

# KEMRI Bioethics

*Review*

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## Reproductive Health Ethics

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**KEMRI Bioethics Review Newsletter** is an initiative of the ADILI Task Force with full support of KEMRI. The newsletter is published every 3 months and hosted on the KEMRI website. We publish articles written by KEMRI researchers and other contributors from all over Kenya. The scope of articles ranges from ethical issues on: **BIOMEDICAL SCIENCE, HEALTHCARE, TECHNOLOGY, LAW, RELIGION AND POLICY.**

The chief editor encourages submission of articles as a way of creating awareness and discussions on bioethics

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## Letter from the Chief Editor

Prof Elizabeth Anne Bukusi,  
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(Bioethics) , CIP (Certified IRB Professional).  
Chief Research Officer and Deputy Director (Research and Training) KEMRI

Welcome to this issue of KEMRI Bioethics Review focusing on **Reproductive Health Ethics**. In this issue we feature three articles on reproductive health. The first article is by Dr Kwena, a Social Scientist within KEMRI-RCTP, he discusses the background and considerations for ethical use of assisted reproduction technologies in the Kenyan social environment. Mrs Kithinji, a long serving member of the KEMRI SERU secretariat highlights the legal, ethical and social issues of surrogacy. Mrs Odoyo, the coordinator of the PreP study, writes on Reproductive Health and HIV-Ethical Dilemmas in Discordant Couples Interventions. Lastly, Everlyne Ombati, an AVAC advocacy fellow shares a piece on Multipurpose Prevention Technologies.

The development and use of Assisted Reproductive Technology (ART) has successfully treated millions of infertile couples worldwide. ART has previously largely been limited only to developed countries, but for the past decade, ART has gained popularity in developing countries, Kenya included. The acceptance, availability and increasing use of ART in developing countries is expected to bring forth new and unprecedented social, ethical, legal and research challenges.

Fundamental bioethical issues in ART include: pre-implantation genetic testing, gamete/embryo donation, financial aspects of IVF; use, storage and destruction of embryos and challenges of surrogacy. The ability to use genetic technologies to perform sex selection raises an ethical dilemma and may skew gender dynamics if practiced on a large or prolonged scale. The use, storage and destruction of excess IVF embryos, and research involving embryos are other contentious aspects of ART owing to the sacred nature of human life. Gamete/ Embryo donation and surrogacy also raise issues of anonymity, financials compensations and emotional attachments. Another aspect is inequitable distribution of access to care in regards to ART. The fact that significant economic barriers to technologies like IVF exist in many countries results in the preferential availability of these technologies only to couples with the privilege of financial resources.

The dynamic nature of ART and the rapid evolution of reproductive health field requires more than legislation, which includes comprehensive ethical guidelines and moral evaluations as well as public discourse that leads to consensus in development of national regulations clarity on acceptable practices as well as sanctions for unacceptable . As Bioethicists/Researchers we have a professional duty to be engaged in the discourse on the utilization of ART and contribute to ethical guidelines that govern new technologies and techniques in ART and also encourage public debate that leads to development of these national regulations and restrictions of unacceptable practices. The development of laws and ethical guidelines to regulate the use of ART must not be left solely to researchers, doctors and biotechnology entrepreneurs. The society also must also be allowed to play a role in development of ethical guidelines in regards to the use reproductive technologies because issues of reproductive health are at the heart of families and also shape the relationships within the family unit.

I wish you all enjoyable reading and take this opportunity to wish you all peace, prosperity, productivity and good health for 2016.



## A word from the Ag Director KEMRI

**Dr Gerald Mkoji**  
Acting Director, KEMRI

**W**elcome to this issue on **Reproductive Health Ethics**. Reproductive health is a crucial component of population health. The WHO defines reproductive health as a state where people are able to have a responsible, satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. The advance in medicine and technology has consequently led to application of technology and other interventions to solve reproductive health concerns. There are several reproductive technologies which are currently in use, including fertility drugs, artificial insemination, in vitro fertilization (IVF), use of a surrogate mother, gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT), and intra-cytoplasmic sperm injection (ICSI). Though these technologies are all different from each other, they all raise certain ethical issues which should be considered by researchers, practitioners and the general public.

One of the fundamental rights in healthcare is access to good quality reproductive healthcare. The medical fraternity continues to address the problems facing infertile couples by researching and developing new technologies to enable couples have children. These technologies have helped many couples conceive and it is estimated that approximately 5 million children have been conceived using IVF (<http://www.livescience.com/21355-5-million-babies-born-ivf-technologies.html>). In Kenya, IVF is becoming popular among couples who are unable to conceive naturally. IVF was pioneered in Kenya in 2004 and since then, there are reproductive health clinics that offer a wide range of Assisted Reproductive Technologies that include IVF and ICSI (Intracytoplasmic Sperm Injection), Egg and Sperm donation, Gestational surrogacy, Embryo and Sperm Cryopreservation, Intrauterine inseminations (IUI), Ovulation induction and others.

As the use of Assisted Reproductive Technologies (ART) continues to flourish, ethical, legal and social challenges

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I urge KEMRI scientists specializing in reproductive health and bioethics to be steadfast and contribute to development of ethical guidelines and moral evaluations on the applications of these new technologies and techniques ART in Kenya

are bound to increase. It is anticipated that complex questions of justice, rights, and conflicting principles will arise. Other important bioethical issues that are already subject of debates include the appropriate use of pre-implantation genetic diagnostic screening, use, storage and destruction of excess IVF embryos, and research involving embryos which requires human participants, donors and donated embryos, oocytes and sperm.

KEMRI remains committed to ensuring the preservation justice, beneficence, non-maleficence and the autonomous interests of all involved in the reproductive health. I urge KEMRI scientists specializing in reproductive health and bioethics to contribute to the development of ethical guidelines on the applications of these new technologies and techniques like ART in Kenya as well as encourage public discourse that will lead to development of appropriate national regulations. KEMRI will continue to provide expertise where needed in all the effort geared towards regulation of reproductive technologies crucial for better health.

