To Test or Not to Test: Evaluating the Biopsychosocial and Ethical Consequences of Positive HIV Tests in a Study-enrolled Population of Kenyan Women

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Abstract

Purpose/Problem/Question

HIV/AIDS has had a devastating effect on global morbidity and mortality. Efforts to halt this pandemic have raised many ethical issues, divisible into four key areas (WHO 2004):

1) Research and clinical trials on HIV medicines and vaccines
2) Testing and counselling
3) Equitable access to prevention and treatment
4) Surveillance

This paper examines some of the ethical issues inherent in HIV clinical trials in developing countries.

Approach/Method

We searched Ovid Medline to identify relevant literature on the ethical issues in HIV/AIDS research in developing countries. An HIV/AIDS research ethics case was developed. In this case, Dr. T, a physician researching maternal-fetal HIV transmission in a Kenyan community, discovers that as a result of the free HIV testing and counselling provided in her study, some women are experiencing higher rates of domestic violence after notifying their partners of their HIV status. She struggles with the dilemma of whether to continue her research protocol as is, or alter her approach to counselling in an effort to protect the women. This case was analyzed by the authors of this paper as well as two expert HIV/AIDS clinicians.

Results/ Support of Argument

The ethical framework established by Gillies (2004) was used to address the ethical issues of HIV/AIDS research on three different levels. At the micro level (doctor-patient relationship), the principles of autonomy, beneficence, non-maleficence and justice were applied (Beauchamp & Childress 2001). At the meso level (public health), the Tavistock principles were applied (rights, balance, comprehensiveness, cooperation, improvement, safety, openness) (Berwick 2001). At the macro level (international relationships), we discussed the role of global factors (international relations) contributing to increasing HIV prevalence.

Introduction

Since the days of Hippocrates, ethical discourse has guided the practice of medicine, providing health professionals with a framework to approach the moral and ethical dilemmas inherent in patient care. The field of medical ethics (also known as bioethics) is broad, dynamic and ever-expanding as a result of continued advances in medicine brought about by science and technology. Since the birth of modern bioethics in the 1960's, global issues such as rapid population growth, widening economic disparities, emerging infectious diseases and armed conflict have had a significant effect on the health of individuals worldwide (Benetar et al., 2005). Globalization has dramatically changed the face of the world, accentuating these issues and weaving an intimate interconnectedness among the global population. With this trend, many health issues have crossed national boundaries, giving rise to considerable expansion of the field of 'global health'; finding feasible solutions to our most pressing global health issues requires that we consider the ethics of our actions towards better health for all.

Despite frequent use of the term 'global health', it is rarely defined. Global health is a discipline where improving health outcomes and achieving equitable health status for all humanity is prioritized (Koplan et al., 2009). There is significant overlap between the fields of global health and community health, as both areas entail synthesizing health care efforts at the scales of the individual patient and the community (Koplan et al., 2009). While global health and international health are nearly synonymous, the term global health is frequently preferred because it incorporates vulnerable populations within national boundaries as well as outside them. As one would expect, the potential ethical issues that could arise in the field of global health are endless, making it impossible to adequately address 'global health ethics' in a project

of this nature. Consequently, we chose instead to focus our ethical examination on a select subtopic within global health.

There is perhaps no other issue in global health that has affected the realm of bioethics more than the HIV/AIDS pandemic that has developed over the last 20 years. Not only has it brought new attention to the traditional ethical themes of the doctor-patient relationship, but it has highlighted policy and regulatory issues in drug research/approval, bringing them to the forefront of bioethics debates (Schuklenk, 2003). As stated by Schuklenk (2003), "HIV/AIDS has been and will be crucial for bioethics, because it has so brutally exposed the political dimensions of health". Given these considerations as well as the current devastating effect of HIV/AIDS on worldwide morbidity and mortality, we felt that examining the ethical issues raised by this pandemic would be timely, interesting, and relevant to the global health ethics debate as a whole. While HIV/AIDS is clearly a global issue, we decided to focus on HIV/AIDS in low- and middle-income countries where poverty, lack of health care infrastructure, and the sheer number of those infected with HIV magnify the effects of the pandemic and therefore where ethical issues are perhaps of greater significance. We hope that through this analysis, it will become clear that the ethical issues inherent in managing HIV/AIDS in developing countries can be seen as a microcosm of global health ethics in a broader sense.

There are numerous ethical issues arising from the HIV/AIDS pandemic, which have been divided by the World Health Organization into four key areas (WHO, 2004):

1. Research and clinical trials on HIV medicines and vaccines
2. Testing and counselling

3. Equitable access to prevention and treatment
4. Surveillance

In an effort to undertake a thorough ethical analysis and perhaps arrive at more substantive views on these issues, we have chosen to focus this paper on the first key area, HIV research and clinical trials in developing countries.

