policy and practice, as seen by participants in these discussions, while noting some challenges for these ideas from the literature. Thirdly, we discuss some implications of the views raised on standard of care for research on HIV/AIDS. Finally, we comment on our experiences of using the community engagement approach described in this paper, although a formal evaluation of the process was not planned as part of the activity.

Gaps between Policy and Practice

Perceptions of gaps between policy and practice in ensuring ethical conduct of research in Nigeria were described in two ways; through poor adherence of researchers and other research staff to guidelines on the ethical conduct of research, and through inadequate oversight of studies by national regulatory bodies with responsibility for the ethical conduct of research. In fact, issues in adherence to research guidelines is directly suggested by the fact that many of the ethical issues raised during Community Dialogues are already covered by many existing ethical guidelines, including those developed in Nigeria. At the same time, the National Health Research Ethics Code[28] that governs the activities of ethics committees in Nigeria clearly stipulates a role for ethics committees in providing regulatory oversight for researchers and for ensuring community engagement in research.

Gaps between policy and practice were seen as particularly important in HIV prevention and treatment research, with high risks of research misconduct linked to the fact that participants are often stigmatised, vulnerable and/or disempowered. While past HIV prevention trials conducted in Nigeria have recruited FSW,[29] the Nigerian legal system is unsupportive of the rights of MSM, IDU and FSW,[30] limiting their ability to seek redress for injustices related to these forms of high risk behavior. Worldwide, HIV prevention trials have included IDUs, MSMs and other high risk groups who often face similar forms of discrimination and stigmatization;[31] as would also be

[28] Federal Ministry of Health, Nigeria *Op. cit.* note 14.

[29] V. Halpern, F. Ogunsola, O. Obunge, C.H. Wang, N. Onyejepu, O. Oduyebo et al. Effectiveness of cellulose sulfate vaginal gel for the prevention of HIV infection: the prevention of HIV infection: results of a Phase III trial in Nigeria. *PLoS One*. 2008; 3(11): e3784. doi: 10.1371/journal.pone.0003784; P.J. Feldblum, A. Adeiga, R. Bakare, S. Wevill, A. Lendvay, F. Obadaki, M.O. Olayemi, L. Wang, K. Nanda & W. Rountree. SAVVY vaginal gel (C31G) for prevention of HIV infection: a randomized trial in Nigeria *PLoS One* 2008; 23; 3(1): e1474. doi: 10.1371/journal.pone.0001474.

[30] The section 214 and 215 of the Nigerian Criminal Code criminalises homosexuality and commercial sex work. This contravenes the section 35(1) of the 1999 constitution which provides that 'Every person shall be entitled to his personal liberty and no person should be deprived of such liberty . . .'

[31] K. Choopanya, M. Martin, P. Suntharasamai, U. Sangkum, P.A. Mock, M. Leethochawalut et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013; 381(9883): 2083–90. doi: 10.1016/S0140-6736(13)61127-7. Epub 2013 Jun 13; R.M. Grant, J.R. Lama, P.L. Anderson, V. McMahan, A.Y. Liu, L. Vargas, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010 Dec 30; 363(27): 2587–2599. doi: 10.1056/NEJMoa1011205. Epub 2010 Nov 23.

likely for research involving these key populations in Nigeria. Despite extensive and active ongoing efforts in the country to build the capacity of ethics committees, their ability to ensure that research approved by the committees are monitored has been recognized as a continuing challenge.[32] Given the importance of HIV and AIDS research and the particular legal and social vulnerabilities of populations likely to be involved in these studies, it is important to give particular attention to building the capacity of ethics committees to review and monitor research in this area, including the plans for community engagement and on-going evidence of its implementation.

