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IAPAC

MONTHLY

**New directions in
HIV prevention:
Serosorting and
universal testing**

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New directions in HIV prevention: Serosorting and universal testing

Gus Cairns

The use of HIV testing and information about one's serostatus as an HIV prevention tool remains a complex and controversial area of debate. Universal testing and serosorting were two of the topics debated at the 13th Conference on Retroviruses and Opportunistic Infections.



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Personal metrics

José M. Zuniga

More than two hundred southern African physicians have written the GALEN Certification Examination since the International Association of Physicians in AIDS Care (IAPAC) started administering the examination two years ago. I have attended each administration, and have walked away with a positive feeling about the important mission IAPAC is advancing through continuing education and certification of HIV/AIDS-treating physicians throughout the developing world. A total of 42 physicians have been certified, meaning they have attained a score of 70% or better. The examination is rigorous, requiring up-to-date clinical knowledge along the continuum of HIV medicine, but with a special emphasis on the delivery of antiretroviral therapy in resource-limited settings.

The GALEN Certification Examination, and its accompanying educational GALEN modules and training courses for physicians who plan to write the examination, have been an unqualified success. Its importance is attested by the fact that those physicians who do not attain a passing score on their first attempt often return after additional study to take the examination a second time. Ensuring the knowledge and competence of physicians who prescribe antiretroviral therapy to HIV-positive patients in the developing world is such a self-evidently important task that the examination has received the support not only of individual physicians, but of entities such as the Foundation for Professional Development (FPD), a continuing education provider in southern Africa aligned with the South African Medical Association (SAMA). Beginning in April 2006, FPD will partner with IAPAC to administer the examination once a quarter in South



Photo Credit: Keith Turner

Pumla Lupondwana, HIV Clinical Specialist in the HIV/AIDS Management Program at Discovery Health in Johannesburg, South Africa, accepts her "Certificate of Clinical Competence in HIV Medicine" from IAPAC President/CEO José M. Zuniga.

Africa's nine provinces, and annually in eight southern African countries in which it conducts educational activities.

The examination has been so successful, and interest is so high, that IAPAC plans to expand its administration from the developing to the developed world, with the goal of creating a global standard for competence in the field of HIV medicine. It is refreshing that this examination, which was created for the benefit of physicians in the developing world, should serve as

the basis for an equivalent examination for physicians in the developed world, since the information flow has so often been in the opposite direction. But in this respect, developing countries are in the vanguard of the creation of a set of universal standards that will help to ensure the provision of one standard of care for HIV-positive patients around the world.

Nevertheless, as I have witnessed the examination's administration, I have found myself wondering why physicians choose to

write the examination. It is understandable that hospitals, patients, and even governments and nongovernmental organizations would encourage physicians to take advantage of continuing education and certification, but the examination requires extensive study and application of clinical data, and it is a gruelling four-hour experience. Since certification is currently not a requirement to practice HIV medicine anywhere in the developed or developing world, why do physicians expend so much effort to take an examination that most will not pass on the first attempt?

A recent perspective piece in the *New England Journal of Medicine* discussed the fact that according to a recent survey conducted by the American College of Physicians and the American Board of Internal Medicine, physicians in the United States seem to be more motivated toward voluntary certification by the desire for professional development than by the desire for monetary gain.¹ The desire to provide quality medical care was the motivating factor for physicians to seek out continuing education, as well as to complete voluntary recertification requirements.

We cannot avoid the implication that physicians in both the developing and the developed worlds wish to provide the best possible medical care to their patients, and are willing to make significant sacrifices of time and effort to do so. Physicians in developed countries take continuing education courses and go through voluntary certification and recertification processes. Physicians in developing countries take every opportunity to gain the knowledge that they receive through study for and completion of the GALEN Certification Examination. Although the monetary benefits to physicians may be slight, they are aware that their provision of care is greatly enhanced by these processes. IAPAC is proud to assist physicians in both the developed and developing worlds in honing their skills and increasing their knowledge, and to partner with physicians in their quest to deliver quality HIV/AIDS care. ■

José M. Zuniga is President/CEO of the International Association of Physicians in AIDS Care (IAPAC), and Editor-in-Chief of the IAPAC Monthly.

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Congratulations!

The International Association of Physicians in AIDS Care (IAPAC) congratulates the following physicians who have passed the GALEN Certification Examination with a score of 70% or better.

Farida Cassim Amod, *South Africa*
 Melissa Budge, *South Africa*
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Silence = complacency

Visit www.iapac.org to learn about how you may join the International Association of Physicians in AIDS Care (IAPAC) in advocating our patients' right to quality HIV/AIDS care and support.



Statins may not affect CD4 response

Chris Gadd

An observational cohort study has found that patients taking statins to lower cholesterol levels do not have impaired CD4 count responses to HIV treatment. The study's findings were published as a research letter in the February 14, 2006, edition of the journal *AIDS*.

Physicians from the University of Miami Medical School recently expressed concern that statins could impair the immunological responses to HIV treatment through their effects on immune system cytokine messengers and CD4 T cells. They called for more research into the drugs' effects in people on HIV treatment.

Now, physicians from Italy have examined the CD4 count increases in patients from their clinic who have been taking statins alongside their antiretroviral regimens for up to 18 months. They found that these patients had similar CD4 count responses to patients taking fibrate drugs, and those who were prescribed exercise and diet modifications to improve their lipid levels.

The physicians recruited 267 patients for their study, all of whom had been taking antiretroviral regimens consisting of at least two nucleoside or nucleotide reverse transcriptase inhibitors (NRTIs/NtRTIs), with a nonnucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI), for at least a year. All of the patients had elevated lipids, with cholesterol above 200 mg/dl or triglycerides above 250 mg/dl for at least six months.

The physicians added a statin to the antiretroviral regimen in 88 (33%) of the patients, in order to lower cholesterol levels.

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They prescribed pravastatin, atorvastatin, or rosuvastatin. In contrast, for the 103 patients (39%) with elevated triglyceride levels, they prescribed bezafibrate, fenofibrate, or gemfibrozil, while the remaining patients began a diet and exercise program. All three groups had similar ages, gender distributions, numbers of AIDS diagnoses, viral loads, and CD4 counts at the start of the study.

After a mean follow-up of 17.4 months, there were no significant differences in CD4 counts across the three arms, with mean CD4 counts remaining stable at around 380 cells/mm³. However, the physicians did not report which statistical tests they used, or the tests' results, in the published letter.

These findings help to relieve some of the concern surrounding the use of statins

alongside HIV treatment. However, prospective and randomized trials including more patients are needed to provide evidence of a lack of detrimental effect of statins on CD4 count rises.

In addition, the Italian findings do not address the concern expressed by the Miami physicians that CD4 count measurements might give an incomplete picture of the effects of statins on immune system recovery. The results of studies examining the effects, if any, of statins on a range of immune system markers and clinical outcomes are needed before their concerns can be put to rest. ■

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BMS announces voluntary ATV licenses

Bristol-Myers Squibb announced this month that it will grant to pharmaceutical manufacturers voluntary licenses for the manufacture of atazanavir (ATV) for sale in India and Africa. The company will also provide technical know-how to its licensees—Emcure in India and Aspen Pharmacare in South Africa—through which to teach them how to manufacture the protease inhibitor (PI).

Atazanavir is the second PI to be offered for technology transfer. In January 2006, Roche Laboratories announced that it was prepared to transfer the technical know-how to make saquinavir (SQV) to any pharmaceutical manufacturer in Africa that wanted to make the PI, and that it would not enforce its patent rights on SQV.

The move potentially broadens the choice of second-line antiretroviral regimens available in resource-limited settings, but ATV use may be limited by the lack of access to the boosting agent ritonavir (RTV), which is manufactured by Abbott Laboratories. Ritonavir is vulnerable to high temperatures and should not be stored outside a refrigerator for more than a few days in a hot climate. Although Abbott Laboratories has developed a heat-stable tablet version of its own boosted PI, lopinavir/ritonavir (LPV/r), it has still to develop a heat-stable version of RTV.

The heat-stable version of LPV/r remains unlicensed outside the United States. Several groups have called on Abbott Laboratories to move quickly to register the new heat-stable version in all countries eligible to receive the drug at the no-profit access price of approximately US\$500/year. — Keith Alcorn



**[DECADE OF HAART]
HISTORICAL PERSPECTIVES
AND FUTURE DIRECTIONS**

September 25-26, 2006 — San Francisco

On the decade anniversary of HAART, the International Association of Physicians in AIDS Care (IAPAC) is convening an historic meeting to review our collective progress, discuss obstacles faced and overcome, lessons learned, and challenges that lie ahead. Registration is limited. Visit www.iapac.org to view the meeting program and to register online!

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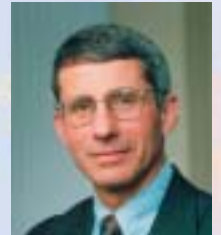
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Corruption and HIV/AIDS

While the corruption that affects HIV/AIDS prevention and treatment does not look very different from corruption found in other areas of the health sector, the scale of the pandemic, the stigma attached to the disease, and the high costs of drugs to treat it magnify the problem. The response to HIV/AIDS must involve an increase in funds available to purchase drugs. But scaling up budgets without paying due regard to the anti-corruption mechanisms

needed to ensure their proper use provides further opportunity for corruption. A case study from Kenya shows a worst-case scenario of corruption and profligacy at the national AIDS body set up to coordinate prevention programs. An examination of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) finds that including all stakeholders in the design of programs, from governments and nongovernmental organizations (NGOs) to the sufferers themselves, could help provide a safeguard against corruption.

The link between corruption and HIV/AIDS

Liz Tayler and Clare Dickinson

It is difficult to draw a causal link between corruption and the spread of HIV. But there is ample evidence that corruption impedes efforts to prevent infection and treat people living with AIDS in many parts of the world. The mechanics of corruption affecting the prevention and treatment of HIV/AIDS are not substantively different from those affecting the health care sector more generally: opaque procurement processes, the misappropriation of funds earmarked for health expenditure, and informal payments demanded for services that are supposed to be delivered free. What are different are the scale of the problem and the nature of the disease—a chronic, usually fatal, and often stigmatized disease that can be contained only with expensive drugs. Moreover, the individuals

responsible for tackling corruption may themselves be severely affected by AIDS. These factors create particular vulnerabilities to corruption.

