

AIDS: bioethics and public policy

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Editors' Introduction

The most significant new disease to emerge since bioethics was born is AIDS. First recorded at the beginning of the 1980s amid the gay population of the US, it took some time for the global dimensions of the disease to be universally acknowledged: the devastation of whole populations in sub-Saharan Africa, and growing pandemics in other parts of the world. More happily, we have also seen the slow emergence of fairly effective anti-viral medications that have, for a fortunate few, made HIV infection into a chronic rather than fatal disease.

Udo Schuklenk argues that HIV and AIDS have not generated significant challenges for the discipline of bioethics at the level of the doctor–patient relationship. At this level the issues may not be entirely straightforward, but are nonetheless quite familiar to medical ethics. Nonetheless, HIV/AIDS has been and will be crucial for bioethics, because it has so brutally exposed the political dimensions of health.

The virus was already more vicious for those whose immune systems were weakened by chronic malnutrition, unsanitary living conditions, and all the other costs of poverty. This is also a disease that flourishes where public health systems are inadequate, where public information and prevention is hampered by dogma or patchy infrastructures, where women are systematically disadvantaged. Partly because of these old and familiar factors, partly because of the recent success of pharmaceutical companies' research, this new disease has become a disease of poverty. Whereas most of those affected by HIV in the rich countries of the world can expect access to anti-HIV drugs, the rest of the world does not live but dies with HIV.

There is nothing new about the correlation between poverty and ill-health or early death. But the way in which globalisation enabled the

rapid spread of this virus was new. The way the global trade system has created means to fight the infection but failed to distribute these is, if not new, then particularly jarring. As Schuklenk argues, bioethics has had to become political to deal with this new constellation. It must be concerned with the effectiveness and the justice of the commercial pharmaceutical system, of patent protections and global trade rights, of public health infrastructures, of clinical research on the desperate or the poor, of sexual inequalities and of poverty. But what is of decisive importance for bioethics is that none of these are issues only for HIV: in one way or another, they are caught up with just about all the forms of ill-health and premature death that bioethics takes its stand against.

Introduction

In few other areas of bioethical inquiry exists as close a connection between bioethical professional advice and policy development as is the case with HIV and AIDS. Historically, the reasons for this have much to do with one of the groups initially affected most severely by HIV and AIDS, namely well-educated middle-class gay men in developed countries. This particular group of people, highly sophisticated and used to political activism in its pursuit of civil rights-related objectives, engaged the medical profession as well as regulatory agencies such as the US Food and Drug Administration, and legislators (more so in the USA than in other countries) in a number of bioethically interesting policy areas. Many of the controversies of the times were framed as civil rights and/or ethical disputes. The initial areas of concern and inquiry focused on: informed consent to HIV testing and trial participation, the confidentiality of HIV test results, access to trials as a means of access to experimental drugs, the length of time it took to get an experimental drug to the market approval stage, and end-of-life decision-making. This line-up of issues explains why AIDS has become such an interesting topic for bioethicists. Bioethicists concerned about the traditional bread-and-butter themes of medical ethics themes of the doctor–patient relationship (e.g., Daniels, 1991; Boyd, 1992), as well as bioethicists more concerned about policy and regulatory issues in the drug research and approval process (e.g., Edgar & Rothman, 1990; Salisbury & Schechter, 1990), found research topics worthy of vigorous pursuit. No surprise, then, that HIV/AIDS led to a probably unprecedented number of books and articles in professional journals (Manuel *et al.*, 1990). HIV/AIDS has become a permanent fixture in all major mainstream bioethics textbooks (e.g., Kuhse & Singer, 1998; Arras & Steinbock, 1999). Reference series in medicine, ethics and law provide for dedicated volumes on AIDS.¹ Even specialist bioethics textbooks, for instance those directed at dentistry students, carry chapters on HIV/AIDS (Ozar & Sokol, 2002).

