J Hum Ecol, 42(2): 95-101 (2013)
PRINT: ISSN 0970-9274 ONLINE: ISSN 2456-6608 DOI: 10.31901/24566608.2013/42.2.01

Medical Injury Compensation Complications in New HIV Prevention Technologies in Africa

Calvin Gwandure[1] and Thokozile Mayekiso[2]

[1]University of the Witwatersrand, South Africa
[2]Nelson Mandela Metropolitan University, South Africa

KEYWORDS Medical Injury Compensation. Clinical Trials. New HIV Prevention Technologies. Africa

ABSTRACT The study investigated complications associated with medical injury compensation in New HIV Prevention Technologies in Africa. The study looked at possibilities of liability in HIV infection during clinical trials and the legal resources that could be used in seeking medical injury compensation in resource poor communities in Africa. A survey of literature on medical injury compensation was used to highlight possibilities and complications associated with medical injury compensation in developing countries. An analysis of research findings on medical injury compensation indicated that it would be difficult for people who get infected with HIV in clinical trials to successfully sue international organisations that sponsor New HIV Prevention Technologies in Africa. It is suggested in this study that African governments could use the no-fault approach in settling medical injury compensation claims in New HIV Prevention Technologies clinical trials.

INTRODUCTION

Medical injury compensation is increasingly posing ethical, legal and financial challenges to researchers in the medical and allied fields. In the early 20th century, medical experiments could be conducted on patients without the need to adhere to medical ethics, law and human rights. In recent years, there has been mounting pressure on medical research organisations to own up and admit wrongdoing in medical procedures (Gwandure and Mayekiso 2012). However, medical injury compensation can be complicated in developing societies due to the bureaucratic processes, inadequacy of laws that deal with medical injury and the low literacy levels of the population to seek redress through the courts. This paper looks at medical injury complications associated with clinical trials in New HIV Prevention Technologies in Africa (Gwandure and Mayekiso 2012). The New HIV Prevention Technologies that will be discussed in this paper are microbicides, vaccines, pre-exposure prophylaxis and medical male circumcision. This study explores medical compensation claim complications associated with each of the New HIV Prevention Technologies in an African context.

Address for correspondence:
Dr. Calvin Gwandure
School of Human and Community Development,
University of the Witwatersrand,
P. O. Box 3 Wits, Johannesburg, 2050.
E-mail: Calvin.Gwandure@wits.ac.za

Medical Ethics in Resource Poor Communities

Most of the researchers agree that getting medical compensation in developing countries can be a nightmare (Douglas 2009; Elliot 2012; Tereskerz and Jagger 1997). For instance, the following statement illustrates it: "If I am injured in the course of medical investigation or treatment, I may be eligible to receive compensation for some of the adverse consequences of my injury-at least, if I live in a developed country" (Douglas 2009: 30).

Even in developed countries, there are complications associated with medical injury claims related to HIV infection and workers' compensation laws do not provide enough protection for employees to get compensation for occupationally acquired HIV infection (Tereskerz and Jagger 1997). Participants in HIV clinical trials in Africa are usually exposed to infection but there seems to be no specific laws in Africa that address medical injury compensation with particular reference to HIV infection in clinical trials (Gwandure and Mayekiso 2012). It should also be noted that New HIV Prevention Technologies largely target resource poor communities in Africa and other developing regions of the world. The larger part of work on HIV prevention clinical trials is done in Africa and Asia and these are regions that have the majority of the population living in poverty (Chant 2007).