There are multiple opportunities for corruption in the prevention and treatment of AIDS. In prevention programs, corruption occurs when false claims are presented for awareness-raising activities that never took place, or for materials that were never purchased. Corruption occurs in programs aimed at alleviating the socioeconomic effects of the disease on victims and their families, such as feeding programs or support for school fees. Corruption can also contribute directly to infection when relatively low-cost measures, such as the use of sterile needles and the screening of blood donations, are ignored because a corrupt procurement or distribution process holds up supplies. Alternatively, health care workers may use non-sterile equipment as an additional source of income by extorting illicit payments from patients who demand clean equipment.

But it is treatment programs that are most vulnerable. Money for high-value drugs can be embezzled at any number of

points in the procurement and distribution chain. At the grand end of the scale is theft by ministries and national AIDS councils of funds allocated for treatment, and the misappropriation or counterfeiting of medicine. At the petty end are doctors who extort “tips” for medicines, and patients who sell their own medication because it is the only valuable commodity they possess.

The international response to the pandemic has increased in recent years, and there is pressure to spend large sums of money in countries with limited capacity to oversee their proper usage. The International Monetary Fund (IMF) reports that HIV/AIDS resource flows were US\$5 billion in 2003 and US\$8 billion in 2004. With this much money in play, and with donors insisting that disbursement be the standard metric for judging program success, recipient nations will find ways to absorb the funds, whether legally or illegally. The prime requirement for recipient nations seems to be “spend it or lose it.”

The numbers of people infected with HIV are high and rising. In sub-Saharan Africa overall, 7% of women and 2% of men aged 15 to 24 are infected.¹ In Botswana, Swaziland, and Zimbabwe, over 25% of

Editor's Note: *Transparency International's Global Corruption Report 2006 is published by Pluto Press, and may be ordered through Amazon.com or through bookshops (ISBN 0745325084). For more information about the report, see www.transparency.org/publications/gcr.*

the adult population is now HIV-infected. In Asian countries the rates are generally lower, but they are rising fast. The impact of a large proportion of a community becoming sick and dying is unclear. Some have suggested that more widespread corruption might be a result of increased “short-termism,” as those infected seek financial security by any means possible for the families they will leave behind, and informal structures emerge to meet the vast needs that formal health care systems are failing to meet.²

Corruption in the treatment of HIV/AIDS

Relatively effective drug treatment has changed the nature of HIV/AIDS in the West. Increasingly, HIV is seen as a condition people can live with. Hospitalization and death rates have fallen, and antiretroviral therapy (ART), when properly administered, offers people with HIV many extra years of productive life, depending on when treatment begins.

In Africa, it is estimated that people live an average six and a half years after infection. If ART is started at the appropriate time, life expectancy is doubled or tripled. Over the past decade, ART has gone from being something that even people in developed countries could not afford to a treatment that over 700,000 people in developing countries now receive. The World Health Organization (WHO) attempted to place 3 million HIV-infected people on ART by 2005 under its “3 by 5” initiative; the organization was not able to meet its goal.

Even with this massive and rapid scaling-up, treatment is not available to all who need it. This is no different from other health services in Africa and the rest of the developing world, where many are excluded through financial or cultural constraints, or because of the distance to health care facilities. Access to ART sharpens these issues, however. Demand frequently exceeds supply even when there is an official policy to determine who gets treatment, such as a cut-off point based on CD4 count. Those whose results are “not quite bad enough” may try to use financial, political, or other inducements to gain access to treatment programs. A 29-year-old Nigerian father of three spoke for many across the continent in the 2005 civil society organization statement to the African Union Summit of Heads of States: “The [antiretroviral (ARV) drugs] that

come to the center are not given to those of us who have come out to declare our status, but to those ‘big men’ who bribe their way through, and we are left to suffer and scout round for the drug.”³

Where ARV drugs are provided for free or at heavily subsidized rates through donor-funded programs, requests for “top-up payments” are common. The Malawi Network of People Living with HIV/AIDS reported instances of abuse from hospital workers demanding sexual, monetary, or material favors in return for proper medication and care. Those who refuse are either neglected or receive substandard care. In cases where patients do report receiving high-quality care, it is followed by suspicion by other care providers and patients that those who furnish it are receiving bribes.⁴

Those who get into programs offering free or highly subsidized drugs receive a valuable commodity. They and their family will have other needs as well, and many elect to share or trade their drugs to meet these needs. There is a ready market for ARV drugs. In Tsavo Road, Nairobi, huge quantities are traded every day.⁵ Some come from patients, others leak out of the health care system, and a large proportion is counterfeit. The drugs are often cheap and there are fewer stigmas, no hassle, and no waiting. Some vendors sell their own treatment drugs; some are registered on multiple programs and have ARV drugs to spare; and others have access to the supply chain through central and hospital pharmacies.

People buy drugs from informal sources such as Tsavo Road vendors because they are convenient and anonymous. The problem with doing so is that ARV drugs are effective only when there is rigid adherence to the treatment protocol. Buying treatment from those who know little about the appropriate combinations, side effects, or dosage, and substituting one drug for another depending upon availability, means treatment is likely to become ineffective and result in the development of resistance to ARV drugs. Moreover, the product may be expired or fake.

The WHO estimates that the global market in fake and substandard drugs is worth US\$32 billion—or around a quarter of all drugs used in developing countries.⁶ Well-substantiated reports from Ethiopia,⁷ the Democratic Republic of Congo (DRC),⁸ and Côte d’Ivoire⁹ indicate that the

problem may be even greater and is increasing. Given the demand for and value of the drugs, faking ARV drugs is potentially much more profitable than faking other drugs. Corruption contributes to the extent of the problem when regulatory authorities turn a blind eye to counterfeiting or public officials receive inducements to procure from less-reputable suppliers.

Concerted advocacy by civil society organizations (CSOs) and governments, and competition from generic and research-based companies, have been extremely effective in lowering the price of ARV drugs in the developing world, resulting in a system of differential pricing between Organisation for Economic Co-operation and Development (OECD) countries and developing countries. A month’s supply of GlaxoSmithKline’s Combivir, for example, costs around US\$610 in Britain and US\$20 in Uganda, Tanzania, and Kenya. The potential profit from re-importation or smuggling is large for vendors in developing countries and drug brokers in developed countries. How much of a problem this is in reality is controversial, however, and there have been allegations that the pharmaceutical companies are exaggerating the scale of the problem in order to dampen pressure for differential pricing.

Competition in the supply of ARV drugs has not stopped corruption in national procurement processes. For example, the Romanian government has launched an investigation following allegations by US Ambassador Michael Guest that ARV drugs were being sold at prices 50% higher than in the United States, and that the health ministry had engaged in corrupt dealings with drug suppliers. A government watchdog agency reported in April 2003 that the ministry had ignored an agreement with GlaxoSmithKline to reduce the price of its ARV drugs by up to 87%,¹⁰ and denied drug importation contracts to foreign companies, granting them instead to four local ones. These levied “taxes and commissions” were worth up to 55% of the drugs’ value.

Fresh approaches and new roles

Where systems are weak and corruption endemic, it is difficult to disentangle corruption from mismanagement and system failure as the root cause of poor HIV/AIDS responses. Nigeria’s ART program attracted

much criticism in 2003 when treatment centers began handing out expired drugs and rejecting patients.¹¹ But it is not yet clear whether the prime cause was corruption or a weak drug procurement, supply, and distribution service that was unable to respond to the demands that the rapid scaling up of the program had placed upon them.

Fresh approaches have developed involving new actors and sectors not traditionally involved in health programs, such as education, security, agriculture, and social services. National AIDS commissions have been established to coordinate the response in many countries. They are often seen as a donor construct, however, and the extent to which they have been assimilated into domestic governance systems is variable. Kenya provides an example of the worst-case scenario: its agency was discredited when it was discovered that senior staff had paid themselves inflated salaries and allowances (see “Corruption in Kenya’s National AIDS Control Council,” page 37).

In Zimbabwe, the government has imposed an “AIDS levy” since 2000, whereby employees contribute 3% of their gross salaries toward a fund administered by that country’s National AIDS Council (NAC). It is estimated that the government collects about US\$20 million per year through this mechanism, but no information about how the fund is used and who benefits from it has ever been made public. In March 2005, the health ministry ordered an audit of the NAC. It had not yet been published.

Civil society organizations are increasingly seen as important providers of services and receive substantial grants to do so, but the transaction costs of processing and monitoring CSO applications are very high. An attendant risk is that CSO directors will siphon off their funding. For example, the director and senior staff at the Zimbabwe National Network for People Living with HIV/AIDS were suspended after allegations of corruption.¹² The network received more than US\$1.8 million from the NAC between 2003 and 2004.

The international response: More money

The sums now being disbursed to tackle HIV/AIDS are huge compared to the existing budgets of many countries.¹³ In Ethiopia, Liberia, and Malawi, the money allocated by global health partnerships

such as the Global Fund represents more than a doubling of the health budget. Funds from the World Bank and the US President’s Emergency Plan for AIDS Relief (PEPFAR) are also massive.

While the need for money is indisputable, the systems to use these funds appropriately are poorly developed. The fact that the “performance” of a grant or loan is assessed by how rapidly it is disbursed gives incentives to donor and recipient to allocate the money carelessly. For corrupt officials, rapidly expanding budgets offer greater scope to siphon off significant volumes without anyone noticing. This is especially true where health systems are fragile, where there is a lack of monitoring and oversight, and where the capacity to channel the money effectively is limited.

Beyond the immediate risk of money being squandered by corruption, commentators such as Stephen Knack (World Bank)¹⁴ suggest that development assistance may actually reduce the quality of governance in recipient countries. Donors may set up parallel systems to avoid the risk of corruption, but this means taking talent and capacity away from the official government system, with the concomitant effect that governments and officials become more accountable to the donor than to their own constituents. For example, PEPFAR combines a political imperative to spend money rapidly within narrow political constraints.

In an attempt to prevent this, some donors—mainly European, but also the Global Fund—are moving toward “budget support,” essentially putting their money through government channels. While recognizing the fiduciary risk, they believe that the benefits—improved efficiency, legitimacy in focusing on public financial management, and support to domestic accountability—outweigh the disadvantages in many countries.

