

HIV This Week: what scientific journals said

Welcome to the thirty-sixth issue of ***HIV This Week***! Thanks for your patience! In this issue, which has been delayed by a number of factors including our efforts to get all the preceding issues on the UNAIDS ***HIV This Week*** website, we cover **blood transfusion** (donating blood for yourself in Ghana: is it practical?; risks of blood transfusion in the USA), **treatment** (methadone dose changes during ART initiation: what to watch for; a plea for recognition and management of oral lesions and discomfort in Uganda), **injecting drug use** (Mauritius, the land of Paul and Virginie - and now of injecting drug use), **human resources for health** (non-physician clinicians: a promising 21st century career!; delivery models for antiretroviral treatment in Cambodia and sub-Saharan Africa: reducing doctor time as services scale-up), **men who have sex with men** (time to take stock from this discouraging tale of 3 cities), **research ethics** (women in 7 countries voice their views on access to antiretroviral treatment for HIV prevention trial participants; how to achieve consensual decision-making for ethical research conduct), **basic science** (pondering the challenges of vaccine design in the wake of the halting September 21, 2007 of the Merck/NIH HIV vaccine (adenovirus 5 gag/pol/nef) trials), **policy development** (is WHO evidence-informed after all?).

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We want to be as helpful to you as we can, so please let us know what your interests are and what you think of ***HIV This Week*** by sending a comment to hivthisweek@unaids.org or by posting one on the ***HIV This Week*** website. If you would like to recommend an article for inclusion in ***HIV This Week*** please let us know.

Don't forget that you can find a wealth of information on the HIV epidemic and responses to it at www.unaids.org

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1. Blood transfusion

Ansah JK, Acquaye J. Ten years of preoperative autologous blood donation in Accra. *Ghana Med J* 2006;40:142-7.

Pre-operative autologous blood donation (PABD) is utilized to circumvent the use of allogenic blood for various reasons. Ansah and Acquaye describe the distribution in terms of demographic characteristic, trends in participation and result of screening test of the PABD programme of the Accra Area Blood Center from 1993-2003. This is a retrospective descriptive study of PABD in patients scheduled for a variety of elective surgical

procedures, in different levels of institutional health care in Accra, Ghana. Data from existing records of patients who had participated in PABD were collated and analyzed. The results showed that five hundred and forty six (546) females and 89 males participated, with ages ranging between 14-74 years. Majority of the patients (76.7%) underwent gynaecological surgery. A total of 330 (52%) donated one unit only, and 299 (47.1%) donated two units. Majority of the patients (56.4%) had the surgery at the Korle-Bu Teaching Hospital. Of the donations, 21 (3.3%), 1 (0.2%), 1 (0.3%) and nil were positive for HBV, HIV I & II, HCV and VDRL respectively. A total of 848 (89.4%) autologous cross-matched units were issued out. There was a steady progressive increase in participation. In conclusion, mainly adult females scheduled for gynaecological surgeries in Korle-Bu Teaching Hospital participated, while almost equal proportions donated one or two units of blood which meets the blood needs of most elective surgeries. Therefore healthy patients going for elective surgeries in regions with limited blood supply must be encouraged to enter a Pre-operative autologous blood donation Programme. Further studies in this field should evaluate motivational factors for participation. **Editors' note: Autologous blood transfusion, storing your own blood ahead of time in case you will need it for an elective surgical procedure, has obvious advantages for the individual but is controversial in many settings because of its potential to undermine emergency blood services if it draws resources away from them.**

Stramer SL. Current risks of transfusion-transmitted agents: a review. *Arch Pathol Lab Med* 2007;131:702-7.