There are ethical concerns surrounding the use of poor or indigent people as research participants in risky experiments or medical proce-

dures that can result in the death of participants or infection of participants with an incurable disease, or exposing participants to injuries that can result in permanent disability (Emanuel et al. 2004). A survey of research on medical compensation claims among low-income groups shows that very few individuals initiate it because of the complications associated with tort law that is used in medical injury compensation (Douglas 2009). The bulk of the cases are processed by attorneys appointed by non-governmental organisations to assist the poor get justice and expose medical malpractice usually by a government health facility or a negligent medical doctor. It is interesting to note that even in the US, it is usually patients with high incomes and not the poor who file medical malpractice compensation claims (Brennan et al. 1996). The argument of this paper is that it is inconceivable that ordinary villagers and the urban poor can raise enough financial resources to challenge international organisations involved in HIV prevention clinical trials in Africa in court for exposing communities to HIV infection. It can be argued that poor people tend to depend on the rich for medical injury compensation in Africa and this is usually made possible by media publicity of the plight of the poor (Brennan et al. 1996).

Currently, the major Western media houses have tended to take a low profile in reporting new HIV infections in New HIV Prevention Technologies clinical trials in Africa (Gwandure and Mayekiso 2012). Researchers on the subject usually report of "acceptability" of the technologies among participants in Africa and how participants are experiencing sexual intercourse differently (Gwandure and Mayekiso 2012). African governments that largely rely on donor funding for HIV and AIDS projects find themselves in a difficult situation when they are legally, ethically and politically expected to sensitize the public about HIV infection in clinical trials (Gwandure and Mayekiso 2012). Overreliance on donor funding for HIV and AIDS interventions tends to overshadow the commitment of African governments to raise funds for other public health maladies and issues of economic development (Morfit 2011).

The Law of Tort in Medical Injury Compensation

The law of tort applies to many medical injury compensation disputes in Africa with slight variation from country to country. Globally, the law has been found to be good on paper but its implementation does not usually result in adequate compensation for the plaintiff if they did not have enough financial and intellectual resources to challenge the health care provider, medical researcher or medical practitioner. In the US, it is stated that, "If a patient is injured as a result of the wrongful behaviour of another (a physician or another medical care provider), then the victim is entitled to recover for all losses-both financial and non-pecuniary-caused by such fault" (Weiler 1993: 14). The law allows for the patient to sue the medical practitioner for medical negligence. However, the patient should be able to prove that there was medical negligence on the part of the medical practitioner. In the US, the law tends to protect the medical practitioner as it is stated that, "In the absence of negligent behaviour, a doctor is not legally responsible for injuries suffered by his or her patients; instead, such losses must be borne by the victims personally or by the broader community through its various programs of public and private loss insurance" (Weiler 1993: 14). This section of the law makes it difficult for people who voluntarily participate in medical research and HIV clinical trials to sue the health professionals and the organisations that carry out the experiments because HIV infection happens through consensual sex. The participant engages in risk sexual behaviour in a private place in the absence of the health professional who advised them to use the New HIV Prevention Technologies. It is argued that medical injury compensation could be made difficult by the fact that, "Disputes over whether an instance of medical treatment was careless and over what injuries the victim suffered as a result are ultimately resolvable in a civil trial before a jury, although in practice 90 percent of such claims are settled by the parties and their lawyers through voluntary negotiation before a trail" (Weiler 1993: 14). It is clear that in HIV infection litigation that involves the participant in clinical trials and the medical practitioner or health professional who provided the pills or performed surgery in New HIV Prevention Technologies, it is difficult to quantify the negligence and injury caused. If getting a settlement is complicated overseas, it could be a pipedream among victims in resource poor communities in Africa. In addition, even if the court proves that there was

malpractice, the health care practitioner is not usually personally held accountable and asked to pay compensation to the patient. It is stated that, "If some legal fault and liability are established through this process, compensation will almost invariably be paid to the victim not by the individual who was careless, but rather by a liability insurer for an independently practicing doctor or by the institution that employed the doctor or other provider in question (or by that institution`s insurer)" (Weiler 1993: 14).

