Ethical issues in HIV/AIDS research

Vasantha Muthuswamy

*Indian Council of Medical Research, New Delhi, India*

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Globally the HIV/AIDS epidemic has presented unique health challenges to populations, including a host of ethical and moral issues related to human life and dignity. The disease has most affected the vulnerable groups of people in the world often leading to stigma and discrimination. Currently the critical areas of concern include access to treatment and developing newer, more effective therapeutic and prevention methods while taking care of ethical values in health care and research. The ethical issues mainly revolve around the standard of care, informed consent across cultures, privacy and confidentiality, stigma and discrimination, protection of vulnerable groups, community consultation, ethical review mechanisms, international collaboration, epidemiological studies, clinical trials and also socio-behavioural studies on HIV/AIDS. In addition major concerns are raised regarding HIV/AIDS vaccine trials, microbicidal trials as well as prevention of parent-to-child transmission (PPTCT) trials especially in resource-poor countries. For international collaborative research appropriate standard of care, community benefits, and host country needs must be kept in mind. Improving our understanding of the various ethical and societal concerns related to HIV/AIDS treatment and research would help in development of appropriate policies for disease control and prevention.

**Key words** Antiretroviral therapy-ethical review-HIV/AIDS-informed current-socio-behavioural studies-standard of care Reprint

HIV/AIDS has affected several nations by knocking down decades of development, widening the gap between the rich and poor nations and pushing the vulnerable populations to the margins of society. According to the recent UNAIDS report an estimated 39.4 million people are living in the world with HIV, the virus that causes AIDS of which 90 per cent are living in developing countries with over 64 per cent in sub-Saharan Africa. The most vulnerable groups of the populations - women, children, young adults, sexual minorities (men having sex with men, lesbians and third sex) are the worst affected with 47 per cent being infected women in general while 76 per cent women in sub-Saharan Africa. The social vulnerability to contracting HIV infection and developing AIDS encompass poverty, illiteracy, stigma and discrimination. The extent of vulnerability is directly proportional to the magnitude of the risk for HIV and access to affordable health care and prevention strategies.

At the 26th session of the UN General assembly in June 2001, the Heads of States declared their commitment on HIV/AIDS, expressed concern and on the devastating impact of HIV/AIDS is one of the most formidable challenges to human life and dignity, a disease that undermines the social and economic development at all levels of society – at the national, community, family and individual levels. There is an urgent need to have a co-ordinated and sustained
response to the HIV/AIDS epidemic built on the experience gained in the last twenty years. Effective preventive strategies, care and treatment provisions along with understanding the behavioural aspects are given priority in all countries.

Critical Issues

(i) Access to treatment: Access to diagnostics, antiretroviral and other therapies and preventive measures such as condoms, microbicides, sterile injecting equipment and safe blood supply are the most critical issues. Currently available treatments can only slow the progress of the disease but does not offer complete cure or eradication. The most effective of all is the antiretroviral therapy (ART) which is complicated to administer, requires close medical supervision, causes significant adverse effects and above all is extremely costly. The most needy groups are not having access to therapy viz., those living in developing countries and the marginalized communities in the developed countries. The WHO has declared the lack of access to ART to HIV/AIDS as a ‘global health emergency’ in September 2003 and announced an emergency plan to scale up access to treatment for at least 3 million people by the end of 2005. This joint WHO/UNAIDS announcement is popularly known as the 3 by 5 initiative and calls for action by all countries and agencies. The Governments of various countries have announced different policies including Government of India which has issued guidelines for phased scale up of access to antiretroviral therapy for people living with HIV/AIDS. According to this 1 million people in 6 high prevalent states will receive antiretroviral (ARV) drugs free of cost from 1st April 2004 targeted to 3 vulnerable groups – mothers who participated in the prevention of parent-to-child transmission (PPTCT) programme as seropositive antenatal cases, seropositive children below the age of 15 yr, and people with AIDS who seek treatment in selected government hospitals. Further, the Government of India is pursuing its dialogue with the pharmaceutical industry and is reviewing fiscal incentives in order to optimize additional potential reduction in the cost of ARV drugs. Thus the ethics of access to health care has received serious attention from various sources. However, the sustainability of these efforts and implementation to ensure the access to rightful beneficiaries are great challenges.

