



alcohol should not only have a beneficial effect on homocysteine levels, but most have long been accepted as offering a benefit to patients with regard to atherosclerotic disease prophylaxis. Innovative ways of promoting such a lifestyle need to be found. Accepting the difficulty regarding the latter, the hopeful enthusiasm for yet another 'pill' and widespread vitamin food fortification programmes in an effort to reduce vascular occlusive disease can be easily understood.

Doctors in the desperate situation of treating patients with accelerated premature atherosclerotic disease in the absence of accepted risk factors or other treatable causes cannot be criticised for prescribing vitamin B complexes. This intervention is relatively cheap, in most likelihood it is safe and it may give the patient the benefit of the doubt of any potential therapeutic benefit. From a health policy and health funding perspective, however, more data are required before resources should be allocated towards the screening and intervention of hyperhomocysteinaemia.

1. Castelli WP, Anderson K, Wilson PW, Levy D. Lipids and risk of coronary heart disease. The Framingham Study. *Ann Epidemiol* 1992; 2(1-2): 23-38.
2. Anand SS, Yusuf S, Vuksan V, et al. Differences in risk factors, atherosclerosis, and cardiovascular disease between ethnic groups in Canada: the Study of Health Assessment and Risk in Ethnic groups (SHARE). *Lancet* 2000; 356: 279-284.
3. Refsum H, Ueland PM, Nygard O, Vollset SE. Homocysteine and cardiovascular disease. *Annu Rev Med* 1998; 49: 31-62.

4. Booth GL, Wang EE. Preventive health care, 2000 update: screening and management of hyperhomocysteinemia for the prevention of coronary artery disease events. The Canadian Task Force on Preventive Health Care. *Can Med Assoc J* 2000; 163(1): 21-29.
5. Whincup PH, Refsum H, Perry II, et al. Serum total homocysteine and coronary heart disease: prospective study in middle aged men. *Heart* 1999; 82: 448-454.
6. Boushey CJ, Beresford SA, Omenn GS, Motulsky AG. A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes. *JAMA* 1995; 274: 1049-1057.
7. Clarke R, Daly L, Robinson K, et al. Hyperhomocysteinemia: an independent risk factor for vascular disease. *N Engl J Med* 1991; 324: 1149-1155.
8. Arnesen E, Refsum H, Bonna KH, Ueland PM, Forde OH, Nordrehaug JE. Serum total homocysteine and coronary heart disease. *Int J Epidemiol* 1995; 24: 704-709.
9. Wald NJ, Watt HC, Law MR, Weir DG, McPartlin J, Scott JM. Homocysteine and ischaemic heart disease: results of a prospective study with implications regarding prevention. *Arch Intern Med* 1998; 158: 862-867.
10. Stampfer MJ, Malinow MR, Willett WC, et al. A prospective study of plasma homocyst(e)ine and risk of myocardial infarction in US physicians. *JAMA* 1992; 268: 877-881.
11. Chasan-Taber L, Selhub J, Rosenberg IH, et al. A prospective study of folate and vitamin B₆ and risk of myocardial infarction in US physicians. *J Am Coll Nutr* 1996; 15(2): 136-143.
12. Folsom AR, Nieto FJ, McGovern PG, et al. Prospective study of coronary heart disease incidence in relation to fasting total homocysteine, related genetic polymorphisms, and B vitamins: the Atherosclerosis Risk in Communities (ARIC) study. *Circulation* 1998; 98: 204-210.
13. Evans RW, Shaten BJ, Hempel JD, Cutler JA, Kuller LH. Homocyst(e)ine and risk of cardiovascular disease in the Multiple Risk Factor Intervention Trial. *Arterioscler Thromb Vasc Biol* 1997; 17: 1947-1953.
14. Alfthan G, Pekkanen J, Jauhiainen M, et al. Relation of serum homocysteine and lipoprotein(a) concentrations to atherosclerotic disease in a prospective Finnish population based study. *Atherosclerosis* 1994; 106(1): 9-19.
15. Fallon UB, Ben Shlomo Y, Elwood P, Ubbink JB, Smith GD. Homocysteine and coronary heart disease in the Caerphilly cohort: a 10 year follow up. *Heart* 2001; 85(2): 153-158.
16. Nygard O, Vollset SE, Refsum H, et al. Total plasma homocysteine and cardiovascular risk profile. The Hordaland Homocysteine Study. *JAMA* 1995; 274: 1526-1533.
17. Mbewu AD, Durrington PN, Mackness MI, Turkie W, Creamer JE, Hunt L. Serum lipoprotein(a) levels in patients receiving streptokinase for myocardial infarction. *British Heart Journal* 1994; 71: 316-321.
18. Homocysteine Lowering Trialists' Collaboration. Lowering blood homocysteine with folic acid based supplements: meta-analysis of randomised trials. *BMJ* 1998; 316: 894-898.