In some countries, medical injury compensation is awarded on the "no-fault" basis (Douglas 2009). Participants who are injured in medical clinical trials can receive compensation from medical aid companies or medical insurers without regard to "…whether their injuries can be attributed to the negligence or other wrongdoing of a medical professional, and if a claim for compensation is successful, that compensation is paid from an account maintained through general taxation" (Douglass 2009: 31). This could be a starting point and a positive development in Africa if governments, sponsors of New HIV Prevention Technologies clinical trials and medical insurance companies could agree on the feasibility of such a project. The ethical dilemma that could arise from this approach is that even if the victim could benefit from the medical insurance fund, the reckless medical practitioner, health professional or health care provider might not be emotionally attached to the suffering patient (Douglas 2009). It is disturbing to note that many people who volunteer to participate in New HIV Prevention Technologies clinical trials in Africa are not covered by medical insurance against HIV infection (Gwandure and Mayekiso 2012). The promoters of New HIV Prevention Technologies are not forthright about the provision of a medical insurance fund to cushion victims of HIV infection in clinical trials. Participant seroconversion happens in the search for HIV preventive medicine and preventive surgery in clinical trials. Medical injury compensation laws such as the "law of delict" in South Africa and countries that use the Roman-Dutch Law, tend to cover a number of situations in which the defendant is asked to pay the plaintiff for loss or harm arising from negligence (Loubserand and Midgley 2010). However, the compensation laws which vary in terminology from one country to another were not developed to deal with HIV infection in clinical trials. Most of the compensation laws were made before the discovery of HIV and AIDS to deal with compensation claims in general contexts.

Litigation and Medical Injury Compensation in HIV Prevention Clinical Trials

Some aspects of the law of tort are explored in this paper to assess how participants who get infected with HIV in New HIV Prevention Technologies clinical trials can be compensated. The law requires that the complainant should show the court that the medical practitioner or health professional that advised the participant to take medical pills or performed a medical procedure did that while on duty. The patient has to show the court evidence of injury or damage suffered and to demonstrate that the medical practitioner was negligent (Douglas 2009). This paper highlights complications that may make it difficult for participants infected with HIV in clinical trials to get medical injury compensation. The paper highlights the New HIV Prevention Technologies that are on trial in Africa and how participants could be exposed to HIV infection. The clinical trials discussed are microbicides, vaccines, pre-exposure prophylaxis and medical male circumcision.

Microbicides are pills or substances that are inserted into the vagina to prevent HIV infection. Some of the women who use these pills become HIV- positive (Gwandure and Mayekiso 2012). In countries where high rates of HIV infection during clinical trials are reported, there are no reported cases of victims successfully suing organisations that are responsible for the clinical trials. In Zambia, between 46 and 50 of the 1 332 women who joined the clinical trials when they were HIV-negative were infected with HIV even though they were using the microbidcides during sex (Moran 2010). The issue of medical negligence and monetary compensation for medical injury was not raised by the Ministry of Health of Zambia apart from reporting that the matter was sensitive and that government was reluctant to elaborate on what happened during clinical trials (Moran 2010). The government of Zambia is not reported seeking legal redress and monetary compensation for the women against the international organisations that were responsible for the clinical trials.

In terms of medical injury compensation procedures, claims for compensation can focus on

deception that comes with experimentation. The attorneys representing victims should single out HIV infection as the "harm" contemplated in law of tort or law of delict (Weiler 1993). The plaintiff`s attorney seeking medical injury compensation can consider failure to disclose full information about HIV infection risk when participants are recruited to the clinical trials as negligent behaviour by promoters of microbicides. Litigation can focus on the concept of "undue inducement" in biomedical research in resource poor countries (Emanuel et al. 2005). This is a form of subtle persuasion in which participants from low-income groups are tempted to participate in HIV prevention clinical trials due to the offer of monetary payment that is regarded by the organisers of clinical trials as token money, or a "thank you" for participating in the in research.