Infectious disease testing has dramatically improved the safety of blood for transfusion in the United States, especially since the introduction in 1999 of nucleic acid amplification testing. In 2004, methods (primarily culturing) for detecting bacteria in platelets were also added. Stramer's objective is to provide current risk estimates for the likelihood of viral transmission by test-negative blood components and to illustrate the safety improvements since the introduction of bacterial testing of platelets. The author's data sources are published literature from 1999 through 2006 and unpublished American Red Cross data sources. The author concludes that the risk of human immunodeficiency virus and hepatitis C virus transmission through blood transfusion since the introduction of nucleic acid amplification testing is approximately 1 in 2 million. Hepatitis B virus risk, for which nucleic acid amplification testing is not performed routinely, remains at 1 in 200,000 to 500,000 using a combination of anti-hepatitis B core and hepatitis B surface antigen testing. Seven cases of transfusion-transmitted West Nile virus have been reported since the introduction of nucleic acid amplification testing in 2003, but none has been reported since system-wide implementation of processes to increase the test sensitivity for use in epidemic areas. The residual risk of receiving a bacterially contaminated platelet component with clinical consequences is estimated at approximately 1 in 75,000, if culture negative and 1 in 33,000 if not tested by culture methods. **Editors' note: The risks of acquiring transfusion-associated infectious agents have dropped significantly in the USA and other countries with the resources to devote to assuring the safety of the blood supply. However, primary prevention starts by preventing accidents in the workplace, on the highway and elsewhere, as well as by reducing the prescribing of blood transfusion in hospitals unless absolutely necessary.**

2. Treatment

Tossonian HK, Raffa JD, Grebely J, Trotter B, Viljoen M, Mead A, Khara M, McLean M, Duncan F, Fraser C, Devlaming S, Conway B. Methadone Dosing Strategies in HIV-Infected Injection Drug Users Enrolled in a Directly Observed Therapy Program. *J Acquir Immune Defic Syndr* 2007 July 1; 45(3):324-7.

Tossonian and colleagues have measured methadone dose adjustments and treatment responses after nevirapine (NVP)-, efavirenz (EFV)-, ritonavir-boosted lopinavir (LPV/r), or atazanavir (ATV; with or without ritonavir)-based highly active antiretroviral therapy (HAART) was initiated in injection drug users (IDUs). The authors identified 120 IDUs receiving HAART and methadone within a directly observed therapy (DOT) program. Follow-up was according to clinical standards, with changes in methadone dose being made as required to achieve clinical stabilization within the first 3 months of HAART. Their results showed that the observed median methadone dose changes from baseline were 20 mg/d ($P < 0.001$) in patients on NVP, with 32 (86%) of 37 patients requiring daily dose increases, and 7.5 mg/d ($P = 0.004$) in patients on EFV, with 11 (61%) of 18 patients requiring daily dose increases. Conversely, median changes were 0 mg/d for patients on LPV/r ($P = 0.56$) or ATV ($P = 0.95$). Virologic suppression (HIV RNA <400 copies/mL) was achieved in 26 (70%) of 37, 12 (67%) of 18, 25 (76%) of 33, and 24 (75%) of 32 patients receiving NVP-, EFV-, LPV/r-, and ATV-based regimens, respectively ($P = 0.89$). The authors concluded that although methadone-based DOT can be a successful tool for the co-administration of HAART, careful monitoring is required to ensure that methadone withdrawal does not adversely affect the goals of treatment, particularly when non-nucleoside reverse transcriptase inhibitors are used. **Editors' note: Monitoring the need for an increase in methadone dosage is clearly required for patients being started on nevirapine or efavirenz. The majority of drug substitution patients placed on these antiretroviral medications will require an adjustment of methadone dose to achieve good drug substitution cover and improve the likelihood of antiretroviral drug adherence and viral suppression.**

Tirwomwe JF, Rwenyonyi CM, Muwazi LM, Besigye B, Mboli F. Oral manifestations of HIV/AIDS in clients attending TASO clinics in Uganda. *Clin Oral Investig* 2007 Sep;11(3):289-92.