Could more be done to minimize corruption?

As with attempts to tackle corruption in the health care sector generally, the terms and conditions of health care workers should be improved in parallel with the introduction of mechanisms to increase their accountability to the communities they serve. However, though paying health care workers and civil servants more is necessary, it is not enough to limit corruption. And minimizing the opportunities for corruption without providing alternative

sources of income may induce health care workers to give up, resulting in an escalation of the human resource crisis in the health sector.

Increasing transparency is vitally important in health services. The public needs to be more aware of the eligibility criteria for ART programs, which should ideally become more consistent within and across countries. They need to be aware of what they have to pay and what they will receive. The quantities and values of drugs supplied at each level of the system should be well-publicized, and health care workers should have to account for them. There also needs to be a mechanism whereby people can complain without fear of victimization.

Pharmaceutical companies also need to take action. To minimize the risk of drugs for developing countries being reimported, GlaxoSmithKline is rebranding and changing the color of ARV drugs sold in developing countries. An alternative approach is to develop different branding and packaging for products designed for use in developing countries.

The European Union (EU) employs a system of registration whereby products are given a number and bar code, and can be identified by customs or drug brokers if reimported. Tight monitoring of pharmaceutical sales within the United States and Europe is an important disincentive to reimportation, and needs to be maintained. However, implementation of the recent World Trade Organization (WTO) agreement regarding compulsory licenses and the export and import of generic varieties of drugs may restrict the availability of cheap generic varieties of drugs, providing additional scope for bureaucratic corruption.

Donors have an important role to play in minimizing corruption, one that is not specific to HIV/AIDS treatment or prevention programs. With vast resources flowing in for HIV/AIDS, however, a new paradigm has been created that distorts the donor-recipient relationship. What rich nations view as the provision of funds to purchase AIDS medicines, many in poor nations have monetized upwards as a currency of street trade.

Donors need to find a choke point to reduce corruption. One step toward making recipient governments more transparent would be for donors to be open and explicit about what they are giving, when, and to whom. This requirement is included

in international recommendations, but the reality is far from ideal. Donors should ensure that aid is used in line with good procurement guidelines, and work with pharmaceutical companies to encourage and ensure responsible behavior.

Ultimately, it is the responsibility of national governments to deal with corruption. Given the associated sensitivities about international action, regional pressure may be more appropriate; in Africa, the New Partnership for African Development (NEPAD) peer review system could become an important tool. Finance and health ministers control the foreign exchange that is used to purchase medicines, and they need to be aware of the long-term effects of their misuse. When medicines are substandard or distributed inadequately, the onset of drug resistance is accelerated, leading to a growing burden of chronically ill people. The cost of medical care to treat them will be far

greater than the price of the legitimate medicines in the first instance.

HIV/AIDS is going to be a major problem for the next two decades at least. Experience gained in other areas of development, and the need for transparency and strong domestic accountability, should not be ignored if sustainable and effective approaches to tackling the disease are developed. ■

Liz Tayler is a UK public health physician, who worked for several years as the UK Department for International Development (DFID) health advisor in Nigeria before joining the HLSP Institute as an advisor. Clare Dickinson is an HIV/AIDS specialist with HLSP, and formerly worked in Indonesia on a health policy project based in the Ministry of Health.

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Corruption in Kenya's National AIDS Control Council

Kipkoech Tanui and Nixon Ng'ang'a

HIV/AIDS is one of the biggest challenges facing the health sector in Kenya, and was declared a national disaster in 1999. The National AIDS Control Council (NACC) was set up later that year to coordinate the prevention and control of HIV/AIDS. Its role became even more critical when the current government placed at the center of its 2003–2007 development plan the goal of achieving 90% awareness of the disease and its effects across society.

The NACC was given control over funds pooled under the Kenya HIV/AIDS Disaster Response Project (KHADREP), financed by the World Bank, the United Nations Development Programme (UNDP), and UK and US development agencies. In the 2004–2005 financial year, the NACC was allocated just under KSh4 billion (US\$41 million). The most significant portion of its budget is channeled into community-based organizations. It claims to have channeled KSh1.8 billion (US\$24 million) to community-based organizations from 2000 to 2003.

The NACC was set up under the Office of the President (OP). However, a more natural home for it is the health ministry, which is also a recipient of large amounts of bilateral funding, and which runs the National AIDS and STD Control Programme (NAS COP). The choice of the OP as home for the NACC was made ostensibly out of the government's desire to control the sizeable budget it manages. The OP's record belies the wisdom of this decision, however. It has been the focus of some of Kenya's most egregious acts of corruption, often perpetrated by well-connected officials who have proved almost impossible for prosecutors to touch.

In April 2003, the OP was enveloped in scandal when it was revealed that the head of the NACC, Margaret Gachara, had been receiving a salary seven times what she should have been entitled to as a senior civil servant. She had negotiated the salary based on a fraudulent letter from her previous employer that exaggerated her earnings there. Once in office, she raised her salary even higher than the already inflated amount she had been offered. In August 2003 she was ordered

to refund US\$340,000 to the NACC.

Fears that the corruption did not end with her high salary were confirmed in April 2005, when a report by the Efficiency Monitoring Unit (EMU), also based in the OP, revealed that for years, high-level public servants had used the NACC as their personal cash cow. There had been a number of early warning signals. An internal audit in June 2002 found irregularities in procurement procedures, and in June 2003 the Global Fund withheld a US\$15 million AIDS grant until the government addressed corruption in the NACC.

The 300-page EMU report revealed that Kenya could not account for KSh3.64 billion (US\$48 million) donated by the United Kingdom over five years since 2001. It put a figure of more than KSh37.3 million (US\$490,000) on the amount used by NACC employees to pay themselves inflated salaries and fraudulent allowances, such as the payment of private water, electricity, telephone, and home security bills. The largest sum was the money embezzled by Gachara, but others were also involved, including eight permanent secretaries or their representa-

tives, and NACC Chairman Mohammed Abdallah, who was charged with embezzlement but later acquitted due to “lack of evidence.”

Even where money did find its way out of NACC to the community organizations it was intended to support, the investigation into its use was damning. The EMU found

that in a sample examination of the community-based organizations funded by the NACC, at least half of the money allocated has been squandered.

Investigators probed three of the 10 national NGOs funded by NACC and several provincial, district, and constituency-level organizations. They found wanton theft of

the NACC money granted to noble-sounding projects that turned out to be sham. The worst cases involved shell organizations purposely formed to cash in on the NACC windfall. The NACC itself had cracked down on some of the so-called “briefcase” NGOs cited in the report, including the Neema Children’s Centre in Nairobi. The

Accountability in a time of crisis

Toby Kasper

The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) was established in January 2002. At the time, international efforts were failing to dent a death toll of 6 million people each year who die of illnesses that in rich countries are controlled or cured. Its foundation coincided with growing concern that corruption was lessening the impact of development aid.

The Global Fund’s mandate was simple: to provide a massive infusion of financing for efforts to combat these three diseases in developing countries. Its role would be limited to supplying funding rather than, as has classically been the case in development assistance, bundling financing with technical support to prepare and implement programs. This model was developed out of a recognition that adequate capacity existed at local level to scale up disease control interventions, should sufficient financing be made available. No country offices would be established, and instead the Global Fund would be created with a small board supported by a small Secretariat in Geneva.¹

To date, the Global Fund has approved proposals totaling almost US\$3.5 billion for combating the three diseases in nearly 130 countries. More than US\$1.41 billion was disbursed as grants in the Global Fund’s first three years, and the figures are growing rapidly. The countries being financed are among the most corrupt in the world: 23 of the 25 lowest-ranked countries in Transparency International’s 2004 Corruption Perceptions Index have received money from the Global Fund.²

Working in countries where corruption is endemic, and under pressure to work fast, the Global Fund’s approach has been to include parties from government, civil society, the private sector, UN and donor agencies, and people affected by the diseases in Country Coordinating Mechanisms (CCMs), which have responsibility for submitting proposals and overseeing the use of funds. The idea is that the different stakeholders will exert peer pressure to promote more effective implementation and reduce the likelihood of money disappearing.

But the experience to date with this approach to

ensuring accountability has been mixed.³ In Armenia, Cambodia, Ghana, and Rwanda, the CCMs have taken on active roles in overseeing implementation, including developing monitoring tools and operating procedures. In other countries, however, they have been appropriated by a single constituency, typically the government—particularly in Eastern Europe and central Asia; have fallen prey to competing political agendas; or simply have not met regularly enough to ensure any adequate oversight role.

A second aspect of the Global Fund’s accountability system is that ongoing funding is performance-based. Global Fund resources are provided as advances and the financial reporting requirements are generally quite streamlined. But expenditure reporting is required to be linked with program monitoring and evaluation, shifting the focus from inputs (whether or not a computer was bought or a shipment of drugs arrived at the port, for example) to outputs (such as whether the financing was used to scale up interventions against AIDS, tuberculosis, or malaria). If expenditures occur without demonstrable results, it is an immediate red flag that corruption may be diverting resources away from their intended purposes. This enables the Global Fund’s Local Fund Agent (LFA)⁴ to pay increased attention to the recipient’s financial records.

However, LFAs are more familiar with financial data than health outcomes, and have not always adequately addressed this weakness by bringing in outside expertise. Adding to the problem, the contracting system does not systematically ensure that an LFA working in a very corrupt country has more resources at its disposal than one working in a country with robust accountability systems. The Global Fund has terminated grant agreements because of corruption concerns in two cases, Ukraine and Uganda. In both cases, the corruption was detected as a result of a combination of the work of the LFA and that of partners in the country.

A third innovation of the Global Fund is its transparency. The Global Fund makes information about the dates and amounts of every disbursement available on its Web site and in its publications. The ideal is that the government and non-government partners with a stake in the program will use this information to ensure that resources are not diverted.

There are concerns that this vision is losing some of its

clarity, however, as the Global Fund Secretariat grows in size and slowly takes on more responsibility for doing the work that its partners were originally expected to be able to assume. This has arisen both because of pressure on the Global Fund to prove itself and because partners have tended to view the Global Fund as yet another external body coming in to finance its own projects, rather than one that simply provides additional resources to a national response that all parties would support.