(ii) Increasing funding for research and development (R and D) for new therapeutics and prevention methods: The WHO released guidelines for the use of antiretrovirals in resource-constrained settings in April 2002, and added 10 ARV drugs to its list of “essential medicines” for all countries. It recognized for the first time generic manufacturers and issued a list of qualified manufacturers. These guidelines have since been revised in June 2003 and by September 2003, WHO declared lack of access to ARV for HIV/AIDS a ‘global health emergency’. These initiatives have put tremendous pressure on pharmaceutical industry resulting in reduction in drug prices, dual drug pricing strategy, drug donation schemes etc., thereby increasing the corporate responsibility towards reducing the disease burden. There is a need to make the currently available drugs accessible by cumulative response from various quarters including pharmaceutical industry and to develop new preventive and therapeutic modalities by accelerated R and D efforts and international co-operation. The potential imbalances in various countries and between communities/groups within countries demand that ethically acceptable clinical trials and strategies are planned in different locations so that communities and countries needing early interventions can be benefitted.

(iii) Ethics of health care and biomedical research: Care and support, and research agenda in various countries as well as national and international agencies have created global debate as the handling of these issues at various levels have caused intense ethical dilemmas. It has become increasingly difficult to adopt a single strategy that can be universally applied to all countries. The revised Helsinki declaration of October 2000 setting guidelines for standard of care and use of placebo in clinical trials has become controversial from the day of its release because of the sensitivities involved in the HIV/AIDS research where uniform policy cannot be adopted in all countries or in all groups of populations within the countries. Further, HIV/AIDS is not a simple viral infection that can be treated with a chemical derivative or prevented with a protective vaccine. It is
associated with various other factors such as sexual act, blood transfusion, behavioural aspects, drug abuse, etc., which are associated with stigma and discrimination increasing the risk of social and psychological harm for people suffering or susceptible to this infection.

The ethics of health care and medical research revolve around the issues related to basic human rights and provision of health care, assurance of safety and benefits to the communities, prevention of harm of any kind while protecting privacy and confidentiality and ensuring global justice in these endeavours. The challenges being faced by the policy makers, health care providers, biomedical researchers, behavioural scientists, pharmaceutical industry and the International agencies are tremendous, mind boggling, complicated and controversial. There is no easy solution at present. Situational analyses are to be done and decisions taken to suit the local needs and sensitivities while taking into consideration cultural nuances at different locations. The dream to have a golden, ‘universal’ ethical standards in the world is totally thwarted by the HIV/AIDS pandemic. However, the silver lining is the emergence of newer partnerships, strategies, policies and political commitments which should help in containment of further spread of the disease.

The basic principles guiding the ethical concerns have been autonomy of individuals, justice in care and participation in research, beneficence and non-maleficence. Added to these principles, the issues of accessibility, affordability, standard of care, stigma and discrimination, post-trial benefits, equity and sustainability of interventions have generated intense consultations and international debate.

**Ethical issues in HIV/AIDS research**

Research in the area of HIV/AIDS encompasses all aspects of biomedical research such as Epidemiological surveys, clinical trials of drugs, diagnostics and preventive vaccines, socio-behavioural studies, etc. involving not only those who are affected but also those who are associated with these individuals and are vulnerable to acquire the infection such as newborns, sexual partners, needle sharers and transfusion recipients. Though the basic principles, procedures and regulations are similar to any other area of biomedical research, there are additional considerations requiring specific attention for the promotion and protection of human rights; specially in the area of international collaborative research as pointed out by Solly Benatar that “ethical dilemmas faced in conducting collaborative international research can only be addressed satisfactorily if research ethics is seen as intimately linked to health care, to human health globally and to the promotion of social and economic processes that could begin reversing widening global disparities in health”. The expansion of HIV research around the world has brought out heightened awareness of the problems of adapting ethical standards developed in countries of the developed world (north) by resource poor settings in the developing countries (south). In a consultation held at WHO, Geneva in June 2004, it was realized that while major investments have been made to formulate guidelines and provide training in different countries, less attention has been paid to the process of implementation, especially in resource poor settings. Further, it is not clear whether the strict ethical standards for ethical clearance have hindered the conduct of research or stimulated innovative responses. The diversity of approaches for operating, financing and supporting ethical review and the emergence of new mechanisms such as “for profit review committees” raise a number of questions regarding optimal institutional arrangements. The major ethical issues include (i) standard of care; (ii) informed consent across cultures; (iii) privacy and confidentiality; (iv) stigma and discrimination; (v) protection of vulnerable groups; (vi) community consultation; (vii) ethical review mechanisms; (viii) international collaboration; (ix) epidemiological studies; (x) clinical trials and (xi) socio-behavioural studies.

