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Ethical Issues in a Stage 1 Cognitive-Behavioral Therapy Feasibility Study and Trial to Reduce Alcohol Use Among HIV-Infected Outpatients in Western Kenya

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Abstract

Epidemics of both HIV/AIDS and alcohol abuse in sub-Saharan Africa have spurred the conduct of local behavioral therapy trials for these problems, but the ethical issues involved in these trials have not been fully examined. In this paper, we discuss ethical issues that emerged during the conduct of a behavioral intervention adaptation and trial using cognitive-behavioral therapy to reduce alcohol use among HIV-infected outpatients in Eldoret, Kenya. The study was performed within our multinational collaboration, the USAID-Academic Model Providing Access to Healthcare Partnership. We discuss relevant ethical considerations and how we addressed them.

Keywords

HIV; AIDS; alcohol abuse; cognitive behavioral therapy; ethical issues; sub-Saharan Africa

With the overwhelming concentration of both HIV/AIDS and alcohol abuse (Ayisi et al., 2000; Seage et al., 2002) in sub-Saharan Africa and other low-resource settings, clinical trials for treatment and prevention of these dual public health problems have begun to be conducted in these nations. The U.S. National Institutes of Health (NIH) now funds a full portfolio of studies in sub-Saharan Africa focused on reducing these public health crises, including interventions to reduce alcohol use and sexual risk behaviors (National Institutes of Health, 2012). Concomitant with this shift in research is the need to attend to ethical

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issues inherent in this work. These issues include having few professional resources for treating maladaptive health behaviors, severe stigma toward those with alcohol use disorders and HIV infection, and issues of informed consent.

The ethical conduct of behavioral therapy trials in resource-limited settings has been largely ignored, in part because these trials have only recently been initiated (Wechsberg et al., 2010; Kalichman et al., 2008). The purpose of this paper is to examine the ethical considerations involved in a recently completed cognitive-behavioral therapy (CBT) feasibility study and trial to reduce alcohol use among HIV-infected outpatients in Western Kenya. To our knowledge, this is the first paper addressing unique ethical concerns associated with conducting a behavioral therapy trial focusing on substance abuse in sub-Saharan Africa.

SETTING

Kenya is a country in East Africa with 39 million citizens. HIV prevalence was estimated to be 7.4% in 2007, with female youth ages 15–24 at four times the prevalence of male youth (National AIDS and STI Programme, 2008). There are few professional resources in Kenya for treating alcohol use disorders; in 2005, there were 47 psychiatrists serving the entire country (Njenga & Kigamwa, 2005). In this setting, strong social networks support and strengthen communities (Ayuku et al., 2003). However, HIV stigma often breaks down social networks and results in discrimination, job loss, and rejection by families and communities (National AIDS Control Council, 2008). Additionally, women are treated as having a diminished cultural and legal status in Kenya. For example, polygamy is a common cultural practice permitted exclusively for men. Within Kenya, while many women drink alcohol, public consumption of alcohol by women remains somewhat stigmatized except within home breweries. Hence, women study participants were at particularly high risk for abuse due to stigma of HIV-infected status and alcohol use.

The Kenya Health Behavior Study

The Kenya Health Behavior Study was a feasibility and treatment adaptation Stage 1 (Rounsaville, Carroll, & Onken, 2001) randomized clinical trial (RCT) of group cognitive-behavioral therapy (CBT) to reduce alcohol use among HIV-infected outpatients (women n=38, men n= 37) in Eldoret, Kenya. The methods and results of this study have been described in detail elsewhere (Papas et al., 2010a; Papas et al., 2010b; Papas et al., 2011). The purpose of the project was to ascertain whether CBT, which has well-documented efficacy and durability for reducing alcohol use in Western settings (Kadden et al., 1989; Miller, Zweben, & Johnson, 2005; Project Match Research Group, 1997), could feasibly be adapted to the Kenyan culture, language, and group paraprofessional delivery. After cultural adaptation, counselor training and piloting, a small RCT was conducted to compare the CBT against an assessment-only condition among HIV-infected Kenyan men and women recently initiated on antiretroviral drugs (ARVs) or ARV-eligible who screened positively for hazardous or binge drinking (n=75).