AIDS, designated by the medical profession a *pandemic* lives up to its classification. It did not stop at the borders of developed countries. As one would expect of a primarily sexually transmitted illness in the age of globalisation, it spread rapidly across the globe. Indeed, in many countries it has become one of the main causes of death, as in sub-Saharan Africa (Shisana & Simbayi, 2002). Dramatic increases in the number of AIDS cases are predicted for many Eastern European countries as well as for the two most populous nations on earth, India and China. Some of the HIV/AIDS-related bioethical and policy issues of concern to developed countries remain the same for developing countries. However, in ethically important ways they are dwarfed by concerns over drug prices, intellectual property rights, and affordable access to essential AIDS drugs for the impoverished masses of infected people in such countries. Of increasing importance have become ethical issues pertaining to the ever-growing research industry associated with clinical trials undertaken in developing countries. Indeed, major funding initiatives both in the USA and UK have brought clinical research in developing countries into focus. Some have questioned whether this attention is appropriate, considering other bioethical problems of arguably greater importance to developing countries (Chadwick & Schuklenk, 2003). Standards of clinical care in a study, and after a trial has concluded, as well as community benefits and access to the trial regime after the trial's conclusion remain contentious issues. It is worth noting that more often than not it was an AIDS-related trial or policy decision that led to a great deal of bioethical analysis, yet the issues discussed almost always have ramifications far beyond AIDS. For instance, decisions about the question of what (if any) standards of care failures in preventive trials (of HIV vaccines or microbicides) ought to receive have important implications for non-AIDS prevention trials.

These, then, are the themes that this article will be concerned with. The introductory remarks also explain the structure chosen for this review.

Developed World

Doctor–Patient Relationship

Duty to treat? The doctor–patient relationship with regard to HIV and AIDS, initially, came under some strain in discussions of the question whether physicians and other health care workers have a moral obligation to treat people with HIV infection. Some health care professionals face a greater risk of acquiring infections in the course of fulfilling their professional obligations than others. Specialist physicians such as surgeons and dentists traditionally have accepted higher levels of infections and, indeed, it seems to be accepted by surgeons that this is part of the professional risks one has to take should one decide to follow this career path

(Daniels, 1991). Still, unlike most other infections surgeons are likely to acquire in the course of their work, HIV is the only seriously life-threatening illness; in many parts of the developing world it remains effectively a terminal illness at the time of writing. Even in countries with fully developed health care systems, an HIV infection means at this stage no less than the prospect of life-long chemotherapy, as well as the prospect of withdrawing from one's career given the risk (e.g.) an infected surgeon could pose to his or her patients. Clearly, then, the stakes are high for health care professionals working in areas with high infection rates. Unsurprisingly, for the USA and other countries, there have been reports that doctors and dentists refused to treat people with HIV infection and, indeed, it seems that some health sciences students choose career paths allowing them to avoid professional contacts with such patients.

Let us have a closer look at the ethical arguments employed in this context. The argument in favour of allowing doctors to discriminate against HIV-infected patients based on their risk assessment can, perhaps, drawing on a conversation reported by Daniels (1991), best be sketched along the following lines: 'Lots of surgeons carry antibodies for hepatitis B. That's a risk we all have taken, but I won't take the chance of bringing AIDS into my bed and killing my wife.' And, in a similar vein: 'We [Texas Medical Association's Board of Counsellors] didn't agree that a physician who diagnoses AIDS is mandated to treat the patient. I don't think it can be called discrimination when it's a matter of a guy [sic!] laying his health and career on the line.' Two influential types of ethical analyses have dealt with this issue, contractarian (as in Daniels' case) and consequentialist (e.g., Smolkin, 1997). Before I evaluate these, however, let me begin by making a historical point. At least until the advent of antibiotics, health care professionals accepted, as a matter of course, great risks to their personal well-being. Albert Camus and others have famously described in many literary accounts physicians' heroism in the line of duty. These traditional attitudes have changed. In any case, although it may well have been the case that health care professionals in the past tended to accept greater occupational risks to their personal well-being than they do today, that does not establish an argument that this is necessarily what they should have done, and it does not establish that doctors' attitudes today are necessarily to be faulted.

Norman Daniels is the best-known proponent of a contractarian approach to resolve the risk-taking and professional obligations problem. He argued, a decade into the AIDS pandemic (1991), that if doctors have a moral obligation to take well-specified risks, this should be the result of their voluntary agreement or consent to do so. Professionals in various areas from fire-fighters to police officers and indeed doctors and nurses have agreed at the beginning of their careers to abide by morally (and often legally) binding professional codes of conduct laid out by their profession. Sometimes, as was seen in the actions of the fire-fighters who