Ethical issues in voluntary HIV testing in a high-prevalence area — the case of Malawi

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The first adult case of HIV/AIDS in Malawi was identified in April 1985,^{1,2} with the first paediatric case in January 1986.³ From that time to 1997, at least 10% of the general population and 15% of the 15 - 49-year age group were infected.^{4,5} Up to 30% of women attending prenatal care at the Queen Elizabeth Central Hospital, Blantyre, are HIV-infected.^{6,7} HIV/AIDS has been associated with a rise in the number of orphans, now

estimated at between 400 000 and 1 000 000 as no reliable data are currently available. The maternal mortality ratio, which had been estimated at about 620 deaths per 100 000 live births in the 1992 Demographic and Health Survey (MDHS),⁸ has now risen to 1 120/100 000,⁹ due *inter alia* to the HIV pandemic. Up to 70% of admissions in the medical wards of Blantyre and Lilongwe are HIV/AIDS-related and tuberculosis (TB) has

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resurfaced as a major public health problem.¹⁰ The education sector has been affected, and has resulted in an estimated 25% of the Ministry of Education budget for the 2001 - 2002 fiscal year being spent on funerals and payment of pensions to families of deceased teachers.¹¹

Malawi's application to the Global Fund to fight HIV/AIDS, malaria and TB has been successful. The country will receive US\$12 million in the first year and about US\$196 million over a 5-year period. There are six components to Malawi's strategy: (i) voluntary counselling and testing (VCT) for HIV; (ii) prevention of mother-to-child transmission (PMTCT) of HIV; (iii) community/home-based care; (iv) management of opportunistic infections and access to antiretroviral (ARV) therapy; (v) cross-cutting issues such as human resource development, management of drug supply, health information management systems, and strengthening of laboratory services; and (vi) management and institutional support with regard to improved programme planning, co-ordination, monitoring and reporting.

Traditionally accepted HIV/AIDS prevention messages have been: sexual abstinence first, the **be** faithful, and if either fails, use condoms (ABC). As the pandemic progresses condoms have been promoted and VCT for HIV has been advocated by the National AIDS Control Programme and the Ministry of Health and Population.^{12,13} While counselling and testing have been encouraged, there is also the possibility that testing may fail to empower the client/patient.

HIV testing programmes in Malawi

There are four main routes for HIV/AIDS testing in Malawi. In all of these situations, except the sentinel sites, VCT is mandatory. The situations are:

1. **Clinical setting.** These patients often have opportunistic infection(s), and such testing has usually been prompted either by a clinician or by patients themselves.
2. **HIV testing walk-in centres.** Individuals may present to testing centres run by non-governmental organisations. Four such centres are operational, located only in towns.
3. **Blood donation.** All blood donors in the country are offered VCT before they can make a donation. In the past, the practice was to collect blood from all persons presenting for donation. Serological and parasitological testing could be done later and the patient was invited to return for test results. Currently, only a small amount of blood is collected and people will only be allowed to donate if the tests results indicate that they are not infected with HIV, hepatitis B and C, malaria and syphilis.
4. **Research settings, including sentinel HIV monitoring sites.** Anonymous testing is done in the sentinel surveillance sites.¹⁴

Suggested benefits of testing

Enormous resources are currently being expended in Malawi to encourage individuals to present for VCT. The mass media is the most frequently utilised vehicle for social mobilisation messages. Some of the benefits of knowing one's HIV serostatus, suggested by social marketing campaigns, are:

1. So that one can 'live positively with HIV/AIDS'. What 'living positively' means is often not explained. Generally, 'living positively' in our setting implies not having multiple sexual partners, always using condoms during sexual intercourse, ensuring adequate nutrition,¹⁵ presenting to health care services as early as possible in the case of a medical problem, and 'making it right' with God.
2. So that one may plan properly, including preparing a will.
3. So that one may decide whether or not to have any (more) children.