Ethical Framework

The ethical challenges in dealing with HIV/AIDS are formidable. The ethical framework we will approach HIV/AIDS is adapted from Gillies (2004*)*. The problems of HIV can be addressed at the micro level (doctor-patient relationship), meso level (public health) and macro level (international relationships).

At the micro level, four principles are applicable (Beauchamp & Childress, 2001):

1. autonomy - we ought to honour the preferences of people
2. beneficence - we ought to prevent harm, remove harm, and promote good
3. non-maleficence - we ought not to do anything which will harm
4. justice - we ought to be fair, and treat similarly all those who are similarly situated (Browne, 2007)

As with all patients, those with HIV/AIDS should have autonomy: HIV testing and treatment must be performed with informed consent. Obtaining truly informed consent may prove more difficult in developing nations with high levels of poverty and illiteracy. Research subjects

may agree to become involved in projects without truly understanding the risks and benefits of participation for several reasons, including misconceptions that research is a recommendation for care, or trust in health care providers and institutions at the expense of failing to critically review proposed involvement (Wolf, 2001).

According to the principles of beneficence and non-maleficence, patients should receive treatments that will be of help and have minimal harmful effects. The fourth principle, justice, which states that like cases should be treated alike, obliges a fair distribution of treatment and is applicable both at the micro and meso level.

At the meso level, the Tavistock principles were developed as an ethical compass for health care systems (Berwick, 2001). They are as follows:

1. Rights - people have a right to health and health care
2. Balance - care of individual patients is central but the health of populations is also of concern
3. Comprehensiveness - in addition to treating illness, there is an obligation to ease suffering, minimize disability, prevent disease and promote health
4. Cooperation - health care can only succeed with cooperation between patients, between health care providers and other sectors
5. Improvement - health care improvement is a continuing responsibility
6. Safety - do no harm
7. Openness - being open, honest and trustworthy is vital to health care

In the context of international observational studies, major questions of debate concern exploitation and whether investigators from high-income countries have an ethical obligation towards participants. Lavery (2010) proposes a "Relief of Oppression" model based on the principles of harm reduction, which serves to clarify ethical obligations of researchers. This model proposes negotiation of benefits to participants in a prospective study with the aim of relieving oppression. The humanitarian assistance focuses on "5 fundamental freedoms" of society - political freedoms, economic facilities, social opportunities, transparency guarantees and protective security.

At the macro level there are global factors contributing to the rise of HIV, including increasing inequality between rich and poor countries, debt crisis and refugee movements. Gillies (2004) suggests that it is important to address the problems of HIV at the global level through:

1. Scientific knowledge - made available to *all* who need it in developing and developed countries
2. Individualism - ethical approaches need to address the obligations placed on others by satisfying the rights of individuals
3. Interdependence - recognition of interdependence in global relationships as a contributing factor e.g. war

Ethical Case in HIV/AIDS

In order to explore the ethical issues involved in HIV/AIDS, we identified a case relevant to research and clinical trials on HIV (a critical area in the field of HIV/AIDS ethics as described by the WHO). This case (see Appendix I) was analysed by the authors of this paper as well as two clinicians in the fields of global health and HIV/AIDS, Dr. Richard Currie and Dr. Richard Bedell.

The ethical case presented to expert interviewees is derived from an account published in the Lancet entitled, "The right not to know HIV-test results" (Temmerman et al., 1995). As described in the case scenario, Belgian researchers encountered high rates of domestic violence in their study population of Kenyan women who disclosed HIV-seropositivity to their male partners, thus raising a host of ethical issues related to HIV/AIDS research.

We based our ensuing analysis of this case on the ethical framework delineated by Gillies (2004), with additional commentary from two interviewees experienced in the field of HIV/AIDS care at an international level. We included the complete verbatim responses of both interviewees (Appendices II and III). The first expert we consulted, Dr. Richard Currie, is a family physician based in Salmon Arm, BC with an interest in global health. He has previously worked in similar environments to that described in the case including four months with an HIV project in rural western Kenya. Additionally, he has served as a field worker with Médecins sans Frontières on projects in rural northern Ethiopia and the Central African Republic. We also consulted Dr. Richard Bedell, a family physician who has previously worked for Médecins sans Frontières as a physician and health advisor for HIV/AIDS field projects. He is currently

working as a medical advisor for Dignitas International (an organization that seeks to increase access to HIV prevention and treatment in resource-limited settings through structured programs and strengthened infrastructure) and is presently developing an HIV learning module for the UBC Division of Global Health.

