

Clinical Review

Clinical Review identifies issues in the medical literature of interest to clinicians in Africa. Essential references are given at the end of each section

Medicine Review

More on sleeping sickness

In these columns, we recently reported on interesting research concerning the drug eflornithine for African trypanosomiasis (sleeping sickness).¹ This research showed the drug to be at least as effective as traditional melarsoprol, but much less toxic. A disadvantage, however, is that eflornithine needs to be administered every 6 hours, by slow intravenous infusion, for 14 days. A new trial has, however, just been reported that suggests that a simpler but equally effective management system may now be available. This is 'nifurtimox-eflornithine combination therapy' (NECT), and the trial has (like the initial research) been led by and funded by Médecins sans Frontières (MSF).²

The trial has compared standard eflornithine treatment (6-hourly slow infusion for 14 days) with simplified shorter-course eflornithine (12-hourly infusions for 7 days) in combination with oral nifurtimox (once-daily for 10 days). Nifurtimox is a trypanosomicide which is too weakly active for monotherapy. The study was multi-centre and randomised, with 143 patients in each treatment arm. All had stage 2 (neurological involvement) Gambian sleeping sickness. Patients were followed up for 18 months after treatment.

Mortality results showed that 131 (91.6%) of eflornithine-treated patients were cured at 18 months, compared with 138 (96.5%) in the NECT-treated group. Side-effects were common in both groups, but significantly lower in the NECT-treated patients (29% versus 14%).

This was a well-planned and conducted study, with a rigorous 'non-inferiority' design. The results are very encouraging, and it is worth noting that even if losses to follow-up turned out to be treatment failures, the analysis would show that NECT is not inferior to eflornithine alone.

An accompanying *Lancet* editorial calls this trial 'more than a small victory over sleeping sickness'.³ Interestingly, the World Health Organization (WHO) has already endorsed the study by putting NECT into its essential drugs list. Certainly, this new system of treatment is considerably simpler and safer (and cheaper) than eflornithine alone.

Though NECT is clearly a major advance in the treatment of human African trypanosomiasis, it is by no

means the 'last word' in its management. We urgently need improvements in treating earlier stages of the disease (haemolympathic or stage 1). It must also be accepted that the recent eflornithine-based trials have been confined to Gambian sleeping sickness only, not the more severe and problematic Rhodesian form. Finally, even though we are finally moving away from melarsoprol, treatment side-effects still remain a problem. Seizures and marrow suppression are the most important adverse effects of eflornithine, though they appear to be dose-related as problems are significantly lower with NECT (which uses half the dose of eflornithine when the latter is used alone).

MSF can be thanked and congratulated on this excellent and highly important clinical trial, which is likely to lead to a major and lasting change in the management of African trypanosomiasis.

Costs of medical care in africa

The financing of healthcare varies enormously around the world, and is a source of much debate and controversy. Even in well-resourced Western countries there are wide differences – for example the United Kingdom (UK) has a free health system (though funded by taxation, of course), whereas in the United States of America (USA) healthcare mostly depends on private insurance. In developing countries either system has its problems – taxation is usually inefficient to cover even basic healthcare needs, and few people can afford private healthcare or medical insurance. Most African countries have partially funded their health systems centrally, and supplemented this with 'user fees' – a payment made by patients at their point of health contact. Though apparently sensible, this system has been highly problematic. Setting the user fee level is itself very difficult, and raises issues of whether the fee should be 'means tested' (i.e. higher for the better-off, and lower for the poor). Most countries have tried to exempt certain groups from payment – for example the very poor, and often children and pregnant women. Again, setting exemption criteria is difficult and divisive. Finally, administration of the user fee system is complex, so much so that in some African countries the income from user fees is entirely needed to administer the system!

Some African countries have responded to these problems by simply removing user fees altogether – for example fees have been removed wholly or partially in Uganda, Zambia, Niger, Kenya, Lesotho, and Ghana. Not surprisingly, outpatient attendances have increased in such countries – an approximate doubling since 2001. This is good for healthcare in general, but of course has put a strain on existing health services. However, an unexpected but welcome effect of user fee removal has been interest from Western financial support agencies – a number of whom have increased aid to resource-poor countries that have removed user fees.

A recent *Lancet* article on this interesting subject⁴ recommends that all African countries that still have user fees, should as soon as possible remove them for children and pregnant women (this is the usual 'partial removal' option), and set an agenda to move towards total user fee removal.

