"Us doctors REALLY help people – you social scientists just study them": Some Unexplored Ethical issues in Social Science Healthcare-Related AIDS Research in South Africa.

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Introduction

Healthcare-related research is, understandably, dominated by medical science. Research ethics bodies ensure that such research is conducted according to rigorous scientific standards whilst protecting the rights and interests of patients. More recently, ethical governance has been extended to social science research in health and other areas – but this has occurred in an uneven way. The various social science associations have yet to agree on a set of universal rules (Hoeyer *et al*, 2005).

When it comes to health-care related research, medical researchers are typically in more powerful positions than social scientists. Power is exercised at the level of ethics committee approval (which in the health arena is dominated by medical researchers) and at the level of healthcare facilities that are, necessarily, controlled by medical personnel (where some of whom may also be researchers). While there is an emerging body of literature commenting on the dominance of medical scientists in research ethics bodies (see e.g. Phal, 2005; Bosk, 2005 and Alderson, 2005), the exercise of power at the level of the health facility has yet to be properly considered. This paper begins to explore this topic by means of two South African case studies of the largely unaccountable exercise of power by medical practitioner/researchers over social scientists with regard to providing access to research subjects. In so doing, it raises questions about how we think about the informed consent.

The first code of ethics for medical research was the Nuremburg code (1947) in which informed consent was codified on the principle that individuals must never be sacrificed for the benefit of society (Hoeyer, *et al*, 2005). This overturned the hitherto existing paternalist and complacent 'Hippocratic' approach which assumed that medical researchers and doctors were the only agents capable of making appropriate judgments about medical research (Alderson, 2005). This was followed by the 1964 Declaration of Helsinki (subsequently revised five times by the World Medical Association (WMA)) that established a set of fundamental principles for medical research. This has been supplemented by a set of additional ethical guidelines for healthcare-related research, each emanating from specific regulatory bodies. These include: the Council for International Organizations of Medical Sciences (CIOMS, 2002); Council of Europe (COE, 2004); European Union (EU, 2001); European Group on Ethics in Science and New Technologies (EGE, 2003); Medical Research Council (MRC, 2004); and Nuffield Council on Bioethics (UK) (NCOB, 2002). The main purpose of all these codes of conduct is to protect the subjects of medical research by requiring their informed consent, protecting confidentiality and ensuring that the real and potential benefits of participation can reasonably be expected to outweigh the costs. Since then, independent review boards (IRBs) in the United

States, and Research Ethics Committees (RECs) in the United Kingdom and elsewhere have applied these basic principles to medical research.

These principles and practices have now been extended to cover social science research. While this is necessary to protect the interests of research subjects, in practice this has tended to result in the prioritization of medical research over that of social science research. Limited representation of social scientists on research ethics bodies results in a typically poor appreciation of social science research techniques – especially with regard to qualitative and ethnographic approaches (Bosk, 2005; Alderson, 2005). This can result in a game of 'my discipline is more rigorous than your discipline' played by medical researchers in IRBs against social scientists (Pahl, 2005). This game is loaded further in favour of medical researchers by the application of the medical risk-benefit paradigm to social science research. Whereas the standard piece of medical research involves a randomized control trial in which research subjects are also patients who stand to benefit directly from the development of new drugs (whilst also facing real risks from unanticipated side effects) – social science techniques are more varied and are, by their very nature, unable to result in the immediate and direct personal benefits to the research subjects of the kind that successful drug therapies could bring. By its very nature, the 'benefits' of social science research are reaped at the level of society rather than the individual. At the very least, it leads to intangible benefits by adding to the body of social science knowledge – and at best it leads to more tangible benefits through informing the development of new and better policy interventions, but even where this happens, the 'benefits' are likely to accrue to individuals in the future, rather than to the research subjects themselves. A narrow application of the requirement that the research 'benefits' the research subject is thus necessarily always going to be biased against the social scientist.

In addition, there are clear difficulties involved in understanding potential 'risks'. In medical trials, the risks are typically and easily understood as 'side-effects' of the new drugs. In social science research, the risks are more difficult to isolate and evaluate. This can result in *ad hoc* and inappropriate (even absurd) judgments. For example, an IRB in the United States refused a social scientist permission to ask his class of university students to participate in and write about their experience of a recreational group activity over the weekend on the grounds that the project might expose student to unanticipated harm by encouraging them to go out on a Saturday night (Bosk, 2005). A similarly risk-averse approach is often evident with regard to evaluation of potential 'risk' to research subjects of being asked potentially upsetting or sensitive questions (Pahl, 2005). Rather than leave it up to the researcher to decide whether a particular research subject should be exposed to a continued line of sensitive question, research ethics bodies are prone to removing such questions – often with no or little appreciation of the fact that research subjects often *want* to discuss such topics as they are of particular interest to them. Pahl thus complains that ethics committees can be seen as standing in the way of patients deciding for themselves whether they want to participate in the research process themselves (ibid).

