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DUESBERG, MBEKI AND AZT: *Contentious science meets contentious politics*

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DUESBERG, MBEKI AND AZT: Contentious science meets contentious politics

The spread of human immunodeficiency virus (HIV) infection has been a major global health concern, particularly in developing countries that do not have the medical infrastructure to support increasing numbers of people with acquired immune deficiency syndrome (AIDS). In South Africa, there were several laudable attempts to combat the spread of HIV before the end of apartheid, but little agreement as to how to tackle the growing epidemic. Following the country's first democratic election in 1994, which led to Nelson R Mandela becoming President, the AIDS response was made a Presidential lead project in the Department of Health under the government's Reconstruction and Development Programme (RDP). When Thabo Mbeki assumed the reins of government in 1999 and the RDP was scrapped, the AIDS programme remained part of the Department of Health but was spread over several ministries and substantially changed.

Shortly after he became president, Mbeki expressed reservations about the use of antiretrovirals to prevent progression from HIV infection to full-blown AIDS. This led to a battle between SA AIDS activists and the African National Congress (ANC), with the former demanding distribution of the antiretroviral drug AZT to pregnant women to avert transmission of HIV to their children, and the ANC refusing on the grounds of expense. Mbeki, former chair of the Inter-Ministerial Committee (IMC) on AIDS and a follower of Peter Duesberg's controversial research claiming that HIV did not cause AIDS, changed the scope of the debate. Mbeki and his Health Minister, Manto Tshabalala-Msimang, sought to increase social involvement in prevention, but refused to provide antiretrovirals to those diagnosed as HIV-positive, even after the SA government won a lawsuit for the right to produce its own cheaper generics. Instead, they sought to promote 'African' remedies such as garlic and beetroot to prevent the onset of AIDS. This policy of 'denialism' that HIV was the cause of AIDS (leading to the conclusion that AZT treatment provided no benefits) did not significantly change until after the election of Jacob Zuma in 2009. It has since been estimated that over 300,000 lives may have been lost over that decade due to the lack of adequate care (Chigwedere et al. 2008).

Background and context

Azidothymidine (AZT, also known as Zidovudine or Retrovir) is an antiretroviral compound targeting HIV through a mechanism that inhibits replication of the virus. Originally synthesised by Jerome Horwitz in 1964 as a cancer drug, it was eventually patented by Burroughs Wellcome (now GlaxoSmithKline). In 1987, it was approved by the US Food and Drug Administration (FDA) for treatment of AIDS after only 25 months of development and one double-blind clinical trial. The trial showed that while the drug had toxic side effects, including bone marrow suppression that on occasion was severe enough to require transfusion (see Fischl et al. 1987; Richman et al. 1987), it could be briefly effective for some patients who could tolerate it. In the absence of any other treatment, patient groups, notably ACT-UP, demanded that the FDA fast-track the drug (Crimp 2011, Jonsen and Stryker 1993). Critics argued that the sample size in the AZT trial was too small, too many

patients had not completed the full treatment protocol, the data showed that any beneficial effects were short-lived at best, and in effect, the FDA had failed to distinguish between experimentation and therapy (Annas 1989). Subsequently, the AIDS Clinical Trials Group was established in the US, involving several thousand patients from asymptomatic to advanced, in a double-blind trial to determine protocols for antiretroviral drug use (Hirsch 1988). However, research into this time period of AIDS drug development has also shown that these so-called 'clean subjects', i.e. candidates who had not undergone any prior treatment, often hid their use of other medication and patients frequently exchanged their given doses in the hope of evening the odds of receiving the drug rather than the placebo (Epstein 1996). How effective AZT was, for whom, and in what dosage, was therefore still subject to some debate.