Micro level (doctor-patient relationship)

At the micro level of ethical analysis (Gillies, 2004), the principles of autonomy, beneficence, non-maleficence and justice may be applied. If one argues that the autonomy of study participants is paramount, then women ought to have the right to elect whether or not to review their HIV test results. However, HIV is a transmissible illness and the implications of contracting the infection may be especially dire in resource-poor nations with limited access to treatment. Therefore, if HIV-positive women remain in the community with no knowledge of their HIV infections (thus at higher risk of transmitting the disease to others), then the argument of autonomy must be considered in the context of the broader community; this will be subsequently illustrated by the Tavistock principles (Berwick, 2001).

Dr. Richard Currie frames the issues in this case as "a conflict between the duty of respecting the woman's right to autonomy (to be informed of her diagnosis and thus empowered to take control of her health care) versus the duty of non-maleficence to the woman ("first do no harm")", however he notes that these must be balanced against the duties of beneficence and justice to the community at large (Currie, 2010, pers. comm.). Ultimately, Currie feels that the best person to balance the conflicting duties of individual autonomy and non-maleficence would be the woman herself (provided she is adequately empowered to make these choices and not under any

coercion). He emphasizes that this would require confidential, individual pre-test counselling that carefully explains the risks and benefits of knowing your HIV status, supportive post-test counselling, and a concerted effort to "create an environment where an informed woman has total control over whether or not to publicly disclose her status", with the goal of "creat[ing] an environment where, eventually, 100% of the women would *choose* to disclose" (Currie, 2010, pers. comm.).

Dr. Richard Bedell also emphasizes the principle of autonomy and the necessity of comprehensive HIV pre-test counselling in this case. He states, "while it is true that some harms may ensure from such knowledge, particularly if privacy and confidentiality around HIV testing and test results are not respected, the crucial requirement here is that counselling around the issue of disclosure to a partner must include the possibility of rejection or physical abuse (Bedell, 2010, pers. comm.). The woman's decision to disclose her status to her husband/partner ought to be her decision and a fully informed one" (Bedell, 2010, pers. comm.). He feels strongly that his job as a clinician would be to "counsel the woman to allow her to make fully informed choices, realistically anticipating both good and bad consequences that ensue", and then leave the decision about disclosure to the woman herself (Bedell, 2010, pers. comm.). He emphasizes that as a researcher or health care provider, his obligations are ultimately to the research subject/patient, and as such, he states "I do not believe we can defend public health goals by compromising the rights of individuals to autonomy, privacy and confidentiality" (Bedell, 2010, pers. comm.).

The second ethical principle relevant to the individual is beneficence. Dr. T. has an obligation to

"do good" for her research participants. Presumably, the planned outcome of her study was to diminish fetal-maternal HIV transmission by identifying HIV-positive women, in order to obtain appropriate antiretroviral treatment for them. In Dr. Bedell's analysis, he emphasizes the various benefits that may ensue from knowledge of one's status, including "access to prophylaxis and treatment for oneself, interventions to reduce mother-to-child transmission of HIV, protection of partners from HIV, or protection from super-infection with another strain of HIV (if partner is seropositive from a different strain)" (Bedell, 2010, pers. comm.). In the course of Dr. T.'s study however, she has come to acknowledge that rather than doing good, at times she is in fact doing harm, therefore compromising the third ethical principle of non-maleficence.

HIV-positive women who notify their partners of their seropositivity seem to be at increased risk of not only physical, but also psychological and socioeconomic harm from these men, secondary to abuse and abandonment. In giving women the right not to know their HIV statuses, Dr. T. can circumvent the harm that the knowledge of seropositivity may bring. However, if the principle of non-maleficence is applied to the greater community, then Dr. T. may be doing harm as infected women would remain unaware of their HIV statuses and could be more likely to engage in high-risk behaviours conducive to transmission.

Dr. T. attempts to quantify the degree of risk by considering the number of her participants involved in stable relationships and thus less likely to be sexually promiscuous and at higher risk of transmitting HIV. Furthermore, she considers the high prevalence of HIV in the community and rationalizes that males have a high probability of already being HIV-positive and reasons that it is better for the community if they remain with their seropositive partners rather than

engaging in new sexual relationships with uninfected women. However Dr. Currie points out that this is a weak argument since in reality the estimated HIV prevalence in the worst-hit areas of Kenya is approximately 30%. Consequently, the majority of men would in fact be HIV-negative and at risk of contracting the virus. There is, therefore, "an obvious duty owed to the community at large" which "must be balanced against the duty of non-maleficence for the individual woman involved" (Currie, 2010, pers. comm.)