lost their lives when the World Trade Centre in New York City collapsed on September 11, 2001, the risk may even extend to the lives of the professionals involved. Whether or not professional health care codes of conduct include obligations to treat those infected with a life-threatening virus remains to be seen at this point. Daniels needs to establish a second point to move closer to his preferred conclusion, namely that of voluntary consent. While it may well be true, then, that health care professionals did not give voluntary consent to be subjected to the occupational risk of an HIV infection, they undoubtedly volunteered to become health care professionals (as opposed to other professionals), and they voluntarily took the Hippocratic Oath or promised, usually in public ceremonies, to abide by their profession's code of conduct. Zuger and Miles have suggested that doctors who refuse to treat HIV-infected patients fall short of the required levels of virtuous professionalism required in their practice (Zuger & Miles, 1987). This cannot come as a surprise. After all, the very notion of professionalism is derived from religious roots, meaning to profess publicly to serve the public good. A virtue ethical approach such as that taken by Zuger and Miles is probably closest to the traditional ethos of the profession. Contractarians such as Daniels would argue, quite rightly in my view, that empirically there is no evidence that doctors in any profession are subjected to an infection risk of a magnitude whereby the continuation of treatment would constitute some sort of supererogatory act. Daniels provides much empirical evidence to support this stance, evidence that has been reinforced in the intervening decade. Therefore, health care professionals have little reason to claim that the HIV risk constitutes a reasonable exception to the general professional rules regarding obligatory levels of risk taking. Certainly, the risks taken by the plague doctors should count as supererogatory acts, because of the magnitude of the risk they subjected themselves to in order to provide continuing care for their patients. This, however, is evidently not normally the case for HIV and AIDS.

Inevitably, consequentialists would take a different approach to the matter at hand. Their primary concern is directly linked to the outcomes of various possible policies. Smolkin discusses the consequentialist pros and cons of policies involving volunteerism on the health care professionals' side versus a policy requiring mandatory treatment of patients with HIV infection. His analysis is based on similar empirical assumptions about risks as Daniels' proposal. Smolkin identifies a number of *harms likely to occur if a policy of volunteerism was implemented*, namely: (1) doctors prepared to treat people with HIV infection will be subjected to greater risks simply because they would have to see all those patients referred to them by colleagues who refuse to treat infected people. (2) The very foundation of the doctor–patient relationship is trust. Volunteerism would undermine this foundation, because patients have an incentive to be dishonest to their doctor, knowing full well that they are likely to have

difficulty finding a practitioner prepared to treat them if volunteerism is implemented. (3) Relatedly, infected patients might suffer various forms of physical and psychological harm, because they would be reluctant to disclose relevant information, they might be treated too late, or they might lose access to health care altogether. People with HIV infection might also suffer in wider society, because of the medical profession's signal that it is acceptable to discriminate against infected people. 'From the point of view of an HIV-infected patient who is trying to get in to see a physician and who is unable to do so, or who finds out that she has to wait long periods of time to be seen, while other non-HIV-infected patients can be seen by a doctor almost immediately, the painful feelings of being "second class citizen", of being "marginalised", of being "an undesirable", must be profoundly wounding' (Smolkin, 1997). (One might add that the consequences of delayed or non-treatment might be not so much wounding as fatal.)

There are also a number of powerful reasons suggesting that a policy of mandatory treatment requiring doctors to treat patients with HIV infection does not come without cost. For a start, the professional autonomy of the health care professional is severely undermined if she is forced to treat any patient with an HIV infection. One might also be concerned about the quality of care a physician who is forced to treat HIV-infected patients might provide to such patients. One might also wonder whether the number of new entrants (students) to the field of medicine is likely to diminish if mandatory treatment is required. Except for the autonomy-related one, these arguments have been discarded in the literature. Writers have found the argument pertaining to the quality of care particularly unconvincing, because it suggests a degree of pettiness in the medical profession that does not seem fair to the professionals in question. History has also proven the worry about diminishing numbers of medical students wrong. The number of medical students the world all over is on a steady increase, despite the statutory medical bodies' of most countries decision to insist on mandatory treatment.

This particular debate, one substantially resolved by the history of HIV treatment and policy responses, should prove to be of some utility for the development of policies guiding health care professionals' responses to future public health emergencies involving infectious agents. In fact, it also shows a remarkable resilience of traditional values in the medical profession, where it has historically been accepted that it is part and parcel of being a medical doctor that one might be at risk of contracting a life-threatening or terminal infectious illness in the course of discharging one's professional obligations towards one's patients.