Results showed that the CBT was significantly more effective than usual care in reducing number of drinking days and drinks per drinking day longitudinally through the 90-day post-treatment assessment. Further, participants reported in debriefings that they found the intervention acceptable and helpful (Papas et al., 2011). The pilot study is being followed by a large efficacy trial, which is currently under way. This study compares the CBT against a group health education intervention among 336 HIV-infected Kenyan outpatients who report hazardous or binge drinking. Participants are interviewed through nine months post-intervention.

The study was conducted within the USAID-Academic Model Providing Access to Healthcare (AMPATH) Partnership, a multinational service, teaching, and research consortium associated with Moi University and Moi Teaching and Referral Hospital in western Kenya (Einterz et al., 2007). AMPATH currently provides HIV care for more than 75,000 active HIV-infected outpatients in 25 clinics in western Kenya (Siika et al., 2005). This healthcare delivery system evolved as a result of a 20-year collaboration between the medical schools of Indiana University and Moi University. Brown University has been a partner in the consortium since 1997. Several issues emerged during the course of the pilot study that we describe below.

COMMUNITY INVOLVEMENT

Our initial alcohol intervention study was proposed following requests by chiefs during *barazas* or local community meetings with AMPATH representatives focusing on curbing the HIV epidemic. Chiefs had noted that alcohol interventions were needed to curb prevalent local use and associated sexual risk behavior. During our initial adaptation of the CBT, we also gained input from local residents who were HIV-infected, alcoholics in recovery, and local mental health professionals. The introduction of an alcohol intervention was heartily supported by local faculty at Moi University, by local residents whom we met, and by subsequent participants. We also invited the local chiefs to attend our community dissemination meeting of pilot study results and future interventions ideas. While several former participants were also in attendance, the male chiefs dominated the conversation. We recognized then that participants, particularly women, did not feel comfortable participating in the discussion. Hence, during the current efficacy study, we have secured the help of an experienced Community Advisory Board (CAB) to explain the study to the community, beginning during the recruitment phase. The CAB members include two HIV-infected lay individuals, a traditional birth attendant, two teachers, and an NGO member. They rotate to different villages in the community to disseminate information, attracting large audiences.

CONSENT ISSUES

The study did not require community entry *per se* as it was based in the outpatient clinic. Hence, we did not seek consent from community members before implementation. It is often culturally expected that women are permitted to consent only after prior authorization has been given by the male head of household. Such permission should always be sought in situations that involve household-based activities. In this trial, individual autonomy was considered to be paramount and permission was not sought from men. This was due to the possibilities that participants may not have disclosed their HIV-infected status to their spouses and since alcohol use can sometimes be concealed, particularly by women, due to stigmatization. Hence, it was left to each individual to decide whether to inform their spouses or other family members of their participation in the study. During screening, one eligible female participant reported that she wanted to discuss the study with her husband and did not return. No other female participants expressed any difficulty or distress with making decisions to consent. Indeed, 37% of participants reported not disclosing HIV to anyone. It is likely that alcohol abuse was also not disclosed to partners. This suggests requiring male consent for participation would have been a barrier to female enrollment.

During the consent process, we emphasized that HIV care would not be affected by refusal to participate. Indeed, 12% of participants refused participation (with no dominant reason), suggesting that participants felt comfortable with refusal. While verbal consent is sometimes considered appropriate within the Kenyan context (Sidle et al., 2006), written consent is generally still preferred in studies that involve more than minimal risk. While the overall risks of this study were small, investigators needed to consider both the physical risks of alcohol withdrawal among subjects and the potential psychological discomfort when

disclosing health behaviors. This study chose to employ written consent documents to ensure that risk/benefit aspects of the study were extensively outlined and understood by potential participants.

PATIENTS' RELATIONSHIP WITH THEIR HIV CLINICIANS

During our early discussions with peer counselors and participants, we learned that some HIV patients were apprehensive about disclosing their drinking behavior to their HIV clinicians. Peer counselors in a remote AMPATH clinic informed us that many participants disclosed drinking after the HIV clinician appointment, saying they denied drinking to their clinicians just minutes beforehand. In order to encourage alcohol disclosure to us, we interviewed participants *after* their clinician appointment. We also developed a policy that we would not disclose to clinicians about patient drinking behavior *unless* the patient agreed to be a participant in our study (in which case participants must agree to allow communication with providers over issues involving health such as withdrawal symptoms and hospitalization at outside clinics). We felt we could ethically do this because the first clinician encounter includes an assessment of alcohol use using the AUDIT-C, the same instrument in our study screening, although many patients did not necessarily disclose at that time (see below). Additionally, if a patient had endorsed alcohol use during the first visit, the record may not be immediately accessible to busy clinicians, who may not have seen the client on the first visit. Because we felt this aspect of confidentiality was important to patients, we added a comprehension check during the recruitment script. Before asking patients whether they were current drinkers, we asked patients to repeat back our policy not to inform clinicians.