A few scientists were not even convinced that HIV was the cause of AIDS, leading to questions not only about the effectiveness of AZT, but about whether drug research was even targeting the correct mechanism of progression in the collection of rare diseases that manifest as AIDS. There is still a small community of dissent on this topic, mostly centred on the work of Peter Duesberg, a professor of molecular and cell biology based at the University of California Berkeley, with a distinguished career working on viral causes of cancer. In 1987, the same year as the Harvard trial, Duesberg published a key paper on cancer genetics in which he concluded that there was little evidence that the human T-cell leukemia virus (HTLV-III) identified by Robert Gallo in 1984 was the cause of AIDS (Duesberg 1987).¹ He argued that most people who had been exposed to HIV (determined through antibody testing) were not symptomatic and only 15% of AIDS patients tested positive for antibodies, that the levels of virus in symptomatic patients seemed too low to be clinically significant and that there were no genes within the virus itself which could cause the illnesses associated with AIDS. While agreeing that there might be some indirect correlation between the presence of HTLV antibodies and the possibility of developing AIDS, Duesberg claimed that exposure to the virus was not a sufficient cause by itself, and pointed to external factors which might affect the immune system and its ability to fight off opportunistic infection. In subsequent work, he has blamed the US/European epidemic on the immunosuppressive effects of recreational drugs and other 'risky' lifestyle behaviours, and on the widening use of 'toxic' antiretrovirals such as AZT at non-symptomatic stages of the disease (Duesberg and Rasnick 1998). Assessing Duesberg's claims through literature review and interviews with experts on both sides of the debate, the influential journal *Science* concluded that while Duesberg had raised 'provocative' questions, the weight of evidence suggested that HIV did indeed cause AIDS (Cohen 1994).

Duesberg has not been the only critic of the toxicity of AZT, and several influential studies of the time noted that the severity of the side effects, which included vomiting, headache and muscle pain as well as bone marrow failure, could negate any gain in lifespan for some patients (see, for example, Lenderking and Gelber 1994). Concorde, the largest double-blind study of symptom-free or early symptomatic HIV-positive adults, tracked 1749 participants for three years, with half using 1000mg of AZT per day. It concluded that AZT conferred 'no statistical difference' in improving symptoms or in halting progression, and argued against its use for symptom-free adults (Concorde

¹ The virus identified by Robert Gallo in 1984 as the cause of AIDS, which he named HTLV-III, is now known as HIV-1. Françoise Barré-Sinoussi and Luc Montagnier jointly received the Nobel Prize in 2008, having independently identified the same retrovirus under the name "lymphadenopathy-associated virus" in 1983 (Barré-Sinoussi *et al.* 1983).

1994). Other studies have shown that AZT is effective in much lower doses (200mg rather than the 1200mg per day used in the 1987 trial), and may be used in conjunction with other drugs in individually-tailored 'cocktails' which may avoid some of the side effects (Fischl et al. 1990).

While AZT was no longer the only antiretroviral option by the late 1990s, it was still considered by the mainstream AIDS community to have the best possibility to render AIDS a manageable chronic disease. And, in the case of pregnancy, to inhibit transmission of the virus from mother to child (Connor and Sperling 1994), although not without some risk of foetal abnormalities if administered before birth (Kumar et al. 1994). Anti-retrovirals, including AZT, administered to the mother during childbirth, and to the child for several weeks thereafter have had good success in reducing mother to child transmission of HIV (Connor and Sperling 1994), and US guidelines now encourage their use, even during pregnancy, to reduce overall viral load and maintain maternal health (NIH 2016).

The dilemma

The first reported South Africans to die of AIDS in the 1980s were white homosexual men. The first black patient not exposed through transfusion was diagnosed in 1987 (McNeil 2012), although it is likely the disease had been present in the population for some time. A statement written after the 4th International Conference on Health in Maputo (Mozambique) in 1990 noted that there were approximately 60,000 HIV-positive people in South Africa and these figures were expected to double every eight and a half months, meaning that southern Africa was now in 'an established epidemic' (Maputo 1990: 386). The National AIDS Convention in South Africa (NACOSA) produced a plan of action in 1992, but this did not include distribution of AZT (Ijsselmuiden et al. 1993). Although Nelson Mandela spoke at the convention (Mandela 1992), and the plan was adopted by the African National Congress (ANC) when he took office in March 1994, its implementation was hampered by the complexities of transition from an apartheid state. By then, HIV infection was estimated to have risen from 0.8% to 12.3% of the total population (Simelela and Venter 2014).² In the Mandela government, the AIDS programme was accorded the status of a Presidential lead programme as part of the RDP with its main base of operations in the Department of Health, but it was not seen as a key concern in the immediate post-apartheid era. Mandela himself did not become a strong leader in the fight against HIV/AIDS until after he left the Presidency in 1999.