Given the Global Fund’s short history, it is difficult to assess fairly how well these various accountability and transparency mechanisms are working. What speaks in the Global Fund’s favor is that it has been willing to amend its processes as corruption concerns emerged; for example, in deciding in mid-2005 to set up an Office of the Inspector General to tackle suspected fraud and abuse. It has also begun to introduce risk management principles into its operations, both to allocate staff resources appropriately and to tailor procedures and responses to varying contexts. ■

Toby Kasper worked at the Global Fund to Fight AIDS, Tuberculosis and Malaria from August 2002 until March 2004. He initially responsible for the management of a portfolio of countries and later acted as policy manager.

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1. Of the 19 board members, 14 are from national governments or regional groups, generally represented by health ministries, HIV/AIDS committees, and development cooperation ministries. Three are from non-governmental organizations, and two are from the private sector. Two of the NGO members were from developing country NGOs, while the 14 governmental representatives were evenly divided between developing and developed countries.
2. Transparency International, *Global Corruption Report 2004*, available at www.transparency.org/cpi/2004/cpi2004.en.html#pci2004
3. See www.theglobalfund.org/en/apply/mechanisms/casestudies/default.asp
4. The Global Fund Secretariat does not have any offices outside Geneva, so it contracts independent firms to assess the capacity of the principal recipients of the funds to handle the large volume of resources and to monitor implementation. The LFAs are generally accountability firms (particularly PricewaterhouseCoopers and KPMG), selected through a competitive tendering process.

NACC awarded Neema US\$14,000 out of a World Bank grant to finance grassroots work on HIV/AIDS. It was closed down in mid-2003 after inspectors could not find a single Neema worker or a single orphan who had benefited from the children's center.

Money was squandered by almost all the AIDS Control Units (ACUs) formed in each ministry to sensitize staff to the disease. Grants were spent on needless seminars, usually involving the same participants. Of the US\$205,000 given to the Ministry of Agriculture, for example, more than 75% was spent on staff accommodation, allowances, and participation fees at various awareness-raising shows, the EMU report noted. Almost one third of the amount spent was not accounted for and was presumed wasted.

Investigations into the three national NGOs revealed similar misdeeds. Par Aid, a well-connected organization based in Eldoret, received US\$100,000 for a proposal to study the efficacy of Par Aid herbal medicine in the treatment of HIV infection. The chairman of the Institutional Research and Ethics Committee at Moi Teaching Referral Hospital, which is part of Moi University, withdrew a letter approving the project because he was concerned that Par Aid was not serious about the study, but his decision was quickly overturned with no explanation given by the hospital's director. The study went ahead, and the EMU report found that most of the money was spent on trips to collect the medicine, or on fuel. The medicine that should have been used in free trials was sold to desperate patients, leading the EMU to conclude that Par Aid was conducting a profitable business with NACC funds.

Corruption in the case of the AIDS Prevention Forum of Kenya (APFK) is even more blatant. Also given US\$100,000 in NACC funds, its directors appear to have gone on a spending binge under the guise of organizing seminars and workshops.

The EMU noted a claim by the organization that it spent US\$16,000 hosting school pupils at a seminar in the Chania Tourist Hotel. The schools said to have been involved denied any knowledge of the activity and said some of the pupils alleged to have participated did not even exist. Similarly, hotels refuted several account entries, saying they were either

paid considerably less, or did not host the seminars at all. For example, the Hotel Big Five in Homa Bay, which was said to have hosted 150 students at a cost of US\$6,200, consists of just 12 rooms and denied ever accommodating the group.

A number of APFK directors were simultaneously directors of the third NGO investigated—Technologies and Action for Integrated Development (Techno Aid)—where similar practices were uncovered. Techno Aid claimed to have organized seminars and workshops for the same people as APFK, consulted academic experts who denied ever working for the NGO, and paid large bills to non-existent hotels. Both Techno Aid and APFK presented receipts for stationery from the University of Nairobi bookshop, which has disowned them as frauds.

The report points the finger of blame at the lax implementation of the NACC's own funding rules and, in the worst cases, outright collusion between crooked NGOs and NACC staff. In some cases the NACC continued to finance organizations even when its own officers had expressed concerns over the accounting for previous allocations.

As isolated cases, the funds may seem petty, especially when juxtaposed with the huge sums that HIV/AIDS attracts. But in their consolidated amounts, and if spent on effective prevention programs, life-prolonging ARV drugs, or income-generating activities for the affected and infected, the sums are significant.

The fight against HIV/AIDS in Kenya attracts massive funding. The Global Fund has promised US\$129 million over five years, while the United States has pledged US\$115 million. Other donors who have responded to Kenya's appeal for more funds include UNAIDS (US\$15 million) for disease mitigation initiatives and the World Bank (around US\$658,000 on top of a 2004 grant of US\$4 million). The bulk of these funds go to NASCOP, which has also fallen under suspicion for failing to deliver results commensurate with its budget. If there were no leakage or inefficiencies in the use of NASCOP funds, they should be enough to provide ART to 200,000 of the 1.4 million Kenyans who are estimated to be infected with HIV. The real figures are scandalously small. By November 2004 only 24,000 people were reported to be on ART.

The EMU is based in the OP, and was

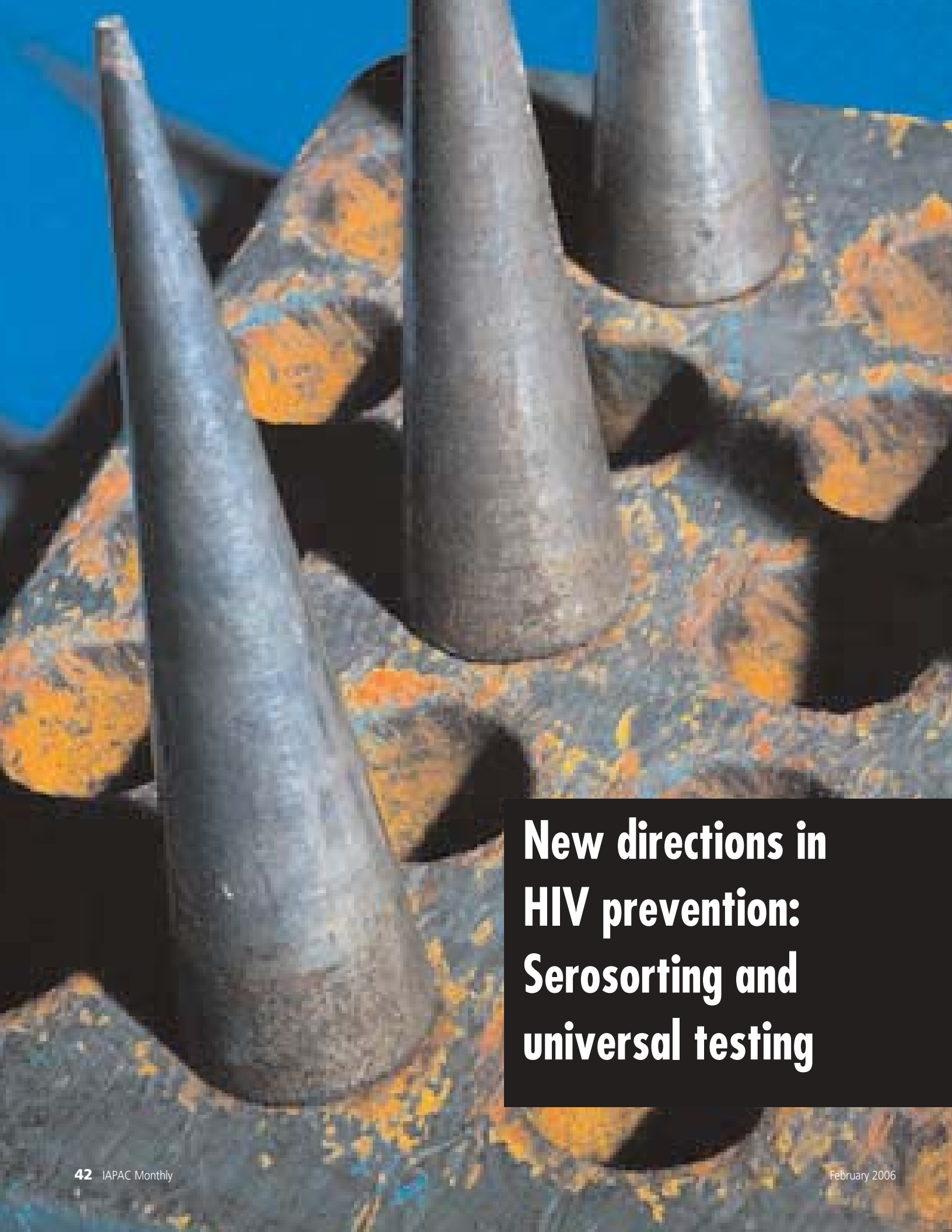
created in response to donor pressure to contain corruption in the institutions they support. Every state institution is liable to be investigated by the unit, but given its scant resources—staffed by just 50 people—it opts to probe those with sizeable budgets, often guided to them by rumors of sleaze. The EMU is reputed to conduct thorough and impartial investigations. Its report, "Financial Management Audit of the National AIDS Control Council (NACC) in the Office of the President," is the culmination of a two-year investigation.

The EMU has called on the Anti-Corruption Commission to investigate all the cases of fraud and abuse of office listed in the report. Gachara, the former NACC director, was sentenced in August 2004 to one year in prison on three counts of fraud and misuse of office. She was granted a presidential pardon in December 2004, along with 7,000 "petty offenders" who had stolen from various government offices. Her release was publicly decried.