Another argument to include in Dr. T.'s rationalization is the rate of HIV transmission between couples with discordant HIV statuses. Infected females are less likely to transmit the disease to non-infected male partners than infected males are to non-infected females (Laga et al., 2001; Quinn et al., 2005). These data may be interpreted to imply that the impact of Dr. T.'s decision to no longer notify women of seropositivity may have less impact on community HIV transmission rates than a likely-infected male leaving his HIV-positive partner for an uninfected partner. On the other hand, viral load may be the best predictor of HIV transmission rates (Quinn et al., 2000). Thus, if women do not know their HIV status, viral loads cannot be determined and women cannot receive ARV treatment if necessary. Therefore, these women may be at a higher risk of transmitting the virus to their partners if they are not already infected.

If, as Dr. T. suggests, men are likely to be infected already, and infected men may leave their seropositive partners for new, uninfected females, then one could argue that men may be the primary vectors of disease because they would spread HIV at higher rates to uninfected female partners, than females would to uninfected male partners. Conversely, if viral load is the best

determinant of HIV transmission, then one may argue that female study participants may be the primary vectors of disease, as they would remain unaware of their HIV status and therefore would not seek ARV treatment to decrease their viral loads and the transmission of the virus. In both cases, harm is done to the community by the transmission of HIV, although, if Dr. T.'s argument that men have a high probability of seropositivity holds true, then perhaps less harm is done to the community through the transmission of disease from a woman to her likely-affected partner, then from a man to a new partner. However, as both Dr. Currie and Dr. Bedell previously identified, this argument is flawed, and given the polygamous nature of certain Kenyan ethnic groups, if a woman with a high-viral load transmits HIV to her male partner, then there is the possibility that he will transmit the disease further through his society-sanctioned sexual relationships with other women.

In either case, harm will come to the community regardless of whether Dr. T. changes her research protocol. If she alters it to give women the right to know their HIV test results, then women may transmit HIV at higher rates to their male partners and secondarily to other females. Similarly, if women are informed of their test results and reveal these results to their partners, then their infected male partners may abandon them and infect other community members. Additionally, women who are informed of their seropositivity and reveal this status to their partners may suffer abuse at the hands of their partners. Given the poor outcome either way, and the additional abuse, one may argue that the principle of non-maleficence is difficult to satisfy at a community level, and that perhaps autonomy should figure more prominently in the ethical decision-making process as suggested by both Dr. Currie and Dr. Bedell.

The final micro level principle is justice. If Dr. T. elects to allow her study population to choose to know their HIV test results, then she should ensure that other community members undergoing voluntary HIV testing have similar rights in order to satisfy this standard. If members of the community at large who undergo HIV testing are indiscriminately informed of their HIV seropositivity, and Dr. T. does not uniformly communicate positive test results to her study participants, then she is violating the principle of justice. Not reporting HIV test results to the patient conflicts heavily with other ethical principles such as beneficence and non-maleficence at both the individual and community level as the consequences of HIV infection are serious and the community would be at higher risk of suffering the ravaging nature of the disease without treatment and prophylaxis.

Meso level (public health)

At the meso level of analysis, the Tavistock principles (Berwick, 2001) highlight the importance of weighing the balance between individuals and the broader population. Many countries have legally negated balancing individual versus population arguments by establishing HIV as a reportable diagnosis. Consequently, those individuals who have a confirmed, positive HIV test are informed of that result so that they may be counselled on how to prevent transmission and their at-risk contacts may be traced (Ontario, 2009). In Dr. T.'s case, however, there is no mandatory reporting of HIV and so she is not legally bound to inform public health authorities of positive test results. Nevertheless, one may make the argument that *ethically* she still has an obligation to the greater population to notify infected women so that the necessary precautions to prevent transmission to others may be taken. However, as stated previously, both Dr. Currie and Dr. Bedell feel that their primary obligation as clinicians/researchers would be to the patient and

that this obligation should not be compromised to defend overall public health goals.

The right to health and health care are also identified in the Tavistock Principles (Berwick, 2001). The rights of the broader community must be considered, as members may be at increased risk of contracting HIV if infected women with unknown seropositivity engage with them in sexual activity or other bodily fluid contact. If Dr. T. changes her research protocol to give women the right not to know their HIV status and stops encouraging women to disclose their HIV status, then the right to health of the community may be violated. However, as stated previously, we concurred with the expert clinicians that individual rights to health and health care take precedence over the rights to health and health care of the community.