Confidentiality. Trust in the confidentiality of information provided by patients to doctors is one of the cornerstones of the doctor-patient relationship. There are several powerful reasons for this. Some have argued

that personal identifying information is *owned* by the patient and only shared with the doctor for the specific purpose of treatment. If the doctor shares this information with other parties without the patient's consent this would constitute something akin to theft or trespassing on someone else's property. Others have argued, on contractarian grounds perhaps, that there is such a thing as an unwritten contract between doctor and patient that intimate patient information remains between the doctor and the patient (and, in the real world, presumably to the managed care organisation the doctor and patient belong to). Sometimes this is compared to the Catholic priest and the believer coming to confess. There is an unspoken promise that the priest will not divulge this information to anyone under any circumstances. I will return to this theme below.

A consequentialist approach to this issue would not necessarily reach strongly opposed conclusions: a *conditional* confidentiality, e.g., one permitting that confidentiality be breached in case of a serious risk of bodily harm for identifiable third parties, might have overall negative undesirable consequences. As Tristram Englehardt, Jr., points out, 'the fact that a particular disclosure of a patient's dangerousness could have saved the life of a particular third party should not obscure the fact that a general rule requiring disclosure may in fact lead to the deaths of more individuals' (1986: 299).

Nonetheless, Sisela Bok (1982) and Grant Gillett (1987), among others, have argued that patients who indicate that they would rather see their partner(s) infected than divulge their HIV status have forfeited the right to see their confidentiality maintained by their doctors. Indeed, this stance has been adopted by countries such as South Africa, where doctors are required by regulators to disclose personal identifying information of their patients to identifiable third parties that are considered by the doctor to be at serious risk of bodily harm. Empirically, it is difficult to judge whether or not Englehardt's concerns are sound, but certainly, *prima facie* they do not strike me as unreasonable, and the jury remains out on wisdom of the South African law.

Informed consent. As we know, informed consent has become a touchstone of modern bioethics. With regard to HIV, the issues focus primarily on (voluntary) informed consent to HIV testing as a necessary ethical precondition for any HIV test, as well as a necessary precondition for participation in clinical AIDS research. Why is informed consent such a central concern to so many bioethical inquiries? (e.g., Faden & Beauchamp, 1986; Wear, 1993) For a start, it seems to connect closely to Kantian notions of rationality, manifested in choices not manipulated or undermined by false or wanting information, but it has become clear in theoretical bioethics that this is only part of the story (O'Neill, 2002): later, more existential notions of a self capable of making authentic choices and accepting responsibility for these, as well as the modern free-

doms to choose that are so important in liberal societies, have also been important here. However this may be, it is clear that substantial understanding of the matters at stake is a necessary condition for a patient to make a decision as to whether or not she wants to undertake an HIV test, or join a clinical trial.

Consequentialists celebrate the utility of informed consent. Unlike Kantians, obviously, they must make some empirical assumptions bolstering the case for a policy requiring informed consent to testing or trial participation. They tend to argue that overall our quality of life is better if we are allowed to live our lives as we see fit, even if on occasion we make choices we arguably should not have made. This argument is very much consonant with Mill's famous view that over our own bodies and mind we should be sovereign, as long as we do not harm anybody else. (This latter argument has been put forward by health care professionals keen on knowing their patients' HIV status, but more on that in a moment.)

So-called 'capacity assessment tools' have been put forward to allow us to determine whether a patient is capable of evaluating the information provided so as to make an autonomous choice (Appelbaum & Grisso, 1988; Torroella Carney *et al.*, 2001). Making informed consent a precondition for HIV testing, legislators across most parts of the globe explicitly rejected the notion that strong paternalistic actions might be acceptable in this case (Schuklenk, 1998). They also rejected the argument that doctors should be allowed to test patients for their HIV status regardless of their consent, because of some supposedly unacceptable high risk to the professionals from infected patients. The view that patients with unknown HIV status ought to be treated as if they were infected, with regard to doctors' risk-management for themselves, became the mainstream stance on this particular matter. Regulators in most countries argued that health care professionals should simply always operate on the basis of professionally agreed upon rules of universal precautions.

With regard to research participation, in the early days of the pandemic in developed countries and more recently with regard to developing countries many research participants felt strongly that they had no choice other than to consent to participate in a trial but also that they were not true volunteers. The developed world's participants argued roughly like this:

At the moment there is no successful standard treatment for HIV and AIDS available. The only legally acceptable possibility to access experimental AIDS drugs is by means of a clinical trial. Doing nothing will almost certainly result in my death from AIDS, while joining a trial gives me at least a fighting chance to survive.

