
ETHICS OF AIDS RESEARCH IN A DEVELOPING COUNTRY – BALANCING POWER IN DISGUISE

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Chairperson, Honourable Ministers of Health, distinguished colleagues, ladies and gentlemen. It is indeed a great honour for me and the organisation I represent, the MRC, to be given an opportunity to share some thoughts and experiences on the issue of “Ethics of Aids Research in Developing Countries on this prestigious plenary. I thank the organisers of the 13th International Aids Conference for this opportunity. For the purpose of this talk, I have modified the title to “Ethics of Aids Research in a Developing Country – Balancing Power in Disguise”.

Breaking my Silence: Twenty years into the HIV/Aids epidemic research continue to focus on women, children, orphans and newborns – many aspects of these have been presented at this conference. We have yet to focus research on boys and men in HIV/Aids. *Let's* remember Aids was first described in men, continues to be spread by men who occasionally infect and affect their female partners. Perhaps one needs to compare research in Aids with research into contraception – 50 years after the female contraceptive pill, we still have to a male equivalent that is universally used.

I shall focus only on two areas: *Power and Informed Consent*. I shall use the South African experience and examples to support my story and draw the following lessons:

- i) Ethics of research in a developing country poses exciting challenges for scholars, practitioners and communities that are driven by the principles of equity, human rights and the genuine protection of both the powerful and powerless.
- ii) Ethics in developing, continues to demystify and destroy the male liberal racial theory that emerged in the last century.
- iii) Informed Consent that is based on the language, idiom and culture of the participant is empowering, not only to the subject but also to the investigator.

- iv) Ethics in developing countries remains an important beacon of hope and an integral component and an instrument of transforming society, consolidating young democracies, defining national identities, reclaiming lost cultures and contributing to the global village.
- v) Ethics allow us to understand the intricate, the multi-faceted nature of and the subtle relationship between power and equality.
- vi) Research focusing on men should receive specific attention and resources as part of the greater understanding of the epidemic.

Chairperson, Homo sapiens-cum-Homo modificans – we are wise, but importantly we continue to modify our environment, ourselves through organ transplants, genetic manipulation and medications – and drive our own evolution – has the following interesting characteristics: the formation of *hierarchies*; the expectation to be *imitated within the hierarchy*; a *culture and language/music* as a means of communication which are determined by the dominant group. It is within the characteristics of hierarchy and imitation that dominance and power are located. You may ask – what has power to do with ethics or why is power so crucial in the ethics of Aids or research in a developing country?

Power organises societies, **power** determines relationship; **power** determines norms and behaviour, **power** determines authority and trust; **power** determines what is right or wrong, **power** determines and appropriates knowledge, information in society – in short **power** is powerful. It is within the context of hierarchies, imitation, culture and language that we should locate and contextualise the ethics of research in developing countries.

The practice of ethics in Health Research has been premised on the notion that it ensures good clinical practice and protects the subject, the weak and the powerless. In short,

the practice of ethics has been based on a clear understanding and recognition of the power balance between the practitioner and the subject. It is in the protection of the abuse of this power that ethics has played a central role and emerged as a critical discipline in the development of medical practice and health research.

Because research is to a large extent motivated by scientific objectives such as developing or testing new knowledge, temptations may remain to subordinate the welfare of the volunteers of these objectives and treat human beings as a means to an end. Research may also be motivated by financial gains where expediency obscures ethics to the detriment of volunteers and the integrity of science. Particularly the history of health research in Africa has gone through three phases – the phase of Federal Express Research up to the late 60s, followed by Safari/Sunshine Research in the 70s and 80s and now we have entered the exciting phase of partnerships. The ethics underlying each of these phases leaves much to be desired. Those that have resources choose African partners that are weak, countries that are so poor that the research priorities are not those of the country but those of the foreign partner. The ethics are really guided by the idiom of “He who plays the pipers calls the tune”. This is power disguised under good intentions.

It is widely acknowledged that science and ethics are closely connected; poor science is unethical. The scientific integrity of research proposal is an important criterion for ethical approval. However, it is not often stated how sound ethics are a necessary component of good science.

The ethical principles of autonomy – personal liberty of thought and action –, beneficence – the moral obligation to minimize possible harm and actively maximise possible benefits; and justice – fairness in distribution, ensuring that benefits and burdens of research are fairly and equitably distributed – are inscribed in research practices such as Informed Consent and the protection of confidentiality. These inscriptions tend to be treated as “add-ons” rather than intrinsic.

What has not been often emphasised is that the intended and unintended consequences of science, medical practice and health research have their greatest impact on patients, subjects and society. These are usually the weak, inappropriately informed and the powerless in society.