In other words, there seems to be a danger that the old problem with the Hippocratic approach (in which doctors made the decision about what was or was not in the interests of the patient) has re-emerged within the context of medically-dominated research ethics bodies deciding what social science is or is not in the interests of

research subjects. Rather than ensure that research subjects understand the potential risks and benefits of participating in a social science research project – i.e. are in a position to give informed consent – the very choice may be removed from them at the outset by a research ethics evaluation process based on a (possibly loaded and biased) understanding of potential risks and benefits.

This removal from research subjects of the right to make an informed choice as to whether they want to participate in social science research can occur both at the level of the research ethics body (i.e. at the point when the social scientist seeks ethics approval for the research) and at the level of the clinic or health facility when the social scientist seeks permission to interview people making use of the facility. Whereas the former problem can (at least in principle) be addressed by increasing the representation of social scientists on research ethics bodies, there are no effective mechanisms in existence to address the exercise of power by medical practitioners who effectively control access to patients by virtue of the fact that they provide medical services to them. This problem is even more acute when the medical practitioners are themselves also researchers – and hence may have research-related, self-interested, reasons to deny access to social science researchers.

Some attention has been paid to the problem of 'dual loyalty' – i.e. when a clinician experiences a role conflict between their professional duties to a patient, and the obligations, expressed or implied, real or perceived, to the interests of a third party (see Physicians for Human Rights and University of Cape Town Health Sciences Faculty, 2003). However, as Singh points out, this problem has yet to be applied to dual loyalty in medical research – especially when the roles of clinician and researcher merge: "In the practice-research context this translates to the physician-researcher's primary interest (duty of care towards the patient-subject) being undermined by secondary factors (such as loyalty to the study/sponsor)" (2005: 395). He cites the example of a 1997 study on the relationship between viral load and HIV-transmission amongst sero-discordant couples as manifesting this problem: should the researcher/clinicians in their role as doctor have been more forthright about the risks of transmission to the sero-negative partner; or should they have withheld the information in the interests of the scientific study? The emerging 'answer' to this problem seems to be for clinician/researchers to explain to their patients about their dual roles, and for it to be made clear to patients that they can withdraw from the study without loss of medical help (see discussion in Singh, 2005: 396-399).

Unfortunately, no attention has yet been paid to the ethical problem of clinicians denying social scientists access to 'their' patients not because they are worried about the adverse implications of the social science research for the patients, but because they do not want any other research (besides their own) being conducted on the patients.

This paper explores some of the ethical issues arising from the exercise of self-interested, research-related, power by medical researcher/practitioners over social scientists. I present two case studies, both arising out of my experience working as a social scientist with, and alongside medical researcher/practitioners in South Africa. It is thus necessarily subjective and impressionistic – but nevertheless provides concrete examples of the kinds of problems that can arise when medical researcher/practitioners and social scientists collide 'in the field'.

Each case study throws up different ethical issues for consideration. However, a common thread running through both of them is my observation that doctors/medical researchers use their power over social scientists not only to protect their own research turf, but because they see themselves as being in a morally and intellectually superior position. They believe that they are in a morally superior position because 'only they really help' people by dispensing medicine (whereas social scientists can, at best, do little more than contribute in some amorphous way to the policy environment) – and they believe that they are in an intellectually superior position because their research is based on 'hard' science (rather than 'soft' social science). Whilst acknowledging the power of medical science, social scientists would nevertheless insist that their research methodologies are appropriate for a different – but equally important – set of questions. Denying social scientists access to patients thus effectively limits to research field to a very narrow set of issues.

Medical researcher/practitioners are in a powerful position to dictate the research agenda largely because they have access to extraordinarily large budgets to treat and research their patients. In a very real sense, these medical practitioner/researchers do indeed control 'their' patients/research subjects – and in the Case 2 below, they do not hesitate to use this power and deny others research access to them. The temptation to regard social scientists as irrelevant at best (and distracting at worst) poses serious problems for research collaboration between medical and social scientists. Not only is there the danger that social science research will be side-lined – but that medical researchers will be in a position to dictate what gets studied, and perhaps also be in a position to appropriate and twist social science results to suit their larger interests (as occurred in Case 1). In other words, there are issues of research ethics and good science at stake.