The Tavistock Principles further identify the importance of comprehensiveness and state that "in addition to treating illness, we have an obligation to ease suffering, minimise disability, prevent disease, and promote health" (Berwick, 2001). By changing her research design to give women the right to decline to know their HIV statuses, Dr. T. hopes to minimise suffering and disability by circumventing the ill effects of domestic violence. In this regard, she is promoting the psychosocial health of her study participants, however, their physical health may be compromised as they could be denied necessary treatment and prophylaxis since their HIV statuses would remain unknown. Similarly, she is not fulfilling her obligation to minimise disease and promote physical health within the community if infected women, unaware of their HIV-positive status, do not take appropriate precautions to minimise transmission.

In his response, Dr. Currie discussed the need to create research and treatment protocols that

provide holistic care (not focused primarily on HIV) in an effort to reduce the stigma experienced by research participants. This approach would address the Tavistock Principle of comprehensiveness as it eases the suffering of individuals involved in this study. He suggests that this could be accomplished by ensuring that "the HIV testing and counselling centre is incorporated into a regular pre-natal care clinic, so that women who are seen coming and going are not automatically stigmatized by proxy" (Currie, 2010, pers. comm.). He also suggests that follow-up visits be encouraged for all pregnant women, and that, assuming that HIV positive women receive antiretroviral prophylaxis at the time of delivery, efforts be made to ensure that ALL pregnant women are seen receiving care throughout pregnancy and delivery regardless of their HIV status. Furthermore, he states, "I would hope that this research project and the counselling that they do would include an effort to combat stigma in the community, [although it] would be naive to think that this alone would solve the problem" (Currie, 2010, pers. comm.). Dr. Bedell mentions that "defence of the public health good can be approached by community-level education about knowing one's status, along with one's partner(s) status" (Bedell, 2010, pers. comm.). Their commitment to reducing the stigmatization of study participants through a holistic care approach and community education is well aligned with the goal of comprehensiveness as outlined in the Tavistock Principles.

Cooperation is another standard highlighted in the Tavistock Principles. According to this principle, Dr. T. has an obligation to cooperate with her study participants. Cooperation may mean polling new participants about the expected outcomes of revealing seropositivity to their male partners and assisting women in deciding whether disclosure is a safe and viable option. Alternatively, cooperation could manifest in the principle of autonomy, by giving women the

right to learn about their HIV statuses, and agreeing to support them whether or not they choose to undergo testing and/or choose to disclose their status to their partners.

The Tavistock Principles also recognize the need for improvement in health care and health care delivery. Dr. T. is cognizant that her study design requires improvement, as its current incarnation is jeopardizing the health of her participants through heightened domestic violence. The question remains whether a change in study protocol will lead to a net improvement in health care or not.

The Tavistock principle of safety incorporates the bioethical principle of non-maleficence. The application of non-maleficence to the individual and community level has been discussed previously.

The final Tavistock principle is openness. This principle obliges health care providers and researchers to be honest and trustworthy in their interactions with patients and research subjects. In Dr. T.'s case, openness could be applied to her pre-test counselling. To satisfy this requirement, she must clearly outline to study participants the risks and benefits of knowledge of HIV status, as well as the risks of disclosing this status to male partners. This approach is emphasized by both expert clinicians, who feel that comprehensive, confidential pre-testing counselling should be provided to each individual and should honestly discuss the risks and benefits of disclosing one's HIV status.

Macro level (global factors)

A macro level analysis of ethical issues in HIV/AIDS (Gillies, 2004) should address HIV/AIDS at global level, through dissemination of scientific knowledge about HIV/AIDS, evaluation of the role of individualism in the context of community-centred societies, and the recognition that global cooperation is in the best interest of all citizens. A thorough discussion of these topics is beyond the scope of this paper.

Appendix I: Illustrative Case Study - HIV Research and Clinical Trials

Dr. T. is working in a Kenyan community with a high prevalence and incidence of HIV. She is researching maternal-fetal HIV transmission and as part of her study she is providing volunteer, pregnant women with free HIV testing. In addition, her study provides the participants with pre and post-test counselling and encourages women to notify their partners of their HIV status. Partners are also invited to participate in the counselling.

Several months into her study, Dr. T. realizes that women who notify their partners of their HIV seropositivity suffer higher rates of domestic violence as a result of their disclosure. Her follow-up reveals that several women were thrown out of their homes by their partners and/or physically abused. One woman even committed suicide.

As a result of the increased violence against women who notified their partners, she reconsiders her research protocol. She contemplates giving women the option to specifically request their HIV test results rather than receive them automatically, as well as no longer encouraging women to disclose their HIV statuses to their partners.