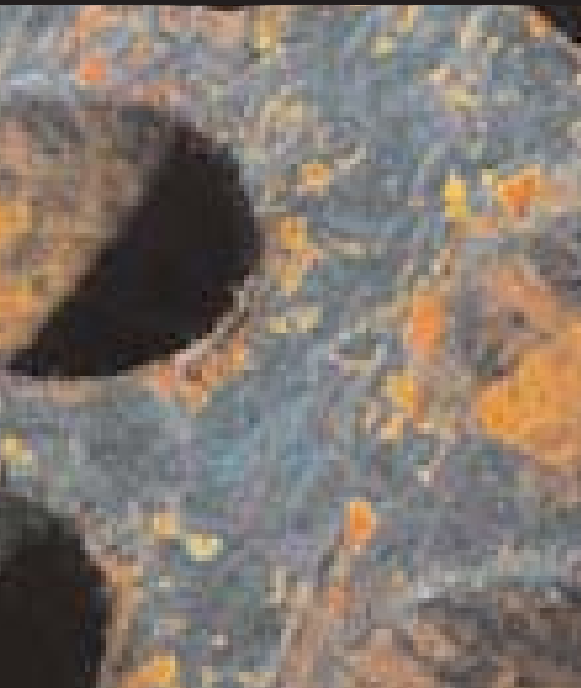
In response to the report, the NACC claims to have hired auditors to probe the accounts of the NGOs it funds. It says it will release funds in tranches, conditional on proof that the previous allocation was properly utilized. It ordered 20 NGOs to refund money that was misappropriated, or face prosecution. At the time of writing, none had refunded the money and none had been taken to court.

The role of constituency-based AIDS councils has also been bolstered in response to the scandals. These had already been given a larger role in resolving the Global Fund's concerns and now have responsibility to scrutinize the expenditure of NACC money. Many members of parliament—who are the patrons of their respective constituency councils—have welcomed moves in this direction and some have called for the NACC to be disbanded in favor of constituency-based AIDS management committees, citing bias in NACC decisions over which NGOs to fund. Whether this will help curb corruption is questionable, however. Civil society groups and the media have leveled accusations of favoritism in appointments to the constituency councils and in their decisions over the disbursements of funds. ■

Kipkoech Tanui is Deputy Managing Editor and Nixon Ng'ang'a is a journalist with The Standard, Kenya.



**New directions in
HIV prevention:
Serosorting and
universal testing**



The use of HIV testing and information about one's serostatus as an HIV prevention tool remains a complex and controversial area of debate, largely due to issues of trust: trust in the confidentiality of information, trust that health care providers will not test without consent, and trust that partners are telling the truth about their status.

Gus Cairns

The use of HIV testing and information about one's serostatus as an HIV prevention tool remains a complex and controversial area of debate, largely due to issues of trust: trust in the confidentiality of information, trust that health care providers will not test without consent, and trust that partners are telling the truth about their status. For all these reasons, prevention experts have shied away from addressing the topic in the developed world, despite the fact that HIV testing is considered an essential ingredient in the prevention mix in developing world countries. However, at the 13th Conference on Retroviruses and Opportunistic Infections (CROI), held February 5-8, 2006, in Denver, it was clear that this issue can no longer be avoided by virtue of its controversial nature.

Universal testing recommended by CDC

A contentious issue in the world of HIV is whether—given that, once tested, HIV-positive people do in general have less unsafe sex—a drive for universal HIV testing is a way forward in the field of HIV prevention.

Two symposium contributions at this year's CROI exposed this as a very live issue, especially in the United States. In one presentation, Tom Coates (University of California, San Francisco) looked largely at drives to normalize HIV testing in Africa, and contrasted Africans' general agreement with normalizing HIV testing—82% of Botswanans, for instance, think that the routine HIV testing introduced in 2004 by Botswana's President, Festus Mogae, was a good thing—with their individual distress at contemplating a positive result. In a qualitative survey, one said: "I have a dream of having children; if I test positive my dream will be shattered." Another said: "My father will chase me away from the house and call me 'Satan.'"

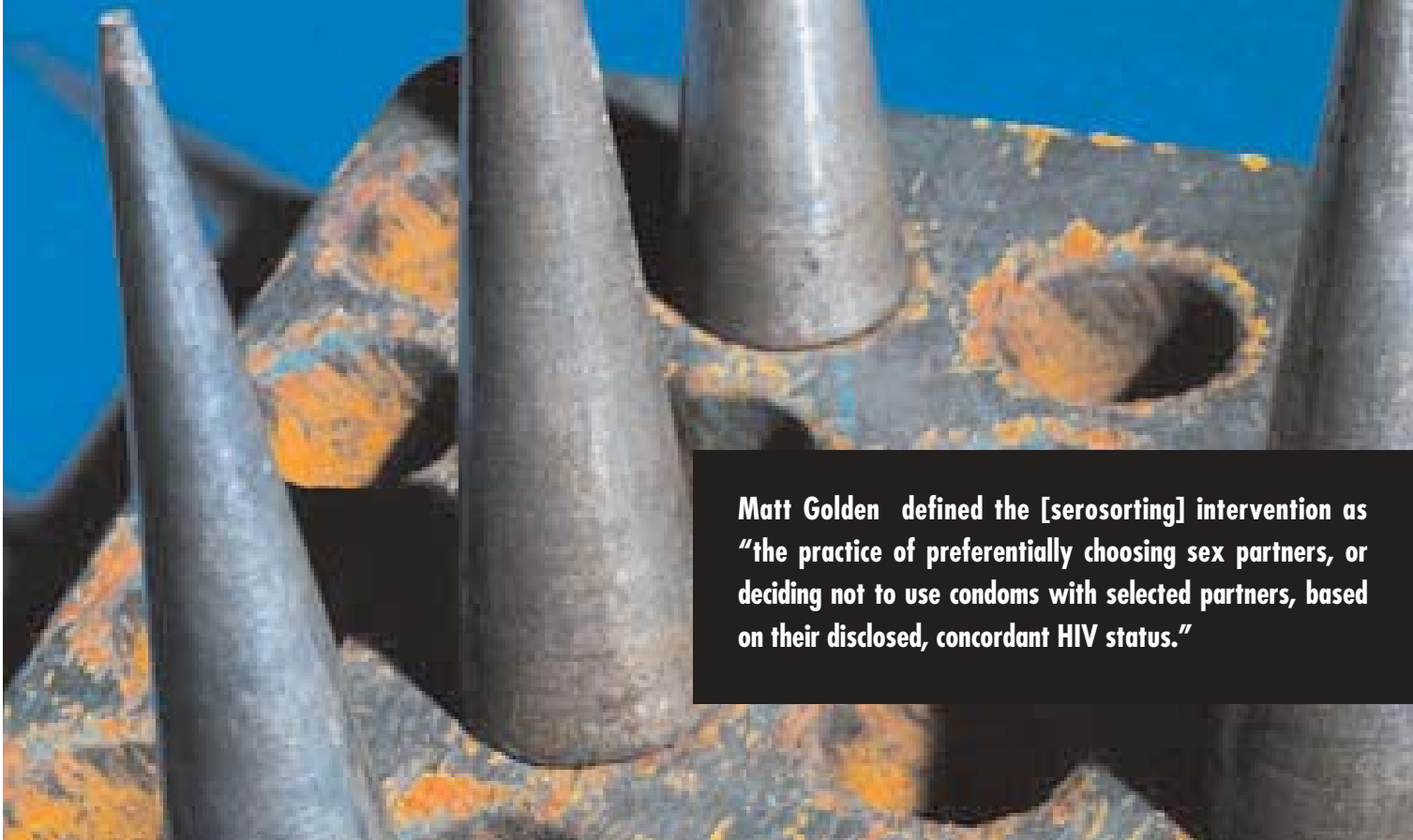
Timothy Mastro (US Centers for Disease Control and Prevention [CDC], Atlanta) got a considerably rougher ride from conference delegates, and session chair Jeffrey Klausner (San Francisco Department of Public Health) extended the question-and-answer session after Mastro's presentation, saying that "It's not often we get the most prominent members of the CDC in one room to answer these questions."

Mastro said that a CDC study showed that HIV-positive patients reduced the amount of unprotected serodiscordant sex they had by 68% after diagnosis.¹ This led researchers to believe that the 25% of people who did not know their HIV status in the United States accounted for about 50% of HIV infections.

He cited the startlingly high prevalence and incidence figures among gay men, and particularly African-American gay men, in cities other than San Francisco. In a large sample of gay men in five US cities, 25% of gay men had HIV and 48% were unaware of their infection; 46% of African-American gay men were HIV-positive and 67% did not know about their HIV infection. Late testing was also common: 45% of AIDS diagnoses were among people who had been diagnosed less than 12 months previously.

Mastro said that HIV testing in the United States had not been increasing in recent years, despite the fact that the CDC had launched its "Advancing HIV Prevention" strategy in 2003, which aims to make voluntary HIV testing a routine part of medical care. He said that only about one in 500 visits to hospital emergency rooms involved an HIV test; a concern given that, when tested, rates of previously undiagnosed HIV among patients varied from 1.3% to 3.2%.

In Dallas, which adopted opt-out HIV testing in its sexually transmitted infections (STI) clinics in 1997, the proportion of patients tested for HIV increased from 78% to 97% in one year,



Matt Golden defined the [serosorting] intervention as “the practice of preferentially choosing sex partners, or deciding not to use condoms with selected partners, based on their disclosed, concordant HIV status.”

and the number of positive tests had gone up 60% from 168 to 268. Mastro showed a notice from a Dallas STI clinic announcing that, “All patients seen in this clinic will be tested for gonorrhea, syphilis, chlamydia, and HIV.”

Mastro added that before opt-out testing had been adopted in pregnant women in the United Kingdom, only 35% had chosen to be tested because they feared it indicated high-risk behavior, whereas 88% accepted opt-out testing. “We think the need for extensive pre-test counseling is less because it [is] 2006 and people now have a high level of knowledge about HIV,” he said.

After two studies published in the *New England Journal of Medicine* last year found that routine screening would also be cost-effective, the CDC decided to revise its HIV screening guidelines to recommend routine, voluntary screening for all individuals aged 13 to 64 in health care settings, not based on risk, and annual HIV testing for people with risk behavior. Pre-test counseling would not be required. Health care settings include all hospital in- and out-patient clinics, as well as community clinics and STI clinics. An exception would be made for prisons, where it was recognised that receiving an HIV diagnosis created profound difficulties both for inmate and institution.

Mastro was bombarded with a battery of questions after his presentation. Among them were:

- How would the CDC move from recommendation to implementation? The CDC had recommended names-based reporting years ago, but states did not move toward implementation until they were threatened with the removal of federal funds.
- If the information given in pre-test counseling and discussion around informed consent is removed, where are patients going to get any opportunity to talk about HIV and harm reduction?

- How real is the voluntary nature of the testing when the photo he showed of the Dallas notice indicated all patients would be tested for STIs, including HIV?
- How is the opting-out process to work and how will it be recorded? Without adequate recording, patients could say they were tested without consent.