The South African case studies presented here illustrate these problems in particularly stark ways largely because of the context of AIDS crisis. With just under a fifth of the adult population HIV-positive, and given the government's reluctance to roll-out antiretroviral therapy with any sense of urgency, there is substantial pressure (both in terms of resources and emotional energies) on healthcare practitioners. Their irritation with social science research is thus in some way understandable. However, as the AIDS crisis is both a social and health crisis, and given that social scientists are better placed than medical practitioners to understand the social and behavioural context governing individual adherence to antiretroviral therapy, the effective control of medical researcher/practitioners over access to research subjects is highly problematic.

The first part of the paper sketches the context of AIDS in South Africa and the particular research challenges posed by the nascent antiretroviral treatment rollout. This is then followed by a discussion of two cases of uncontrolled 'gate-keeping' by self-interested medical practitioners/researchers in Cape Town. The first illustrates the problem of placing narrowly defined institutional interests over that of a broader social interest. The second illustrates the problem of self-interested gate-keeping by medical researchers who place bio-medical concerns over social-psychological considerations.

The Context: AIDS in South Africa and the Challenge of Providing Highly Active Antiretroviral Therapy

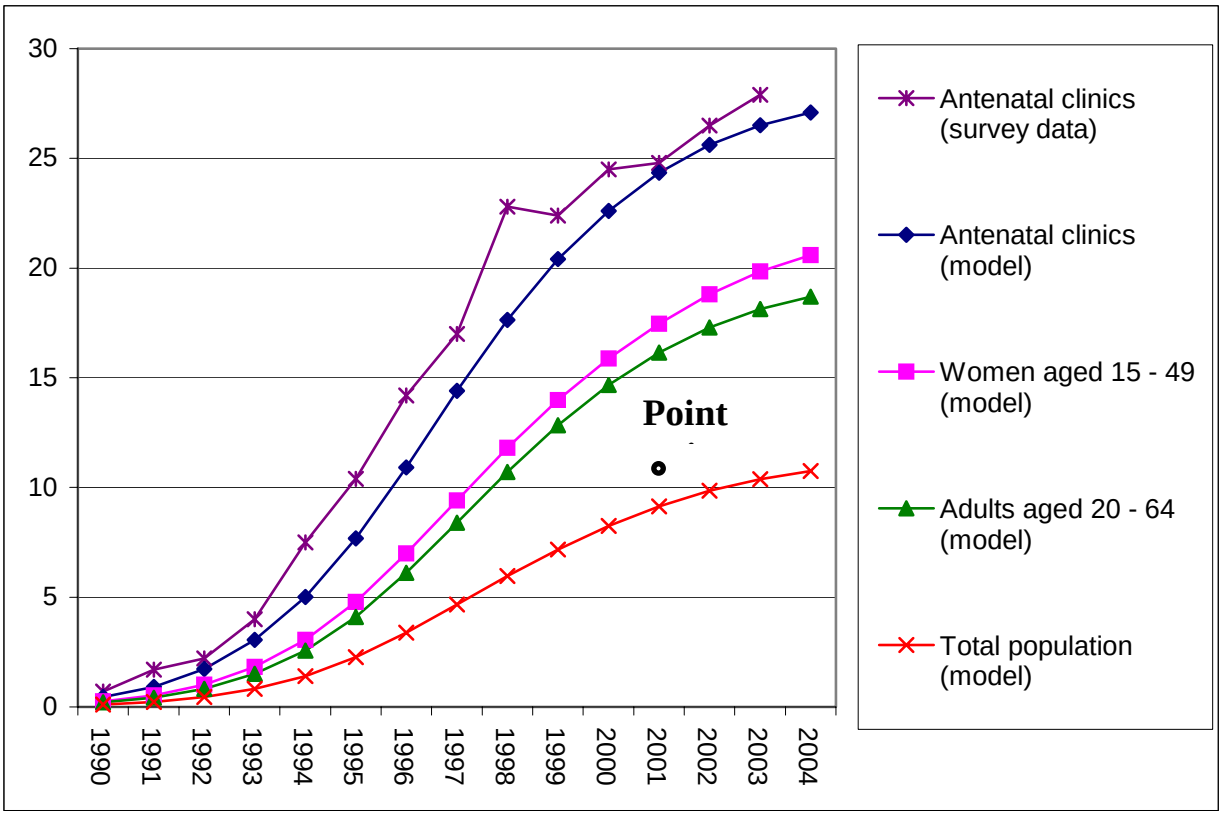
AIDS is a very serious problem in South Africa. Over a quarter of pregnant women who attend antenatal government clinics are HIV-positive. Using this and other demographic data such as deaths by age, gender and race, South Africa's premier demographic model (ASSA2002) estimates that 18.7% of adults between the ages of 20-64, and 10.8% of all South Africans, were HIV-positive in 2004. These estimates are consistent with the results of a national survey of HIV prevalence conducted in 2001 (Shisana and Simbayi, 2002). Figure 1 plots trends in the raw HIV prevalence data from the government antenatal survey as well as key outputs from the ASSA2002 model.