She reasons that this approach will protect women from violence and stigma associated with known HIV seropositivity. However, she is concerned that if HIV-positive women do ***not*** wish to know their HIV status then they might spread the disease. (Assume no mandatory reporting).

She considers that 80% of women in her study identified that they were in monogamous, stable relationships at the outset of the study. Furthermore, she reasons that given the high HIV

prevalence rate within the community, male partners have a high probability of being HIV-positive already. She also fears that there may be a risk of males abandoning their HIV-positive female partners and possibly spreading HIV to new, uninfected female partners.

Should Dr. T. give women the option to learn about their HIV statuses and no longer encourage them to discuss their seropositivity with their partners?

What is your approach to this scenario? How would you handle the situation?
What factors do you consider most strongly in the decision-making process?
What ethical principles or moral obligations guide your decision?
What do you feel are your obligations to individual women? To male partners? To the community?
In your career, have you experienced ethical dilemmas relating to HIV/AIDS research? If so, please describe the scenario and dilemma.
Is there anything else relating to this topic that you feel is important to include?

Appendix II: Dr. Richard Currie's Response

A very interesting case!

I should begin by emphasizing that my responses stem from my clinical experiences treating HIV in the developing world, and not (unfortunately) from any formal training in medical ethics. Certainly Dr. T. would do well to consult a medical ethicist early and often as she embarks on this research!

The issues raised in this case do seem all too familiar. In 2007-2008 I spent four months working on small islands in rural western Kenya with FACES – an HIV project partnering UCSF and the Kenyan Ministry of Health to provide HIV care in remote parts of the country. In 2008-2009 I worked for 10 months in rural northern Ethiopia with Medecins Sans Frontieres, at a hospital that included a robust HIV treatment program (both inpatient and ambulatory). In 2009-2010 I worked for 6 months in the Central African Republic, again with MSF, again at a hospital that included a very active HIV treatment program. I think you've done an excellent job of capturing a very realistic scenario in your case example.

It's not specified but I'm going to assume that the pre-test counselling here is done individually and privately, using an opt-in approach, and not as a group counselling session with opt-out at the end as is often done in most busy African prenatal clinics. That is to say, I'm going to assume that they have the resources on hand to provide confidential pre-test counselling to all participants.

Certainly the issue of stigma, and the direct implications for seropositive study participants, should have been considered early in the planning process. The case is appropriately vague on geographic details, but one needs to understand the cultural subtext – and understand it well – before embarking on this kind of research. As an example, the second largest cultural group in Kenya – the Luo – practice active polygamy. It is not uncommon for each man to have 2 wives (or more), and "wife inheritance" is common. This latter practice means that if a man dies, his wife (wives) automatically become the extra wives for the man's next oldest brother. This has very positive implications in terms of social abandonment (there are very few "HIV widows" or orphans in that part of the country for example!), but – important women's rights implications aside – this practice does have devastating consequences on the spread of HIV throughout the community. It also means that while an HIV positive woman who chooses to disclose is at risk for violence and discrimination from her husband, she is also at risk of anger and isolation on the part of her "co-wives" as well who, by association, will now also be subject to discrimination. To be shunned from the female social community is just as devastating as any consequences that she may face from her husband. It also means that the implications for NON-disclosure are much broader – not only would that place a potentially discordant husband at direct risk of seroconversion, but all of the co-wives as well!

I won't belabour the obvious importance of addressing stigma in general here (unique to this socio-cultural context), aside to say that it is almost certainly deeply rooted and multifactorial. While I would hope that this research project and the counselling that they do would include an effort to combat stigma in the community, it would be naïve to think that this alone would solve the problem at hand. Stigma in the community most definitely can be overcome, but not in the

time frame that Dr. T. requires to complete her study. Nevertheless, dedicating time and resources to this area as a whole should not be overlooked.

Thus, as a non-ethicist I would very roughly frame this problem as a conflict between the duty of non-maleficence to the woman ("first do no harm"), versus respecting her right to autonomy (to be informed of her diagnosis and thus empowered to take control of her health care), versus a larger duty of beneficence and justice to the community at large (the desire to decrease the spread of HIV, and the right of seronegative individuals to protect themselves).

With respect to the latter issue (the right of others to be protect themselves), I think her argument "given the high HIV prevalence rate within the community, male partners have a high probability of being HIV positive already" is weak. I wouldn't be comfortable using ANY figure for this justification, but in this particular case, even in the worst parts of the country (such as the western islands) the prevalence in the adult community is about 30%, which is to say that the vast majority of the population is very much at risk. Thus I think that there is an obvious duty owed to the community at large.