The debate on the ethical requirements for conducting medical research in developing countries has been heightened since the HIV/AIDS pandemic and the growing global disparities in wealth and health, resulting in multiple guidelines from developed world. This underlines the ethical dilemmas facing the researchers of the North while collaborating with countries in the south in various research programmes.
related to HIV/AIDS. The HIV Preventive Trial Network (HPTN) Ethics guidance document developed by HPTN Ethics Working Group of, Family Health International, USA attempts to guide ethical decision making and practice aimed at promoting the welfare of HPTN research participants and communities\(^{11}\). While identifying acceptable standard of care for research participants, defining parameters for relevance of research to host countries, reducing risk associated with stigmatization, ensuring informed consent for complex research with potentially vulnerable participants, determining ethical authority and accountability in international collaborative research and designing research that meets local needs as challenges, the document provides guidance on four points: (i) general considerations; (ii) meeting local needs and priorities; (iii) care and prevention; and (iv) informed consent.

Many countries such as India, Philippine and South Africa\(^ {12-14}\) have come out with guidelines to suit the local requirements. However, it is a dynamic process and all the guidelines need constant revision and updating to keep pace with the changing scenario and the policies adapted by the countries on a continuing basis. Some of the major issues facing the specific research areas are as follows:

**Epidemiological studies**: There is a need to collect public health data to assess the real burden of the disease to plan interventional strategies. Underreporting, especially in countries with weak health care services results in improper surveillance or management programmes. Studies based on small or questionable samples do not give a realistic picture and hence a continuous surveillance programme is to be put in place. However such screening programmes have the following ethical concerns: (i) Extent of community consultation – when, how and whom to consult; (ii) informed consent from individuals/ community leader – individual consent to be; insisted in addition to consent of community leaders, tribal chief or ‘gate-keepers’; (iii) privacy and confidentiality- of all data collected; (iv) disclosure to third parties – including partner notification; (v) stigma and discrimination – prevention at all levels; and (vi) screening high risk groups in addition to general population.

Any screening or testing demands right to self autonomy with the provision of best possible services of pre-test and post-test counselling. The physical environment in which counselling is carried out should be conducive and enabling, to prepare those tested positive cope up physically and mentally with accurate information on how to live with positive status, safe practices to prevent spread of infection and availability of treatment facilities before informed consent is given. While screening those with diminished autonomy in addition to consent of legal guardians, wherever possible, the individual consent should also be taken. Although pre-test counselling is aimed to advise testing, the right to refuse testing should be respected. No undue pressure or coercion should be exercised. Right to privacy and confidentiality of the test results should be kept in mind while disclosing positive test result to individuals. It is important to remember that confidentiality is fundamental in any public health strategy and especially in a physician-patient relationship where trust is the foundation. Maintaining confidentiality helps in integrating positive people into mainstream society by avoiding stigma and discrimination. However, law does recognize exception to the role of confidentiality when public interest to disclose positive status of an individual outweighs their private interest for the benefit of others. This shows the conflicting rights of confidentiality vs. right to information. The classic example is the case of a positive groom whose status was informed to the would be bride by the physician and the Supreme Court of India upheld the action when the groom pleaded for breach of confidentiality\(^ {15-16}\). It also added that an HIV positive person who marries and transmits the infection to the spouse would be criminally liable under Sections 269 and 270 of the IPC (Indian penal code) which criminalize those who perform a negligent or malignant act likely to spread a disease dangerous to life. The court however, did not lay down any condition or protocol by which such disclosure was to be made. Ideally partner notification is done by the individual themselves or with their informed consent. The case in question is an exception where the girl’s right to safety and information was considered more important than the privacy issue. However, in situations related to employment, insurance, etc. privacy should be maintained. But the
issue of stigma and discrimination needs great care as it is widely prevalent in spite of the fact that the public and private health care institutions have a duty to treat all cases. In the absence of anti-discrimination legislation in most countries, the discriminatory practices continue. Further denial of employment benefits to the family of diseased HIV-positive workers should also require appropriate policy guidelines. The general belief that the disease is prevalent in high risk groups is no more tenable as in many countries including India the highest mode of transmission is unprotected heterosexual route in the least vulnerable low risk partners namely the unsuspecting women. Hence screening of general population has to be carried out with proper ethical safeguards.