The AIDS pandemic amounts to a socio-economic crisis of significant proportions. AIDS undermines the economic security of households by reducing the productivity of (and eventually killing) mainly prime-age adults whilst simultaneously diverting scarce household resources towards medical expenditure. This has been especially problematic for poor African households in South Africa (see evidence cited in Nattrass, 2004). Under these circumstances, the provision of highly active antiretroviral therapy (HAART) has the potential to impact positively on the lives of AIDS patients and on society as a whole.

According to the ASSA2002 model, about 500,000 people are in Stage 4 of AIDS and thus in need of HAART. Yet as of April 2005, fewer than 30,000 people were on HAART in South Africa – this despite the fact that the government promised as early as October 2003 to have provided HAART to 50,000 people by March 2004. The human costs of this procrastination are enormous. It has been estimated that if the government opted to rollout HAART rapidly to reach 90% of all those who need it, then by 2015 average life expectancy would be 50 (as opposed to 42), there would be 913,000 fewer maternal orphans than would be the case in the absence of a rollout (see Nattrass, 2004). Similarly, if the government opted to boost the pace of its current rollout to this rapid rate, then there would be 2.3 million fewer AIDS cases in total between 2003 and 2015 and 430,000 fewer HIV infections[1] (see Figure 2).

Figure 1. HIV Prevalence in South Africa (% of population that is HIV-positive)

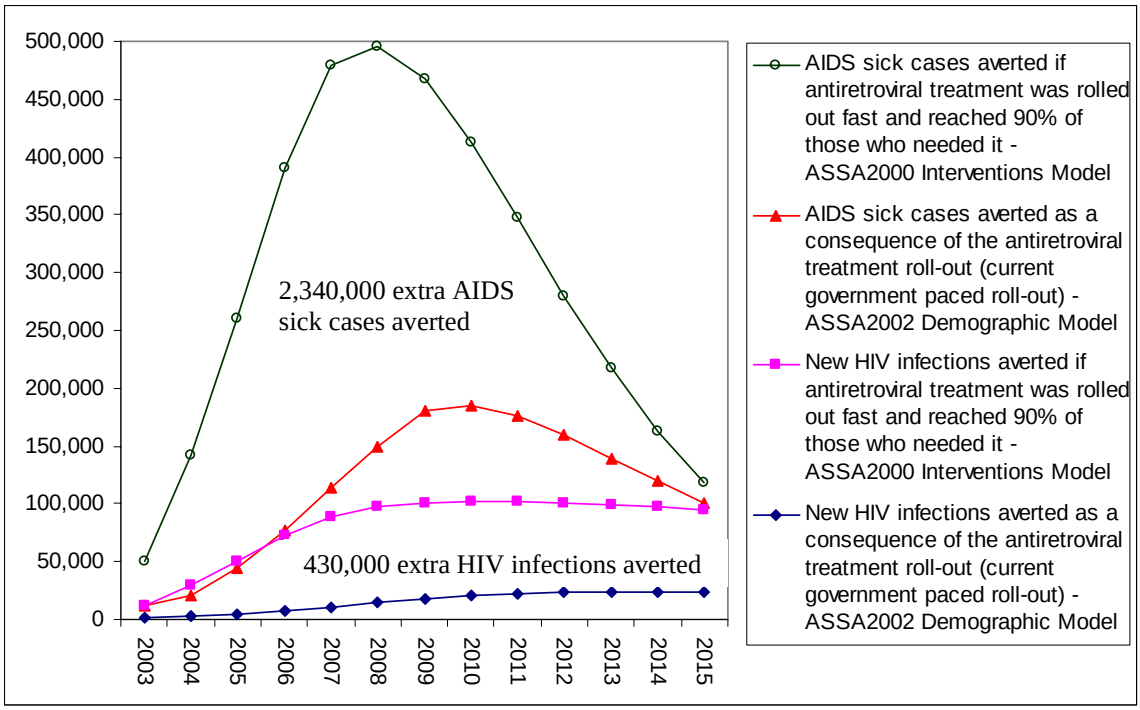
[1] The ASSA model estimates that rolling out HAART helps prevent new HIV infections because people on HAART have lower viral loads and hence are less infectious during their lives – even though they live longer (for more discussion, see Nattrass (2004).