Ethical challenges facing VCT programmes

The principle of VCT is similar to that of screening. As early as 1968, Wilson and Jungner¹⁶ proposed prerequisites for screening which included: (i) the target condition should have a detectable preclinical stage; (ii) there should be an appropriate screening test; (iii) both screening and follow-up procedures should be acceptable to the target population; and (iv) there should be acceptable early treatment. With regard to HIV testing all four prerequisites should be met in selected situations. AIDS has a detectable preclinical stage, which is the period when the individual is infected but has not yet developed symptoms, and an appropriate HIV test is available. What may not be met in our setting are conditions (iii) and (iv) in that follow-up procedures are non-structured and almost non-existent or in formative stages, and effective early treatment is far beyond the reach of the majority of people.

In December 2001, only 88 patients were on ARVs in the government-subsidised HIV/AIDS treatment programme. This service is also only available in the major cities, mainly Blantyre and Lilongwe. In addition, ARV supplies run out because of management and logistical shortfalls, even in situations where people can afford to pay for them. ARV treatment for 1 month costs about US\$35 in public health services, and not less than US\$150 in private clinics.

The general socio-economic situation in Malawi has remained poor for the past decade.^{17,18} Health care infrastructure and trained human resources are inadequate. This has made it impossible to establish adequate VCT centres in all the districts of the country.¹⁹ There are only four walk-in centres and these are located in towns. However, as eighty-five per cent of Malawians live in rural areas,²⁰ these communities have virtually no centres within reach.



Malawi is a male-dominated society, with most decision-making roles occupied by men. Clinicians are generally male,²¹ while nursing is considered a feminine job. In such an environment, where the power balance is in favour of men, there could be situations where female patients may be coerced into giving consent because of the unequal power balance between health care provider and client.

In our community female patients are often dependent. Important life decisions such as desire for family planning or an HIV test may have to be made by or in consultation with a male family member such as the husband.²² In such a situation, society has already created and maintains an environment where confidentiality may not be guaranteed. What is the role of the health care provider — to support the structures in society, or to suggest that HIV testing is a matter for the individual? We also know that in many cases other important decisions, such as deciding to spend money on health care (possibly including purchase of ARVs) may be made by a man on behalf of the female client.

The other issue that should be tackled is whether it is unethical for a health care provider not to offer HIV testing for a patient exhibiting clinical features suggestive of HIV/AIDS. Our society continues to associate sexually transmitted infections (STIs), especially HIV/AIDS, with 'sin' and promiscuity. Having multiple sexual partners is a risk factor for HIV. This practice is common among and culturally acceptable for Malawian men.²³ If a health care provider offers an HIV test, such offers may be construed as saying, 'I think you may be a sinner or promiscuous'. Such beliefs have resulted in health workers not suggesting HIV testing even in situations where a positive result is likely.²⁴ The dilemma is that the patient is entitled to information, and in the case of HIV testing, she or he can only be tested if informed consent is sought and given. But even suggesting that an HIV test should be done (whether the patient accepts or not) may jeopardise the patient socially. This is because clinicians do not normally request a test unless there is suspicion that a positive result is likely. An exception, of course, is when testing is done to establish a baseline for future reference.

Anonymous and unlinked HIV testing, as utilised in sentinel surveillance sites,^{6,14} also raises important ethical questions. In this exercise, patient or client confidentiality is maintained and the result cannot be matched to the person. But is it ethical for a positive result to be unavailable to the person and his/her sexual partner?

Medical research that involves determining HIV serostatus, or even research among known HIV-infected persons, has attracted a significant amount of ethical debate.²⁵⁻²⁷ The Declaration of Helsinki²⁸ states that 'medical research is only justified if there is reasonable likelihood that the population in which the research is carried out stands to benefit from the results of the research'. The UNAIDS also indicates that 'the desired outcome of the proposed research should potentially

benefit the population from which research participants are drawn.²⁹ With regard to ARVs, is it likely that the populations selected as study subjects will benefit from wide availability of drugs in the short term? The answer does not seem to be in the affirmative. Perhaps the difficulty lies in the definition of the population in question — are the Helsinki and UNAIDS documents referring to the present generation, or to future generations?

The usual practice among VCT centres is to provide counselling and testing. We believe that there is a need for voluntary counselling centres that do not necessarily go on to test clients.