Mandela was succeeded by his former deputy, Thabo Mbeki, an economist trained at the University of Sussex in the early 1960s while he was exiled from South Africa for being a leader of the ANC. Under Mandela, Mbeki had been largely responsible for the co-ordination of AIDS policy and has been characterised as a 'workaholic who sets himself impossible standards of trying to become an expert on every subject his government has to deal with' (Sparks 2003: 254). Mbeki encountered Duesberg's writing while self-educating about AIDS via the internet (Specter 2007) and thereafter became convinced that poverty, not HIV or sexual transmission, was to blame for the rising death toll due to AIDS. Taking office with a plan of liberating South Africa from reliance on donor agencies,

² However, it has also been noted that diagnosis at this time was often through observation, not antibody testing, and many of the symptoms ascribed to HIV are also symptoms of common diseases, such as malaria, making exact numbers difficult to verify. This also made it difficult to calculate AIDS mortality, as many such deaths were instead ascribed to related conditions such as tuberculosis, with no record of HIV status (Groenewald et al. 2005).

he then proceeded to staunchly reject the knowledge, programmes and arguments put forward by the international AIDS community about the best way to combat the spread of HIV.

The role of scientific advice

In 2000, Mbeki invited Duesberg, fellow molecular biologist David Rasnick and Harvey Bialy,³ general practitioner Sam Mhlongo, and several other 'AIDS dissidents' together with representatives from the mainstream AIDS community, the WHO and other agencies, to participate in a Presidential AIDS Advisory Panel. The final recommendations, which were not agreed to by all the members of the Panel, called into question the epidemiological statistics and suggested that the apparent increased mortality from AIDS might be due to other factors.

The report divided many of its recommendations into two competing suggestions, one provided by those who did not believe that HIV was the cause of AIDS, and another by those who did. The former group suggested that HIV infection should no longer be publicly spoken of as potentially fatal, and that all HIV testing should be suspended until a link was proven. On the use of antiretroviral drugs, the dissenters also claimed that Africans diagnosed as having AIDS would not fit the criteria in use in the USA, Europe and Australia, that AIDS was neither contagious nor sexually transmitted, and that the compromised immunological condition defined as AIDS was actually induced by poverty and the use of toxic anti-HIV drugs (Presidential AIDS Advisory Panel Report 2000). The dissenting views supported Mbeki's longstanding argument that even if the expense of AZT could be mitigated through donor programmes, the drug should not be distributed through the public health system (including programmes to prevent mother to child transmission) until its toxicity was determined (Weinel 2007).

Those who believed HIV was the cause of AIDS and supported the use of antiretrovirals did agree that the South African situation was different than that in the US, that local research and guidelines were needed, and that interventions such as provision of clean water and better sanitation were also necessary as a matter of increasing general health. However, they maintained that transmission occurred primarily through sex, contact with infected blood, or through childbirth and breastfeeding, and that this was where specific public health measures should concentrate, with distribution of AZT organised through the public hospital system. Despite concluding with a discussion of the importance of experiments to answer the causality question once and for all, the report as a whole leaned heavily towards the dissenters, who argued that experiments can 'never prove or disprove the HIV theory of AIDS' (p. 97).⁴

Because the panel expressed oppositional conclusions, the report was immediately criticised as confusing and unhelpful. Manto Tshabalala-Msimang, an obstetrician who had been appointed by

³ Rasnick was a collaborator on several key papers (Duesberg and Rasnick 1998; Duesberg et al. 2009). Bialy (2004) went on to write a laudatory biography of Duesberg. Mhlongo was another ANC member who obtained his medical degree while exiled in London in the 1960s. He had returned to South Africa in 1999.

⁴ Mhlongo went on record shortly thereafter reiterating his doubt that the HIV virus even exists (Shenton 2000), a position he continued to advocate until he died in a road accident in 2006.