Source: ASSA2002 Demographic Model; Department of Health (2004), Shisana and Simbayi, 2002.

It is thus unsurprising that people working in the AIDS arena in South Africa are infused with a sense of frustration with government. Those conducting research are under enormous pressure from AIDS activists and health practitioners to produce findings that could help promote the cause of a faster rollout. This is the politically and emotionally charged context within which the two case studies presented below take place.

Figure 2. A Slow and Limited versus a Fast and Comprehensive HAART Roll-out



Source: ASSA2000 Interventions Model; ASSA2002 Model

Case One: Repressing Social Science Research in the Supposed 'Best-interests' of the Patients and the NGO providing HAART

In 2002, two employees of a large European non-government organisation (NGO) approached me to collaborate in a study of the socio-economic benefits of providing HAART in a resource-poor setting. The NGO had, with the support of the Western Cape provincial government,[2] been operating a pilot project to provide HAART in a local African township. Their clinical data indicated that adherence was good, and that in terms of standard medical measures (viral loads, CD4 cell counts), almost all of their patients were responding positively to treatment. The NGO thus decided to supplement these results with a socio-economic survey of the impact of providing HAART.

They approached me for three reasons: 1) my background in AIDS and survey research; 2) the fact that the research unit I direct also operates an AIDS outreach programme in the local African townships; and 3) because they saw me as a natural ally because of the supportive work I had done for the Treatment Action Campaign's court case to force the government to implement a mother to child transmission prevention programme (see chapter 4 of Nattrass, 2004). In retrospect, this political dimension my selection as a 'politically safe' researcher should have been more carefully considered at the outset – but such is the benefit of hindsight.

[2] Although the national Ministry of Health in South Africa has proved reluctant to rollout HAART, the Western Cape Provincial government has not been – and in fact has been proactive in securing the help of foreign charities and NGOs to help provide HAART to people who need it in the Western Cape. Most of the people on HAART in South Africa are located in the Western Cape as a result.

During our initial discussions, it became clear that their working hypothesis was that HAART would boost household income because previously sick people would become well enough to work (and because people who had left employment to become full-time caregivers would be able to return to work). I warned them that this happy scenario might not materialise quite as they expected because of South Africa's high unemployment rate. Given that over a third of working-age adults in South Africa cannot find wage employment,[3] there was no guarantee that better health would translate uniformly into better income.

Undaunted, the employees of the NGO expressed their desire to embark on the study, and asked me to pilot it through the relevant medical research ethics committee at the University of Cape Town.[4] This I did in my capacity as being listed as the University Principle Investigator (PI) on the application (with the senior employee of the NGO listed as the 'Principal Investigator' (PI)). The NGO undertook to collect the data from their HAART patients. I understood my role to be a purely academic one – i.e. to analyse the data and write papers for publication. I signed no formal contract, but was happy with the wording that appeared on application to the Faculty of Health Sciences Research Committee. In particular, under Section E – *Financial and Contractual Information* – the application recorded 'no' to the question: "Are there any restrictions or conditions attached to publication and/or presentation of the study results". I thus assumed that I would be free to present and publish any findings from the study.

Although the NGO paid for the survey, I provided advice on the survey design and supplemented the project with additional resources from my research unit in the form of paying for data capture, facilitating the collection of extra comparative data, and supporting a Master's student to work on the data. This student, in turn, spent many hours at the NGO's clinic conducting a quality control operation on the questionnaires. It seemed to me, in other words, to be a genuine collaboration between medical practitioners/ researchers and social scientists.

All went well until the Master's student and I presented our first report to the NGO. The PI based at the NGO expressed her dissatisfaction with several results – the most important being that unemployment rates had risen in the sample of people on HAART. I was not surprised by this result (indeed, I had tried to warn her to expect it) – but she clearly saw this as a negative reflection on the NGO's intervention. I tried to explain that the unemployment rate is calculated as the number of unemployed (i.e. people seeking work) divided by the labour force (i.e. the sum of the number of unemployed plus the number of employed). People who are sick are non labour-force participants and do not get included in either the numerator or the denominator of the unemployment rate. When people get better, they enter the labour force. In a context of previously existing high unemployment, it is not surprising that these previously sick individuals would result in a rise in the unemployment rate.