As we felt the primary concern about confidentiality was associated with alcohol disclosure to HIV clinicians, we provided no other comprehension checks during the recruitment and consent process. During group debriefings, participants reported that this policy was helpful and also instilled trust to disclose. Participants reported various reasons for not disclosing alcohol use to clinicians— no resulting benefits (no available treatment besides detoxification), perceived negative consequences (e.g., treatment refusal), or lack of a relationship with clinicians.

For patients enrolling in the study, the informed consent procedure made it clear that clinicians might be informed of alcohol issues important to the participant's health. However, in practice this only occurred in isolated instances where withdrawal symptoms necessitated initiation of benzodiazepine treatment or were confused with other illnesses such as malaria.

DIFFERENT LEGAL STANDARDS FOR MENTAL HEALTH CARE

Another consideration related to confidentiality was the different legal standards related to mental health care in Kenya. In the United States, there are mandatory reporting laws for suspected abuse to children, the elderly, or disabled individuals, who are considered vulnerable populations. The requirement to report domestic violence against adults who are considered competent varies by state. There are also laws that vary by state allowing involuntary psychiatric hospitalization for individuals deemed to be at imminent risk of physically harming themselves or others. In Kenya, licensing is required only for physicians and no other mental health professionals (e.g., clinical psychologists). There is no legal protection of confidentiality and conversely no requirement for reporting suspected abuse of children, the elderly, or disabled individuals. There is also no law allowing involuntary hospitalization for individuals deemed to be at imminent risk of harming themselves or others. Attempted suicidality is a criminal offense in Kenya, and one who makes a failed suicide attempt may be brought to court before being referred for treatment (Laws of Kenya,

2001), although in practice this rarely occurs due to humanitarian concerns as well as the burden of paperwork. In place of required reporting for suspected abuse of children, the elderly, or disabled individuals or domestic violence, our policy was to follow local procedures to take action only if there is a visible injury present. In those cases, we could refer clients to the AMPATH legal center and/or to the local rape center. For those deemed to be at imminent risk of harming themselves or others, our policy was also to follow the local practice to encourage an inpatient stay, although not involuntary. Participants who endorsed the broad suicidal screening item of the PHQ-9 were referred to psychiatry. No issues of abuse or imminent self-harm were reported or observed during the pilot study. Participants appeared to freely disclose suicidal intent (reported to be passive suicidal ideation, which does not involve intent or a plan), as there were many referrals to psychiatry. Because we wanted to promote a broad perspective on mental health care, we also educated paraprofessional staff about how legal issues would be handled in the country of the study sponsor (e.g., therapist's privileged communication) (Papas, Belar, & Rozensky, 2004). Counselors were also required to keep therapy notes and clinical assessment records similar to U.S. standards (using study IDs).

PSYCHIATRIC SCREENING AND FOLLOW-UP CARE

There is limited screening for mental health issues in HIV primary care, although a weekly psychiatry clinic is available for referrals. Hence, our study mental health screenings (for depression, anxiety, and psychotic symptoms) provided additional benefits for those with general psychiatric symptoms. Those with positive screens were referred to psychiatry within the AMPATH clinic, which enabled free immediate psychiatric care, i.e., a diagnostic interview and psychotropic medications as necessary. During the study, several participants, mostly women, were diagnosed for the first time with bipolar disorder as a result of these screenings. No participants were excluded from treatment due to their identified psychiatric problems. Two psychotropic medications (antidepressant and antipsychotic medications) were available free at the AMPATH pharmacy. The study offered to pay for other necessary psychotropic medications on a limited basis; however, no participants required additional psychotropic medications during the pilot study. The study also assessed participants for withdrawal symptoms at every visit. A positive screen resulted in a referral to psychiatry and, if necessary, withdrawal symptom medications (benzodiazepines) or inpatient treatment, both provided for free by the study. Several participants required medications, but no inpatient stay was required.