Quite understandably, a 50:50 chance of receiving a placebo was considered anything but enticing or even fair. Trial participants were known to

have taken their capsules to pharmacists to find out whether or not they were recipients of the 'real thing' or whether they had been randomised into the placebo arm. Sharing of the active drug took place, the trial results arguably became less useful than they would have been, had patients not thought they were given a coercive offer. Philosophers have argued for (Minogue *et al.*, 1995) and against (Arras, 1990) this interpretation, and depending on one's concept of justice one can take legitimately different views on this matter. With the relative success of anti-HIV medications in the last decade, this particular point may have become moot. But the issue resurfaces in sharper form in developing countries, where the vast majority of patients are unable to afford access to essential AIDS drugs, largely but not only because of the high price tag attached to these medications. Many AIDS patients in the developing world 'volunteer' for clinical research, not primarily because they want to help humankind, or advance research or for similarly altruistic reasons, but because they are desperate for access to anti-AIDS drugs and trials are more often than not their only chance of this. One possible response, recently voiced by some US authors, is to insist on a clear-cut distinction between therapy (provided by doctors) and research (undertaken by investigators). But this simply does not do justice to much clinical research in the developing world, where there has always been a strong emphasis on providing much-needed health care to participants of clinical trials (Miller & Brody, 2003).

It was mentioned in the introductory remarks that, initially, a large number of patients affected belonged to well-informed and politically organised groups. Their capacity to give individual informed consent was never seriously questioned. However, when the demographics of the epidemic began to change, both within the developed world and also with regard to developing countries, questions arose as to the possibility of informed consent when the patients concerned were anything but well-educated or politically empowered. Some empirical research undertaken in developing countries suggests that consent may be given but can not really be described as voluntary (Abdool Karim *et al.*, 1998), while other work indicates, more reassuringly, that it is accepted as a necessary and important precondition of ethical research by the people undertaking the research (Hyder & Wali, 2004).

Regulatory Issues

Transmission of HIV infection in sexual relations. A great deal of discussion has taken place in bioethics, legal and policy journals with regard to regulatory questions, most notably that of discrimination against HIV-infected people in the context of employment and access to health and life insurance, as well as with regard to the question of whether an HIV infection acquired during voluntary consensual sexual intercourse should be

classified as a harm-to-others or a harm-to-self case. Libertarian philosophers such as Richard Mohr were quick to point out that AIDS' 'mode of contagion assures that those at risk are those whose actions contribute to their risk of infection, chiefly through intimate sexual contact and shared hypodermic needles' (Mohr, 1987). Others have argued that the question should not be reduced to one of individuals infecting themselves or others, but should rather be seen as a public health matter. Ronald Bayer (1989) maintains that infectious diseases such as AIDS can only be kept under control if people stop infecting themselves and others. If it proves difficult to prevent this, eventually societal interests are at stake. His point is that we should not ignore the accumulative effect of individual infections as far as societal interests are concerned.

Legislators in different countries have reached diametrically opposed answers to this question. In South Africa, at the time of writing, the country's law reform commission proposes to classify voluntary sexual intercourse between two people as rape when one of the two is HIV-infected, knows about it and does nothing to disclose this to her sexual partner (Schuklenk, 2003). At the heart of the problem, it seems, is the following question: if you have voluntarily unsafe sex with a person whose HIV status is unknown to you, and you acquire an infection during your sexual relationship with that person, have you been harmed by that person or have you harmed yourself? I have for many years maintained that an infection occurring as a consequence of sexual intercourse, under the circumstances described, should be interpreted as a form of harm to self. After all, you could have inquired about your sex partners' HIV status or you could have played it safe and insisted on safe sex regardless. In the bioethics literature this view was traditionally defended with reference to the (presumably Aristotelian) *volenti non fit iniuria* principle. If you voluntarily agree to the risk of infection, and you become infected, no moral harm is done to you. This argument could certainly be applied to many cases where infections occur, that is between sexual partners who know very little or quite possibly nothing about each other. Here it can reasonably be argued that if you volunteer to have unsafe sex, it is your responsibility to protect yourself. It is less clear, however, that this argument could succeed when applied to people in long-term relationships, be they married or otherwise. Such relationships are usually based on the unspoken premise of trust that your partner will not put your life at risk, certainly not for reasons as trivial as having unsafe sexual relations outside the relationship. This trust-based relationship is violated by a partner who engages in unsafe sexual relations outside the relationship and puts his or her partner's health at risk by not informing him or her of this. (Outside of the developed world, we should also note the substantial power differential between men and women in many developing countries, whereby it would be plain impossible for women to refuse to have unprotected intercourse with their sexual partner, even if by standard

definitions this might not be considered to be rape. Surprisingly little can be found on this issue in mainstream bioethical discourse on HIV/AIDS (and other sexually transmitted illnesses).)