[3] According to the September 2003 Labour Force Survey, the official (strict) rate of unemployment (which includes only those without work who are also actively seeking it), was 28.2%. If those who say they want work but are not looking for it are also included amongst the ranks of the measured unemployed (the broad definition), then the rate rises to 41.8%.

[4] All healthcare related research in South Africa has to have approval from a Research Ethics Committee registered with the National Health Research Ethics Council. Many of these Research Ethics Committees are in tertiary institutions.

Rather than celebrating the fact that people now felt well enough to seek work (even if most did not find it), the NGO PI wanted to suppress this result. She assumed that because I was on the side of the AIDS activists in the political struggle to provide HAART, that I would automatically agree with her interpretation of what results we should present.

In the course of this rather protracted confrontation over 'the results', it became clear to me that the NGO PI's idea of 'collaborating' with me was for me to do the data analysis and initial writing, and then for her to select what should be included and what should be omitted/suppressed. She did not provide us with written comments and never offered to write anything or contribute materially to the paper – but kept on insisting that I was the person who was 'not collaborating' because I was refusing to suppress or change the results.

I then contacted the head of my university's Senate Ethics Committee to ask him for his advice. He initially interpreted the issue as being one of 'authorship' and referred me to the principles upheld by the International Committee of Medical Journal Editors – the key one being that 'acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship'.[5] This suggests that the NGO PI had no basis for insisting on equal authorial status in deciding what did or did not go into the paper. I also pointed out that the NGO PI had signed a statement saying that there were no "restrictions or conditions attached to publication and/or presentation of the study results" and asked him if this protected me from the harassment I was currently experiencing. At this point, he observed that this particular clause was designed to protect university researchers from undue pressure from funders (such as pharmaceutical companies) who may have an interest in seeing one set of findings rather than another. I asked whether I should be afforded the same protection from the NGO PI who clearly felt that her organisation had an interest in one set of findings rather than another. He said that the case was complicated by the fact that the NGO PI was claiming to be a collaborator rather than merely a funder – and concluded that the available research ethics procedures were not designed to deal with problems arising between collaborators.

Eventually, under pressure from one of my funders (who was expecting me to run a workshop on the research being undertaken by the Master's student involved in the research), the student and I presented a couple of papers at an in-house workshop (to which a limited number of people were invited – including the NGO PI, but she declined). Our papers included the results about labour market participation. The NGO PI then wrote to me declaring the collaboration over, and demanding that if the Master's student was to continue to gain access to 'their' data that she would need to get a new supervisor – who in turn was expected to sign an agreement saying that none of the data could be used in any publication.

What are the lessons of this sorry saga? To some extent, the problem was one of clashing personalities. However, what struck me during the tiresome and draining process was that the NGO PI was convinced that she was acting in the best interests of the patients when she demanded that I perform massage and surgery on my papers.

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[5] "News from the International Committee of Medical Journal Editors" in *Annals of Internal Medicine*, vol.133, no.3: 229-31,

She was worried that my findings may cause 'bad press' and in this way undermine the impact of this NGO-lead pilot project to provide HAART in a resource-poor setting. She genuinely seemed to believe that I was pursuing narrow selfish academic goals, when I should be 'collaborating with', i.e. agreeing to abide by her interpretation of what results were politically strategic. After all, as she pointed out on several occasions, she was 'really' helping people by being part of an NGO located in the middle of an African township whereas I operated out of a comfortable office on the slopes of Table Mountain.

Her worry about possible negative publicity is understandable (although it should be said that nothing of the sort materialised once my papers entered the public domain – so in actual fact, her fears were unfounded). But even if there had been the possibility of negative publicity, was this sufficient to justify suppressing the results? I would bet that most social scientists would say no. After all, it is precisely by exposing and analysing the complex ways that people respond to policy interventions and changes in their social environments that social scientists can alert us to new challenges.

Let's consider the controversial result once again. The data showed that once people had their health restored by HAART, they entered the labour market – but that many of them did not find work. In other words, a social scientist would conclude that if we care about the welfare of HAART patients, a broader range of services is necessary. Rather than simply worrying out their viral load (which is what medical researchers concentrate on) we should also be making sure that programs are put in place to help them find jobs. By wanting to suppress the unemployment results, the NGO PI effectively put (what she believed to be) the interests of the NGO's medical intervention first. She may have believed that this was in the interests of the patient (on the grounds that good publicity is good for the NGO which is good for the patients), but this conception of the interests of the patient was a very narrow one. It discounted entirely the important role that social science research might play in guiding the design of other HAART provision programs in other sites.