**Clinical trials in HIV/AIDS**

*Drug trials:* Clinical trials with the view to develop new therapeutic antiretrovirals as well as preventive interventions are undertaken in different countries to assess the safety and efficacy of these products. While all the issues relevant to any clinical trial such as Institutional Ethics Committee / Institutional Review Board (IEC/IRB)\(^{15}\) approval, regulatory clearances, informed consent, protection of vulnerable populations, etc. are to be taken care of, additional issues like access to products after trial and sustained availability of successful products are also to be deliberated before approving the trials. Issues of partner notification and tackling discordant couples are of special concern. But the most controversial issue that has dominated the whole debate on clinical trials in HIV/AIDS, specially in resource-poor countries and particularly those in collaboration with the developed countries or funded by international agencies is the issue of standard of care and use of placebo in control arm during the trial. While standard highly active antiretroviral treatment (HAART) is available in all western countries, neither these drugs are available nor if available, affordable to the affected populations in the poor countries. Hence any clinical trial with new drug which demands standard treatment in the control arm as a comparator cannot be used in these countries either because the drugs are not available or very expensive resulting in having a placebo in the control group since no treatment is the norm in these countries. Further studies are also designed to use lower dosage or reduce duration of treatment to suit the affordability or feasibility factor in the poor countries. Such trials were ongoing until the landmark publication of Marcia Angell appeared in 1998\(^{19}\) which questioned the perinatal transmission studies to prevent mother-to-child transmission of HIV infection conducted in Africa with US collaboration. This generated heated debate amongst the ethicists and resulted in series of publications in various journals leading to revision of Helsinki declaration in 2000 stipulating in its guidelines that all trials should have the goal of achieving the “highest attainable standard” with no placebo in the control arm if a standard treatment is available. However, this generated heated controversies and debates questioning the validity of such statements when the ground realities in various developing countries cannot allow compliance to these guidelines. From the day of its release in October 2000, the amended Helsinki declaration was severely criticized forcing the World Medical Association (WMA) seriously consider further revision in 2002, but which decided to issue an explanation subsequently without amending the 2000 text. But these debates lead to guidelines being developed by the National Bioethics Advisory Council of USA, Nuffield Council of UK, and European Commission on “ethical guidelines for research in developing countries” giving emphasis on local socio-cultural perspectives. The world has still not reached a consensus on this issue and the debate is still on. Increasing resistance to existing drugs and severe adverse effects are the driving forces for the continuing search for newer drugs either from modern medicine or traditional systems of medicine to find a solution to the problem.

*Vaccine trials:* In the meantime, major efforts are ongoing in the preventive aspects to find appropriate vaccines, vaginal/rectal microbicides or strategy for preventing perinatal transmission of infection to the foetus through appropriate trials in vulnerable or risky groups and antenatal mothers. The UNAIDS guidance document for ‘ethical considerations in HIV preventive vaccine research’ released in May 2000\(^{19}\) call upon countries and agencies involved in development of vaccines and conduct of their trials to foster the early and ethical development of effective
vaccines. It elaborates the strategies to be adopted for capacity building, community involvement, informed consent process, protection of vulnerable populations, justice and equity in subject selection for the clinical trials, use of placebo or any other vaccine in the control arm, continued counselling for risk reduction methods, monitoring mechanisms, care and support for HIV/AIDS and associated complications during the trial, inclusion of women and children with adequate safeguards, etc. In addition, the UNAIDS document also recommends counselling programme for condom promotion, microbicidal agents and control of STD/RTI since vaccine administration may encourage risky behaviour due to faulty sense of protection too prematurely. Provision of antiretrovirals (ARV) to those who become HIV-positive during the vaccine trial was a matter of debate till recently while it is more or less agreed by all that provision of ARV should be included in the protocol as also extensive array of services that well go beyond what is locally available at the vaccine trial sites. Many vaccine trials are ongoing in different countries. The first vaccine trial in India is scheduled to start in early 2005. However, no vaccine so far has been found to have the desired results but the trials are on.