Discrimination. Discrimination against HIV-infected people took various forms, ranging from social stigmatisation, including not wanting to shake hands with an infected person and refusing to share a room with a person with AIDS, to attempts at discriminating against HIV-positive people in the workplace. While most forms of discrimination in the workplace were quickly outlawed in most Western democracies, one issue remained on the agenda for a long time: that of HIV infected doctors. Would it or would it not ethically be acceptable to discriminate against doctors and other health care professionals who have acquired, by whatever means, the HI virus? Initially the discussion was marred by accusations and counter-accusations as regards discrimination in the workplace. When the dust settled, overwhelming empirical data suggested that health care professionals do not show higher infection rates than the rest of the population, and that, furthermore, those who become infected tended to belong to the same risk groups affected by HIV and AIDS than in the general population.

However, this did not solve the problem of whether those health care professionals might pose an unacceptable risk to their patients, and whether or not they should be required to withdraw or change roles as health care providers. Some bioethicists have suggested that indeed there is a group of patients who could be subjected to an unacceptably high risk, namely those undergoing invasive procedures. For example, Larry Gostin (1990) suggested that such health care professionals ought to be required to report their infection to their employers but not to their patients, and that they should be carefully monitored in their performance, without necessarily refraining from engaging in invasive procedures. Gostin and others arguing in the same vein were primarily criticised for suggesting these (and more drastic) infringements on the professional work of health care workers, while there was (and still is) a complete absence of evidence that the participation in invasive procedures actually increased the number of HIV infections among such professionals' patients. A minority of legal scholars has even argued that the infected health care professional's HIV status should be disclosed to their patients even if the patients' risk of infection is remote. Authors based this conclusion on the doctrines of informed consent and the doctor's fiduciary obligations (Lieberman & Derse, 1992). This position has not, to my knowledge, been implemented in the legal systems of any country.

Developing World

The ethical issues encountered in developing countries are arguably of greater significance than those discussed so far, primarily because the

number of infected individuals and of people with AIDS is dramatically higher than in the developed world, where AIDS has remained largely a problem of gay men and i.v. drug users. At the time of writing the country with the largest reported number of HIV infections is South Africa. The prevalence of HIV in that country stands at roughly 15% of the sexually active population. The United Nations AIDS organisation, UNAIDS, predicts dramatic increases in the number of HIV infections in the two most populous countries on earth, namely in India and in the People's Republic of China as well as in some of the countries of the former Soviet Union. The ethical issues most widely discussed internationally have had to do with the standards of care during and after a clinical trial undertaken in a developing country, and with the issue of affordable access to essential AIDS drugs for the impoverished masses living in the developing world.

Research Ethics

An acrimonious and lengthy international debate on the ethically appropriate standards of care provided in clinical trials in developing countries was triggered by an AIDS trial that took place in South Africa, among other countries. The trial in question was responding to a perceived need in developing countries to investigate a potentially affordable medication that might reduce the transmission of HIV from a pregnant infected woman to her offspring. Before the trial started, a trial undertaken only in developed countries had established that 25% of HIV-infected pregnant women who use no antiretroviral medication transmit the virus to their offspring, but less than 8% of those who used a particular regime of the drug zidovudine do. Not unexpectedly, this trial regime soon became the gold standard for mother-to-child-transmission (MTCT) prevention in the developed world. Unfortunately, this drug regime proved to be unaffordable for the majority of infected women in developing countries. The developing world trial aimed at testing a cheaper yet effective MTCT regime. In order to do so, the investigators sought to establish *not* whether a lower dosage was as efficient as the higher one provided in the developed world, but whether it was more efficient than doing nothing. In other words, the test regime was matched against a placebo control. Because the developed world standard of care was unaffordable to developing country public health systems, this was effectively no drug at all.