The above must be balanced against the duty of non-maleficence for the individual woman involved. With that in mind, the best person to find that correct balance would be the woman herself (in the spirit of embracing autonomy), provided that she is adequately empowered to make the best choices possible. Obviously if she is not aware of the diagnosis then she is not informed or empowered, and so I would be reluctant to embrace a research policy whereby the woman is only informed by special request. I think that adds a dangerous moral ambiguity to the

situation that, while tempting, should be avoided. The act of informing a patient of her diagnosis confidentially is very different from the act of public disclosure. If the risks of learning your HIV status are very carefully explained in advance of testing (and this should be a major component of any routine pre-test counselling), and the post-test counselling and support are robust, than the woman can be fully informed and empowered to make the decision to disclose or not to disclose on her own. In such an event it is the community members that have the direct responsibility for protecting (or not protecting) their fellow community members, and not the foreign study director.

Taking that approach, one must then focus on creating an environment where an informed woman has total control over whether or not to publically disclose. Most obviously, this means providing all test results in a private and confidential manner. More generally, one needs to embrace a more holistic approach to prenatal care – one that is not focused primarily on HIV and thus is seen in the community as less stigmatizing. It is important for example to ensure that the HIV testing and counselling center is incorporated into a regular pre-natal care clinic (not a separate HIV treatment center) so that woman who are seen coming and going are not automatically stigmatized by proxy. Follow-up visits should be encouraged for ALL pregnant women – seropositive and seronegative alike – again to avoid obvious identification of the HIV positive. This would expand the budget of the study, but has the added benefit of providing an important service (comprehensive prenatal care) to the community as a whole. The details of the study are not specified, but assuming that HIV positive woman will receive antiretroviral prophylaxis at the time of delivery, then an effort must be made so that ALL pregnant women are seen as receiving care throughout pregnancy and delivery as well. This can be in the form of

multivitamins, iron tablets, malaria protection, or a simple home delivery kit (for example a cloth, sterile tie and razor blade for the umbilical cord, one set of gloves and a bar of soap). Everyone – seropositive and seronegative alike – then has incentive to return frequently to the center, and nobody is leaving empty handed. In the event of a perceived material gain (ie. the free cloth and bar of soap), husbands will WANT their partners to seek regular care at the clinic. Of course it's important to add here that these services should also be provided to woman who opt not to be tested at all – thus eliminating the risk that some will feel inappropriately pressured to complete the testing process in order to receive free care.

Presumably seropositive mothers will also need to be followed post-delivery to test for seroconversion of the children. Not sure whether that would be by PCR at an early age (if resources available), or by standard testing 6 months after the cessation of breast feeding. Regardless, one can make this aspect of care less stigmatizing by providing infant clinics and providing a program of infant vaccination – once again ensuring that ALL study participants have a reason to return to the center.

The end result is an environment where all women can be informed of their HIV status safely, and then have true control over whether or not to disclose that status to their partners.

I should finish by emphasizing that I do not wish to suggest in any way that non-disclosure is a healthy outcome – certainly everything should be done to create a community in which women can safely disclose to their partners. However, while that important work is taking place separately, I would see this as a practical compromise in the interim. The goal is to create an

environment where, eventually, 100% of the women CHOOSE to disclose – at a time and in a situation that is safe and appropriate for their unique situation.

Once I got started I opted not to answer your specific questions individually, but I hope that I touched on most of them in my response. Please let me know if you have any further questions. Would love to hear more about the outcome of this study as well. Sounds like a great project.

Appendix III: Dr. Richard Bedell's Response

What is your approach to this scenario? How would you handle the situation?

RB: This case study illustrates the way that the pertinent facts of a situation can have a bearing on the ethical analysis. [I will respond to the case as written—without introducing my own 'facts'-- but I will point out that 2 assumptions above are incorrect: (1) in a population of married HIV+ women studies often show about 50% discordance with husband's status, and (2) the phenomenon of concurrent sexual partnerships is thought to hold considerable explanatory power in the HIV epidemics of sub-Saharan Africa; the practice of sequential monogamy is more typically Western than African. This means many men will already have sex with women other than their wives.]

RB: The women should still be offered HIV tests after appropriate counselling as to the meaning of the test result. Various goods may potentially ensue from knowledge of one's status, including access to prophylaxis and treatment for oneself, interventions (including some pharmacological and some non-pharmacological ones such as safe delivery and safe infant feeding practices) to reduce mother-to-child transmission of HIV, and protection of partners from HIV (if partner is seronegative) or from superinfection with another strain of HIV (if partner is already seropositive due to a different strain). It is also true that some harms may ensue from such knowledge particularly if privacy and confidentiality around HIV testing and test result are not respected. The crucial requirement here is that counselling around the issue of disclosure to a partner must include the possibility of rejection or physical abuse. The woman's decision to disclose to her

husband/partner ought to be her decision, and a fully informed one.