However, there is no doubt that medical practice and medical research over time and through out the world has benefited and improved enormously through the application of ethical guidelines; since the first code of ethics in 1947, the Declaration of Helsinki in 1964 and the later modification by the World Medical Association. Later, the WHO and CIOMS guidelines attempted to deal with transcultural and inequalities issues. The recent UNAIDS codes of ethics specifically deal with international vaccine trials for HIV/Aids. These guidelines require operational elaboration and implementation by investigators, sponsors, host governments and community representative – *they require contextualisation and a transdisciplinary approach.*

Equally the development of ethics as discipline has benefited from this constructive tension between power and the abuse of power.

In a simple, monolithic society – the tension has been the power between the “haves and have-nots” and also the power between the genders – that culture-specific construct between *males and females* that has dominated society in a variety of ways including ethical principles and philosophy. Men in their hunger and quest for more power have formulated most ethical codes – of course for all of humanity and “with good intentions”.

In a complex society such as South Africa and some developing countries, in addition to the above, it has been the tension of power between the former oppressors and the oppressed and dealing with the legacy thereof, the tension of power between whites and blacks and the tension of power between the educated and the uneducated.

It has been the tensions between the African perspective and the other perspectives – a world-view tension; a tension between the cultures – African, European and Oriental; a tension between the identities (African, European and Oriental) and a tension between the languages (African and non-African). Thus the definition, the evolution and understandings of ethics in our country and other developing countries are both simple but complex.

It is simple in the sense that there are international norms and principles but complex in the sense that firstly we were not part of the developments of these norms and at times their applications often appear to represent and remind us of an era we are crossing i.e. the era of *legalised inequality and unequal power relationships.*

They have also become complex because of the multifaceted and multilayeredness that disguises power in subtleties.

As ethics are loaded with value, power, a world-view, a perspective, and a culture one often has to question the relevance of concept of international ethics – is this a reality or simply an ideal to aspire towards. Common sense, which is not often common, indicates that no nation practices ideal ethics. Every nation is constrained by its institutions, its legal framework, its level of development and democracy and its commitment to the principle of equality. However, every nation should practice the best ethics that is attainable within its own constraints. This is the context in which ethics of research in developing country are taking place.

The challenge for us all in South Africa is the management of these complex and multi-layered tensions in a constructive manner such that we as a society nuance our ethical guidelines and principles in manners that allow us to improve our science, clinical practice and research but also protect and empower the weak, the powerless in our society. The developments of our ethics mirror the development of our societal transformation, our constitution and our democracy – they are informed by broad consultations and participation from different sectors of our society. No longer can academics or researchers – despite their good intentions – sit in the ivory towers to construct guidelines without engaging civil society in an open and transparent process. The history of our past is riddled with mistakes that are too ghastly to list or repeat.

Ethics of research are not only an instrument of liberating ourselves from the legacy of apartheid but also a crucial instrument in liberating our former oppressors and setting a blueprint for the future.

If we were today to honestly interrogate our ethics in South Africa as the Truth and Reconciliation Commission did, there is no doubt that we would find many shortcomings. These shortcomings provides lessons and demand that we take a new path and trajectory in the development of ethics for research, science and clinical practice.

We would find that health professionals just like all human beings are by and large products of their environments and the political systems under which they live and operate. There is no doubt that ethics in South Africa evolved from the male superiority race model of apartheid in which blacks and women were inferior. This white androgenic ethical model whilst couched in reasonable language and principles, it was in reality a mere facade for and an extension of the powers and political systems that be. Theory and practise of ethics in science and research were at times like day and night.

As a result several research projects were approved that with hindsight would not be e.g. the approval of the biological warfare programme under the leadership of Dr. Wouter Basson to develop substances that would either render most blacks infertile or selectively poison or maim black people; the suppression to publish results of asbestosis in our mines that would lead to litigation of white mining officials and finally the failure to publish results that would indicate that whites our country "had thick skulls" or that some alleged pure Afrikaners were the products of mixed sexual liaisons. Of course some of these today occasionally feel entitled to affirmative action programmes – thanks to the new dispensation. There are also cases where ethics were simply ignored such as the Professor Bezwoda case at the University of the Witwatersrand where patients were subjected to inappropriate treatment trial protocols, the results of which were also "doctored". While these were suppressed to protect the powerful – the white community; there are numerous examples both in clinical practice and research that would certainly count as examples of the abuse of the weak and the powerless in our society.

Perhaps examples in this arena fall within the area of *Informed Consent* for research and generally for operations. There are many understandings of the notion of Informed Consent. The moral, legal and ethical aspects of informed consent and the practical implications of each of these factors must be carefully considered in the design of Informed Consent procedures for HIV/Aids vaccine trials.

While informed consent has been the cornerstone of clinical practice and trials and is a critical requirement for participation in studies, Informed Consent has also become one of the major ethical transgressions of our time – particularly in developing countries. Informed Consent has four essential components: disclosure of all relevant information about the research; comprehension by the prospective participant of this information to make informed decision; freedom from all coercion of the prospective participants; explicit and formal consent by the participant, usually in written form.