Mbeki as Minister of Health,⁵ dismissed as 'elitist' the subsequent declaration signed by 5000 doctors affirming that HIV was indeed the cause of AIDS (Durban 2000), while the President's spokesman, Parks Mankahlana, called the declaration worthy only of 'a dustbin' (Dempster 2000).⁶ An international furore subsequently erupted over Mbeki's address to the 13th International AIDS Conference in Durban in July, in which he reiterated the argument that poverty, not HIV, was the main cause of death and illness in Africa (Mbeki 2000).

Stating that he was causing 'confusion', Mbeki withdrew from the debate on HIV, leaving Tshabalala-Msimang to process the panel report. This lack of direction from the administration meant that 40% of the AIDS budget from the year 2000 remained unspent (Sparks 2003: 265), leading to substantial pressure on the government and the ANC by civil society activists, health professionals and the international community. This culminated in the government's loss of a constitutional court lawsuit demanding the provision of drugs to prevent mother to child transmission of HIV (Cullinan and Thom 2009). In 2002 the government finally began instituting programmes for delivering antiretroviral drugs through public hospitals to pregnant women and in 2004, the Cabinet of Mbeki's government passed a resolution to make antiretroviral therapy available in public hospitals to patients with a CD4 cell count below 200 (indicating progression to full-blown AIDS). Implementation, however, was slow and despite the 2002 declaration that the 'government's starting point is based on the premise that HIV causes AIDS' (statement of Cabinet, quoted in Simelela and Venter 2014) was repeatedly obstructed by governmental red tape, so that the situation did not significantly change until the regime itself changed hands in 2009 (Motsoaledi 2013). Today, despite better policies that include provision of antiretroviral drugs, the economic and cultural change needed to make prevention initiatives more effective (such as medical infrastructure, better nutrition, and acceptance of the need to use condoms) is still lacking. South Africa still has the highest percentage of HIV-infected people in the world (AFSA 2016).

It has been claimed that approximately 330,000 people died between 2000 and 2005 because of the lack of adequate treatment (Chigwedere et al. 2008). Others have challenged that figure, including Mbeki himself, who has recently addressed the controversy in a series of Facebook postings discussing his legacy (Mbeki 2016). Seen as part of Mbeki's larger project for South African unity and economic development post-apartheid, it has been argued that his actions may have ultimately helped people in Africa living with HIV and AIDS by drawing international attention to the structural aspects that exacerbate ill health, such as endemic poverty, lack of resources for medical care, and the exceptionally high prices being charged for life-saving drugs (Sheckels 2004), which are now available in Africa at a fraction of the price charged in the West. However, poverty, stigma, denial and long waiting lists for treatment remain.

Wider lessons and insights

Mbeki's self-education programme illuminates specifically what can happen when a policymaker, reading primary source material, comes to consider him/herself an expert on a scientific matter, without perhaps understanding the full significance of the criteria used, and the way in which

⁵ Although initially supporting the use of another antiretroviral, nevirapine, to prevent mother-to-child transmission, Tshabalala-Msimang quickly fell in line with Mbeki's denialist views.

⁶ Mankahlana died soon after, of an undisclosed condition many claimed was AIDS (Dempster 2000).

science evolves over time and with the invention of better instruments (Weinel 2007). Having become persuaded by the arguments of scientists whose views were marginalised by the main AIDS community, but whose scientific credentials in an adjacent field were widely lauded, Mbeki was also able to use this work to claim a scientific basis for health policies which were more closely aligned with his stated overall objective of creating national cohesion and freeing South Africa from Western control by seeking local solutions for South African problems.⁷ Paradoxically, despite the Western origin of his own dissent, Mbeki continued to reject conflicting scientific advice about HIV from South Africa's top scientists, including those who were closely aligned with the ANC and with his other goals, as being influenced by established interests.

However, aspects of the dissenting arguments are not without merit, and had credibility amongst AIDS activists in the early years when the toxicity of AZT was greater due to higher dosage, and Burroughs Wellcome was generating enormous profit as its sole supplier despite the lack of evidence that it provided any clear benefit in the long term (see Crimp 2011, also Garfield 1993). The Maputo statement had also agreed that poverty, homelessness and poor health care were a contributing factor in the spread of HIV in Africa and condemned the apartheid government for 'sexism, victim-blaming, and racial stereotyping' in its handling of the crisis. Pharmaceutical company profits, undesirable side effects, inadequacy of public health care, and confluence with other diseases of extreme poverty have continued to inform discussions of AIDS in the developing world, regardless of the speaker's position on HIV or AZT. Therefore, while the weight of scientific evidence now clearly links HIV infection to AIDS, it is equally clear that there are also structural conditions that contribute to its higher mortality and morbidity in poorer nations.