But was the issue merely that she believed (doctor-like) that medical research is morally and intellectually superior to social science research and that her views thus ought to prevail because she had the best interests of the patients at heart? Again, I think not. There is another, broader, structural issue at heart. When medical researchers are also medical practitioners, there is a real danger that their intellectual judgement (and output) may be clouded. After all, if you are putting your heart and soul into working to help people, and then the research shows that they are not being helped in the ways that you had hoped – you may be under particular emotional pressure to massage the presentation of the findings. For this reason, particular attention needs to be paid to the conduct of the researchers collaborating under such circumstances. There is probably a case for developing codes of conduct to help manage the kind of conflict we found ourselves immersed in.

Case Two: Gate-keeping by Medical Practitioners/Researchers

In addition to several large NGO's providing HAART, the wider Cape Town Metropolitan area is also home to a couple of treatment and vaccine interventions funded by pharmaceutical companies. All of these entail collaboration with the

Western Cape government (which provides the clinics) and most have strong links with university-based medical researchers – some of whom also offer medical or related support services to the projects.

In this world of over-lap between service provision and research interests, patients are simultaneously beneficiaries and research subjects. They enter a world entirely controlled by doctor/researchers. Although the clinics are technically under the control of the government, decision-making power in effect is ceded to the largely foreign-funded doctors and researchers who run the intervention. They decide who can be on the premises, what research is 'acceptable', and who can interview the patients. This gatekeeper role has serious implications for social scientists trying to conduct research – as one of the PhD students funded through my research unit discovered to her cost.

The student, a clinical psychologist, wanted to conduct research into the psychological well-being and coping of low socio-economic status mothers in the era of HAART. Her research entailed recruiting 75 HIV-positive mothers and interviewing them when they start HAART, and then again after four, 12 and 24 weeks on treatment.[6] A sample of 75 HIV-negative mothers from the community was to be recruited as the comparison group. The aim of the research was to explore the challenges to women's care-giving and psychological well-being posed by negotiating the multiple roles of living with HIV, caring for young children and dealing with the general stressors associated with poverty. She was particularly interested in drawing out the implications of these multiple roles for women's adherence to HAART.

In addition to interviewing the women, the student stated her intention to ask the participants for permission to access their medical files so that she could collect data on CD4 counts, viral loads, clinical staging and adherence information. She stressed that this information would only be collected at the convenience of the clinic. In her research protocol, she acknowledged that she would need the help of clinic staff in accessing the files, but argued that this cost was small in relation to the benefits of her study. In particular, she pointed out that she and her researchers are clinically trained (and registered with the Health Professions and Social Work Councils) and thus in a position to provide useful feed-back to the clinic on patients who were deemed to be at risk for poor adherence due to their mental health and social difficulties. She also pointed out that some of the empirical indicators being developed in her study may become useful tools for the counselors associated with the HAART program to use in the future should they wish to asses the extent to which a patient's psychological well-being places them at risk for poor adherence: " More broadly, the research aims to make recommendations about the kinds of psychosocial services which can enhance women patients' quality of life and psychological well-being, as well as enhancing their adherence to treatment".[7]

The student developed her research protocol through consultation with her supervisors in the Psychology Department, and those who were funding her study. She then

[6] The questionnaires were designed to take an hour. They covered socio-demographic and household information, care-giving history and HIV and other health-related information as well as four brief standardised measures to assess depression, anxiety, social support and coping strategies.

[7] Student research protocol presented to the University and to the various clinics.

approached a clinic in a local African township for permission to invite potential respondents to participate in her study. The medical practitioners/researchers associated with the HAART project at the clinic considered her request to approach some of their patients for study purposes – but rejected it. As can be seen from the three reasons listed below, the fact that the research and HAART intervention was funded in part through a large pharmaceutical company seemed to pose particular problems. The reply she got gave her the following reasons for denying her access to patients:

1) "the population is over-researched and your study is not the primary focus of the research" ('the research' referring, of course, to the research already being conducted by the medical professionals at the clinic);
2) "None of the (*pharmaceutical company*) Exco members are senior authors of the project." ('the project' referring of course to the student's doctoral project); and
3) "It has not been approved by the same Ethics Committee as the other (*pharmaceutical company*) projects"

The student was referred to a clinic in a second African township – but was again turned down by the relevant committee of medical practitioner/researchers. This time she was turned down on the following grounds:

1) They were concerned about the "space implications" (i.e. her finding a space somewhere in the clinic to do the interviews);
2) They did not believe that there were "sufficient direct and tangible benefits to the clinic patients" who would participate in the study;
3) They were concerned about the "amount of time" which respondents would have to spend on the study; and
4) They did not "feel that the research addresses the needs which they have as a clinic at this point in time, and only want to permit research which does so".