**Dr Gerald Mkoji**  
**Acting Director KEMRI**





By Zachary Kwena, PhD  
RCTP-FACES

#### Value of children in African societies

Children are valued in many societies in sub-Saharan Africa and remain the symbol of pride for couples and families (Lesthaeghe, 1989). Thus, parenthood is thought of as an automatic set of feelings and behaviors that is switched on by pregnancy and childbirth. It is an experience that is said to be profoundly shaped by social and cultural contexts; as children are seen as a sign of a couple's completeness and future investments. Couples who, for one reason or another, are unable to bear children are stigmatized and devalued in the community. These couples also suffer from self-stigma due to their inability to satisfy their creative urge of giving birth that is deeply entrenched in their hearts. Such couples are often pressured to do everything possible, including use of conventional and unconventional means, to have children. For instance, it is common to see couples who are unable to bear children visiting traditional healers/herbalists, fortune tellers and religious leaders for interventions. Some are even willing to act as though they are pregnant and eventually secretly buy newborn children to try and conceal their inability to conceive. This is because of the societies' expectation that every couple should have children. The media has covered many stories of newborn theft and trafficking to couples without children. Childlessness, and particularly infertility, have been associated with many psychosocial problems. For instance, it has been responsible for unstable families, infidelity, polygyny and even separations. In many instances, women have always been blamed for inability to conceive; never mind the fact that men may be the problem.

#### State of childlessness

Medical conditions are the main reasons for inability of cou-

***Childlessness, and particularly infertility, have been associated with many psychosocial problems. For instance, it has been responsible for unstable families, infidelity, polygyny and even separations. In many instances, women have always been blamed for inability to conceive; never mind the fact that men may be the problem.***

ples to conceive and carry babies to term. There are many causes of these conditions. It is estimated that a third of infertility cases are caused by a male factor, such as low sperm count, another third are linked to a female factor, like blocked fallopian tubes, and the remainder consists of either a combination of both male and female factors, or unexplained infertility. Whatever the case, affected couples require interventions to have children. Traditionally, there were several interventions that would see such couples have children. For instance, if a woman was confirmed to be the source of infertility, arrangements would be made to have her sister or niece get married to her husband to bear children for her. If it was the man, one of his brothers or cousins would occasionally have sex with the wife to bear children on his behalf. This latter arrangement was kept secret to protect the man's image and the choice of the brother and cousin to step in was made with the secrecy of the arrangement in mind. Thus, a person to be chosen was one who was excellent in keeping secrets. The Bible also has several accounts where couples who could not have children would collectively agree to bring in a third party to bear children on their behalf. For instance, when Sarah (Genesis 16: 1-4) and Rachael (Genesis 30: 1-5) were unable to bear

children with their husbands, they gave their house helps to their husbands to have children with them on their behalf.

#### **Assisted reproductive technologies for infertile/childless couples**

Advancement in science has provided new tools to help couples who desire to have children but are unable to conceive. The introduction of Assisted Reproductive Technologies (ART) in late 1970s marked a major turning point in reproductive health. There exists many different forms of ART such as in vitro fertilisation (IVF), intrauterine insemination (IUI), and intracytoplasmic sperm injection (ICSI) (Holbrook, 1990; Van Leeuwen, Repping, Prins, Reiss, & Van Der Veen, 2009). However, the most popular form of these technologies seem to be in vitro fertilization (IVF) that increased rapidly in developed countries and spread to developing countries. In IVF, a woman is given a course of hormone treatments for ovaries to produce multiple eggs. The eggs are surgically removed just prior to ovulation and transferred to a culture dish with the father's sperm for fertilization. When the embryos reach the eight cell stage, those that appear healthy and are growing normally are transferred into the uterus for implantation. Multiple embryos are transferred to the uterus to

increase the chances that at least one will get implanted and develop to term. This route of ART presupposes that both couples have no problem with fertility or uterus implantation. However, where this is not true, the process involves securing a donated egg or sperm or embryo and/or a rented uterus. Currently, IVF accounts for approximately 1% of all live births in the United States (Schieve et al., 1999). As of 2009, ART utilization in developed countries was increasing at the rate of 5–10% annually and had helped to deliver over 3.4 million children worldwide (Chambers, Sullivan, Ishihara, Chapman, & Adamson, 2009).

The concept of surrogacy has been in existence for a long time. Traditionally, this involved a surrogate mother donating an egg that is fertilized to bear a child for another couple. Today, different forms of surrogacy exist. There is surrogacy necessitated by medical conditions such as when a woman is unable to conceive and or carry a baby to term due to blocked fallopian tubes or problems with the uterus. Another form of surrogacy is when a couple desires a biological child but do not want the woman to go through the gestation process. Couples who secure surrogate mothers when they are capable of conceiving and carrying a baby to term do it because they want to avoid risks associated with pregnancy and childbirth. This has given

rise to commercial surrogacy that is now allowed in a number of countries. The state of Gujarat in India, for instance, has been reported to be the capital center of commercial surrogacy. The state has IVF clinic equity with surrogate homes where surrogate mothers stay to be monitored for the entire duration of pregnancy. Although this service has been available for both Indian and non-Indian (foreign) couples who can afford, the Indian government has issued directive that limits service to only Indian couples. The concern has been that most non-Indian couples come from countries where the procedure is either outlawed or very expensive and thus the government feels that the Indian women who accept surrogacy are being exploited. The average of ten thousand US Dollars paid to surrogate mothers who are often poor Indian women is in itself seen as a coercion.

ARTs are still shrouded in numerous controversies especially in developing countries where technology seems to be growing at a faster rate than legislation can cope (Banerjee, 2006; Brezina & Zhao, 2012; Thiankolu, 2007). The fears and concerns about the technology have changed over time. The original fears were around the health status of babies fertilized in vitro. These fears have now transformed to center on the

***Even as we embrace the use of ART to help rightly deserving couples who are unable to get children in the natural way such as couples infected with HIV, we need to identify and appreciate realities and dilemmas that accompany this technology. Many countries in Africa such as Kenya fall far behind the technology and are therefore not prepared to handle situations that result from it***

complex ethical, philosophical, religious, legal and social issues. While we agree that the increasing availability of these technologies over time has received public attention that require careful scrutiny, the technologies have provided relief for many couples that genuinely need interventions to get children (Banerjee, 2006). Such couples do not include same sex couples or men and women who choose to be single or wealthy couples who do not desire to go through gestation process but want to rent wombs. Instead, these technologies should be strictly for couples with medical conditions that prevent conception and gestation. Among such couples are HIV sero-discordant or HIV infected sero-concordant couples.