Research on vaccines invites HIV-negative people and vaccinates them against HIV infection. The rationale behind this approach is that populations at risk of HIV infection could benefit from the immunization against HIV infection (Gwandure and Mayekiso 2012). Litigation for medical injury compensation for participants who become HIV-positive can focus on the degree of exposure to HIV infection and blameworthiness of the medical procedures in preventing HIV infection. The anticipated complications relate to the ability of participants to demonstrate how medical practitioners vaccinating participants against HIV infection behaved in a negligent manner that resulted in participants contracting HIV (Douglas 2009). Compensation claims by participants who become HIV-positive after vaccination can be based on vulnerability to HIV infection that resulted from exaggerated scientific claims of HIV prevention by promoters of vaccines (Gwandure and Mayekiso 2012). The compensation claims could be weakened by the fact that health care professionals who administer vaccines do advise participants to use condoms in each sexual encounter. If participants became HIV positive, the organisations managing the vaccine programme in the country could blame the participants for failing to use condoms correctly. The promoters of vaccines are less likely to attribute the HIV infection to vaccine failure. The ambiguity that comes with the combined use of technologies in HIV prevention most likely deters victims from laying medical injury compensation claims against providers of vaccines in HIV prevention clinical trials in Africa.

Pre-exposure prophylaxis requires HIV-negative participants to take antiretroviral drugs daily to prevent HIV infection. Medical injury compensation claims in case of HIV infection can be based on the law of tort or law of delict, or no-fault claims (Douglass 2009; Loubser and Midgley 2010; Weiler 1993). The psychological contract can be used to justify claims for medical injury compensation (Guest 1998). The grounds for compensation claim arise from the fact that a participant volunteered to participate in the clinical trials being HIV-negative and left the programme HIV-positive. Disclaimer clauses or medical error disclosure injunction by medical insurance companies that are used to avoid responsibility for patient or participant injury in biomedical clinical trials can be challenged in a court of law (Hammami et al. 2010). Insurance companies advise medical practitioners to deny wrongdoing in case of a medical error, be it that the harm is major, moderate, minor or a near miss, the medical error is denied or not reported to the patient (Hammami et al. 2010). This is in line with the medical practice insurance "cooperation" clause (Banja 2005). This "cooperation" clause forbids the health professional from admitting liability to an injured or harmed party and it defends the insured health professional against medical injury compensation claims (Banja 2005). However, this requirement by insurance companies poses an ethical dilemma for the health professional because medical ethics requires them to truthfully disclose medical errors that happen in the course of duty but in the case where a health professional works as a "hired gun" with interests in financial gain, they might not disclose the errors they made and the health risks they caused (Pope and Vetter 1992). It can be argued that patients have a right to claim for medical injury compensation for experiencing side effects such as drug toxicity due to continued use, viral resistance or behavioural disinhibition associated with pre-exposure prophylaxis (Paltiel et al. 2009).

Medical male circumcision involves the removal of the foreskin in HIV prevention clinical trials. Litigation for medical injury compensation can assess the damage or mutilation caused by equipment that is used in medical male circumcision (Hill 2007). Some of the participants die due to excessive bleeding and some develop

medical complications as a result of the surgical removal of the prepuce (Hill 2007). The operation is based on the premise that once the tissue containing cells that can easily be infected with HIV is removed and the skin of the penis toughens within six weeks, it follows that the chances of contracting HIV will be reduced for the man. Litigation can be based on HIV infection damages during clinical trials because the law of tort and law of delict empower victims to seek medical damages that arise from medical negligence. Up to now, there are no reported successful lawsuits in which participants that became HIV-positive after undergoing medical male circumcision got compensation in Africa.

It should be highlighted that New HIV Prevention Technologies tend to worsen the HIV pandemic in Africa by exposing HIV-negative people to infection. New infections in clinical trials, even though the numbers are small, contribute to the spread of HIV. Instead, HIV prevention clinical experiments should recruit HIV-positive participants. In this regard, the effectiveness of a technology in reducing HIV transmission among participants living with HIV and AIDS could be measured in terms of HIV reinfection reduction. The efficacy of a new technology could also be assessed in relation to the reduction or prevention of sexually transmitted diseases among participants.