Microbicidal trials: Microbicides potentially offer an important preventive alternative for individuals and couples who are unable or unwilling to use condoms. However, the clinical trials should include use of condoms in both arms with active microbicides and placebo and should involve women of all strata of society. Reducing infection in women and girls is essential if AIDS is to be brought under control. Current prevention programmes are not achieving this. The trials should include high risk women as well as monogamous women with single partners who perceive themselves at low risk. In these studies socio behavioural scientists play a critical role in designing behavioural interventions and for collecting sexual behaviour data. Special provisions are to be made for the women who may become positive or pregnant during the trial. Though there is a directed need for the overall prevention and management of sexually transmitted infections (STIs) among women, specially in developing and resource-poor countries, more targeted preventive means are required which women can use to protect themselves. However, post-trial availability and access to these products are the major issues for consideration. All the stakeholders should be thoroughly educated on the role of microbicides in the prevention programmes. The HPTN guidance document developed by the Ethics Working Group emphasizes protecting the vulnerable from exploitation, promoting equality through non-discriminating access to the benefits of research and minimization of research related harms including medical, psychological, social and economic harms. Whenever possible, HPTN researchers are directed to seek ways to improve local access to care rather than contribute to the creation of a dual standard that privileges research participants and the potential for undue inducement. The guidance stresses the desirability of seeking resources and building capacity for that care so that access can be maintained once the research ends.

MTCT/PPTCT (mother-to-child transmission/ prevention of parent-to-child transmission) trials: The UNAIDS estimates that 3.8 million children have died of AIDS before their 15th birthday and another 1.3 million are currently living with HIV and most will die before they reach their teens. The vast majority of these are born to HIV infected mothers. Provision of antiretrovirals to antenatal mothers have considerably reduced the mother-to-child transmission in developed countries. However, in developing countries high rate of HIV infection and child bearing, coupled with lack of counselling and treatment facilities and safe alternatives to breast-feeding resulted in majority of positive children born in such countries. Hence there is an urgent need for alternative regimens that can be used in resource poor countries. Studies in Thailand in early 1998 showed that a simple one month course of ARV given during late pregnancy could halve the rate of HIV transmission to their infants if breast-feeding was avoided. In Burkino Faso similar regimen followed by breast-feeding reduced the transmission by one third. In late 1999, it was shown in Uganda that use of niverapine at the onset of labour followed by breast-feeding reduced the transmission by one third. In late 1999, it was shown in Uganda that use of niverapine at the onset of labour followed by use in the infant after delivery showed similar results. However, this study was criticized by Marcia Angell that kicked off the debate on standard of care in different settings. Subsequently several developing countries have initiated pilot projects and national
programmes to help HIV-infected women give birth to healthy children. However, there are lots of ethical issues involved in these studies. Perinatal HIV counselling and testing programmes are not available in many developing countries. Even the short course antiretroviral therapy is beyond the reach of most women. Majority of the women present themselves for care during late pregnancy or delivery and many deliveries take place without the help of trained health care professionals. Breast-feeding cannot be avoided for social reasons or breast milk substitutes are unaffordable or cause more harm to the child. The role of breast-feeding is still discussed. The psychosocial issues in preventing breast-feeding have assumed a major role in these discussions. Further it is criticized that the entire exercise is to prevent transmission from mother-to-child not taking into consideration its effect on the mother or the fate of the untreated mothers. The criticism that these strategies are resulting in saving the children from HIV infection but to lead a life of an orphan is worth the attempt or not, is a matter of debate. As the epidemics toll grows, more grandmothers are now caring for orphans than they did a decade ago. Hence, policies are to be developed to save both mother and the child so that the healthy child is taken care of by the treated mother.

Women in general, and high risk groups such as sex workers and sexual minorities, children and adolescents, injecting drug users and people living with HIV/AIDS constituting the vulnerable segment of the population are more prone to develop HIV infection. Measures to protect their human rights need to be taken expeditiously. Human rights should be an integral part of all prevention programmes. The HPTN guidance document for research is a compilation of best practices, accepted standards and emerging consensus for the ethical conduct of HIV prevention research. The goal is to ensure that HPTN ethical decision making is of the highest quality, in keeping with the scientific agenda.