#### **Assisted reproductive technologies for HIV infected couples**

Diagnosis of HIV positive status within a couple usually brings intense stress. This is especially so for childless couples in Africa where childless couples are mocked and despised. This is because the couples think about many things, among them, the risk of transmission of HIV within the couples and to their unborn children should they attempt to conceive. The thoughts are based on the fact that heterosexual intercourse is the main mode of HIV transmission in many settings including in Ken-

ya. The technologies of sperm-washing and artificial human insemination are available to assist HIV positive couples conceive safely (Savasi, Mandia, Laoreti, & Cetin, 2013). Even though technologies existed in the pre-antiretroviral era existed, this period was characterized by HIV discordant or concordant positive couples being immensely counseled against conceiving (Van Leeuwen et al., 2009). In fact, couples who happened to conceive were counseled to abort during the first tri-semester. According to van Leeuwen et al., the reasons for counseling against conception revolved around the concerns about (a) the inherent chances of vertical and/or horizontal transmission, and (b) short life expectancy of the future parent. The introduction of combination therapy in 1996 that saw a spectacular increase in life expectancy, AIDS-free survival, and quality of life of HIV infected persons led to debates about reconsideration of the near ban on reproduction for HIV infected couples (Baker et al., 2003). With confirmation that plasma HIV RNA below the limit of detection (50 copies HIV RNA/ml) is associated with low-

er risks of disease and lower levels of HIV in semen coupled with the technology of sperm washing and human artificial insemination, ART for HIV positive or sero-discordant couples blossomed. The rationale of providing assisted reproductive technologies to HIV infected couples was (a) to overcome sub-fertility so that it is at the same level as in non-HIV infected couples, (b) to minimize the risk of HIV transmission in HIV sero-discordant couples while attempting to have children and, (c) to prevent HIV super-infection with a different HIV strain in sero-concordant couples (Van Leeuwen et al., 2009).

#### **Legal, ethical and moral challenges of assisted reproductive technologies**

Even as we embrace the use of ART to help rightly deserving couples who are unable to get children in the natural way such as couples infected with HIV, we need to identify and appreciate realities and dilemmas that accompany this technology. Many countries in Africa such as Kenya fall far behind the technology and are therefore not prepared to handle situations that result from it. But we cannot fail to embrace useful technologies that respond to modern day challenges simply because our governments are not up to speed. Historically, it is not uncommon to come across technologies that developed ahead of countries providing legislative and policy framework (Thiankolu, 2007). These countries, by necessity, have done a good job in providing legislation behind the technology. One such technology in Kenya and, indeed Africa, that has developed in

this way is the use of mobile telephony which spread like wild-fire in the last two decades. Similarly, it is anticipated that there will be prompt legislation to provide a framework to manage the process of using ARTs as well as solve disputes that may result from the technologies. For instance, definition of parent in the Kenyan laws may be challenged for heterologous insemination (where a woman is fertilized by a sperm from unknown/non-spouse donor). As Thiankolu observes, the legal rights of parties to heterologous insemination as well as rights and status of children conceived and born from such insemination, largely depend on whether the sperm donor is anonymous or known and whether the woman's husband (if the woman is married), had assented to artificial insemination of the wife by the sperm of another man (Thiankolu, 2007). Otherwise,

***In Kenya, the Reproductive Healthcare Bill 2014 that is before parliament seeks to provide clarity and answer some of the difficult questions arising from ARTs. The Bill, among other things, provides legislative and policy framework for gestational surrogacy; specifically addressing such issues as surrogate parenthood agreement, genetic origin of a child, artificial fertilization of surrogate mother among other things***

if the commissioning father denied parenthood of the child the law statutes would still protect him in many countries including Kenya.

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arising from ARTs. The Bill, among other things, provides legislative and policy framework for gestational surrogacy; specifically addressing such issues as surrogate parenthood agreement, genetic origin of a child, artificial fertilization of surrogate mother among other things. Generally, this Bill forms a major milestone towards providing benchmarks for all stakeholders in assisted reproductive technologies. However, it seems to legitimize single parenthood which is not the design of African families even though they exist. Unless with sufficient reasons, it is morally wrong for a child to be denied the right of having two parents. Thus, it is not a good thing that knowingly we can design families with one parent and allow them to have children. Given the many ethical and moral issues that are inherent in assisted reproductive technologies, it is better if the technologies are restricted to only couples that for biological and medical reasons cannot naturally bear children. Another oversight of the Bill is its failure to directly address HIV infected couples who stand to benefit from these technologies in a big way. Addressing their needs would speak to safe conception as well as confidentiality. However, we recognize that ARTs are rapidly evolving to the extent that legislation is often unable to keep pace and address all of the ethical and legal issues that are constantly emerging in the field. As argued by Brezina and Zhao, it is incumbent upon the technology stakeholders to continually monitor emerging issues to ensure that the technologies are offered and delivered in a manner that balances patient care

with social and moral responsibility (Brezina & Zhao, 2012).

In terms of using ARTs, there have been exceptional concerns about medicalizing the technologies that in the process dehumanize human reproduction. The feeling that a human being can be produced in a petri dish is incomprehensible to lay people and brings a picture of the outcome being an object far less than a human being. People who are products of such processes may be stigmatized and looked at differently and thus creating divisions within human race. Other concerns about ART have been around existence of blood related people who are unknown to each other. As observed by Holbrook, although sperm donors consent to donate and dissemination of their sperms, they are never informed about the outcomes of their donations so that they are aware of other persons who are related to them (Holbrook, 1990). As it is, they have no idea whether a human being exists who is genetically related to them. In some instances, donors have been shown to have second thoughts of having sired children they never come to know or meet (Holbrook, 1990). For those who live in sparsely populated areas, the reality of their children ending up marrying their half-siblings without knowing is non-zero.