References

1. Delay P. AIDS in Malawi. *Malawi Medical Journal* 1990; **6**(1): 2-4.
2. Ratsma E, Manjolo EP, Simon J. Voices from the epidemics. *Malawi Medical Journal* 1992; **8**(2): 60-64.
3. Phillips J. HIV reactive children in KCH. *Malawi Medical Journal* 1990; **6**(1): 15-16.
4. UNAIDS. Epidemiological fact sheet on HIV/AIDS and sexually transmitted infections, 2000 update. Geneva: UNAIDS, 2000.
5. Strategic Planning Unit, National AIDS Control Programme, Ministry of Health and Population. Estimating national HIV prevalence in Malawi from sentinel surveillance data. Lilongwe, Malawi: Ministry of Health and Population, 2001.
6. Taha TE, Dallabetta GA, Hoover DR, et al. Trends of HIV-1 and sexually transmitted diseases among pregnant and postpartum women in urban Malawi. *AIDS* 1998; **12**(2): 197-203.
7. Semba RD, Miotti PG, Lan Y, et al. Maternal serum lactoferrin and vertical transmission of HIV. *AIDS* 1998; **12**: 331-332.
8. Malawi Demographic and Health Survey 1992. Zomba, Malawi: National Statistical Office, 1992.
9. Malawi Demographic and Health Survey 2000. Zomba, Malawi: National Statistical Office, 2001.
10. Crampin AC, Mwaungulu F, Floyd S, et al. The value of two versus three smears in identifying culture positive tuberculosis patients in Karonga district. *Malawi Medical Journal* 2002; **13**(4): 9-11.
11. Semu-Banda P. Local teachers' death make headlines in UK. *The Nation* 2002; 7Aug., p. 3.
12. National AIDS Control Programme. Malawi National HIV/AIDS Strategic Framework 2000 - 2004. Annex I. The Agenda for Action. Lilongwe, Malawi: Strategic Planning Unit, National AIDS Control Programme, Ministry of Health and Population, 1999.
13. Malawi National Health Plan 1999 - 2004. Lilongwe, Malawi: Ministry of Health and Population, 1999.
14. Damisoni HJ, Kaluwa O, Feluzi HG, Zingani AM. HIV/syphilis seroprevalence in antenatal clinic attendees. Lilongwe, Malawi: National AIDS Control Programme, Sentinel Surveillance Report, 1997.
15. Pivovoz EG, Preble EA. HIV/AIDS and nutrition. Support for Analysis and Research in Africa (SARA) Project/US Agency for International Development. Washington, DC, 2000.
16. Wilson JMG, Jungner G. *Principles and Practice of Screening Disease*. Geneva: World Health Organisation, 1968.
17. Malawi Poverty Reduction Strategy Paper. Lilongwe, Malawi: Ministry of Finance and Economic Planning, 2002.
18. National Economic Council. Economic Report 2001. Lilongwe, Malawi: Ministry of Finance and Economic Planning, 2002.
19. Chimzizi R, Hargreaves NJ, Harries AD, Godfrey-Fausset P, Salaniponi FML. Lack of voluntary counselling (VCT) in rural Lilongwe is a barrier to interventions for people with HIV. Proceedings of Meeting on Gender and Equity in Health in Malawi. Lilongwe, Kalikut Hotel, 7 - 8 February 2002.
20. National Statistical Office. Malawi Population and Housing Census 1998. Zomba, Malawi: National Statistical Office, 1998.
21. Muula AS, Broadhead RL. Gender distribution of students and staff at the University of Malawi College of Medicine. Proceedings of Meeting on Gender and Equity in Health in Malawi, Lilongwe: Kalikut Hotel, 7 - 8 February, 2002.
22. Bossyns P, Miye H, v Lerberghe W. Supply-level measures to increase uptake of family planning services in Niger: the effectiveness of improving responsiveness. *Top Med Int Health* 2002; **383**-390.
23. Anonymous. Sexually transmitted diseases. *Malawi Medical Quarterly* 1986; **3**(2): 15-16.
24. Makura ZGG. Competent inadequacy. *Cent Afr J Med* 1991; **37**(2): 67-68.
25. Aaby P, Babiker A, Darbyshire J, et al. Ethics of HIV trials. *Lancet* 1997; **350**: 1546-1547.
26. Lurie P, Wolfe SM. Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries. *N Engl J Med* 1997; **337**: 883-885.
27. Ramjee G, Morar NS, Alary M, et al. Challenges in the conduct of vaginal microbicide effectiveness trials in the developing world. *AIDS* 2000; **14**: 2553-2557.
28. World Medical Association. The Declaration of Helsinki, 2000. Edinburgh: World Medical Association. http://www.wma.net/e/policy/17-c_e.html (accessed 24 August 2002).
29. UNAIDS. Ethical considerations in HIV preventive vaccine research. UNAIDS Guidance Document. Geneva: UNAIDS, 2002.