The objective of the study is to establish the prevalence of oral manifestations and their influence on oral functions. A total of 514 subjects aged 18 to 58 years (mean 42 years) were randomly recruited from five *The AIDS Support Organization (TASO)* clinics in Uganda. They were clinically examined for oral lesions under field conditions by four trained dentists based on World Health Organization criteria. Women constituted 74.5% of the study population. Oral manifestations were recorded in 72% of the subjects, out of which 70% had candidiasis of pseudomembranous, erythematous, and angular cheilitis variants. Non-Hodgkin's lymphoma, atypical ulcers, necrotizing periodontitis, and hairy leucoplakia were least frequently observed in the subjects. Of those who had oral lesions ($n = 370$), 68.4% had some form of discomfort in the mouth. Tooth brushing, chewing, and swallowing were frequently associated with discomfort. Reported forms of discomfort were dry mouth, increased salivation, and burning sensation especially on taking salty and spicy foods or acidic drinks. Only 8.5% ($n = 44$) of the subjects were taking medications specifically for oral lesions, which included antifungal, antiviral, and antibacterial agents. None of the subjects were on antiretroviral therapy. Oral lesions associated with human immunodeficiency virus/acquired immunodeficiency syndrome in TASO clients is a major public health problem requiring education in recognition and appropriate management. **Editors' note: Oral candidiasis, also known as thrush, is common among people living with HIV in Uganda**

attending TASSO clinics. Identifying the problem and treating it is important as eventually the pain and discomfort do affect eating and eventually nutritional status.

3. *Injecting Drug Use and HIV prevention*

Abdool, R, Sulliman FT, Dhannoo, MI. The injecting drug use and HIV/AIDS nexus in the Republic of Mauritius. *African Journal of Drug & Alcohol Studies, Special Issue: Substance Abuse and HIV/AIDS in Sub-Saharan Africa* 2006;5.

<http://www.sahealthinfo.org/admodule/afrjourinjecting2006.pdf>

Mauritius has the highest per capita injection drug use in Africa and, in the last 6 years, injecting drug use has become the main mode of HIV transmission. To report on the drug use, high risk injection practices, and high risk sexual behaviour among imprisoned injecting drug users (IDUs), sex-worker IDUs, and non-prisoner, non-sex worker IDUs, Abdool and colleagues drew data and findings from a 2004 rapid assessment of drug use in Mauritius, and from the Mauritius Epidemiological Network on Drug Use, the AIDS Unit at Ministry of Health; and the Mauritius Prison Service. The findings showed that there are an estimated 17,000-18,000 IDUs in Mauritius of whom 4,800 are sex workers and 2,871 are prisoners. Prevalence of use of unsterile needles among IDUs is estimated at 25-50%, and 75-90% of IDUs report using condoms "seldom" or "never." Mauritius is facing a serious concentrated HIV epidemic among IDUs. The Mauritius government, through bilateral and multi-lateral collaboration, is making considerable progress in providing comprehensive services for people living with HIV/AIDS. Strengthening prevention interventions targeting IDUs will be critical to addressing this emerging epidemic. **Editors' note: Although heterosexual transmission is generally the most common mode of HIV transmission in sub-Saharan Africa, injecting drug use is on the rise in Mauritius and other countries. The peer reviewed papers in this supplement review research findings from seven countries—Kenya, Mauritius, Nigeria, Rwanda, South Africa, Tanzania, and Zambia on injecting and non-injecting drug use and on alcohol misuse, and their links to HIV transmission. The issue, which should help inform policy and programmes addressing drug- and alcohol-related HIV risks, is freely available at <http://www.sahealthinfo.org/admodule/journal52006.htm>**

4. *Human resources for health*

Mullan F, Frehywot S. Non-physician clinicians in 47 sub-Saharan African countries. *Lancet* 2007; [Epub ahead of print].

Many countries have health-care providers who are not trained as physicians but who take on many of the diagnostic and clinical functions of medical doctors. The authors identified non-physician clinicians in 25 of 47 countries in sub-Saharan Africa, although their roles varied widely between countries. In nine countries, numbers of non-physician clinicians equalled or exceeded numbers of physicians. In general non-physician clinicians were trained with less cost than were physicians, and for only 3-4 years after secondary school. All non-physician clinicians did basic diagnosis and medical treatment, but some were trained in specialty activities such as caesarean section, ophthalmology, and anaesthesia. Many non-physician clinicians were recruited from rural and poor areas, and worked in these same regions. Low training costs, reduced training duration, and success in rural placements suggest that non-physician clinicians could have substantial roles in the scale-up of health workforces in sub-Saharan African countries, including for the planned expansion of HIV prevention and AIDS treatment programmes. **Editors' note: "Clinical Officers" rather than physicians are providing care on the frontlines directly to patients in many countries throughout sub-**

Saharan Africa, meaning that task shifting has already been underway for many years. As work proceeds to examine provider roles, patients' needs, and rational deployment of human resources for health, the potential of clinical officers is receiving increasing attention.