The trial regime was quickly denounced in international medical (Lurie & Wolfe, 1997) as well as bioethics (Schuklenk & Ashcroft, 2000) journals, because it violated a standard provision of the world's pivotal research ethics guideline, the World Medical Association's Declaration of Helsinki. The Helsinki declaration would have required the developing world investigators to compare their trial regime against the existing gold

standard of HIV MTCT prevention, i.e., the locally unaffordable regime. High profile defenders of the trial in question argued that the Helsinki declaration was not a particularly useful ethical yardstick to hold the developing world-based trial against. They proposed adjusting the declaration to the realities of developing world health care (Levine, 1999). At the heart of their analysis were two ethical arguments. The first argument was that women in the trials in question were no worse off by virtue of their trial participation. The participating pregnant women would not have had access to anti-retrovirals at all, in the public health care sector of their countries. Hence, those in the placebo arm were not in any way worse off, while those in the active agent arm were almost certainly better off. The second argument states, in a nutshell, that the Helsinki requirement to test a new experimental agent always against the best proven diagnostic and therapeutic method of treatment is preventing useful research in developing countries. If one always has to test a new agent against the best medication that exists somewhere in the world, no matter whether people in a given location can access or afford it, one would not be able to investigate cheaper treatment regimes that could actually make a difference in a developing country.

The counter arguments employed questioned the need to develop cheaper drugs, asking whether or not there is such a thing as a natural (in the sense of: not subjected to human choices) price for any given medication. Proponents of this point of view argue that the prices people pay for essential drugs are the result of pricing decisions made by major multinational pharmaceutical corporations. Solutions to the matter of drug pricing then could be sought in internationally accepted regulations such as the World Trade Organisation's TRIPS agreement, which allows for compulsory licensing and parallel importation of essential drugs in cases of public health emergencies. This obviously would eliminate a lot of the persuasive power of the position I have just described. If it is possible to simply compulsorily remove the patent protection of essential AIDS drugs and, as a corollary of this their high price tag, the need to develop cheaper AIDS drugs for developing countries may well all but disappear. Arguably, however, this would not solve other issues such as the lack of systems for the delivery of antiretroviral drugs in many developing countries. The success of such treatment regimes relies on regular counts of certain blood cells, satisfactory levels of nutrition, and so on and so forth. Still, it is widely accepted that the drug price is one of the primary hindrances of poor people's access to essential AIDS drugs. One might even argue that prices for diagnostic instruments could be subjected to a critique similar to that deployed against high prices for patented drugs. I shall have a closer look at this issue in the next and penultimate section of this article.

Before I turn to this matter, however, two other interrelated issues need to be looked at. Both have to do with standards of care. One such issue

is what standards of care participants can reasonably expect after a trial has concluded; the other question concerns what standards of care are ethically required for people who contract HIV during preventative vaccine or microbicide trials. Preventative vaccine or microbicide trials are designed to test whether a vaccine candidate or a microbicide is capable of reducing the number of HIV infections transmitted in a given cohort of patients. As no preventative agent currently exists, it is legitimate to compare the candidate agents against a placebo control. Invariably in any given clinical trial there are a number of participants who labour under a therapeutic misconception. They believe, despite the best efforts of the investigators, that they are receiving a working preventative agent against HIV. If such a participant becomes infected as a consequence of risk-taking triggered or influenced by the therapeutic misconception, such a participant's situation has worsened as a consequence of his or her trial participation. The question then is whether or not one should accept the UNAIDS view that an infection acquired under such circumstances does not constitute a trial-related injury that should be subject to compensation. The policy implications of this question obviously go far beyond AIDS research and affect all prevention trials. The evidence suggests that these questions are being answered quite differently across the world. The investigators in Thai HIV preventative vaccine trials seem to agree that infections acquired during the course of the trial should not be seen as a trial-related injury. Authorities in that country decided that those who become infected during the trial should not receive anything other than what is available through the public health delivery system. This does not extend to the provision of anti-retrovirals and other essential AIDS drugs. While the debate is still ongoing at the time of writing, in South Africa two pivotal research ethics committees withdrew approval for up-coming preventative vaccine trials, because the committees did consider unacceptable the investigators' intention not to provide essential AIDS drugs to trial participants who become infected. Clearly, then, different decision-makers in different parts of the world have taken different ethical stances on this matter. Interestingly, the ethical evaluation of this question is once again one strongly influenced by economic factors. If a given investigator has to find the additional funds to guarantee life-long treatment (or, as South African ethics committees suggested, while there is a therapeutic benefit to be gained) with essential AIDS drugs, he or she may well decide not to proceed with the trial at all. In turn, this could severely increase the time it takes to develop a preventative HIV vaccine. More lives might be lost in the medium- to long-term if this was a consequence of demands pertaining to standards of care to be provided to failures in preventative trials. Arguably, microbicide trials might be even worse affected, because historically it has been difficult for those wanting to investigate such agents to find the funding required for undertaking the research.