Stroke in Arica

Stroke is an important, common, and debilitating problem in Africa; yet it is rarely the subject of clinical research. A paper from Port Harcourt in Nigeria is, therefore, very welcome.⁵ The researchers carried out a notes review of 202 consecutive adults admitted with stroke over a 3-year period. Stroke patients constituted 9.3% of all medical admissions, their mean age was 63±14 years (±1 SD) and the male-to-female ratio was approximately equal (1.0:1.2). The commonest risk factor by far was hypertension (91%) – others included diabetes (24%), hyperlipidaemia (10%), alcohol excess (8%), and obesity (7%). HIV infection, atrial fibrillation, and smoking were relatively rare (<1%). On clinical grounds, 67% of strokes were ischaemic and 28% haemorrhagic. There was an overall 33% mortality.

This study confirms that stroke is common in Africa – making up 1 in 10 of all medical admissions. Almost all patients are hypertensive, and we know from other studies that the majority have poorly controlled blood pressure (BP) levels. Stroke is a major cause of disability in Africa, and it represents a burden to individuals, their families, and healthcare providers. Screening for hypertension and its adequate treatment would greatly reduce the prevalence of this problematic disorder.

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Paediatrics Review

Time of childhood vaccinations

When one examines vaccination data it is often presumed that immunisation has been given at the correct time. This may not be so.

A study of time of vaccination was undertaken using demographic and health survey methods in 45 low- and middle-income countries for years 1996–2005 (median 2002).¹ Most of the countries were African, seven were from Central and South America and a few were from Asia, including India. Documented information was available from vaccination cards for only 68% of vaccinations.² The remainder was obtained through mothers' interviews and estimates. Twenty-eight countries used the standard WHO schedule (American

countries differ slightly from WHO recommendations). The WHO schedule is Bacillus Calmette-Guérin (BCG) at birth (lowest and highest target: birth–8 weeks), diphtheria–pertussis–tetanus (DPT)/polio 6 weeks (4 weeks–2 months), 10 weeks (8 weeks–4 months), 14 weeks (12 weeks–6 months), and measles 9 months (38 weeks–12 months).

Overall, median BCG coverage increased from 49% at 4 weeks to 89% at 12 months, DPT1 from 57% at 12 weeks to 82% at 6 months, and measles 54% at 12 months to 82% at 3 years. Only 12% received measles vaccine at 9 months. Countries with generally very high coverage included Egypt, Peru, Rwanda, and Kyrgyz Republic and low rates were recorded for Chad, Nigeria, and the Yemen. However, in 75% of countries, one-quarter of children had delays of only around a week for BCG, DPT1, and measles. Chad, Cambodia, Mali, Mauritania, and Niger both had consistently long delays before vaccination and poor coverage rates. Delays were generally longer in rural than urban areas.

Although for some vaccines late vaccination may have the advantage of improved immune response when the child has developed a more mature immune system, there are disadvantages. In an HIV-infected child the earlier the vaccination the more likely they will produce an adequate immune response before there is a decline in immune function, e.g., Hib, conjugated pneumococcal, and measles vaccines. In HIV-infected women, placental transfer of measles antibodies may be impaired.³ Thus, for HIV-infected children, measles vaccine is advised at 6 and 9 months. An HIV-seropositive child is more likely to be born into a family with tuberculosis and thus for protection BCG must be given if possible before contact. Conversely, if a child is known to be HIV-infected, BCG is now no longer advised. However, there are practical implications when HIV-DNA polymerase chain reaction (PCR) for early diagnosis is unavailable.⁴ HBV vaccination should be given within 7 days of birth and is advised to be administered along with BCG.² Three doses of pertussis vaccination are required to provide reasonable defence against whooping cough but the highest mortality is within 6 months of birth, so timely vaccination is essential to provide adequate protection.

Currently, rotavirus vaccination is given along with DPT, so a delay in DPT vaccination would be likely to result in delayed rotavirus vaccination at a time when the infant is most vulnerable to gastroenteritis, especially when it is weaned. Although intussusception has not been connected with the two new rotavirus vaccines, Rotarix (GSK) and RotaTreq (Merck), because of its previous association with the RotaShield (Wyeth-Ayerst) vaccine it is advised that the first dose of current rotavirus vaccines should not be given later than 12 weeks.⁵

Thus families should be advised about the importance of having their children vaccinated at the correct time.

Sexual violence of children and young women

Sexual abuse of girls and young women has been known probably since the beginning of time but unfortunately mainly ignored or condoned until relatively

recently. The same could be said of physical abuse of children. However, subtle types of the latter in the form of fractures and intracranial haemorrhage have only been recognised since around the 1960/1970s when paediatricians and paediatric radiologists developed expertise in this field, which was further enhanced when brain imaging became readily available.