The Mbeki case also highlights the political dimensions of science advice from both sides, particularly when there is a potential career cost for advisors who disagree with power and/or a mutually reinforcing benefit when – for different reasons – politics and science agree. An additional factor is the very complex science of etiology (determination of causality in disease), from which criteria known as 'Koch's postulates'⁸ (if virus X is the cause of disease Y, then X must be present in all Y patients, and all people with X must develop Y) have been called upon to disprove the claim that HIV is the cause of AIDS. However, other potential causal agents, which have failed the strict letter of Koch's postulates, are still widely accepted – most notably for poliovirus, which could not be isolated from every case, and hepatitis B, in which the indicator of exposure is also an antigen in the absence of an isolated virus (Harden 1992). It should also be noted that Koch himself was not able to fulfil his own postulates when he discovered the bacterium that causes tuberculosis. The claim that HIV is a harmless passenger virus which may be co-present but is not the cause of AIDS (Duesberg et al. 2009)⁹ cannot, therefore, be proven without identification of another definitive agent. However, there is little incentive and even less funding for such research.

⁷ Some of the treatments proposed for those diagnosed as HIV-positive, such as the herbal remedy *ubhejane*, may indeed have had some strengthening effects on the immune system which led users to feel objectively better, while others, such as virodene, a drug derived from an industrial solvent, most likely did more harm than good (Specter 2007).

⁸ Named after a founding father of nineteenth-century bacteriology, Robert Koch.

⁹ *Medical Hypotheses* was forced by its publisher, Elsevier, to withdraw the paper after complaints led to its being subjected to an external peer review, where it was rejected. The controversy also led to the removal of the journal's editor.

In offering to act as Mbeki's advisors, Duesberg and his fellow travellers were able to project their theory into the international arena outside the AIDS community, thus attempting to right what they saw as a great wrong, and where – particularly thanks to the internet – they have found enduring support.¹⁰ An equally difficult dilemma for science advice is that dissent is part of the process by which scientific paradigms change, and therefore it does play a legitimate function. For example, the other Nobel prize in Medicine for 2008 was given to Harald zur Hausen, who proved the role of human papilloma virus in cervical cancer, a claim that was also dismissed by the scientific consensus of his time. Therefore, while some of the dynamics at play were specific to the particular time, place and personalities involved, understanding the complex relationship between science and politics in this case may also shed light on other equally complex situations, such as climate change denialism, where politicians also point to the research of a small number of credentialed scientists as evidence that a largely-accepted causal effect is wrong, and therefore the recommended remedies need not be taken.

QUESTIONS FOR REFLECTION

- How should complexity and uncertainty be communicated without simplifying to the point that science becomes inaccurate, particularly when a dispute turns on nuances of methodology for validation not familiar to those outside the field?
- The designation of 'epidemic' was originally based on the presence of HIV antibodies, not full-blown AIDS, in a time when it was not known how long it might take people to become symptomatic. How can good advice be given when there is a lack of useful data upon which to base it?
- What is the best way to advise a policymaker who considers him/herself an expert on a scientific matter? How might the international and national aspirations of policymakers affect the choice of science advisor, as well as that advisor's capacity to give good advice?
- Two specific problems in South Africa were the legacy of apartheid, which left a situation of distrust of former elites (including international donor agencies), and cultural attitudes towards condoms which were important to people's sense of wholeness and identity but complicated prevention programmes. Should a science advisor take account of the social and political context of the questions s/he might be asked, and if so, how might that affect the giving of impartial advice?

¹⁰ See, for example, <http://virusmyth.org>, <http://rethinkingaids.com> and <http://aidswiki.net>.

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EDITORIAL NOTE

This case is developed by and for members of the INGSA network. Although efforts have been made to ensure that cases are as factual as possible, we welcome feedback and suggestions for revision.

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