Behavioural studies

Despite best efforts of researchers, there is neither a cure nor a vaccine to treat or prevent the AIDS epidemic as we are already in the third decade for its emergence. Yet it is generally agreed that behavioural changes may alter the scenario. Research is needed to understand the dynamics of behaviour changes, STD rates and HIV incidence. Risk reduction strategies at individual levels and promotion of social norm changes to encourage risk avoidance at the community level seem to be major component of interventions. Increase in condom use, reduction in number of sexual partners, changes in risk behaviour like changing injecting needle use, etc. are some of the expected behavioural changes resulting in almost 100 per cent effective protection against HIV. While behavioural studies should also adhere to the same ethical requirements followed for any biomedical research, the complexities of this disease and its close link with the societal issues necessitates specific additional considerations. Participants in socio behavioural studies may face additional social, psychosocial or legal risks. Hence multifaceted community mobilization approaches may be taken combining mass media, social marketing, community activation and empowerment and policy targeted strategies. A close collaborative relationship must be developed between behavioural researchers and community based organizations concerned about HIV/AIDS so as to ensure progress in HIV prevention programmes. Behavioural scientists are confronted with unique challenges and opportunities in the prevention of HIV/AIDS.

International collaboration

International collaboration in the area of HIV/AIDS research has assumed such proportions in the recent years necessitating intense ethical debates all over the globe. On the one hand, collaborative studies suggest an intense human and civil responsibilities while on the other it could give the impression of experimentation on the population of one country by another with exploitative connotations. This led to the Helsinki declaration of 2000 but matters still stand unresolved. Given the magnitude of the severity of the HIV/AIDS problem in the developing countries which affects the global scenario, there is a genuine need for collaboration between developed and developing countries and the other sponsors including multinational pharmaceutical industries. However, certain ground rules are to be kept in mind in such
collaborations and the recent guidelines on the issue are to be consulted. It is necessary that such collaborations should take into consideration the need of the host countries where trials are to be conducted. Strategies are to be adopted to build capacity in various countries and communities so that they can practise meaningful self determination in tackling the problems thereby function as equal partners with sponsors and others in the conduct of any research including clinical trials. It is also to be ascertained that host communities should be involved early and in a continued manner in the design, conduct and monitoring of trials including distribution of benefits from such trials and dissemination of research findings. The social contexts and cultural specificities of the host communities and countries should be given due consideration to protect the dignity, safety and welfare of the trial participants. The burden and benefit of any collaborative study should be equally borne by the collaborating countries. Guidelines, rules, regulations and laws of the participating and sponsoring countries should be equally respected. All issues related to intellectual property rights, exchange of biological materials, data transfer, security issues and protection of confidentiality are to be given due consideration. The role and responsibility of international community in controlling the further spread of infection is tremendous and should be taken seriously.

**Ethical issues for health care providers**

All health care providers have a moral obligation to care for any individual seeking health care. However, no one is ethically or legally obliged to put his/her life at risk while treating HIV cases where facilities for application of universal precautions do not exist. Hence it should be made mandatory to provide highest level of internationally recognized and recommended universal precautions in all institutions and in all clinical conditions. It is necessary to have a comprehensive programme in place to deal with anticipated accidental exposure. Post-exposure prophylaxis (PEP) should be made available to all concerned. It is also necessary to counsel the health care personnel the need for maintaining confidentiality of the status of the positive individuals under their care. In case there is a need for disclosure, it is essential to obtain patient’s free and informed consent. There may be exceptional circumstances of public interest where there can be breach of this confidentiality clause. PEP should be carefully followed wherever there is any doubt.

**The Indian scenario**

India with a population of more than 1 billion has 4.58 million HIV seropositive individuals, second only to South Africa in terms of number of affected individuals. Though the infection rate is around 0.75 per cent in the 6 high prevalent states, the sheer absolute number of positive individuals put India accounting for 10 per cent of global HIV burden and 65 per cent of that in South and South East Asia as per UNAIDS and NACO estimates. Though the infection is spreading mostly among the intravenous drug users, sex workers, sexual minorities, etc., the reason for concern is the fact that the disease is entering the non-suspecting group in the rural populations which includes housewives and children. This has led to the threatening questioning of moral and cultural values, breaking taboos about discussing sex and raising questions about human rights and healthcare. Since it affects most aspects of people’s lives, it raises many social, economic and cultural issues that relate to human rights, ethics and law and is increasingly regarded as a socio-economic problem in addition to health issues.