Van Damme W, Kheang ST, Janssens B, Kober K. How labour intensive is a doctor-based delivery model for antiretroviral treatment (ART)? Evidence from an observational study in Siem Reap, Cambodia. *Hum Resour Health* 2007;5:12.

Funding for scaling-up antiretroviral treatment (ART) in low-income countries has increased substantially, but the lack of human resources for health (HRH) is increasingly being identified as an important constraint for scaling-up ART. In a clinic run by Médecins Sans Frontières in Siem Reap, Cambodia, Van Damme and colleagues documented the use of doctor-time for ART in September 2004 and in August 2005, for different phases in ART (pre-ART, ART initiation, ART follow-up Year 1, & ART follow-up Year 2). Based on these observations and using a variety of assumptions for survival of patients on ART (between 90 and 95% annually) and for further reductions in doctor-time per patient (between 0 and 10% annually), the authors estimated the need for doctors for the period 2004 till 2013 in the Siem Reap clinic, and in a hypothetical district in sub-Saharan Africa. In the Siem Reap clinic, the authors found that from 2004 to 2005 the doctor-time needed per patient was reduced by between 14% and 33%, thanks to a reduction in number of visits per patient and shorter consultation times. In 2004, 2.06 full-time equivalent (FTE) doctors were needed for 522 patients on ART, and in 2005 this was slightly reduced to 1.97 FTE doctors for 911 patients on ART. By 2013, Siem Reap clinic will need between 2 and 5 FTE doctors for ART. In a district in sub-Saharan Africa with 200,000 inhabitants and 20% adult HIV prevalence, using a similar doctor-based ART delivery model, between 4 and 11 FTE doctors would be needed to cover 50% of ART needs. The authors conclude that ART is labour intensive. Important reductions in doctor-time per patient can be realized during scaling-up. The doctor-based ART delivery model analysed seems adequate for Cambodia. However, for many districts in sub-Saharan Africa a doctor-based ART delivery model may be incompatible with their HRH constraints. **Editors' note: Physician time considerations in resource constrained settings should prompt consideration of alternate delivery models for scale-up, involving clinical officers, nurse practitioners, nurses and community adherence and support counsellors, among others. Determining the best utilisation of available human resources is a key to achieving favourable outcomes for patients and their families.**

5. Men who have sex with men

Dodds JP, Johnson AM, Parry JV, Mercey DE. A tale of three cities: persisting high HIV prevalence, risk behaviour and undiagnosed infection in community samples of men who have sex with men. *Sex Transm Infect* 2007 Aug;83(5):392-6.

Dodds and colleagues' study objectives were to examine geographical variations in HIV prevalence (diagnosed and undiagnosed), sexual health service use, sexually transmitted infections and sexual behaviour in a community sample of men who have sex with men (MSM) in three cities in England, specifically London, Brighton and Manchester. The authors used cross-sectional surveys of men visiting gay community venues in three large cities in England. Men self-completed a questionnaire and provided an anonymous oral fluid sample for HIV antibody testing. The results showed that HIV prevalence ranged from 8.6% to 13.7% in the three cities. Over one third of HIV infections remained undiagnosed in all sites despite 69%

of HIV positive men reporting attending a Genito-Urinary Medicine (GUM) clinic in the last year. Similar and high levels of risk behaviour were reported in all three cities. 18% of negative men and 37% of positive men reported unprotected anal intercourse (UAI) with more than one partner in the last year. 20% of negative men and 41% of positive men reported an STI in the last year. The authors concluded that across all cities, despite widespread availability of anti-retroviral treatment (ART) and national policy to promote HIV testing, many HIV infections remain undiagnosed. Data from this community sample demonstrate high levels of risk behaviour and STI incidence, especially among those who are HIV positive. Renewed efforts are needed to increase diagnosis and reduce risk behaviour to stem the continuing transmission of HIV. **Editors' note: This tale speaks volumes about the need for serious rethinking about effective prevention in the community of men who have sex with men in England. For a start, the fact that so many HIV infections are unrecognised suggests that introduction of provider-initiated offers of HIV testing and counselling in sexually transmitted disease clinics could go a long way to reducing the number of undiagnosed infections.**

6. *Research ethics*

MacQueen KM, Namey E, Chilongozi DA, Mtweve SP, Mlingo M, Morar N, Reid C, Ristow A, Sahay S, Hptn T, Team SO. Community perspectives on care options for HIV prevention trial participants. *AIDS Care* 2007;19:554-60.