Communities' Contributions to Closing This Gap between Policy and Practice

Participants in these discussions emphasized that community engagement should support stakeholders in identifying unethical practices as well as adequately resolving them. These views are particularly important given challenges for ethics committees in providing sufficient research oversight functions, as described above. One important form of community engagement recognized in these discussions was an effort to promote research literacy within populations likely to be involved in research, to counter low understanding of clinical research. An interesting element of these recommendations was the potential role of CSO's in Nigeria as *sustainable* and *independent* bodies in promoting research literacy. CSO are not-for-profit, non-governmental organisations operating in the public interest, seen as a 'third sector' of governance[33] and strongly developed in many Western European countries. Knabe and McCathy[34] and Koen et al.[35] identified the significant roles CSO can play in the politics of public health research. The same role of CSO in HIV treatment and prevention research is well recog-

nised.[36] Knabe and McCathy[37] described CSO's roles within the public health sector as mobilizing researchers and communities, supporting research themes, and lobbying to use public health evidence in policy and decision-making. While recognizing that 'third sector organizations' have also been critiqued, including for their potential to serve special rather than general or public interests,[38] it seems likely that CSO in Nigeria can play important roles in promoting community research literacy roles if they receive the needed education and support.

A further form of community engagement seen as essential in these discussions was consultation with the community. As also discussed in the literature,[39] participants advised that consultation should happen early in the research process; should occur during the design, development, implementation, and dissemination of research results; and the consultative process should occur in a sustained manner. The GPP,[40] the National Health Research Ethics Code,[41] the HIV Research Policy[42] and several other key documents[43] all address and promote the same practice.[44] At the same time, it is well recognized that community consultation is not a straight forward process either in theory or practice; these issues could not be explored in these discussions, given limitations of time and scope. Further discussion would

[32] A.J. Ajuwon & N. Kass. Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university. *BMC Med Ethics* 2008; 24(9): 1. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2246144/?tool=pubmed [Accessed 5 May 2014].

[33] A Ghaus-Pasha. Role of civil society organizations in governance. Sixth Global Forum on Reinventing Government Towards Participatory and Transparent Governance. 24–27 May 2005, Seoul, Republic of Korea. Available at: http://unpan1.un.org/intradoc/groups/public/documents/un/unpan019594.pdf [Accessed 5 May 2014].

[34] A. Knabe & M. McCarthy. Civil society organisations and public health research – evidence from eight European union new member states. *Cent Eur J Public Health* 2012; 20(4): 287–293.

[35] J. Koen, Z. Essack, C. Slack, G. Lindegger & P.A. Newman. 'It Looks Like You Just Want Them When Things Get Rough': Civil Society Perspectives on Negative Trial Results and Stakeholder Engagement in HIV Prevention Trials. *Dev World Bioeth* 2012 Sep 24. doi: 10.1111/j.1471-8847.2012.00338.x. [Epub ahead of print].

[36] K. West Slevin, M. Ukpong & L. Heise. Community Engagement in HIV Prevention Trials: Evolution of the Field and Opportunities for Growth. *Aids2031 Science and Technology Working Group*, No 11, November 2008.

[37] A. Knabe & M. McCarthy. *Op. cit.* note 27.

[38] M. Taylor & D. Warburton. Legitimacy and the role of UK third sector organizations in the policy process. *Voluntas: Independent Journal of Voluntary and Nonprofit Organizations* 2003; 14(3): 321–338.

[39] L. Miller et al. *Op. cit.* note 8.

[40] UNAIDS/AVAC. *Op cit.* note 9.

[41] The page 27 of the 2006 edition of the National Code of Health Research Ethics notes that Ethics Committees should protect communities participating in research from exploitation. It then further went on to state specific requirements of actions.

[42] National Agency for the Control of AIDs, Nigeria. National HIV/AIDS Research Policy. 2010.