APROACHES TO DIMINISHING GENDER BIAS AGAINST WOMEN

We recognized the diminished cultural and political status of women and sought to prevent reinforcement of this status in several ways. All study activities (survey interventions and study interviews) were gender-stratified. No collateral report of alcohol use was sought from significant others, a common method of verification, to prevent the possibility of violence against women. Counselor and staff training efforts included discouragement of gender bias. Predominantly female participants reported in debriefings that gender-stratified intervention groups were preferred, while men were indifferent. Clinical observations suggested that the gender-stratified approaches promoted disclosure and maintained focus on the intervention. Complacency toward violence and discrimination against women was expressed by some members of the team, and female counselors expressed beliefs that polygamy and gender bias were worldwide phenomena. Hence, additional education and team discussions were initiated around gender bias. New hiring policies were implemented requiring written essays and interview questions intended to reveal discriminatory attitudes toward women, substance users, and those who are HIV-infected. For example, counselor hiring essays provided facts about a fictitious client, then requested a case conceptualization of the issues and applicant ideas of how to address them.

STRATEGIES TO PROTECT PARTICIPANTS FROM FURTHER HARM

During early piloting, participants reported that if they were to refuse alcohol from partners, it might evoke suspicion of HIV infection and raise the possibility of harm toward participants. Also, cultural values entail avoiding "loss of face," or awkwardness or rejection due to disagreement or refusal. Hence, we placed heavy emphasis on practice of alcohol refusal skills in pairs. We also adapted alcohol refusal skills to include the option of giving medical excuses (e.g., acute infection, pregnancy, high blood pressure) for not drinking.

We provided general, rather than specific, text message reminders for appointments, so as not to disclose a clinical affiliation. Women, in particular, opted for text message reminders such as "meet you at the shop tomorrow." While these practices were somewhat deceptive in nature, our rationale was that they are protective of clients, who are in the best position to evaluate the potential benefits or harm of disclosure.

Counselors did not advocate HIV disclosure as it was not a focus of the intervention and might increase the possibility of harm toward participants. While HIV disclosure has been linked with improved health and social behaviors including improved family and social functioning and marked improvement in medication adherence (Stirratt et al., 2006; Rotherman-Borus et al., 2010), disclosure can also result in severe discrimination or harm in the current climate in Kenya.

During our intervention, participants reported implementing medical excuses in social contexts. During the debriefing, most participants did not advocate HIV disclosure and a majority of men stated that nondisclosure was important to "self-esteem." Also of note, homosexuality is illegal in Kenya and no study participants reported engaging in this practice. We may in future work test the addition of a "pros" and "cons" exercise about HIV disclosure so that participants can individually evaluate the potential harms and benefits.

In the efficacy trial, we discontinued one of our retention techniques that appeared to increase the possibility of harm to participants during the piloting phase. Because of late treatment initiation in two pre-pilot groups, we offered voluntary pickup in taxis before the first CBT session only. We offered to pick them at a designated junction, rather than at their homes. Several participants initially requested pickup; however, all subsequent participants opted out of this assistance. We learned from staff that being seen in a private taxi, which costs approximately 10 times the cost of local *matatus* (vans), suggests relative wealth and may invite future victimization.

POST-TRIAL CARE FOR CONTROL GROUP MEMBERS

Another change we made was in relation to post-trial obligations. As a behavioral intervention study offered in the context of HIV primary care in the AMPATH system, we initially conceptualized no specific post-trial obligations. Our original proposal involved a "usual care" comparison condition using HIV support groups, which had been established for several years and were attended at that time at least once by 25% of all HIV outpatients at the study site. However, when we began the trial 2.5 years later, support group attendance had dramatically diminished. Attendance recorded from actual attendance logs showed that only one participant in the usual care condition had regularly attended an onsite support group. Because there was no onsite behavioral therapy program for alcohol use, we felt an ethical obligation to provide post-trial individual CBT for those enrolled in the comparison condition who reported drinking on a weekly basis during the final three-month follow-up. Those interested participants were offered from 3–6 individual CBT sessions with CBT counselors trained in the project. Only two participants contacted attended a total of two individual sessions. Some participants did not have phones and hence were unable to be contacted. In the current efficacy trial, we now offer a health education intervention as an

active control, in response to the limited health knowledge demonstrated during the pilot study.

