ADHERENCE ISSUES

The HIV epidemic has led to a burgeoning number of journals devoted to HIV disease, social impacts, management, etc. I was interested to receive an inaugural copy of *Leadership in HIVAIDS*, sponsored by, among others, the Department of Trade and Industry. A very nice glossy mag it is too, with lots of interesting reading material aimed not only at the health professional but civil society in general. One piece reported on an open letter from the Hudson Institute, Washington, and including a number of authors from around the world, challenging the Global AIDS Coordinator, Randy Tobias, and calling for safe proven AIDS drugs for Africa. The World Health Organization was formed in 1948 and its constitution drafted then included the elimination of substandard pharmaceutical production and improving the quality and safety of health care infrastructure in developing countries throughout the world. This letter questions quality and safety of pharmaceutical standards and implementation of guidelines in general of the WHO in recent times. It asks for a clearer plan from the WHO on exactly how 3 million people should be treated with antiretroviral (ARV) therapy by 2005, claiming that the present plan is vague on medical supervision and follow-up. It also highlights the concerns around the WHO's recommendation for fixed-dose combination (FDC) ARV drugs.

While fixed-dose drugs are attractive in simplifying therapy and promoting adherence, they should undergo stringent human bioequivalence testing verified by a rigorous regulatory body. The pre-qualification system employed by the WHO, which is *not* a regulatory agency, does not mean that adequate quality control has been performed on these drugs. The generic FDCs are also attractive for reasons of cost. However, it should not always be assumed that generics and FDCs are cheaper than patent drugs – the latest price comparisons done by Médecins Sans Frontières show that in many cases single-component patented drugs are cheaper than the equivalent generics. Sobering lessons learnt in treating malaria are that cheaper copies may not be as effective and may thus lead to more morbidity and mortality than before. Thompson Ayodele, director for public policy analysis in Lagos, Nigeria, makes the following salient statement: 'the extent of the HIV epidemic and the emergence of resistant strains makes the need for testing more, not less acute. HIV medicines, whether original or generic, should meet the most stringent rigorous clinical and testing reviews. If the proposed drugs are rejected by pharmacies in Brussels, Geneva, London, Tokyo or Washington, accepting the use of the same drugs in Africa, with little resources and lack of equipment to do proper clinical and scientific evaluation, may further compound the woes of HIV/AIDS victims.'

Another factor that may well have a negative impact on adherence, and thus the success of the '3 by 5 Initiative', is the high rates of alcohol use in communities also needing widespread implementation of ART. Alcohol abuse has been associated with poor adherence to highly active antiretroviral therapy (HAART). The relationship between adherence to HAART and alcohol consumption at baseline and over a 6-month follow-up was investigated by the CARE unit in Boston.[1] In this group of 267 HIV-infected participants, alcohol consumption was the most significant predictor of adherence, with better adherence associated with recent abstinence from alcohol compared with at-risk level use (OR = 3.6) or moderate use (OR = 3.0). The study concluded that any alcohol use in HIV-infected persons with a history of alcohol problems is associated with worse ART adherence, and surmised that addressing alcohol use may improve clinical outcomes. In a further study by Ena *et al.*[2] from Spain, which looked at risk and determinants of developing severe liver toxicity during therapy with nevirapine- and efavirenz-containing regimens in HIV-infected patients, multivariate analysis showed the association of severe liver toxicity with hepatitis C antibody positivity (RR = 7.64), combination of non-nucleoside reverse transcriptase inhibitor with a protease inhibitor (RR = 3.07) and alcohol intake greater than 40 g/d (RR = 3.09). The study concludes that alcohol should be avoided during ART therapy.

Two good reasons why we need more support for our communities where ART programmes are happening. In any of these communities, shebeens, beer halls and bottle stores far outnumber alcohol support groups such as Alcoholics Anonymous. In one of the communities where we work there is not a single NGO devoted to alcohol support, yet alcohol use continues to be one of the big social problems cited by our therapeutic counsellors, who often consider it a significant factor in possible non-adherence. As the national ARV programme rolls out, perhaps SANCA needs to be looking at a parallel 'roll-out' of services throughout South Africa.

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1. Samet JH, Horton NJ, Meli S, Freedberg KA, Palepu A. Alcohol consumption and antiretroviral adherence among HIV infected persons with alcohol problems. *Alcohol Clin Exp Res* 2004; **28:** 572-577.
2. Ena J, Amador C, Benito C, Fenoll V, Pasquau F. Risk and determinants of developing severe liver toxicity during therapy with nevirapine- and efevirez-containing regimens in HIV-infected patients. *Int J STD AIDS* 2003; **14:** 776-781.