Children conceived through artificial human insemination are, in many cases, never told about the circumstances leading to being conceived this way. Couples are usually counseled not to tell anyone about conception by artificial human insemination to protect the name of infertile parent. Such children are unknowingly deprived of the basic facts about their origins which is an enormous violation of their rights (Holbrook, 1990). Another ethical concern is the possibility of rogue medical staff using their position to manipulate donated gametes to sire their own children. While we believe that medical staff conducting these procedure are people of integrity and morally prepared for the work, there is possibility that a few may act contrary to their training and oath. Another concern is the cost of accessing ARTs. There may be many couples in Kenya and other African countries who genuinely need assisted reproduction technologies. However, the average cost of KES 300,000 (<http://www.ivfcost.net/ivf-cost/ivf-cost-at-the-nairobi-ivf-centre-kenya-great-information>) is, for instance, prohibitive to many. This raises a moral question for those providing the service. It is important to note that currently most of assisted reproduction services are done in private clinics. One such clinic is Nairobi IVF center which has been largely successful in its operations

(Noreh, Tucs, Sekadde-Kigonde, & Noreh, 2009). The cost of these services are unlikely to come down significantly to be available to the poor majority unless the government subsidizes. This could be through setting up government IVF clinics.

Another ethical dilemma that has been the argument about when human life begin. It is argued that life begins when fertilization of the egg takes place. If this is true, then it is expected that the resultant embryos are treated as having life. IVF provides for harvesting and fertilizing numerous eggs to increase the chances of successful implantation in the womb. However, only few selected ones end up being used. The rest are either frozen indefinitely or destroyed. If we believe that life begins at conception, any destruction of the embryos is ethically equivalent to destroying human life. Religious organization have been very concern about this which has formed their basis for opposing some of the ARTs. Related to this is the question of freezing embryos for future use. For those who believe in life at fertilization, this action is basically putting hold on human growth. With all these manipulations of human life, are human beings taking over the role of God? Certainly we embrace science and all that it stands for but we need to move in measured steps so that we are not fast-tracking and rapidly scaling up technological advancements whose consequences we are not sure about.

## CONCLUSION

ART has emerged as one of the most widely adopted and successful medical technologies. While these technologies give hope to many couples suffering from infertility, and several other conditions that preclude them from bearing children in the normal way, they also present new ethical, legal, and social questions that societies must address. We are aware that many countries such as Kenya have taken, or are in the processing of taking steps to regulate certain aspects of ART. Although everything is being done to regularize access to ARTs, many ethical and legal questions that exist surrounding ART have yet to be resolved. Society must reconcile how to fund ART in a responsible and equitable manner to increase access to care. Additionally, the unresolved issues surrounding gamete and embryo donation must continue to be addressed in ethical, social and legal dialogues keeping in mind that ART is a field that is dynamic and ever changing. In areas of ART such as preimplantation genetics, new technologies continually change the capabilities of ART.

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By Josephine Odoyo  
RCTP-FACES

The HIV scourge has brought challenges in providing discordant couples with interventions for reproductive health and HIV, not only in sub-Saharan Africa but in Kenya as well. "HIV Discordant couple" sounds like a new phenomenon in many people's mind. It is defined as "a couple in a heterosexual relationship where one partner is HIV positive and the other partner is HIV negative. Discordant couples' challenges include societal expectations of couples' relationships and the product of the same relationship, fears of contracting HIV by the uninfected partner and HIV transmission to the unborn child from a HIV positive mother. These issues complicate the use of known reproductive health interventions to prevent HIV. In this article, we share experiences from our ongoing Partners Demonstration pilot study interaction with HIV-discordant couples. Family issues, condom use and impact of regulation and structures will be discussed. The ongoing Partners demonstration study aims to assess whether there is demand for daily oral Pre Exposure Prophylaxis (PrEP) as a bridge to ART initiation among couples in discordant relationships. A total of 281 couples were enrolled from 2012 for follow up, which ends in mid-2016. Pre exposure prophylaxis (PrEP) and anti-retroviral therapy (ART) were made available at the site clinic and informed consent sought for all study participants. From our study experience, HIV-discordance was not clearly understood by most participants. They continually asked several questions such as: how can this be possible? What will happen in the future if we continue living together? Should we continue having sex? Can we have children? Will

I get infected (for the HIV uninfected partner) and when will this happen? How is it possible to remain negative in such a relationship? Are we still in the "window period"? All these questions present ethical dilemmas in accessing discordant couples' interventions in the context of reproductive health and HIV. These pose challenges even to the health care providers, who do not have all the answers to these questions. We experienced ethical dilemmas when attending to discordant couples, especially when offering risk-reduction counseling. According to Springs et al (2003), various issues arise when offering HIV discordant couples reproductive health interventions, for example, offering assisted reproductive technologies; the moral question often asked is if it is right to question whether a couple in discordant relationship should get pregnant and have children or not, knowing very well they are human beings with feelings and sexual desires. Similarly, our participants have desires to have children and to fulfill societal expectations. Such questions however do not arise in concordant HIV negative couples.

#### Family Issues

Social harm is a very common occurrence in discordant relationships and can either be verbal or physical. Experiences from our study indicated that during family discord, a HIV-negative partner would sometimes verbally abuse the HIV positive partner that they were not present when the partner got infected with HIV. If this happened in the hearing of others, third parties would get to know the HIV status of the infected partner, causing embarrassment and stigma. This often led to separations with further non-disclosure if the HIV positive partner entered into a new relationship. Consequently, the new partner would be placed at risk of acquiring HIV because of

the unknown HIV status. This also led to non-adherence to treatment as they sought to keep their HIV status a secret. As a health care provider you may want to let the new partner know the truth, yet in the process you may breach confidentiality. This partner often also fails to keep their clinic appointments. The other challenging situation that posed an ethical challenge in our study was in polygamous relationships where, for instance, one female partner was HIV positive and the second female partner was HIV negative. Third party presence posed complications in offering services such as family planning or even ARVs/PrEP as non-disclosure made it difficult for the infected to adhere to their medication for HIV prevention. Hence, there was either a delay in taking the medication or

***Condoms are therefore, important in preventing HIV acquisition as they make their decisions in sexual and reproductive health. Although discordant couples in our study were counseled on condom use even during preconception counseling, condom use was often overridden by the couple's desire to have children. Couples were therefore counseled on when it was safe to have unprotected sex.***

defaulting, for fear of the other negative partner finding out and asking questions. Confidentiality may be breached in the process. In such a case, the dilemma the provider faces is whether the other female partner who is not enrolled in the study should be told about the HIV-infected female partner. Is it right for the health care provider to disclose confidential information or should he/she withhold the information knowing well that this may put the other partner at high risk of getting HIV. In rolling out family planning as a reproductive health service, challenges arose where a male partner refused to receive care believing that the health care provider had convinced the female partner to use family planning against his wishes. In a case where the woman was HIV negative and she wanted a family planning method, sometimes the partner, due to religious beliefs, completely refused an intervention that could be beneficial in planning their family. Decision making-by male dominance potentially hindered family planning access even if the woman was ready to receive the service.