[43] The page 109 of the National HIV/AIDS response review 2005 to 2009 published by the Federal Government in December 2009, identified community engagement in HIV/AIDS research throughout the entire phase of the research process as an emerging issue. It notes that policies that promote community engagement in all phases of research processes is welcomed; Page 55 of the October 2009 National HIV/AIDS policy review report notes that the current Food and Drug Regulatory Agency (NAFDAC) guidelines not facilitating community engagement efforts is a challenge and something that needs to be addressed. An actionable policy recommendation made was that '*host communities should be involved at every level of community based research.*'

[44] Of note, the 2002 CIOMS International Ethical Guidelines for Biomedical Research guidelines do not describe the principles of community engagement. As these guidelines are currently under review, we would strongly advocate that a full articulation of expected standards of community engagement should be included in the forthcoming version.

have been valuable in relation to challenges in the literature, including: identifying the 'community' itself; understanding who should represent a community in a process of consultation; ensuring that consultation is a genuine attempt to include the views of community representatives in fundamental decisions about research; and being clear about ways in which informed and balanced views from community representatives can be sought, given the technical and often complex nature of many studies and research ethics itself.[45] In relation to mechanisms, Round Table discussants promoted both informal and formal approaches for community consultation, including seeing formal mechanisms (such as MOUs) as likely to be important where negotiation between different research stakeholders was needed.

Standard of Care for Research on HIV/AIDS and Community Engagement

One area of community consultation recommended by UNAIDS/WHO guidelines is discussion and negotiation with communities about the standard of care provided to participants during studies. In this respect, community members in Abuja seemed more interested in discussing standard of care packages in the context of overall 'compensation' for study participants, while those in Lagos were more fixed on the need for local implementation of international standards of care, for both local and internationally-funded research. Findings in Lagos differ from the position on standard of care packages in resource-limited settings, which argues that use of local standards of care is acceptable in the conduct of international research.[46] In the Lagos discussions, community members argued that applying global standards of care during the conduct of local HIV research has an important long term potential to 'ratchet-up' the standards of care. This was seen as particularly true where community involvement in research is based on concepts of continuous mutual education and respect, partnership, and consensus-building to promote local ownership of research outcomes. This stance aligns with Benatar and Singer's[47] aspirational goal of promoting access for study participants to the highest achievable standards of care in research.

At the same time, there are concerns that the standard of care in HIV prevention and treatment research in Nigeria are only required to conform to national research ethics guidelines, which describe standards that are lower than those in other countries and those obtainable in Nigeria. This disparity at the national level resulted from a delayed revision of the national guidelines despite evolving evidence in the field. A good example is the national STI guidelines.[48] At the time of the meeting, the national guidelines for the management of STIs were last revised in 1996. The management of many STIs have since evolved and the practice in the field differs significantly from that defined by the national guidelines. In other words, practice can outstrip guidance documents in Nigeria, and this is a significant concern if the slow development and review of guidelines hinder access to obtainable (global) best practice.

As for community consultation on standards of care, discussions on the way that study participants should be compensated for their involvement in research are likely to be challenged by differences between researchers and community members' understanding of research aims and procedures. There are also likely to be different levels of awareness regarding research ethics guidelines including the importance of balancing risks of 'exploitation' of study participants against those of 'undue inducement'. Ensuring greater mutual understanding between different research stakeholders on these issues would help to ensure compensations packages are fair and objectively determined as much as possible, and avoid compensation being seen as payment for labour.[49] Where this happens, ethics committees may play a lesser role in determining compensation packages: a departure from a defined traditional role.[50]

Many community members believe that researchers are responsible for ensuring access to care for participants, including for chronic conditions. Such views are linked to standards of care and 'compensation' packages within a wider concept of 'fair benefits'.[51] This concept describes the value of considering study benefits that include those

[45] P.O. Tindana, J.A. Singh, C.S Tracy, R.E.G. Upshur, A.S. Daar, P.A. Singer, J. Frohlich & J.V. Lavery. Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. *PLoS Medicine 2007, 9, e273, pp1451–1455.* V.M. Marsh, D.M. Kamuya, M.J. Parker & C.S. Molyneux. Working with concepts: The role of community in international collaborative biomedical research. *Public Health Ethics* 2011; 4(1): 26–39 doi: 10.1093/phe/phr007.

[46] U. Schüklenk & D. Hare. Ethical issues in international research and multicentre studies. *Elec J Commun Inf Innov Health* 2008; 2: S19–S29; U. Schüklenk. The standard of care debate: against the myth of an 'international consensus opinion'. *J Med Ethics* 2004; 30: 194–197.