What factors do you consider most strongly in the decision-making process?

RB: The balance of benefits and harms of our actions is likely to be my starting point. I should emphasize that any deliberations I make are to be used to inform the woman in question. My judgement about the situation is not the determinant of how disclosure should be handled. My job is to counsel the woman to allow her to make fully informed choices, realistically anticipating both good and bad consequences that may ensue. There will always be some uncertainty about how the individual will respond to a positive HIV test, and how a partner or other family member will respond to disclosure of HIV+ status so the final decisions should be made by the individual herself, not others.

What ethical principles or moral obligations guide your decision?

RB: This is a somewhat special case since you are describing a research setting rather than a routine health care program. The demands of research ethics are usually more rigorous than those of routine health care (although one could certainly argue whether or not this should be the case). Potential harms to research subjects are particularly important to avoid but even more important is the issue of informed consent for participation in research –which is central in this case. [You can see that I also think it central to an analogous clinical care context]. The core value here is respect for autonomy. Beneficence is also a motivating value since I see goods that may ensue from both knowledge of one's status (and often with disclosure too). Non-

maleficence (also called nonmalfeasance) would be upheld by fully discussing potential negative consequences—which are contingent and uncertain (ie not inevitable). Harms which were inevitable for each woman would be a different matter and might be serious enough to halt the research.

What do you feel are your obligations to individual women? To male partners? To the community?

RB: I have commented above on how I see my obligations to individual women in this case so I won't repeat myself. Obligations to male partners are of a different kind, in my view. The woman is the research subject (and/or patient) and as such my obligations as a researcher or a health care provider are first of all to her. I may indeed recognize a public health good of decreased sexual transmission of HIV, but I have no way of knowing which partners are uninfected, or what consequences could ensue from a decision to disclose the woman's status directly to the partners. The defence of this public health good can be approached by counselling the woman about the possible benefits to her partner, and by community-level education about knowing one's status (along with that of one's partner(s)). Obligations to the community are recognized (we wish to decrease the burden of HIV for all) but less morally pressing than my obligations to a specific individual, particularly one who is a research subject or a patient. I do not believe we can defend public health goals by compromising the rights of individuals to autonomy, privacy and confidentiality. These goods must be attained together---not set in opposition.

In your career, have you experienced ethical dilemmas relating to HIV/AIDS research? If so, please describe the scenario and dilemma.

RB: I can think of a few situations where a dilemma arose:

(1) Years ago, before HIV treatment was as widely available in Africa as it is now, a question arose in a remote area of Sudan. There was suspicion that HIV was an important cause of morbidity and mortality but we had no data on HIV prevalence in the population. Was it ethically acceptable to test people (ill individuals, or in a survey) where we had no treatment to offer? Ultimately people who wanted to know their status were told about it (and counselled about what it meant), with the reasoning that, even without available treatment, they might change their (sexual behaviour), alter their reproductive plans, or accept their illness (if palliative for example). It turned out that people want to know, even if there is no treatment.

(2) In Malawi, we had no data to evaluate a District-wide project with the Ministry of Health on Prevention-of-Mother-to-Child Transmission of HIV. We had antenatal clinic and delivery registers from all health centres indicating all HIV+ women who had delivered. How could we approach them to find out which interventions they had taken, and what were the health outcomes (survival) of these women and their babies? It could be stigmatising and a breach of privacy to approach them. We ended up selecting an equal number of HIV-negative mothers from the registers, which had 2 benefits: there was no association between maternal HIV status and the study (avoiding a potentially stigmatising association), and we also had community-specific comparisons for mother and baby health and nutrition outcomes—making our results more meaningful. We obtained informed consent from all study participants. We also called most mothers to the health centre for their interviews so that also preserved privacy generally.

There were no complaints—mothers were happy to participate and most wanted their babies tested for HIV.

Is there anything else relating to this topic that you feel is important to include?

RB: 2 points: (1) the concept of 'relational consent' is helpful in understanding consent in real life situations, particularly where large power imbalances exist (between researcher or physician and patient, for example). (2) Consent is also better understood as a process taking some time (hours or days or weeks) rather than something occurring at a point in time: people accommodate to certain facts over time, and this can shift their feeling (and understanding) about their situation and the choices available to them.

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