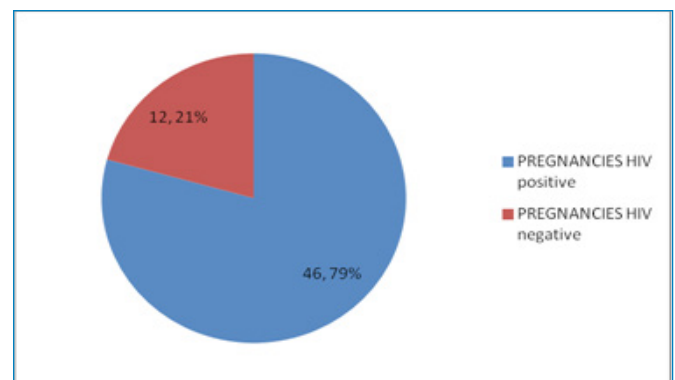
#### Condom Use

Behavioral measures are particularly important in HIV prevention. In our study, the dilemma arose during data collection, where a partner reported condom use and the other partner confided in the health care provider that the partner refused to use condoms, requesting the provider to intervene. This posed a challenge to the provider, because it was difficult to let someone know that his or her partner may not be telling

the truth. Dishonesty regarding condom use, could lead to HIV transmission, but at the same time it was challenging to engage both partners on risk reduction counseling since one partner was not telling the truth. Condoms are interventions that have been recommended to discordant couples for their multipurpose benefits, namely, prevention of sexually transmitted diseases including HIV and unwanted pregnancies. Condoms are therefore, important in preventing HIV acquisition as they make their decisions in sexual and reproductive health. Although discordant couples in our study were counseled on condom use even during preconception counseling, condom use was often overridden by the couple's desire to have children. Couples were therefore counseled on when it was safe to have unprotected sex. This worked for some as was shown in below that illustrates the number of pregnancies observed in Partners Demonstration study in HIV positive and HIV negative women in discordant relationships during the follow up period. HIV-positive women had a higher number of pregnancies than their HIV-negative counterparts.

#### Pregnancies with live outcome per HIV status

		PREGNANT		
		YES	NO	Total
HIV Status	Positive	46(24%)	152(76 %)	198(100%)
	Negative	12(14%)	71(86%)	83(100%)



#### Regulations/Structures

With the new ART treatment National guidelines, ethical dilemma arises as the guidelines states that all HIV positive adults in serodiscordant relationships should be started on ART regardless of their CD4 counts. Some of the reasons for the HIV positive partners delaying starting ART treatment because of being in a state of good health and fears of side effects for the drugs. The negative partner on the other hand may refuse take oral PrEP daily simply because they know and argue that they are not sick despite the knowledge that PrEP will protect from HIV acquisition. As a health care provider, you understand there is a high risk of the negative

partner getting HIV infected, yet the couple still asks for advice, the challenge is how to approach such an issue. At other times delays also occur in implementation of the National guidelines recommendations at referral care centers when the health care provider gives a contradictory recommendation, making it very difficult to discuss new policy guidelines.

#### Assisted Reproductive Technologies

With continued advances in HIV and prevention technologies, ART has improved and prolonged life expectancy of HIV infected individuals. This therefore means they can have a similar life expectancy to that of their uninfected counterparts, during which they would have desires of having children. Assisted reproductive health technologies such as sperm washing become handy in such instances, but the cost of such services is prohibitive for most couples in discordant relationships. Therefore, in our study we provided counseling and assistance on vaginal insemination to discordant couples who desired to conceive to. In this technique, the HIV-discordant couple would have sex using a male condom (condoms were provided at the study clinic); the semen in the used condom would first be

drawn into a plastic syringe and then inserted in the HIV positive woman's vagina to help her get pregnant. Couples were counseled on when it was safe to have unprotected sex, as repeated acts may put the uninfected partner to a much higher risk of acquiring HIV. This worked for some as was shown in the graph above though for some the male partners were often uncooperative and were at times unwilling to come to the clinic together for counseling.

#### Conclusion

Reproductive health and HIV interventions are of public health importance because they are safe and reduce the chances of HIV transmission to the uninfected partner and to the unborn baby. The ethical challenges discussed here are however real and need urgent answers for the recommended reproductive health and HIV interventions to fully be effective. This will only be realized if policy recommendations consider the associated ethical dilemmas vis-à-vis the discordant couples' concerns, needs and desires.

## COURSE ANNOUNCEMENT

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**VENUE: Manhattan, New York**

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# The Childless couple:

## At what cost should childlessness be remedied?



Photo by google images

By Caroline Kithinji  
KEMRI-SERU

Two women go to a fertility clinic for artificial insemination in order to conceive. One is African American and the other is Caucasian. Let us call them Aisha and Ashley. They become friends in the course of their countless appointments the gynecologist. The treatment procedures included a hysteroscopy/HCG to determine the fallopian tubes are clear and the size and shape of the uterus. An infectious disease test, to ensure that there are no contagious diseases present. A mock cycle to see how the uterine linings will react to hormone replacements, a Pap smear to see if there are any physiological impediments that would hinder them from carrying the baby, and a trial transfer to check the length of the uterus to find out how far to insert the catheter, which will be loaded with embryos. After the onerous procedures were completed Aisha found out to her delight that not only was she pregnant, she was carrying twins. Ashley on the other hand did not get pregnant. Aisha bore the challenges of pregnancy with joy, notwithstanding the backaches, swollen ankles and bed rest from 7 months of her pregnancy. She delivered both babies safely at term and her joy was complete. Imagine her shock and surprise when one baby was African American and the product of her ovum and her husband's sperm, the other baby was Caucasian. It was clear that the fertility clinic had mixed up the embryos! As it turns out the Caucasian baby was from the embryo of Ashley and her husband. So here is the question? Who does the baby belong to? Aisha the one who carried the baby? Or the genetic/biological parents of the child? Who is the mother of the child?