TRAINING OF THE PARAPROFESS IONAL STAFF

During the efficacy trial, we also attempt to improve the sustainability of the intervention. Our model of intervention delivery by paraprofessionals in groups is quite feasible in this setting and our training efforts have built capacity of local counselors. However, U.S. mental health professionals have been brought in to perform initial training and subsequent supervision of the intervention. The few Kenyan mental health professionals on site lack time to learn empirically based interventions and to supervise the team of paraprofessional counselors. Hence, during the five-year efficacy trial, a paraprofessional counselor trained during the pilot study is being mentored into a leadership role. Some local supervision of paraprofessionals will still be required, however, given the lack of training in psychiatric risk assessment and other behavioral treatment modalities.

Discussion

Adapting and testing a behavioral therapy trial in a resource-limited setting requires attention to a host of ethical considerations that may not be evident from the start (Anderson & DuBois, 2007). Some of these issues are anticipated in existing global standards for research involving human subjects (CIOMS, 2002; WMA, 2008), but not all. For example, ethical considerations involving the consent of women in low- and middle-income countries are the source of an emerging literature (Omonzejele, 2008; Grady & Denny, 2008). However, new challenges may emerge in the course of developing and conducting a study due to changing circumstances and limited infrastructure. A substance abuse therapy trial requires a number of considerations involving the protection against stigmatization, including whether existing guidelines and regulations designed for the United States and other economically developed countries are applicable or feasible in this setting. Finally, a behavioral therapy trial in the context of low mental health service provisions and knowledge may call for a new appraisal of the ethical obligation to provide both concurrent and any post-trial care (NBAC, 2001; Emanuel, 2008).

Best Practices

Based on our experience, we propose a number of best practices that should be considered in the design and implementation of behavioral clinical trials or trials involving stigmatized and vulnerable groups in resource-constrained settings:

1. *Design of clinical trials should, when possible, address needs that are of importance to the participants and their communities.* In this study, community leaders had strongly advocated for alcohol interventions to address the problems of alcohol abuse and sexual risk within their communities, and feasible widespread interventions for alcohol abuse are lacking in Kenya.
2. *When feasible, a Community Advisory Board (CAB) should be used to ensure that study practices are responsive to participant and community needs and that potential stakeholders are properly informed or educated.* In this study, a CAB was instrumental in educating communities during the recruitment phase, since our earlier work revealed a limited voice for women in discussing issues of alcohol within public forums.
3. *Studies may need to adopt more stringent practices for informed consent than would normally be required locally if doing so improves the protection of participants and their ability to properly weigh benefits and risks when considering*

enrollment. For this study, we chose a rigorous written informed consent process, even though verbal informed consent might have been culturally acceptable.

4. *In situations involving extremely vulnerable or stigmatized groups, principles of respect of persons and beneficence may necessitate deviation from accepted cultural norms in situations where vulnerable groups must be protected from harm.* In our study, male partners were not involved in the consent or enrollment of female participants, although women were given the opportunity to involve their partner or spouse if they felt it was necessary.

5. *Participant concerns over confidentiality and potential harm should inform the design and conduct of study practices.* In our study, clinicians were not informed about the participants' alcohol use at the request of the participants, except in cases when disclosure would improve their care or safeguard their health.

6. *Even when data suggest that certain practices would have benefits to participants, research staff should allow participants to decide for themselves when those practices are appropriate to their own situation.* In our study, disclosure of HIV status and alcohol use to those outside the study was left up to the participants, who could better assess their own risk of harm from disclosure.

7. *Study design may need to incorporate systems or practices to minimize harm, even when local legal and regulatory mechanisms do not require it.* In this study, the absence of legal reporting requirements for abuse and involuntary admission for suicidality required development of procedures that would assist at-risk participants to receive proper care and protection. We created and used a referral system for patients reporting suicidal or other psychiatric risks. While we deferred to the local standard of taking action on suspected abuse only if visible injury were present, we were able to incorporate referral processes for legal advice and rape treatment into our operating procedures, although no referrals for abuse were needed during this trial.

8. *Study procedures or practices that are found to increase risk should be abandoned at the earliest opportunity.* In our experience, the provision of free cab rides to patients to improve retention was abandoned due to perceptions that this would result in their future victimization.

