After discussions with the Editor of the SAFP journal we decided to change the format of the updAIDS column. As from this edition it will consist of two sections, namely an editorial that will focus on a topical issue and a review article compiled by leading clinical experts. I am extremely excited about the fact that Natasha Bolognesi, highly respected and world class medical journalist has joined me to assist with the research and writing of the editorial. This month we have taken a look at a recently published mathematical modelling study that suggests that it would be beneficial to provide antiretrovirals only to urban patients rather than urban and rural patients. A number of South African health care provid

### Editorial: Ethics in Antiretroviral Therapy

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Introduction

A mathematical modelling study entitled “The effect of the urban-rural divide on predicting the epidemiological impact of antiretroviral allocation strategies in KwaZulu-Natal” was published in September 2006 in the American Proceedings of the National Academy of Sciences. Study researchers from the University of California at Los Angeles (UCLA) AIDS Institute and the University of California used a mathematical model parameterised by urban and rural HIV/AIDS data in KwaZulu-Natal (KZN) to predict the impact of three drug allocation strategies (DAS) on the South African government’s aim to treat 500 000 AIDS patients in KZN by 2008. The researchers claim that their model is the first model, to their knowledge, to combine a dynamic epidemiological model with an allocation model for scarce resources to evaluate ethical decision-making. According to the study design one of the DAS allocated antiretroviral therapy (ART) only to Durban and two allocated drugs to both urban and rural areas. While the study revealed that all three strategies would result in the treatment of 500 000 people in KZN by 2008, the Durban-only DAS would prevent the greatest number of HIV infections, transmitted resistance and AIDS deaths.

Equity or efficiency?

Professor Sally Blower, senior study author and head of the Disease Modelling Group at the Semel Institute of Neuroscience and Human Behaviour at UCLA, was motivated to do this research by a strong interest in the ethical concepts of treatment equity. She chose KZN as a study base as it has one of the highest HIV rates in the world. In an interview Blower explained her position to updAIDS: “I wished to find out whether it was possible to achieve both treatment equity and achieve the maximum impact on reducing the epidemic – unfortunately our analysis shows that it is not possible to achieve both simultaneously and that therefore health officials in KZN will have to decide on which objective they wish to attain.” Blower added, however, that the ethical implications of a Durban-only DAS need to be regarded extremely seriously and that “health policy officials in KZN should strive to obtain treatment equity rather than to maximize the epidemiological impact.” On the other hand study co-author, Dr Jim Kahn of the University of California San Francisco Positive Care Program, told updAIDS that, in his opinion, local health officials should “concentrate ARV [therapy] in the urban environment – in Durban, and work hard to make sure that the ARV systems for drug delivery, procurement and adherence are key to expand the ARV rollout strategy.”

The ethical principles of treatment equity versus utilitarianism and efficiency raised by this research have sparked strong sentiment amongst local HIV clinicians and researchers as well as health officials at the KZN Provincial Department of Health. KZN ARV Project Manager Mr Roger Phili and General Manager of the HIV, AIDS, STI and TB (HAST) Programme, the Integrated Nutrition Programme (INP) and the Maternal, Child and Women’s Health (MCWH) Programme, Mr Sandile Buthelezi state “The suggestions as being recommended in this publication reveal very little regard for human lives (PLWHA), and for equitable access to healthcare, including ART specifically.”

Chair of the Rural Doctors’ Association of Southern Africa

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(RuDASA), Dr Bernhard Gaede, says: “If the government would allocate ARV’s only to the urban areas, the rural areas would be disaster zones... It would be a holocaust of the poor—where man-made decisions cause extensive death and suffering. I cannot believe that people in such rich and resourced settings can even suggest something based on such dubious assumptions.”

Professor Solly Benatar, head of the Bioethics Unit at the University of Cape Town believes that “While utilitarian calculations often predominate in the public health arena, it is neither possible nor desirable to ignore considerations of equity - and especially not in the South African context and in the face of such a devastating pandemic.”

Fundamentally flawed
Gaede believes that the study, as well as being unethical, is unrealistic as the mathematical model, based on erroneous assumptions, does not approximate reality. “[The study] poses pseudo-options of having to choose ‘if the universe corresponds to how they have created it’. If all the assumptions are flawed, how can one choose?” he asks. Gaede’s main concerns with the study are:

• The assumption that ARVs are scarce in South Africa. The researchers state in their introduction: “Antiretroviral therapy (ART) is becoming available in South Africa. Demand will exceed supply; thus difficult decisions will have to be made in allocating ART.” Gaede says that “there is a current oversupply of ARVs due to the government’s rollout being behind schedule. As the rollout has accelerated slower than expected, it has allowed pharmaceuticals to catch up and the manufacturing of ARVs should not be a bottleneck either.”

• The assumption that people in rural areas will migrate from rural locations to urban centers to receive treatment; our current results are robust to migration (results not shown) unless migration rates are extremely high”. But, says Gaede, “There is a very dynamic flow of people between the city and rural areas – people exercise much greater choice than the model gives them. So it would be impossible to restrict access to ARVs from rural areas... It would create a further ‘medication-migrancy’ where rural people would travel far for the medication.”

• The assumption that ARV provision service stands separately from the rest of the health care service. According to Gaede ART must be integrated with the health care system as a whole. “From a number of [South African] rural sites,” says Gaede, “it is clear that if you plan the service within the existing health care service you will be much more successful in providing ARVs to the population.”

• The assumption that it is easy to shift resources between rural and urban areas and that a simple shift guarantees that more patients will be receiving treatment. “The study,” says Gaede, “is silent about the much more complex health care system issues that are more rate-limiting in ARV provision, particularly in urban areas.”

The research divide between the developed and the developing world
The study further raises the issues of ethical and practical perspective of Western researchers suggesting ART initiatives for a region they are perhaps not sufficiently familiar with. “Another level of questionable ethics is that a number of people (in a generally over-resourced setting) make a whole of rather bizarre assumptions of a health care system that they seem to know nothing about (in a poorly-resourced setting) and say ‘this is how you can let a whole lot of people die’,” says Gaede. Benatar feels that a study relying on both international and local research resources would be more realistic: “I should prefer if ‘developed world’ researchers work together with researchers in the developing world so that they could learn from each other and design solutions that would meet both theoretical and local practical requirements.” Buthelezi concurs pointing out that the researchers have perhaps wasted valuable time by not targeting South African HIV/AIDS research priorities: “This study, in my opinion is of no use to the department, as we do not have a problem in drug allocation, budget, distribution or management. The resource constraints that we have are to do with other materials and infrastructure, and not drugs. Had this study gone through us we would have been able to advise authors of the nature of research that would be useful in answering the questions that we want [answered]”.

The researchers, however, believe the study to be of value to South African health officials in wrestling with choices between having a maximum impact on the epidemic and being ethical: “Government health officials in KZN and other resource-constrained regions must unfortunately face these difficult policy decisions, of which there will be no consensus. This scientific study assists these authorities so that they can make informed decisions,” they conclude.

References