Surrogacy raises the stakes even higher because in this case they can be a possibility of three mothers depending on what type of surrogacy plan there was. A surrogate mother is a woman who carries and gives birth to a child usually for an infertile couple. Surrogate mothers are not a new solution to an old problem of infertility. Surrogacy has been around since biblical times. An interesting bible scenario is Sarah, the wife of Abraham. Sarah could not have children for a very long time and getting tired of waiting for the promise she had been given by God that she would bear a child, she gave her handmaid, Hagar, to her husband Abraham to produce them a child. The method of surrogacy was copulation. The outcome of the arrangement ended in disaster. Sarah became jealous (the spouse), the surrogate became proud (Hagar) and refused to give up the identity of the child and consequently, Sarah had both Hagar and her son (Ishmael) sent away. The above is an example of altruistic surrogacy where no contract was written.

It is no different today and surrogacy raises many complex ethical, social and legal issues. In the biblical story the surrogate arrangement involved three (3) parties. Today, surrogacy arrangements may involve numerous parties, depending on the law there may be from two parties (the surrogate mother and one intended parent) up to eight (8) parties (the surrogate mother and her partner, the intended parents, donors of the sperm and ova and their partners). In addition, there may be agents, intermediaries, lawyers and clinics: all of whom who stand to gain financially.

There are two types of surrogacy, traditional and gestational. In order for pregnancy to take place, a sperm, egg, and a uterus are necessary. The traditional form of surrogacy in-



volves the surrogate mother being artificially inseminated with the sperm of the intended father or sperm from a donor if the sperm count is low. In either case the surrogate's own egg will be used. Therefore, genetically the surrogate becomes the biological mother of the resulting child. Traditional surrogacy is recommended when the intended mother has medical disorders to the ovaries and cannot produce an ovum. In gestational surrogacy, the surrogate mother has no genetic ties to the offspring. Eggs and sperm are extracted from the donors and in vitro fertilized and implanted into the uterus of the surrogate. This is an expensive procedure. The unused embryos may be frozen for further use if the first transfer does not result in pregnancy.

#### **Ethical, social and legal issues of surrogacy.**

In western countries where surrogacy is legal, surrogates are usually educated women with 13 or more years of education, mostly these women are employed and are not undergoing financial difficulties and are predominantly Catholic or Protestant (Update of "Surrogate Motherhood" in Ethics in Obstetrics and Gynecology, Second Edition, 2004). In contrast, Low and Middle Income Countries (LMIC) surrogates are poor and illiterate. The economic and power differential between the surrogate and clinician, or intended parents, is extreme (Deonandan R, Green S and van Beinum A, JME 2012; 38:742-745).

So the first ethical issue is the autonomy and informed consent. Imagine if you will, your colleague or neighbor becomes pregnant, a 20-something single lady, but the pregnancy is shrouded with mystery. She will not divulge the father of the child. She can suddenly afford to eat well and go to the most expensive hospital for ante-natal clinic. Even more surprising after the baby is born, the baby disappears and it is rumored that the baby was Caucasian! Imagine the social stigma that will follow this lady when all the facts are revealed? When considering the risks of being a surrogate, in addition to the physical and psychological risks, social risks such as stigma from the community should be considered. Is the benefit of surrogacy usually measured in monetary terms, Indian surrogates can make as much as US\$6000 (Bardale R, JME 2009; 6: 56-7) equal to more than the risks of surrogacy. In this light, should then informed consent extend to the family, extended family and neighbors?

Going back to Ashley and Aisha scenario given at the beginning of this article, the second ethical issue is custody. Who was the rightful mother of the African baby? The genetic mother or the one who carried the child? How should custody issues be agreed upon? Who will obtain guardianship of the child if the intended parent/parents die when the child is a minor? President Barack Obama is fondly referred to in some circles as a son of Kenya. If President Obama was a product of surrogate arrangement would the sperm donor be allowed to claim rights on his success? Depending on

***So the first ethical issue is the autonomy and informed consent. Imagine if you will, your colleague or neighbor becomes pregnant, a 20-something single lady, but the pregnancy is shrouded with mystery. She will not divulge the father of the child. She can suddenly afford to eat well and go to the most expensive hospital for ante-natal clinic. Even more surprising after the baby is born, the baby disappears and it is rumored that the baby was Caucasian!***

the jurisdiction, a surrogate's custodial rights can be strong (Michigan's surrogate Parenting Act) or robust providing more assurance for the intended parents (Ramasubramanian, Indian surrogacy <http://blog.indiansurrogacylaw.com>).

A third ethical issue is quality and limit of surrogate care. Perhaps no topic related to surrogate motherhood is more contentious than compensation of the surrogate mother by the intended parents (Moody-Adams MM, Public Aff Q 1991; 5:175-90). Should payment be made contingent on the delivery of an "acceptable product"? What if the surrogate miscarries? Does she forfeit payment? A good lawyer would ensure that these issues are spelt out clearly in the surrogacy contract. What may be overlooked though is whether surrogate care should extend beyond the gestation period. Carrying a child for nine months will result in bonding and the expectation of the baby evokes feelings that do not just disappear after the baby is given away. Should payment extend then to the post-partum period? Given the likelihood of post-partum injury (depression), it remains unclear who is ultimately responsible for assuring that a surrogate is given sufficient care to recover from such conditions (Deonandan R, Green S and van Beinum A, JME 2012; 38:742-745). In the instance that a surrogacy clinic is involved, as is the case in India, a woman with proven gestational ability is an asset and it would be rational for that clinic to ensure her continued health and gestational capacity. It is likely, however, that clinics would extend this care for economic reasons rather than ethical reasons. The motivation notwithstanding, granting extended care is ethically correct.