However, codes and requirements alone do not guarantee protection as exemplified by the Tuskegee case. In South African and most developing countries, most of our subjects speak and live for the rest of their lives in a different language from the languages of the researchers and practitioners; secondly most subjects in our countries are poorly informed with substandard education. Thirdly the power and magic of the investigators or doctors continue to give disproportionate trust and power by patients and subjects to the practitioner or researcher. "The doctors know it all and have my interest at heart" – this is how our societies have operated and that is also how Africans have been so well colonised and exploited through out history.

As we globalise the language and tactics have changed but the effect remains the same. The weak and powerless in our society require a different form of approach, education and communication in order to fully understand the magnitude and implications of signing an informed consent form. This is an area that the HIV/Aids epidemic has begun to interrogate into with telling lessons. The SAAVI Group led by Dr. Graham Lindegger and Professor Linda Richter funded by the South African government, has made seminal contribution into the whole area of designing Informed Consent within the South African settings – language and culture-sensitive.

How does one sign a consent form when one hardly understands the concepts in the projects and their roles in it? **In such instances the tendency is for power to prevail above protection.**

This is also partly the major reason why trials are always done more easily in the developing countries rather than the developed ones – because the subjects in the developed countries understand Informed Consent, demand higher standards of protection than ours in the developing countries. Perhaps for me a telling example was of a patient in 1975 who had a carcinoma of the vulva and consented to undergoing a total vulvectomy without telling her husband, her family because she did not fully appreciate what the operation would do. Clearly the surgeon and the patient could not have fully understood each other but at what and whose cost? When she woke from theatre she required psychiatric treatment rather than surgical or medical treatment – the rest of her life was totally ruined and her whole world had completely changed. The second classic example documented in the TRC's health section is how the medical profession, the state and the security system colluded in the murder of Steve Biko in 1977.

Perhaps no disease has challenged the ethical and moral principles of a society such as HIV/Aids. The areas that are of most concern here are the ethics of vaccine development and clinical trials; the areas of anti-retrovirals for HIV/Aids patients and the prevention of mother to child transmissions. These areas have posed serious moral and ethical dilemmas in our society. The affordability, sustainability of these treatments within a society that prides itself in human rights and the promotion of equity and development have posed great ethical dilemmas.

The clinical trials for our vaccines (the VEE-based clade C vaccine) are due to start early next year. Much of this vaccine

work will take place in under-resourced communities, where people are at high risk of HIV infection, so human rights implications for participants and other members of the community need careful consideration in issues of resource allocation to HIV vaccine development, the protection of trial volunteers from the risks of participation, and access to a successful vaccine.

In preparations for these Community Advisory Boards, researchers, counsellors and educators have mounted a massive education, counselling, information campaign to ensure that communities do fully understand the nature, extent and implications of these trials. These campaigns are to ensure that individuals and communities are fully empowered to know and exercise their rights as they participate in the trials. These are done in the languages, idioms and within the culture of the participant – i.e. language and culture-sensitive.

It is vitally important to recognise that empowering the participants also empowers the researcher and improve substantially the integrity of the research and the science.

Potential participants often ask whether they are simply guinea pigs—we have heard these statements from Uganda, Kenya, South Africa and many parts of the developing world – and what it is in it for them, how will they benefit themselves and society at large, what happens to them if they should get breakthrough HIV infections and what happens to them in terms of access to ART treatment – all sensible and germane questions.

Perhaps a crucial issue for ethics in developing countries is to tease the underlying assumptions from the perspective of the participants. Too often communities are researched upon ad nauseum without any benefits accruing or flowing back to that community. **Simply stated the researcher gets the publications, the glory amongst his/her peers while the community or the participant remains dis-empowered and underdeveloped. This is the story of many African participants and many African communities.**

As part of our own ethical dilemmas in relation to HIV treatment, the government continues to seek advice and information from best practice and the results of anti-retroviral treatment regimens in order to formulate its own – equitable, affordable, accessible and sustainable – strategy for anti-retroviral treatment. The emerging consensus are: the treatment of STDs and opportunistic infections; the treatment of advanced symptomatic HIV/Aids and the prevention for mother to child transmission in the context of a basic infrastructure are critical. These are programmes that should be prioritised for implementation within our country. We have every faith and confidence that our government will negotiate these dilemmas with success.

In conclusion, i) ethics of research in a developing country poses exciting challenges for scholars, practitioners and communities that are driven by the principles of equity, human rights and the genuine protection of both the powerful and powerless.

ii) Ethics in developing countries continues to demystify and destroy the male liberal racial theory that emerged in the last century.

iii) Informed Consent that is based on the language, idiom and culture of the participant is empowering, not only to the subject but also to the investigator.

iv) Ethics in developing countries remains an important beacon of hope and an integral component and an instrument of transforming society, consolidating young democracies, defining national identities, reclaiming lost cultures and contributing to the global village.

v) research that specifically focus on men, their socialisation, their biology should be identified and allocated resources.

vi) Finally, ethics allow us to understand the intricate, the multifaceted nature of and the subtle relationship between power and equality.

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