Investigators have pointed out that in the preventative trials undertaken so far, despite some possible infections due to a therapeutic misconception, overall the number of infections was below what it would have been in the trial population had the trial not taken place. They argue, quite persuasively, that this was a result of their trial-related counselling regarding safe sex. While this argument may well satisfy some, it won't satisfy those who believe that each individual who is worse off as a result of trial participation should be adequately cared for and ought to receive essential AIDS drugs even if those are not available through the public health delivery system.

Access to Essential AIDS Drugs

Bioethicists and political philosophers have joined in an international debate centring about the relationship of intellectual property rights, patent protection, drug prices and access to essential drugs for the poor in developing countries. At issue is the fact that pharmaceutical multinationals charge prices for patented drugs that prevent the overwhelming majority of people in developing countries from access to their products. The primary reason for the protection of intellectual property rights and patents is, interestingly, a public interest-based argument. It states that in order for such companies to be able to achieve a desirable public objective, that is to research and produce new drugs, they must be able to reap or anticipate a profit from their products sufficiently high to support a significant research effort. Precisely this reason, however, provides a possible justification for overriding some patents in some countries. If patents are protected to ensure that the public has continuing access to privately developed drugs, something is going wrong when the public cannot actually afford access to those drugs at all. If the owners of those patents price their drugs out of the reach of the majority of those in need, so goes the argument, there is very little point in protecting those patents any longer (Schuklenk & Ashcroft, 2002). Of course, the issues are more complicated than this. For a start, in developed countries, many people in need of expensive, patented AIDS drugs are able to access those drugs. The same, however, cannot be said for developing countries. Here the argument seems to succeed. Indeed, the World Trade Organisation's TRIPS agreement expressly permits developing countries to override the patents for drugs that could be utilised in public health emergencies such as HIV and AIDS. Furthermore, even if one accepts the public interest argument requiring pharmaceutical companies to reap sufficiently high profits to sustain their research agendas, it is worth noting that these profits have never been generated in the developing world.

What is interesting with regard to this debate is that bioethicists have moved on from arguments suggesting that pharmaceutical multinationals should provide some donations to worthy projects, and engaged in argu-

ment at a policy level. The discussion, in other words, is no longer operating on the usual ethics level of ‘please do the right thing’ and investigating ‘what is the right thing to do’; rather, it has moved on to proactive policy development (Cohen & Illingworth, 2003).

Conclusions

It is noteworthy that bioethicists’ analyses of clinical ethics issues generated very little by way of innovative thought and creative conclusions. Predominantly their views were more-or-less liberal answers to a myriad of not altogether novel problems, most of which incidentally were implemented in national legislations in liberal democracies the world over. The areas where, to my mind, bioethicists have followed innovative and creative avenues of thought are in research ethics and the issue of patent protection. HIV/AIDS may well have been the reason for some professionals in the field of bioethics to focus their attention on matters much more political than the traditional bread-and-butter topics of ethical issues in the doctor–patient relationship. Recent developments in bioethics, with its renewed focus on public health issues, consensus development, genomics, and similarly political matters, suggest that we will see more rather than less reflection on such issues. This certainly is to be welcomed. Quite possibly the future will see a split within the profession, a split resulting in some colleagues continuing to legitimately focus their attention on matters pertaining to the healthcare professional–patient relationship, and a new category of bioethicists who are more concerned with issues pertaining to health care management, public health, rationing and similar problems. Ever-growing demand on health care delivery systems worldwide is likely to exacerbate resource allocation conflicts, and to increase demand for ethically sound policy advice as to how to resolve these conflicts.

Note

1. E.g., Schuklenk, 2001. This reference work provides a fairly comprehensive collection of the most important ethical and legal papers on AIDS-related issues that have been published in professional English language journals. Many of the papers referred to here can be found in this volume.

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