The student responded to the main research gatekeeper of this clinic by saying that the demands on the clinic posed by her study were minimal. The clinic was to be used only as the initial point of contact in the form of a five-minute presentation to potential participants at the end of a counselling session inviting them to become respondents in her study. After than, no further demands were going to be made on the clinic – other than a monthly visit to check on clinical indicators such as CD4 cell counts (for those patients who have given permission for such access to their medical information).

The student also reiterated that her research could be of potential direct and immediate benefit to the counsellors who work with people on antiretroviral treatment as well as to the patients themselves:

> "In addition, on the positive side, we could provide support (either formally or informally, depending on their needs) to the counseling team and thereby in that way contribute to the very important role which they play in ensuring that the patient's well-being does not place them at risk for poor adherence thereby undermining desired viral load suppression. Depending on the clinic's need, feedback from the research could either be restricted to liaising with the counseling team, or direct input could also be given to the other members of the

clinic team if relevant and useful. Whichever approach minimizes the negative impact of our presence on the running of the service, while maximizing the support and benefits, is desirable for me."

She never got a reply to this email.

What are the lessons of this case study? I think there are three:

1) When medical researchers exercise control over very large health interventions, they are in a position to prioritise their own (narrowly defined) research interests over that of other researchers. Simply because they are delivering a medical service, they effectively have control over a facility (like a clinic) – even though this may in fact be the ultimate preserve of the government.
2) True to the medical paradigm of benefit and risk, medical researchers seem to believe that *only* their research is of direct benefit to their patients. They certainly appeared not to accept the argument that psychological research could help patients directly (through referrals of the kind suggested by the doctoral student) and indirectly by helping to guide policy and practice with regard to support groups.
3) Medical practitioner/researchers are accountable to no-one when they deny other researchers access to 'their' patients. Their effective control over clinics is not a subject for ethical review, and hence it is impossible to hold them to account for their seemingly capricious and self-interested actions.

When medical researcher/practitioners effectively control the provision of health services, they have enormous *de facto* power to assert their own research interests over those of social scientists. It is they who decide who has access to 'their' patients (or data pertaining to 'their' patients) – and what is and what is not in the interests of their patients.

This, I believer, runs counter to the spirit of the principle of informed consent. Although the principle of informed consent was designed to ensure that prospective research subjects have the right to refuse to participate – it surely also protects these same subjects from others deciding on their behalf that it is not in their best interests to participate. The principle should surely be that research subjects have the right to decide whether they want – or do not want – to participate. In my experience (and others – see e.g. Pahl, 2005), research subjects often enjoy being interviewed and having the opportunity to discuss matters of concern to them. Other research subjects, of course, could get irritated by the research process – but they can always refuse to participate at any point (as is typically – if not always – pointed out in consent forms). Most often, the 'risks' to the social science research subject tend to be little more than the opportunity cost of the time taken to conduct the interview. In most cases, it is the research subject who is in the best position to calculate the risks and benefits of participating in the research. Medical practitioner/researchers are often not in an appropriately informed position to make the judgment call.

Most research ethics codes are silent on the issue of ensuring that potential research subjects have the right to choose whether they do or do not want to participate in research. The European Group on Ethics in Science and New Technologies (EGE, 2003) and the Nuffield Council on Bioethics (UK) (NCOB, 2002) note that in some

local contexts, it may be appropriate to obtain family- or community-level agreement before approaching research subjects (see discussion in NCOB, 2005: 73). However, this is a concession to local culture – it cannot be used to justify giving medical practitioner/researchers the right to make decisions on the behalf of their patients – especially in cases where these same medical practitioner/researchers are not disinterested observers.

Conclusion

In conclusion I would like to reiterate that the two case studies presented here subjective experiences, do not represent any official position and would obviously benefit from the addition of the medical practitioner/researcher's other side of the story. It was written in the spirit of generating debate about some of the lesser-considered ethical issues that arise when social scientists and medical practitioner/researchers collide in the field. It is also worth reiterating that the cases I discussed occurred in a particularly charged environment in which research has political and policy implications.

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