With the huge health infrastructure available in the country, all types of research in the area of HIV/AIDS is undertaken in India. Epidemiological and behavioural studies have been initiated. Clinical trials with ARV drugs, vaginal microbicides, prevention of mother-to-child / parent-to-child transmission and more recently AIDS vaccine preparedness are all going on full swing. However, the ethical concerns mentioned earlier are troubling the researchers involved in these studies to arrive at consensus in tackling the issues. Some of the ethical dilemmas are as follows:

(i) Use of standard ART in the control arm— Almost all the antiretroviral drugs are available in the Indian market. As these are not provided in the national health services, inclusion of these in the trial situation
is a dilemma. Even if the drugs are provided in the trial situation by the sponsors, the issue of sustainability beyond the trial period is troubling the researchers. With the new paradigm shift in the National AIDS control programme announced in 2003\textsuperscript{27} whereby from 1\textsuperscript{st} April 2004, 3 target groups will be receiving ART free of cost in identified centres in the 6 high prevalent states (Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu), there is a possibility of some benefit at least to these groups. However, it is expected that the situation will improve if the cost of the drugs will be further brought down through various drug pricing policies and the efforts of pharmaceutical firms.

(ii) Prevention of mother-to-children transmission studies were initiated at 11 centres along with establishment of testing and counselling centres. Issues of privacy and confidentiality of test results, problem of non breast-feeding the infant and not providing ART to mothers became major concerns. Provision of care and treatment to women and follow up after delivery including contraceptive and supplementary feeding advice were crucial matters. The ill effects of supplementary feeding vs. HIV infection were debated and women were given the option to decide. The recent decision of NACO to provide ARV to all the positive women who participated in the MTCT (now renamed PPTCT-prevention of parent-to-child transmission) programme is a major accomplishment of those who were arguing for the cause of these women for the benefit of the women as well as their children. At least one of the ethical concern has been addressed and it is expected that in the near future all antenatal positive mothers will be beneficiary of this policy.

(iii) Clinical trials with vaginal microbicidal agents are ongoing with both international funding and indigenously developed products. While this is a method which has the option to empower the women in protecting themselves, consent of the partner during the trial is an ethical requirement which may be difficult to accomplish in all cases. A strong programme of counselling for both the partners is to be in place if these trials are to proceed further. Provision of ART to those becoming positive during the trial is again a major issue.

(iv) HIV vaccine trial–India is at the threshold of launching the first AIDS vaccine trial. A exhaustive process has been put in place to accomplish all the ethical concerns – informed consent process, maintenance of privacy and confidential at all levels, risk benefit analysis and provision of insurance coverage and appropriate management to all trial related adverse effects, careful monitoring mechanism, assurance of post trial access, etc. However, when there is an increase in number of trials and at more sites, replication of such extensive process is going to be a challenge for the researchers and the policy makers. But the model created for the first vaccine trial can benefit all countries planning to launch vaccine trials in their countries. It is also a good example of a public private partnership (PPP) between government and International AIDS vaccine initiative (IAVI).

(iv) Legislation: India is in the verge of introducing a comprehensive legislation for HIV/AIDS which has taken into consideration all ethical, legal and social issues into consideration. The fundamental principles of human rights, concerns of the different vulnerable and target groups, the issues related to treatment and care including insurance and social security, special areas such as blood transfusion and transplantation, research ethics and the role of media are all taken into consideration while developing this legislation. The moral issues addressed by the ethical principles and the legal support to maintain the ethical standards will be taken care by this comprehensive legislation. This is a major initiative to protect the human rights and ethical, legal and social issues (ELSI). This legislation and the preceding consultation document have been premised on the belief, that now, more than ever, a law is critical for the protection of persons living with HIV/AIDS, for the promotion of their rights, to address issues of stigma and discrimination and to ensure that people have access to accurate information about HIV to protect themselves\textsuperscript{28}.

Conclusion

HIV/AIDS has highlighted the multiple problems faced by all societies, including differential access to medical care and biomedical research, discrimination on multiple arenas against segments of society that lack both the political force and the economic base to
halt such practices and the disintegration of family and social networks as a result of this debilitating and financially costly illness with financial implications. Our increasing experience during the HIV pandemic has underscored the complexity of HIV research and its ethical connotations as we are grappling to find new treatments, cures, preventive therapies and educational interventions that are both effective and appropriate for persons of diverse races, ethnicities, cultures, languages, religions, ages, gender, sexual orientations, etc. The obligations of governments to promote health and prevent disease should enable development of appropriate policies and programmes lacked by suitable legislation.

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Reprint requests: Dr Vasantha Muthuswamy, Senior Deputy Director-General, Indian Council of Medical Research Ramalingaswami Bhawan, Ansari Nagar, New Delhi 110029, India e-mail: muthuswamyv@icmr.org.in

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