Serosorting

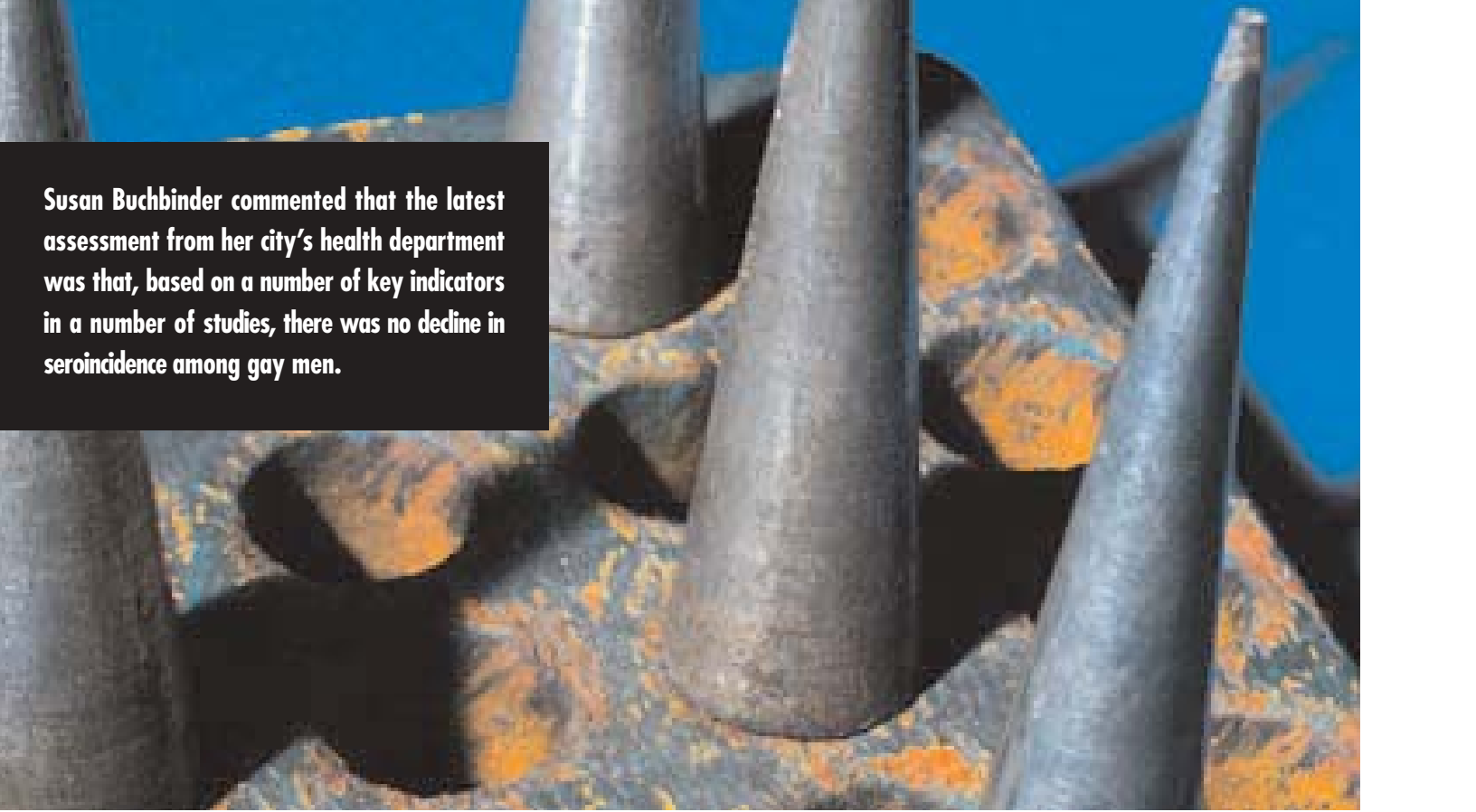
Matt Golden (University of Washington, Seattle) looked at a controversial prevention intervention adopted by gay men: serosorting.² He defined the intervention as “the practice of preferentially choosing sex partners, or deciding not to use condoms with selected partners, based on their disclosed, concordant HIV status.”

Five studies conducted from 1992 to 2005 found that gay men were between 2.5 and 9.1 times more likely to have unprotected anal intercourse with partners they knew were of the same HIV status as themselves than with partners of differing HIV status.

Data from Golden’s own clinic found that HIV-positive patients were particularly likely to serosort. Forty percent and 49 percent of his HIV-positive patients, respectively, had unprotected receptive and insertive sex with HIV-positive partners but only 3% and 6%, respectively, with HIV-negative partners.

In his HIV-negative patients, 31% and 37%, respectively, had unprotected receptive and insertive sex with HIV-negative partners, and 19% and 15%, respectively, had unprotected receptive and insertive sex with HIV-positive partners—less, though still a surprisingly high figure.

“Where the whole system breaks down,” Golden commented, “is where the other partner is of unknown status.” Here partners were almost equally likely to have unprotected insertive sex



Susan Buchbinder commented that the latest assessment from her city's health department was that, based on a number of key indicators in a number of studies, there was no decline in seroincidence among gay men.

regardless of whether their own or their partner's status was unknown. In the case of receptive sex, there was some evidence that HIV-positive gay men were attempting to adopt "strategic positioning." HIV-positive men were somewhat more likely (31% versus 24%) to have unprotected receptive rather than insertive sex with partners of unknown status; conversely HIV-negative men were somewhat less likely (16% versus 22%). Golden did not say whether any of these differences reached statistical significance.

Golden then investigated whether serosorting was actually reducing the number of serodiscordant partners that gay men had, regardless of condom use. The answer was yes. In a population such as Seattle's, where 15% of gay men have HIV (not dissimilar to London), if gay men chose partners completely at random, and if they all had the mean number of partners rather than a few having many and many having a few, you would expect 54% of gay men to have at least one serodiscordant relationship per year (with the figure obviously lower for people with few partners and higher for those with many).

In fact about 35% of gay men had had at least one serodiscordant partner, so serosorting appeared to be reducing the number of serodiscordant relationships by about 40%, though Golden also suggested some of this was due to the fact that gay men tend to have sex with men fairly near their own age, and that because young men are less likely to have HIV than older men, some of this concordance was purely due to age similarity. Golden also found that between 13% and 18% of gay men were exclusive serosorters (ie, only had unprotected sex with seroconcordant partners).

Is serosorting actually protective? When it comes to HIV-negative men, Golden found that the rate of new HIV diagnosis

among patients who had unprotected sex but tried to do it only with same-status partners (2.6%) was intermediate between men who had unprotected sex regardless (4.1%) and men who attempted always to use condoms (1.5%). Adjusting for the number of partners, whereas condom use was 76% effective in preventing new HIV infections, serosorting was about 40% effective.

As a control, Golden also looked at the rate of STIs. In this case, as could be expected, there was no difference in the STI rates between serosorters and non-serosorters.

Was serosorting increasing? Golden showed data from London and San Francisco that suggested the proportion of unprotected sex that was discordant, especially as practiced by HIV-positive men, was decreasing, but said he had not seen the same pattern in Seattle.

Susan Buchbinder (San Francisco Department of Public Health) commented that the latest assessment from her city's health department was that, based on a number of key indicators in a number of studies, there was no decline in seroincidence among gay men. However, she added that these data did not preclude the possibility that serosorting could drive down infection rates. ■

***Editor's Note:** Reprinted with permission from www.aidsmap.com. Look to the March 2006 issue of the IAPAC Monthly for Mark Mascolini's comprehensive coverage of the 13th Conference on Retroviruses and Opportunistic Infections.*

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A B S T R A C T S

New England Journal of Medicine

Tenofovir, emtricitabine, and efavirenz versus zidovudine, lamivudine, and efavirenz for HIV

Gallant JE, DeJesus E, Arribas JR et al, for the Study 934 Group.

BACKGROUND: Durable suppression of replication of the human immunodeficiency virus (HIV) depends on the use of potent, well-tolerated antiretroviral regimens to which patients can easily adhere. **METHODS:** We conducted an open-label, non-inferiority study involving 517 patients with HIV infection who had not previously received antiretroviral therapy and who were randomly assigned to receive either a regimen of tenofovir (TDF), emtricitabine (FTC), and efavirenz (EFV) once daily (TDF-FTC group), or a regimen of fixed-dose zidovudine (ZDV) and lamivudine (3TC) twice daily plus EFV once daily (ZDV-3TC group). The primary endpoint was the proportion of patients without baseline resistance to EFV in whom the HIV RNA level was less than 400 copies/mL at week 48 of the study. **RESULTS:** Through week 48, significantly more patients in the TDF-FTC group reached and maintained the primary endpoint of less than 400 copies/mL than did those in the ZDV-3TC group (84% versus 73%, respectively; 95% confidence interval [CI] for the difference, 4% to 19%; $P = 0.002$). This difference excludes the inferiority of the TDF, FTC, and EFV regimen, indicating a significantly greater response with this regimen. Significant differences were also seen in the proportion of patients with HIV RNA levels of less than 50 copies/mL (80% in the TDF-FTC group versus 70% in the ZDV-3TC group; 95% CI for the difference, 2% to 17%; $P = 0.02$) and in increases in CD4 counts (190 cells/mm³ versus 158 cells/mm³, respectively; 95% CI for the difference, 9 to 55; $P = 0.002$). More patients in the ZDV-3TC group than in the TDF-FTC group had adverse events resulting in discontinuation of the study drugs (9% versus 4%, respectively; $P = 0.02$). In none of the patients did the K65R mutation develop. **CONCLUSIONS:** Through week 48, the combination of TDF and FTC plus EFV fulfilled the criteria for non-inferiority to a fixed dose of ZDV and 3TC plus EFV and proved superior in terms of virologic suppression, CD4 response, and adverse events resulting in discontinuation of the study drugs.

N Engl J Med. 2006;354(3):251-260.

South African Medical Journal

Financial and economic costs of scaling up the provision of HAART to HIV-infected health care workers in KwaZulu-Natal

Deghaye N, Pawinski RA, Desmond C.