Medical Injury Costing in HIV Clinical Trials

The compensation claims can be based on the degree of damage or harm suffered by the complainant (Douglas 2009). Litigation requires so many specialists such as medical specialists, social scientists, legal experts, scientists, and actuaries to quantify and cost the degree of injury the complainant suffered as a result of medical negligence or omission. This level of interdisciplinary intervention in quantifying and costing harm suffered by the victim could hinder patients or participants from resource poor communities or low-income groups in clinical trials from seeking medical injury redress through the courts unless they got assistance from patient advocacy civil rights groups. It is argued by some researchers in medical ethics that ethical guidelines in medical research tend to protect the researcher more than the participant (Elliott 2012). The costing of medical injury is complicated by the fact that if the research participant is injured in experiments or clinical trials neither the researcher nor the research sponsor has a legal obligation to pay for the research participant‘s medical care costs due to complications associated with the law of tort and informed consent obligations (Elliott 2012). In fact, medical scientists employed by the international organisations that sponsor medical research usually blame the participant for not following the procedures of research or that the patient or participant had other underlying medical problems or behavioural problems that contributed to intervention failure (Elliott 2012). In HIV infection compensation claims, the argument that can dampen the lawsuit is that the promoters of New HIV Prevention Technologies can accuse participants in clinical trials of reckless and promiscuous behaviours and failure to use condoms correctly and consistently.

Despite the limitations posed by laws protecting medical practitioners and health professionals, victims of HIV prevention clinical trials can still pursue the compensation claims in court. Financial models for calculating payments can be based on costs associated with the consultation of health professionals and the costs associated with the HIV medication. Lawsuits in New HIV Prevention Technologies can make use of the input from psychologists, psychiatrists, neurologists, physicians, virologists, dieticians and pharmacists. The final analysis can also look at the costs associated with the participant‘s deteriorating physical health and associated mental health problems such as depression, suicide ideation or mood disorders. Sometimes it is difficult for victims of a medical experiment or medical procedure to come together and sue with one voice for compensation. The following quotation illustrates the complications associated with medical injury compensation in clinical trials: “…because research subjects are not a coherent community, they have developed none of the solidarity that has enabled other disenfranchised groups to demand their civil rights. Subjects do not share a common ethnic, religious, or political identity; they are socially and physically disconnected from one another; and they have no natural institutions for organizing, such as churches, universities, or labor unions. In theory, patient advocacy groups might have played a role in organizing support, but today many such groups are financially dependent on the pharmaceutical industry and other research sponsors” (Elliott 2012: 7).

Loss of Earnings Claims

The law of delict and law of tort allow for patients injured in clinical trials to claim for damages that relate to economic loss or loss of earnings (King and Mahoney 2012). Participants who contract HIV in clinical trials sometimes report that they might not be able to carry on with their career aspirations or perform their duties properly as they used to do in good health. Some of the victims might not be able to continue operating their businesses in industries that require participants to be HIV- negative. Financial loss can be calculated based on previous earnings the individual received before they were infected with HIV. The financial computations on loss of income could be based on the impact of the injury. If the HIV infection or AIDS caused permanent impairment or disability the size of the compensation should be huge. It is usually difficult for attorneys representing the plaintiff and those representing the defendant to reach a consensus on the degrees of loss of earnings and disability (Spieler 2012). Chronic conditions and terminal illnesses associated with HIV and AIDS that cause patients to fail to generate an income can be used by the victims to claim for medical injury compensation in HIV clinical trials in Africa.

CONCLUSION

This paper highlighted the possibilities of initiating medical injury compensation claims for participants who get infected with HIV during clinical trials in resource poor communities in Africa and it has also highlighted the complications of seeking compensation. In medical injury compensation claims, the burden of proof lies with participants who were infected with HIV in clinical trials to demonstrate wrongfulness and medical negligence on the part of the health professional who invited them to the clinical trials and how the health professional harmed them during the medical intervention. The probability of victims in resource poor communities instituting legal proceedings for medical injury compensation is low considering the prohibitive financial costs and high intellectual skills required to prove medical negligence against international sponsors of New HIV Prevention Technologies in Africa who have vast financial and legal resources at their disposal to defend their interests, actions and intellectual property. The no-fault approach to medical injury compensation could be the starting point in New HIV Prevention Technologies in Africa.