There is on-going global debate and policy-setting concerning researchers' obligations to meet the health needs of people participating in HIV prevention trials in resource-poor settings. The perspectives of local community stakeholders on this issue are poorly understood as most of what is presented on behalf of communities where research takes place is anecdotal commentary. Using qualitative methods (130 in-depth interviews and 20 focus groups) MacQueen and colleagues assessed perceived fairness of different strategies to meet the health needs of women who become HIV-infected during a hypothetical vaginal microbicide trial. Respondents included HIV prevention research participants, community stakeholders and health-care service providers in ten sites in seven countries (South Africa, Malawi, Tanzania, Zimbabwe, Zambia, India, US). Many respondents perceived referrals to be a potentially fair way to address care and treatment needs but concerns were also voiced about the adequacy of local health-care options and the ability of trial participants to access options. Most respondents viewed the provision of antiretroviral treatment by researchers to HIV-infected trial participants as unfair if treatment was not sustained beyond the end of the trial. The results underscore the importance of effectively linking trial participants to sustainable, community-based treatment and care. **Editors' note: This formative research with women in ten communities in Africa, India and the USA informed policy, not only at Family Health International, but among other research and community partners around the world. More information on the issues of standard of prevention and access to care is available from UNAIDS through two publications: Ethical considerations for biomedical HIV prevention trials and Good Participatory Practices in biomedical HIV prevention trials.**

Tarantola D, Macklin R, Reed ZH, Kieny MP, Osmanov S, Stobie M, Hankins C. Ethical considerations related to the provision of care and treatment in vaccine trials. *Vaccine* 2007 Jun 21;25(26):4863-74.

Ethical principles of beneficence and justice combined with international human rights norms and standards create certain obligations on researchers, sponsors and public health authorities. These include treatment provision for participants enrolled in clinical trials of vaccines, drugs and other new preventive and curative technologies and methods. However, these obligations are poorly defined in practical terms, inconsistently understood or inadequately applied. Vaccine clinical trial designs normally define standards of prevention applicable to the population where the trial is to take place. The present document addresses specifically the setting of standards applicable to care and treatment in vaccine trials. The lack of clear guidance on how to achieve the optimal synergy between the development of new health technologies, on the one hand, and the promotion and protection of ethical and human rights principles, on the other, is a barrier to the progress of health research and therefore to the advancement of public health. The World Health Organization and UNAIDS have engaged in a series of consultations in Africa, the Americas, Asia and Europe to reflect on how this aim could best be achieved. This document highlights the outcome of these consultations. It proposes a structured approach to consensual decision making in the context of the clinical trial of vaccines against such public health challenges as HIV and newly emerging or threatening epidemics. A structured approach involving investigators and sponsors in a consultative process with trial communities and other stakeholders in research will ensure that the needs and legitimate expectations of trial participants are appropriately met, obligations towards them are delivered and, as a result, ethical research is facilitated in the interest of public health. **Editors' note: Who will provide and who will pay for the treatment and care of people who become infected during a biomedical HIV prevention trial has been hotly debated now for ten years. UNAIDS in collaboration with WHO has revised Ethical considerations for biomedical HIV prevention trials and in collaboration with the AIDS Vaccine Advocacy Coalition, and a Working Group with diverse membership, has created Good Participatory Practices in biomedical HIV prevention trials. Both of these documents make it clear that providing access to antiretroviral treatment for those who seroconvert in an HIV prevention trial is the accepted standard.**

7. Basic Science

Nickle DC, Rolland M, Jensen MA, Pond SL, Deng W, Seligman M, Heckerman D, Mullins JI, Jovic N. Coping with viral diversity in HIV vaccine design. *PLoS Comput Biol* 2007;3:e75.