OBJECTIVES: To provide new information on the financial and economic costs of providing highly

active antiretroviral therapy (HAART) to health care workers in public-sector hospital settings in KwaZulu-Natal. **DESIGN:** An Excel model was used to estimate the cost of providing HAART to health care workers at two state-subsidized hospitals in Durban. Staff members were interviewed and protocols reviewed to identify the time and resources used to provide HAART to health care workers. The cost of the program was estimated for various patient numbers. **RESULTS:** The financial cost of treating a patient for a year ranged from R5,697 to R8,762 depending on the hospital and the number of patients treated. The economic cost of treating a patient for a year ranged from R6,123 to R8,893. These costs were shown to be robust to changes in key variables. **CONCLUSIONS:** This study provides evidence on the cost of providing HAART to health care workers and suggests that this strategy could reduce absenteeism and alleviate future staff shortages at moderate cost to hospitals. This is crucial, given the impending human resources crisis in health care in South Africa and the growing burden of HIV/AIDS. These cost estimates should be good indicators of the costs of extending antiretroviral therapy to health care workers in public-sector hospitals in KwaZulu-Natal.

S Afr Med J. 2006;96(2):140-143.

HIV Medicine

Depression and neurocognitive performance in individuals with HIV/AIDS: 2-year follow-up

Gibbie T, Mijch A, Ellen S, et al.

OBJECTIVES: The aims of this study were to follow a cohort of HIV-infected individuals for two years to assess changes in depression and neuropsychological performance over time, to explore the relationship between depression, HIV illness, and neuropsychological performance, and to examine the natural history of the effect of highly active antiretroviral therapy (HAART) on depression and neurocognitive performance. **METHODS:** HIV-seropositive outpatients were assessed at baseline and at two-year follow-up. At each assessment, patients were assessed for depression [using the Beck Depression Inventory (BDI) and Structured Clinical Interview (SCID-CV)] and completed a battery of neuropsychological tests including the Cambridge Neuropsychological Test Automated Battery (CANTAB) and the Hopkins HIV Dementia Scale (HDS). **RESULTS:** At baseline, 34.8% scored ≥ 14 on the BDI [≥ 14 suggests depressive symptoms (DS)]. The SCID-CV revealed that 27% of participants met the criteria for current mood disorder. Seven percent of the participants' scores on the HDS indicated HIV-associated cognitive changes. Eighty participants were retested at two-year follow-up and were split into two groups based on BDI scores at baseline. CANTAB results revealed that the cohort were significantly impaired on nine of 10 measures compared with age-matched normative

data. Neurocognitive performance significantly improved for participants with no DS at baseline, whereas participants with DS at baseline did not show as much improvement. Multivariate analysis revealed that 40% of the change in cognitive performance was attributable to the variables age, AIDS, and HAART regimen. **CONCLUSION:** These results suggest a significant decline in depression scores and an improvement in several neurocognitive domains over time, with a relationship between HIV illness, HAART, symptoms of depression, and neurocognitive performance.

HIV Med. 2006;7(2):112-121.

PLoS Medicine

Associations among race/ethnicity, apoC-III genotypes, and lipids in HIV-1-infected individuals on antiretroviral therapy

Foulkes AS, Wohl DA, Frank I, et al.

BACKGROUND: Protease inhibitors (PIs) are associated with hypertriglyceridemia and atherogenic dyslipidemia. Identifying HIV-1-infected individuals who are at increased risk of PI-related dyslipidemia will facilitate therapeutic choices that maintain viral suppression while reducing risk of atherosclerotic diseases. Apolipoprotein C-III (apoC-III) gene variants, which vary by race/ethnicity, have been associated with a lipid profile that resembles PI-induced dyslipidemia. However, the association of race/ethnicity, or candidate gene effects across race/ethnicity, with plasma lipid levels in HIV-1-infected individuals, has not been reported. **METHODS/FINDINGS:** A cross-sectional analysis of race/ethnicity, apoC-III/apoA-I genotypes, and PI exposure on plasma lipids was performed in AIDS Clinical Trials Group studies ($n = 626$). Race/ethnicity was a highly significant predictor of plasma lipids in fully adjusted models. Furthermore, in stratified analyses, the effect of PI exposure appeared to differ across race/ethnicity. Black/non-Hispanic, compared with white/non-Hispanics and Hispanics, had lower plasma triglyceride (TG) levels overall, but the greatest increase in TG levels when exposed to PIs. In Hispanics, current PI antiretroviral therapy (ART) exposure was associated with a significantly smaller increase in TGs among patients with variant alleles at apoC-III-482, -455, and Intron 1, or at a composite apoC-III genotype, compared with patients with the wild-type genotypes. **CONCLUSIONS:** In the first pharmacogenetic study of its kind in HIV-1 disease, we found race/ethnicity-specific differences in plasma lipid levels on ART, as well as differences in the influence of the apoC-III gene on the development of PI-related hypertriglyceridemia. Given the multi-ethnic distribution of HIV-1 infection, our findings underscore the need for future studies of metabolic and cardiovascular complications of ART that specifically account for racial/ethnic heterogeneity, particularly when assessing candidate gene effects.

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Non-invasive probe can stage liver disease

Chris Gadd

A new, noninvasive test can be used to diagnose the degree of liver damage in patients coinfecting with HIV and hepatitis, according to the results of a French study presented in the February 2006 edition of *The Journal of Acquired Immune Deficiency Syndromes*. This new technique may reduce the need for painful liver biopsies in coinfecting patients.

Infection with the hepatitis C virus usually leads to progressive liver damage, called fibrosis, culminating in irreversible scarring of the liver. This scarring, or cirrhosis, causes complications such as liver failure, fluid retention, bleeding in the gut, and liver cancer.

The current “gold standard” for the assessment of fibrosis and cirrhosis is to take a biopsy of the liver. This painful, invasive procedure can cause life-threatening complications and its reliability is

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limited by the small size of the sample and variability between observers.

The new technique, which measures the stiffness of the liver with a probe that is held against the skin, has been shown to be effective in HIV-negative patients. A scan takes around five minutes, has no side effects, and is painless. The new findings confirm its effectiveness in patients coinfecting with HIV.

“Liver stiffness measurement could reliably be used for first-line pre-therapeutic evaluation of fibrosis in coinfecting patients,” the researchers write. “Moreover, for the diagnosis of cirrhosis, liver stiffness is more accurate than other noninvasive biochemical tests.”

The investigators studied liver biopsies and transient elastography measurements in 72 patients. They found that the results of the noninvasive technique correlated significantly with the degree of liver fibrosis detected in the liver biopsies ($P < 0.001$). This indicates that the probe, called FibroScan, can be used to detect the degree of fibrosis.

“Liver stiffness measurement is a promising noninvasive method for the assessment of fibrosis in HIV-infected

patients with chronic hepatitis C virus infection,” they conclude.

FibroScan was also very effective at diagnosing cirrhosis of the liver in the patients, with 97% accuracy. The investigators calculated that a stiffness measurement of 11.8 kPa or greater indicates that the patient has cirrhosis of the liver. This is similar to the value found in two studies of HIV-negative patients.

The investigators also compared the results of transient elastography to blood measures that can be used to detect cirrhosis. They found that the new technique was more accurate than all four measurements: platelet count ($P = 0.02$), the ratio of the liver enzymes aspartate aminotransferase (AST) to alanine aminotransferase (ALT) ($P < 0.001$), the AST-to-platelet ratio index (APRI) ($P = 0.01$), and FIB-4 ($P = 0.004$).

If future studies confirm these findings, the introduction of FibroScan may improve the management of hepatitis C patients with and without HIV coinfection. ■

Reference

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HCV protease inhibitor does well in early clinical trial

Michael Carter

A hepatitis C virus (HCV) protease inhibitor (PI) has done well in early clinical trials. The oral drug, VX-950, which is being developed by Vertex Pharmaceuticals, achieved significant reductions in hepatitis C viral load when used in combination with pegylated interferon alfa-2a (PEG-IFN alfa-2a).

Current treatment for hepatitis C virus

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involves weekly injections of PEG-IFN and daily doses of ribavirin (RBV). This treatment is not universally effective and has unpleasant, often intolerable side effects. Coinfection with hepatitis C is common among HIV-positive individuals, and the current standard of treatment is less effective in coinfecting individuals than in patients who are only infected with hepatitis C.

In the phase 1b study, the combination of VX-950 and PEG-IFN alfa-2a produced a significant reduction in hepatitis C viral load in the first two days of treatment, and by day 14, 50% of patients provided with the investigational therapy had undetectable

hepatitis C viral loads (below 10 copies IU/mL).

The 14-day randomized, blinded, placebo-controlled trial involved 20 individuals with HCV genotype 1. This is the most common and hardest to treat of the HCV genotypes. Patients were randomized to receive VX-950 at a dose of 750 mg every eight hours in combination with PEG-IFN alfa-2a, the same dose of VX-950 alone, or PEG-IFN alfa-2a alone. On entry to the study, patients had a median hepatitis C viral load of over 4 million copies IU/mL.