A fourth ethical issue is multiple embryo transfers and abortion. As mentioned previously gestational surrogacy is expensive. In certain cases a clinician can opt to implant more than one embryo in the surrogate mother. This is when more than one child is desired by the intended parents, to maximize the probability of a successful implantation and to reduce the cost to the intended parents (Hurst T, Shafir E, Lancaster P, Assisted reproduction series no. 3. Sydney (AU):AIHW National Perinatal Statistics Unit, 1997). It must be said though, that multiple embryo transfers is a dangerous medical condition and is avoided by fertility doctors in

the West (Schieve LA, Meike SF, Ferre C et al., N England J Med 2002; 346:731-7). Unfortunately, in LMIC this is seen as a viable cost saving measure and touches on the autonomy of the surrogate and the nature of her informed consent.

The American college of Obstetrics and Gynecology in its Committee Opinion No. 397 states that "it is preferable that surrogacy be overseen by private nonprofit agencies with credentials similar to those of adoption agencies". However, many existing agencies are entrepreneurial and for profit (Surrogate mothers. American Fertility Society. Fertil Steril 1994;62 (suppl 1): 71S-77S). This brings me to the fifth ethical issue. Medical advocacy. If the clinic receives payment from one party (the intended parent) and performs a procedure on a second party (the surrogate), it is highly likely that interests of the paying client will take precedence, even to the detriment of the health of the surrogate. The surrogate is therefore at the mercy of the clinic. This situation is similar to a research participant in a clinical trial negotiating for Post-Trial Access to the drug once it is registered and on completion of the trial. The negotiating power of both compared to the other stakeholders is not commensurate.

Several stakeholders with competing interests are at play: the client, her spouse, the surrogate and of course the child. The potential for conflict of interest is great, especially when clinical decisions must be made that weigh monetary cost against the health of the surrogate. There is tension therefore between business ethics on one hand and medical ethics on the other. On one hand medical ethics demands that the one considers the best interest of the patient on the other, in business ethics all actors are expected to consider only their own needs, not

the needs of the other party. One solution is to assure that each surrogate is given the support of a separate medical advocate to counterbalance the great power held by the client to influence decisions made about the surrogate's health (Deonandan R, Green S and van Beinum A, JME 2012; 38:742-745).

The sixth and final ethical issue is one of exploitation of the poor. As mentioned previously there is a vast difference in the context in which individuals in the West become surrogates and that of women in Low and Middle Income Countries. The prime motivator in LMICs would be financial as opposed to the altruistic surrogacy in countries that prohibit paid surrogacy, as Indian surrogates for example are universally poor (Bardale R, JME 2009; 6: 56-7). Is it ethical to use this desperation to encourage participation? Is it ethical to "rent a womb?" irrespective of the possible risks the mother may face? On the other hand is it ethical to deny the poor mother the opportunity to lift her family out of perennial poverty standing on principal that financial need is an inappropriate lever? Can exploitation ever be beneficial?

In conclusion, the World Health Organisation (WHO) now defines infertility as a disease meriting medical treatment (The Warnock Report, 1984). Assisted Reproductive Technologies (ART) have gone some way towards "curing" the disease. The ethical balance of respect for persons, beneficence and justice is between the certain and debilitating burden on the childless couple and the potential burden that will be placed on the surrogate if she were to rectify the state of childlessness of the childless couple. It is the greatest gift one can give to another and should not be taken lightly.

**FURTHER READING.**

<http://www.surrogacyabroad.com/blog/tags>

<http://www.healthlawcentral.com/assisted>

<http://www.hfea.gov.uk/fertility-treatment>

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# Multipurpose Prevention Technologies As Seen From a Bowl of Salad Combo



freedigitalphotos.net

By Everlyne Ombati  
CMR-RCTP

*This article was published on the AVAC website, blogs section on  
14th November 2014*

<http://www.avac.org/blog/mpts-seen-bowl-salad-combo>

**S**alad! Fruit salad! Vegetable salad! You know, the type that come with all the goodness served in one bowl. Or those that you get to choose the combinations that sate your palate's desire? Sometimes I'm perfectly okay with slicing a succulent cucumber and sprinkling it with some creamy garlic vinaigrette. When I want to outdo myself, I love taking my time to make a good chopped salad, and I will add a variety of nuts and seeds to make it richer. The result is a yummy bowl named Chef Eve's Saturday Special. My neighbor calls it "The rabbit diet". Some of my friends would rather have the nuts and leave the "leaves" alone; others think I need prayers for some of my food choices. My mother tells me I need to eat "real" food more often. Well, we all have diverse tastes, and different food preferences. This salad combo works perfectly for me. No burned fingers, and most importantly no scrubbing burnt cooking pots afterwards.

And salad, my dear friends is what exactly I think about when someone mentions Multipurpose Prevention Technologies (MPTs). These are products in development that would simultaneously address multiple sexual and reproductive health needs, including prevention of unintended pregnancy; prevention of sexually transmitted infections (STIs), including HIV, and/or prevention of other reproductive tract infections (RTIs), such as bacterial vaginosis or urinary tract infections.

Several MPT formulations were presented at the recent HIV Research for Prevention or "R4P" conference in Cape Town (October 27-31, 2014). The ones discussed in Cape Town combine contraceptive and microbicide approaches to prevent pregnancy, HIV—and, in some cases, other STIs like herpes—into one product. How can this not be exciting to anyone? While these products do not exist yet, the idea is a great one: You pop a pill, and voila! You hit the freeway.

Not really, but it could be liberating to have a prevention tool that allowed you not worry about pregnancy or HIV.

Daily oral PrEP using tenofovir is already an option women could use—and lots of women talked about it in Cape Town—as a way to take control over HIV prevention and stop worrying about our husband or boyfriend having a "mpango wa kando" (Swahili slang name for multiple sexual partners).

In the future, an MPT injection might be developed that would let you get a tiny unpainful jab (at least that's what I hope it will be; no one likes needles!), and for one, or two or three months or more, you need not think about pregnancy, or HIV, or herpes. And then there are those of us who would want to have a baby but then would not want to have an infection. Well, guess what? MPTs could have our backs covered too. There is research into MPTs that will prevent HIV and STIs but allow for pregnancy. Just like salad, if you don't like nuts, we can make you a garden "combo" or we can just slice up the cucumber; there are many options! The choice is yours. Dr. Nelly Mugo, a researcher at KEMRI likes to say "The same thing does not work for the same woman all the time." I agree, whole heartedly. Some days, I don't even want to see my best



combo salad. Some days I just want a giant mug of the over-priced pumpkin spice latte! If only we had Starbucks in Kenya!