REFERENCES

Banja JD 2005. Does medical error disclosure violate the medical practice insurance cooperation clause? *Advances in Patient Safety: From Research to Implementation,* 3: 371-381.

Brennan TA, Sox CM, Burstin HR 1996.Relation between negligent adverseevents and the outcomes of medical malpractice litigation. *The New England Journal of Medicine,* 335: 1963-1967.

Chant S 2007. *Gender, Generation, and Poverty: Exploring the "Feminization of Poverty" in Africa, Asia, and Latin America*. Massachusetts: Edward Elgar Publishing.

Douglas T 2009. Medical injury compensation: Beyond "no-fault". *Medical Law Review,* 17: 30-51.

Elliot C2012. Justice for injured research subjects. *The New England Journal of Medicine,* 367: 6-8.

Emanuel EJ, Currie XE, Herman A 2005. Undue inducement in clinical research in developing countries: Is it a worry? *Lancet,* 366: 336-340.

Emanuel EJ, Wendler D, Killen, J, Grady C 2004.What makes clinical research in developing countries ethical? The benchmarks of ethical research.*The Journal of Infectious Diseases*, 189: 930-937.

Guest DE1998. Is the psychological contract worth taking seriously? *Journal of Organisational Behaviour,* 19: 649-664.

Gwandure C, Mayekiso T 2012. Reservations on the use of new HIV prevention technologies in sub-Saharan Africa. *Journal of Human Ecology,* 37: 173-184.

Hammami MM, Attalah S, Al Qadire M 2010. Which medical error to disclose topatients and by whom? Public preference and perceptions of norm and current practice. *BMC Medical Ethics,* 11: 17-17.

Hill G 2007. The case against circumcision. *The Journal of Men's Health and Gender,* 4: 318-323.

King WD, Mahoney MS 2012. Assessing economic damages in personal injury and wrongful death litigation: The state of Michigan. *Journal of Forensic Economics,* 23: 63-89.

Loubser M, Midgley R (Eds.) 2010. *The law of delict in South Africa.* Cape Town: Oxford University Press.

McMillan J R, Conlon C 2004. The ethics of research related to health care in developing countries. *Journal of Medical Ethics*, 30: 204-206.

Moodley K 2007. Microbicide research in developing countries: Have we given the ethical concerns due consideration? *BMC Medical Ethics*, 8: 10.

Moran A 2010, (January 22). HIV Vaccines in Zambia Leaves 46 Women Infected with the Virus. From <https://www.blendzpolitik.blogspot.com/2010/01/hiv-vaccines-in-Zambia-leaves-46-women.html.> (Retrieved January 1, 2013).

Morfit NS 2011. "AIDS is money": How donor preferences reconfigure local realities. *World Development,* 48: 64-76.

Paltiel AD, Freedberg KA, Scott CA, Schackman BR, Losina E, Wang B, Walensky RP 2009. HIV pre-exposure prophylaxis in the United States: Impact on lifetime infection risk, clinical outcomes, and cost effectiveness. *Clinical Infectious Diseases,* 48: 806-815.

Pope KS, Vetter VA 1992. Ethical dilemmas encountered by members of the American Psychological Association: A national survey. *American Psychologist,* 47(3): 397-411.

Spieler EA, Burton JF 2012. The lack of correspondence between work-related disability and receipt of workers‘ compensation benefits. *American Journal of Industrial Medicine,* 55: 487-505.

Tereskerz PM, Jagger J 1997.Occupationally acquired HIV: The vulnerability of health care workers under workers’ compensation laws. *Health Law and Ethics,* 87: 1558-1562.

Weiler PC 1993. *A Measure of Malpractice: Medical Injury Malpractice Litigation and Patient Compensation.* New York: Harvard University Press.