trials have usually operated on a different basis. The principal investigator, his or her employer (often a university), a funding body (which might be a charity, the Medical Research Council, or part of the NHS research and development programme) and a clinical host organisation (typically one or more NHS trusts) collectively take responsibility for various aspects of research governance. However the UK regulations are framed, there will need to be more explicit allocation of responsibilities between partner organisations. This is right in principle both for the protection of patients and the assurance of scientific rigour, though the details of how this is best achieved continue to be debated. Some concern has been expressed at the penalties to which the sponsor would be liable. These should be seen in the context of liabilities which already exist. To use an analogy, the introduction of compulsory testing of motor vehicles created a new penalty for driving a vehicle without a valid test certificate—but it reduced the larger risks, financial and physical, of driving on bald tyres.

For good clinical practice and pharmacovigilance, the appropriate level of supervision would be expected to differ for a drug undergoing first use in humans and a long marketed drug now being tested in a new indication. Such proportionality would answer many of the concerns raised about needless bureaucracy. Neither the directive on good clinical practice nor the guidance on pharmacovigilance has yet been agreed within the European Union. This has delayed the drafting of UK regulations, which will be influenced by the level of detail specified in the directive. The United Kingdom has a treaty obligation to transcribe the directive into national legislation, and thereafter it will be the task of the Medicines and Healthcare products Regulatory Agency to act as the regulatory body. Much will therefore depend on the degree of discretion permitted by the directive with regard to good clinical practice and pharmacovigilance.

If monitoring is made proportionate to risk, no logical basis exists for a different standard of supervision in commercial and non-commercial clinical trials. The directive makes no distinction between the two. More research staff with better professional training and support may be needed in some publicly funded research in order to safeguard quality and safety. The case for extra funds is best supported by an objective examination of the infrastructure needed to attain the required standard.

Research is an essential component of a high quality healthcare system, not an optional extra. Publicly funded clinical trials in the United Kingdom have made a large contribution to improved care. A wider debate is beginning on how clinical trials can be fostered in the NHS, and how therapeutic innovation can be encouraged and the research potential of the NHS better used.[9 10] All research partners (investigators, universities, funders, and NHS organisations) have a shared interest in achieving high standards of research governance, but their procedures for doing so need to be better coordinated. Compliance with the directive will challenge us to review many details of current practice. Can we find ways of streamlining the initiation of trials without compromising patient safety?

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Competing interests: KW was director of the NHS Health Technology Assessment Programme and chairman of the MRC/DH joint project before joining MHRA in January 2004.

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Access to antiretroviral treatment in Africa

New resources and sustainable health systems are needed

Education and debate p 280; *Papers* p 249

The demand for people living with HIV and AIDS in Africa to access treatment cannot be ignored. At the same time the challenges to meeting this demand are many. They include the shortfalls in health services and lack of knowledge about treatment, making decisions about newer regimens, and the risk of resistance to antiretrovirals highlighted in the paper by Stevens et al (p 280).[1 2] The challenges also include ensuring uninterrupted drug supplies, laboratory capacities for CD4 monitoring, accessible voluntary counselling and testing, trained healthcare workers, and effective monitoring of resistance to antiretroviral drugs.[3] A series of papers produced in 2003 through the southern African regional network on equity in health raised further concerns about measures to ensure fairness in the rationing of scarce treatment resources and the diversion of scarce resources from strained public health services into vertical treatment programmes.[4–8]

The reasons for these challenges are not a mystery. They stem from the chronic under-resourcing of health systems, the underdevelopment of strategic

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public health leadership, the attrition of health personnel, and the high prevalence of poverty, factors that already limit the delivery of many less complex primary healthcare services.[5–7] Given this context, how should resources best be allocated to ensure access to treatment for HIV/AIDS in Africa?

Existing initiatives provide some indications of what to do and what not to do. Making treatment accessible through private and non-government sectors or through redeployment of personnel without addressing the staffing, pay levels, and working conditions of health personnel in public health services can further increase attrition from essential services and aggravate uncoordinated health planning.[7]

Providing treatment on a "first come, first served" system favours urban, higher educated people who are not poor. It also unfairly delegates frontline healthcare workers to decide who does and does not access treatment, resulting in inconsistencies and even corruption.[8]

Providing treatment at central hospitals without strong links to community outreach or primary healthcare services weakens the link between prevention and care. It also limits the benefits that treatment brings in reducing stigma to the higher income users of these hospital services.[5 7]

Vertical programmes established to achieve rapid delivery against unrealistic targets can divert scarce resources from strained public health services and bring undesirable opportunity costs and inefficiencies through the creation of parallel management and administrative systems.

In contrast, approaches to expand access to treatment can simultaneously strengthen health systems; build synergies between treatment, prevention, and primary healthcare services; and reach vulnerable groups. For example, when treatment is linked to prevention of parent to child transmission of HIV, provided through maternal health services, the likelihood of women having enhanced access to treatment, reduced social stigma around AIDS in women, and strengthening general maternal health services for all women is greater.

Criteria for selecting patients that explicitly target low income groups or particular subgroups of the population such as health workers and teachers (because their job promotes services for poor people), or that involve communities in decisions about selecting patients, can enhance equity and prevent the development of patronage or corrupt practices around treatment. Community health workers have had an important role in Africa in nutrition, immunisation, maternal health, child spacing, and many interventions that enhance health and treatment related literacy. Developing their role in access to treatment could strengthen primary health care and should be further explored.[7]

Such approaches to treatment access on a national scale will be possible only if the health system is properly organised, coordinated, and managed, and if it is adequately resourced. Organisationally, the principles of a district health system should remain paramount as a remedy to the destructive effects of uncoordinated, disease focused, vertical interventions. For such systems to be functional, we need to address the growing shortfalls and maldistribution of personnel and resources in African countries.[8 9]

If effective, equitable, and sustainable approaches to treatment access are to be replicated, considerable new resources will need to be channelled to Africa's health systems, particularly for district level services. Such resources should come from national public budgets, overseas development aid, global funds, and from the cancellation of debt. The International Monetary Fund and World Bank medium term expenditure framework constraints currently limiting the uptake of increased resources in the public health sector also need to be revisited.

The global recognition of rights to treatment reflects a significant shift in mindset. Another shift is now needed to deliver on those aspirations. Health systems cannot be built from a patchwork of non-government, vertical, ad hoc services around a crumbling public sector core. For treatment access to become a reality for more than a minority, a further step needs to be taken towards an explicit global and national commitment to refinance Africa's public health sector and district health systems.

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