[47] S.R. Benatar & P.A. Singer. A new look at international research ethics. *BMJ* 2000; 321(7264): 824–826.

[48] Federal Ministry of Health, Nigeria. National Guidelines on the Syndromic Management of Sexually Transmitted Infections (STIs) and other Reproductive Tract Infections. 1996.

[49] M.O. Folayan & D. Allman. Clinical Trials as an Industry and an Employer of Labour. *Journal of Cultural Economy* 2011; 4(1): 97–104.

[50] The Ohio State University. Human Research Protection Program Policies and Procedures. Section 6D of the recruiting methods, recruitment materials, and participant compensation. Available at: http://orrp.osu.edu/irb/osupolicies/documents/RecruitingMethodsRecruitmentMaterialsandParticipantCompensation.pdf. [Accessed 5 May 2014].

[51] Participants in the 2001 Conference on Ethical Aspects of Aspects of Research in developing Countries. Fair benefits for research in developing countries. *Science* 2002; 298: 2133–2134.

given to study participants and study communities both during and after the completion of studies. These include structural benefits such as employment and capacity building. Further, the questions raised about study participants' rights to access forms of care not included in study protocols reflects a prominent debate in the literature on researchers' ancillary care responsibilities.[52] The GPP refers to this as non-HIV related care and encourages researchers to refer study participants for care. While ethical practices in HIV research recognizes the place for morally praiseworthy[53] efforts in research, decisions on the feasibility of including such care packages should take account of community views regarding the importance of these forms of ancillary care, prior to research budgeting. The responsibilities of researchers to provide such care has been seen as dependent on the prevalence and seriousness of the condition needing care, the availability of such care from other sources, the nature of the relationship (duration and intensity of engagement) between researchers and participants in particular studies, and the cost/resource implications, including for the conduct of similar studies in the future, and other research in the same community.[54] At the same time, provision of care for participants in studies can also generate ethical issues. For example, where clinical trials facilitate access to care and support services that might not otherwise have been available, this ease of access to much needed care can serve as a form of *soft coercion*.[55]

Model for Community-Research Dialogue

Finally, the authors determined that the community-research interface can be empowering for both community representatives and researchers when a platform for dialogue is created. Indeed, such opportunities to have such engaging discussions are rare. The informal 2-stage consultation method used in this community engagement activity was very much appreciated by researchers and community participants. The process created an opportunity for communities to become more research literate and for researchers to become more community literate; one of the key operational requirements identified for successful engagement of communities in research.[56] The authors however do not think that this single event is all that is required for empowerment of community members and researchers to enable both parties to address all ethical concerns with research design and implementation. Mechanisms need to be defined to promote and sustain dialogue between the two parties, the ramification of which is beyond the scope of this paper to discuss. Also, more discussion of this nature on both formal and informal methods for consultation are central to taking the issues identified through this consultation forward.

CONCLUSION

Facilitating platforms that promote community dialogue about the conduct of research in communities are important to shape critical discussions about ethical practices in research conduct. One critical outcome of this dialogue is consensus on a view that unethical practices have less to do with the multiplicity of ethical guidelines but rather, the ability of researchers to imbue the practice of ethics. Efforts therefore need to be invested in teaching and training researchers on ethical conduct of research in general and the ethics of HIV prevention and treatment research specifically. Additionally, for countries where human rights abuses are prominent, research community members need to be empowered to ask the right questions about research through support for and promotion of research literacy programmes.

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[54] Ibid.
[55] M.O. Ukpong & O. Akanni. HIV prevention clinical trial participation: incentive to participate, coercion to stay. 2nd INTEREST workshop, Senegal. May 23rd to 25th, 2008. (Abstract number 22); K. Oyedeji, M. Ukpong & O. Ezechi. Addressing coercion in the conduct of clincial trials on microbicides. Microbicide 2010, Pittsburgh, USA. May 22nd to 25th, 2010. (Poster Discussion 374).

[56] UNAIDS/AVAC. *Op cit.* note 9.

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