Let's just pause for a minute, and do the math. No, not advanced calculus, just big numbers and percentages. Statistics show that globally, approximately 35.3 million people are living with HIV. Sub-Saharan Africa remains most severely affected, accounting for 71% of the people living with HIV worldwide.

More than half of them are women. Approximately 40% (80 million annually) of all pregnancies are unintended. 80 million! That's about twice the population of my lovely country Kenya! This is a mind-boggling number. More than three-quarters of these pregnancies occur among women with an unmet need for contracep-

tion living in low-resource countries. It is estimated that approximately half of all unintended pregnancies end in illegal abortions likely occurring under unsafe conditions, leading to maternal deaths, and either temporary or permanent disabilities among millions of women. The WHO maps provide an over view of the global SRH burden. In the MPT session this morning, the maps were dubbed as "the warm colored maps" showing large regions of unmet SRH needs, and seems that the brighter the colors the higher the prevalence of HIV/STI or unmet family planning needs or the more deaths they indicate. How sad. Some of those colors are really fancy. I hope they do maintain those lovely colors when MPTs will be out in the market doing what they were developed to do, and then the colors can show the decline in HIV, decline in maternal health, decline in unintended pregnancy. Decline. Decline. Decline. Am a dreamer. And all dreams are valid. Ask Lupita Nyong'o.

Now, imagine the possibility product that would reserve this numbers! I am looking forward to that day. It is so exciting to know that developers, scientists, social behavioral scientist and market researchers are all burning midnight oil in a collaborative effort to ensure successful development and delivery of MPTs. To suit our diverse SRH needs, MPTs are being developed in diverse formulations. For instance a single sized diaphragm is being evaluated in South Africa as a reusable delivery of a microbicide gel that could reduce the risk of HIV. The

diaphragm is already a contraceptive that prevents unwanted pregnancy. It also presents an option for non-hormonal barrier contraception. With an anti-HIV gel, it could be a one-two punch.

There are several other MPTs under development including intravaginal rings that combine contraceptive hormone with ARVs for HIV and HSV2 prevention; and multipurpose injectables. These different formulations provide many op-

tions for women and could also allow women to use a product without necessarily negotiating with their sex partners. The need to have HIV prevention options that do not require negotiation with a partner, was emphasized in one of the lunch time session at the Advocate's Corner. At HIV R4P. One of the participants expressed concerns



Microbices

Photo by google images

that all options currently available need some form of negotiation, and if one is not negotiating one is wondering if their partner is "wearing their ARVs". Such are the issues that make me think MPTs could not have come at a better time.

Even though MPT are still at the very early stages of development, a lot of progress has been made so far. But even as stakeholders continue with the development process, there are a number of unanswered questions that need to be addressed; do we know if MPTs will be effective? Do we know what women want? Do women know what they want? When these products will be found to work how will they be provided to those who need it? Will the MPTs be easily assessable when available? Will the women afford the products? How do we address issues around provider attitude? Will we be able to manufacture them? These are just a few of the many questions that need answers. As Prof Elizabeth Bukusi said in Cape Town, the process is like navigating your way on a very muddy road, one is never really sure if they will get to the end, but there is always hope that you will get there, "and if you can't take the road, take the boat" she said. We need to think about where we have come from so far, where we are at with the epidemics, and find a way to get us to where we are going.

**For more information on MPTs, visit <http://www.avac.org/prevention-option/multipurpose-prevention-technologies>**



# Case Challenge: Evaluating sexual health and family planning programmes

*Adapted from WHO CASEBOOK ON ETHICAL ISSUES IN INTERNATIONAL HEALTH RESEARCH, 2009, Case 2, pg 43*

The Institute for Family and Youth has a contract with a bilateral funding agency to implement family planning and sexually transmitted infections (STI) and HIV prevention programmes in developing countries. The funding is conditional on inclusion of an evaluation component. Through its “Healthy Ideas!” programme, the Institute has recently established three public health prevention projects in developing countries:

- An HIV testing and counselling programme for adolescents with sites in one country in each of three regions (eastern Europe, sub-Saharan Africa, and South-East Asia ) which will be evaluated using questionnaire surveys of adolescents over a 3-year period to investigate frequency and types of drug use, sexual activity, and sexual preference.
- The second project will provide prenatal care to a poor, urban community located in a country where HIV infection is still highly stigmatizing. The evaluation component will examine the frequency of partner notification among married and unmarried women whom the clinic diagnoses as HIV-positive.
- The third is a condom education project which will be located in a South American city with rapidly rising incidences of STIs and HIV. It has been modelled after a “100% condom use” programme found to be effective in South-East Asia, in which graduated sanctions are imposed on brothel owners based on the rate of STIs found among female sex workers in brothels. Ultimately, the brothel runs the risk of closure if sex workers repeatedly get STIs. An evaluation is planned to assess the feasibility of implementing the condom programme.

The Institute for Family and Youth says these projects do not need clearance from a research ethics committee because the activities are low risk, do not test an intervention, and are “operations research,” not bio-

medical research. The head of evaluations at the Institute cites “human subjects research” regulations in the United States of America under which she believes ongoing evaluations of actual interventions are not subject to ethical review. She also stresses that the findings of the evaluations will be used to help design better public health programmes for the other sites where the Institute runs disease prevention programmes.

## QUESTIONS

- 1 Are any of these projects research studies? Explain why or why not.
- 2 What distinguishes research from ongoing evaluations of public health interventions?
- 3 Do these activities require any ethical oversight?
- 4 The Institute for Family and Youth says that these projects are low risk. Discuss what is meant by “low risk” in the context of an ethics review? Does the level of risk affect whether or not it needs to be reviewed?

*Adapted from “What is Research” contributed by Joan Atkinson and Nancy Kass, Johns Hopkins Bloomberg School of Public Health and Johns Hopkins Berman Institute of Bioethics.*

The first three respondents in will receive a prize.  
The first correct response will also receive a prize.  
Answers should be submitted to [ddrt@kemri.org](mailto:ddrt@kemri.org)