The ability of human immunodeficiency virus type 1 (HIV-1) to develop high levels of genetic diversity, and thereby acquire mutations to escape immune pressures, contributes to the difficulties in producing a vaccine. Possibly no single HIV-1 sequence can induce sufficiently broad immunity to protect against a wide variety of infectious strains, or block mutational escape pathways available to the virus after infection. The authors describe the generation of HIV-1 immunogens that minimizes the phylogenetic distance of viral strains throughout the known viral population (the center of tree [COT]) and then extend the COT immunogen by addition of a composite sequence that includes high-frequency variable sites preserved in their native contexts. The resulting COT(+) antigens compress the variation found in many independent HIV-1 isolates into lengths suitable for vaccine immunogens. It is possible to capture 62% of the variation found in the Nef protein and 82% of the variation in the Gag protein into immunogens of three gene lengths. The authors put forward immunogen designs that maximize representation of the diverse antigenic features present in a spectrum of

HIV-1 strains. These immunogens should elicit immune responses against high-frequency viral strains as well as against most mutant forms of the virus. **Editors' note: These scientists are using computer programmes to design immunogens that could be used in vaccines to stimulate immune responses against a broad array of HIV-1 strains, including mutated strains. This is one of many different avenues being explored in the race/marathon to find an effective HIV vaccine.**

8. Policy development

Oxman AD, Lavis JN, Fretheim A. Use of evidence in WHO recommendations. *Lancet* 2007 Jun 2;369(9576):1883-9.

WHO regulations, dating back to 1951, emphasise the role of expert opinion in the development of recommendations. However, the organisation's guidelines, approved in 2003, emphasise the use of systematic reviews for evidence of effects, processes that allow for the explicit incorporation of other types of information (including values), and evidence-informed dissemination and implementation strategies. Oxman and colleagues examined the use of evidence, particularly evidence of effects, in recommendations developed by WHO departments. The authors interviewed department directors (or their delegates) at WHO headquarters in Geneva, Switzerland, and reviewed a sample of the recommendation-containing reports that were discussed in the interviews (as well as related background documentation). Two individuals independently analysed the interviews and reviewed key features of the reports and background documentation. The authors found that systematic reviews and concise summaries of findings are rarely used for developing recommendations. Instead, processes usually rely heavily on experts in a particular specialty, rather than representatives of those who will have to live with the recommendations or on experts in particular methodological areas. The authors interpreted in this that progress in the development, adaptation, dissemination, and implementation of recommendations for member states will need leadership, the resources necessary for WHO to undertake these processes in a transparent and defensible way, and close attention to the current and emerging research literature related to these processes. **Editors' note: This article received a lot of attention in public health circles. Although there are often difficulties in trying to obtain international consensus, it is clear that guidelines from normative agencies such as WHO need to be adapted by countries to their own epidemiological circumstances. For the record, the recommendations from the WHO/UNAIDS convened consultation on male circumcision and HIV in March 2007 were definitely anchored in the results of the three randomised controlled trials in Orange Farm, South Africa; Kisumu, Kenya; and Rakai District, Uganda but other evidence and information also came into play and influenced the recommendations (please see the UNAIDS website or WHO website).**

That was *HIV This Week*, signing off.

Editors' notes on journal access

For readers in all countries:

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For articles available through ScienceDirect, you should follow the link <http://www.sciencedirect.com/> to the ScienceDirect website. Then, type in the title of the journal for which you are searching.

Some journals are open access, available to readers in all countries: American Medical Association journals (<http://pubs.ama-assn.org/>), American Society of Clinical Oncology (2 journals), Australian Medical Association (1 journal), BioMed Central journals (<http://www.biomedcentral.com/>), BMJ journals (<http://journals.bmj.com/>), Canadian Medical Association (1 journal), Nature Publishing Group journals (<http://www.nature.com/>), Public Library of Science journal (<http://medicine.plosjournals.org/>) and Science (1 journal).

Other journals offer free access to full-text articles after a certain period of time (see lists at High Wire Press <http://highwire.stanford.edu/lists/freeart.dtl> and PubMed Central <http://www.pubmedcentral.nih.gov/>).

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