9. *Post-trial obligations should be carefully considered, and those in control groups may require special consideration for post-trial benefits if existing programs or social services become unavailable.* In our experience, the reduction of alcohol support group availability to controls resulted in an offer of post-trial counseling to those participants. Inability or unwillingness of those participants to access this benefit resulted in a change in design for our subsequent trial to involve an active health education intervention for all control participants.

10. *Study staff may hold personal beliefs that run counter to the interests of participants, and careful screening and education of the entire research team is necessary to ensure that participants are treated in an equitable manner.* In this study, deeply held prejudices regarding the status of women and misconceptions regarding the prevalence of such beliefs required implementation of staff education and new hiring practices to better protect female participants from discrimination.

11. *Protection of participants from harm may sometimes involve practices that run counter to our own ethical frameworks and should be considered carefully.* In our experience, the decision to provide participants who feared disclosure with possible alternative explanations for abstinence from alcohol was questioned as "deceptive" by some members of the team. However, we chose to defer to a strategy that would

increase protection of subjects. Based on our experience, we are also considering incorporation of disclosure education into future trials to assist participants in making better decisions about these issues.

Research Agenda

The examination of ethical issues within the context of this study suggests several areas of research that would be productive:

1. What are the best practices to combat prejudices surrounding participant groups when working with vulnerable populations?
2. When is deviation from cultural or legal norms necessary to properly protect participants or maximize benefits for them?
3. What post-trial obligations exist when considering the needs of control groups if usual standards of care are deemed insufficient to meet their health or social needs?
4. What are the best practices for involving communities and participants in the design of research studies to ensure that local needs and concerns are met?

Educational Implications

The application of ethical principles in the design and implementation of research is complex and may differ within cultural contexts, particularly in studies that involve marginalized populations or resource-constrained settings. While we are not proposing any new educational agenda based on our experiences from this study, we contend that all study personnel involved in design and conduct of research need intensive training on the ethical issues involved in research. The current paradigms for human subjects protection education required for research may not be sufficient when considering the application of ethical principles in some cultural contexts. Greater attention to cultural considerations, potential discrimination in differing contexts, and the role of communities and participants in determining the appropriate measures is needed. At times, this may require research projects to implement internal training initiatives for their staff if existing training opportunities and modules fail to address these issues.

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Biographies

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Benson N. Gakinya is Senior Lecturer and the Chair of the Department of Mental Health at the Moi University School of Medicine in Eldoret, Kenya. He provided psychiatric consultation throughout the pilot study, conducted weekly psychiatric risk assessments, and contributed to the writing, review, and critique of manuscript. He participated in the initial conceptualization of the efficacy trial and is the Site PI for it.

Steve Martino is Associate Professor in the Department of Psychiatry at the Yale University School of Medicine in New Haven, Connecticut, USA, and the Chief of Psychology at the VA Connecticut Healthcare System. He participated in the initial conceptualization of both projects, provided consultation on training activities and counselor fidelity monitoring, and contributed to the writing, review, and critique of manuscript.

Joyce B. Baliddawa is Senior Lecturer in the Department of Behavioral Sciences and Ethics at the Moi University School of Medicine in Eldoret, Kenya. She participated in the initial conceptualization of both projects, conducted several group debriefings, provided consultation on retention activities, and contributed to the writing, review, and critique of manuscript.

Kendall J. Bryant is Scientific Officer and the Director of Alcohol and HIV/AIDS Research at the National Institute of Alcohol Abuse and Alcoholism in Bethesda, Maryland, USA. He participated in the initial conceptualization of both projects, provided consultation about scientific issues, and contributed to the review and critique of manuscript.

Eric M. Meslin is Founding Director of the Indiana University Center for Bioethics, Associate Dean for Bioethics and Professor of Medicine, Medical and Molecular Genetics, Public Health and Philosophy. He is also the principal investigator and director of the Indiana University–Moi University Academic Research Ethics Partnership. He contributed to the writing, review, and critique of manuscript.

John E. Sidle is Associate Professor of Medicine at the Indiana University School of Medicine and a Visiting Lecturer at the Moi University School of Medicine. He is a Field Co-Director of Research for the AMPATH consortium. He participated in the initial conceptualization of both projects, provided onsite support and conducted withdrawal symptom assessments throughout the pilot project, provided ethical consultation throughout the pilot study, and contributed to the writing, review, and critique of manuscript.