Analysis of preliminary results showed that individuals taking the investigational

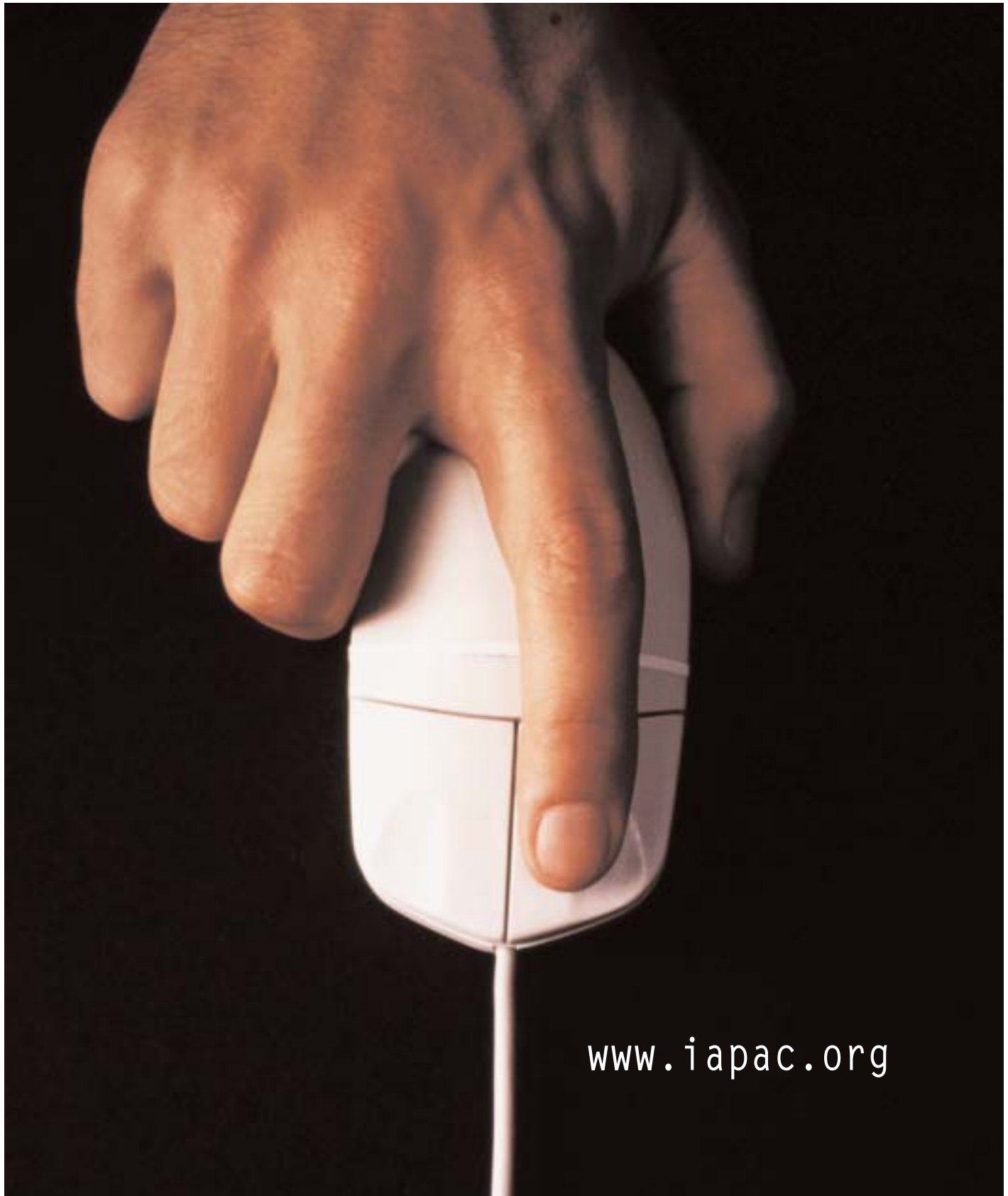
PI with PEG-IFN alfa-2a had a median viral load decrease of 5.5 log₁₀, compared to a median decrease of 4 log₁₀ in patients taking VX-950 alone and 1 log₁₀ in individuals randomized to

take PEG-IFN alfa-2a monotherapy.

No serious side effects were reported, and patients taking VX-950 reported only mild adverse events.

Vertex has announced plans for larger

phase 2 clinical trials, which will investigate the safety and effectiveness of VX-950 in combination with both PEG-IFN alfa-2a and RBV. The trial will start in the next few months and involve 200 patients. ■





I N T H E L I F E



Charles Farthing

For more than three years the *IAPAC Monthly* has featured members of the International Association of Physicians in AIDS Care (IAPAC), who are asked to bare their souls by answering a series of questions similar in nature to those asked in the famous *Proust Questionnaire*.

This month, *IAPAC Monthly* is proud to feature Charles Farthing, Chief of Medicine of the AIDS Healthcare Foundation in Los Angeles.

What proverb, colloquial expression, or quote best describes how you view the world and yourself in it?

I would like to think of something very erudite, but all that comes to mind are the words of my first school report at my New Zealand high school, where the headmaster's report read: "Cheerful, frank, and diligent." I have always liked to think it summed me up fairly well and is not too bad a way to be.

What activities, avocations, or hobbies interest you? Do you have a hidden talent?

No hidden talent. Like many I love the arts—the visual arts, drama, classical music, opera, and the ballet.

If you could live anywhere in the world, where would it be?

France.

Who are your mentors or real life heroes?

I do not hero worship a lot, but I would say many people who have made major contributions to HIV medicine are my heroes—people such as David Ho and Doug Richman stand out, but there are several.

With what historical figure do you most identify?

Charles Darwin.

Who are your favorite authors, painters, and/or composers?

Authors: Jane Austen, Charles Dickens, Patrick O'Brien. Painters: Claude Monet, Pierre-Auguste Renoir, Anthony Van Dyke. Composers: Ludwig van Beethoven, Frédéric Chopin, Gustav Mahler, Felix Mendelssohn, Wolfgang Amadeus Mozart, and Giuseppe Verdi.

If you could have chosen to live during any time period in human history, which would it be?

In the late 18th century.

If you did not have the option of becoming a physician, what would you have likely become, given the opportunity?

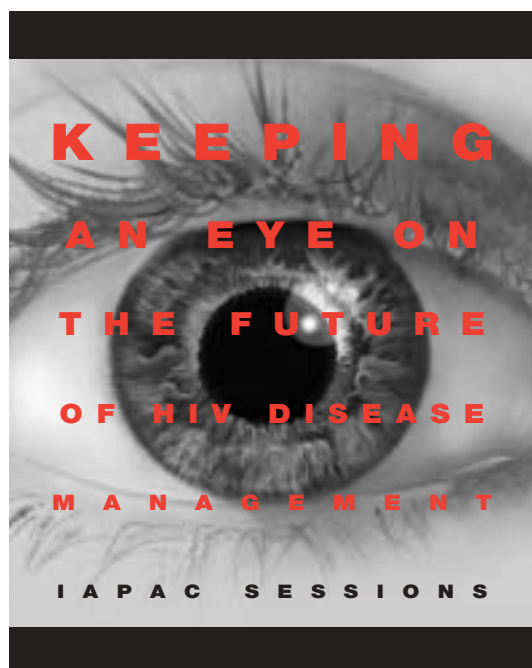
An actor.

In your opinion, what are the greatest achievements and failures of humanity?

Greatest achievements: the arts and progress to equality and prosperity for all. Greatest failures: an inability to live in peace and to let go of old ideologies that divide us.

What is your prediction as to the future of our planet one full decade from present day?

Very difficult—I think it will continue to progress to a greater humanity for all; for example, many millions on antiretroviral drugs throughout the world, and better health care for tuberculosis, malaria, and hepatitis as a knock-on consequence. I fear a further heightening of the current faith-based conflict and war as a consequence, but think that common sense is more likely to prevail. ■



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Early (Until February 28, 2006)	US\$100	US\$200
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Late (May 1-10, 2006)	US\$200	US\$300

Questions?

Contact Aimee Clark at (312) 795-4934
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SAY ANYTHING

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Brazil, France, and other nations already foresee using funds from new sources to contribute to an international facility for the purchase of medicines which would permit the production of [antiretroviral] drugs and facilitate their availability to people suffering from AIDS.

Kofi Annan, United Nations Secretary-General, during the opening of the Paris Conference on Innovative Development Financing, as related in a February 28, 2006, Deutsche Presse-Agentur report. Annan specifically praised the French program of taxing airline travel at the rate of US\$1.18 to US\$47.20 per ticket. All proceeds from the program, which is due to begin July 1, 2006, will be used to purchase medications to combat HIV, tuberculosis, and malaria in developing countries.

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Stopping the AIDS epidemic is going to require more than just a medical approach.

Peter Piot, Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS), in a February 27, 2006, Reuters report discussing the problems encountered in ensuring that funds allocated for HIV/AIDS programs in Africa reach their targeted population. Although international aid for HIV prevention and treatment is at an all-time high (US\$8 billion worldwide in 2005, compared to US\$250 million in 1995), structural problems within government departments, community groups, and health care systems are preventing the money from being spent appropriately. Piot mentioned that although items such as bicycles for public health workers are needed, "Donors say you can't buy things like bicycles. They see that as leakage... These bottlenecks are everywhere."

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I would rather shock patients than have them get infected or re-infected because of a lack of information or testing.

Marilyn K. Volker, a clinical sexologist, as reported in the February 26, 2006, Bradenton Herald. Volker was participating in a conference convened in Florida by the Manatee and Sarasota County Health Departments. Health care professionals were advised by HIV/AIDS experts to test all their patients for HIV as a matter of routine, and to make taking sexual histories a standard practice. In addition, because 11% of new HIV diagnoses in Florida occur in senior citizens, health authorities cautioned physicians against ruling out groups not ordinarily considered to be at high risk.

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If we don't get over the stigma of HIV/AIDS soon, we will be in a situation where we have a generation that's no longer on this Earth.

Eric Whitaker, Director of the Illinois Department of Public Health, in a February 17, 2006, Rockford Register Star article about the racial disparity in HIV infections in Illinois. African Americans make up 15% of the population of Illinois, but comprise 52% of new HIV diagnoses in the state. A US\$2.5 million program, Brothers and Sisters United Against HIV/AIDS, has been initiated to inform and educate the African-American community about HIV/AIDS. The program involves state officials speaking about HIV/AIDS prevention at colleges, churches, and other venues.

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We can't turn our backs on all these people and let them die.

Ira Magaziner, Director of the William J. Clinton Foundation's HIV/AIDS Initiative, in a February 23, 2006, Associated Press report about the foundation's aim to place 2 million HIV-positive patients worldwide on antiretroviral therapy by 2008. Magaziner added, "It's scaling up very quickly. We went from zero to about 250,000 [patients on medications] in a year and a half." The foundation has negotiated agreements for lower-priced antiretroviral drugs for 52 countries, and provides antiretroviral drugs and diagnostic tests at a 50% to 90% discount.

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We have to understand aspects of their everyday life in order to craft a message that people can identify with, because the alternative, really, is to create confusion, stigma, and to ultimately make the problem worse.

Winston Husbands, Co-Chairman of the African and Caribbean Council on HIV/AIDS in Ontario (ACCHO), in a February 17, 2006, article in the Globe and Mail about problems experienced by HIV-positive people who have moved from less-developed to developed countries. In 2005, 19% of new HIV infections in Toronto occurred in people who had relocated from developing countries with a high prevalence of HIV. The more than 20 HIV/AIDS organizations working under the ACCHO umbrella are working to craft prevention and treatment programs that are likely to be successful in communities of African and Caribbean origin.