The diagnosis of physical abuse, especially the subtle, less overt types, is still in its infancy in many low- and middle-income countries. This is complicated by the problem of deciding what constitutes the dividing line between the right of parents to chastise their child and child abuse. In Europe this has been solved by the recent legal ban on smacking children, although this is still controversial. In general, no specific facilities other than laboratory tests (e.g. for HIV and other sexually transmitted infections (STIs) are required for management of sexual abuse and thus there is no excuse for ignoring this common problem in any part of the world today.

A large study of sexual violence in girls and young women was recently undertaken in Swaziland.⁶ Information was obtained from 1244 women and girls aged 13–24 years (response rate 96%). One-third of respondents reported sexual violence of various forms before 18 years of age. More than a third of subjects were orphans; only 10% were married and the majority of incidences occurred in rural areas. The main types of sexual violence were attempted unwanted intercourse (43%), coerced intercourse (15%), forced intercourse (10%), and unwanted touching of respondent or perpetrator (32%). Perpetrators included: a man or boy from the same neighbourhood (32%), boyfriend or husband (26%), male relative (other than father, stepfather, or husband (14%), stranger (13%) and school teacher (3%). The location of the incident occurred in the home (26%), a public place or the veldt (23%), house of friend, relative, or neighbour (20%), school (13%), and on journey to and from school (12%). Alcohol or drug abuse by the perpetrator was suspected in a third of cases.

Sexual violence was associated with STIs, pregnancy complications, unwanted pregnancy, and depression. The adult HIV prevalence in Swaziland is currently 26% which puts victims at particular risk in sexual abuse.⁷

The Lihlombe Lekukhalela (shoulder to cry on) community-based programme was established in Swaziland in 2002.⁷ Major roles include education (especially children) about forms of abuse and linkage to HIV/AIDS, to provide counselling for abused people and refer traumatised children for support.

In many low-income countries post-rape care services are poorly developed. There is limited access to medical, legal, and social support services and particularly a deficiency of post-exposure prophylaxis (PEP) against HIV infection. In 2003 the Liverpool VCT, Care and Treatment Kenyan NGO established services for post-rape care in three districts of Kenya (Thika, Malindi, and Rachuonyo).⁸ This included a wide range of facilities in the respective emergency departments, viz. emergency contraception, empirical STI treatment and two-drug HIV PEP. Police were involved and had to sign for any specimens removed. Post-rape counselling

services were provided on the VCT sites. By the end of 2007, 784 survivors of sexual violence had been seen in the three sites of whom 84% arrived in time to be eligible for PEP. Forty-three per cent of survivors were children under 5 years. The average cost per patient was US\$27.

In 2005 the Kenyan Division of Reproductive Health instituted national guidelines for medical management of rape and sexual violence. By June 2007 services were delivered to 2000 adults and children, of whom 96% of those eligible received PEP.⁸

The success of these programmes should encourage other low-income countries to invest in post-rape management and care services.

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Africa HEALTH CPD Challenge
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STI Review

Male circumcision and sexually transmitted infections

There is now strong evidence that male circumcision reduces acquisition of HIV among heterosexual men. Results from several randomised controlled studies conducted in South Africa, Uganda, and Kenya between 2002 and 2006 found that circumcised men had greater than a 50% reduced risk of acquiring HIV following circumcision.¹ In March, 2007, the World Health Organisation/UNAIDS recommended that male circumcision be promoted as part of a comprehensive HIV-prevention package in countries with a high prevalence of HIV infection, a low prevalence of male circumcision, and high acceptance of male circumcision. UNAIDS has calculated that one HIV infection is averted for every 5–15 male circumcisions.²

There is growing evidence that male circumcision also reduces the risk of other sexually transmitted infections (STIs). In a male circumcision trial in Orange Farm, South Africa, the prevalence of high-risk human papillo-

mavirus (HPV) genotypes among men aged 18–24 years was 14.8% among circumcised men and 22.3% among the control group.³ Adjusting for possible confounding based on sexual behaviours and condom use did not affect the outcome. Data from another randomised controlled trial of male circumcision for HIV prevention in Rakai, Uganda show that male circumcision significantly reduces the incidence of herpes simplex virus type 2 (HSV-2) infection and the prevalence of HPV infection.⁴ After 24 months, the cumulative probability of HSV-2 seroconversion among males aged 1–49 years was 7.8% among circumcised males and 10.3% among the control group. The prevalence of high-risk HPV genotypes was 18.0% among the circumcised group and 27.9% in the control group. However, the study found no difference between the two groups in incidence of syphilis.

Another study confirms the synergy between HIV and HSV-2 infections, and the protective effect of male circumcision. Using data collected during the Orange Farm, South Africa male circumcision trial, mathematical modelling showed that HSV-2 infection in either partner increased the female-to-male transmission probability of HIV three-fold (relative risk of 3.0, 95% Confidence Interval (CI): 1.01–7.3). HIV infection in either partner increased the female-to-male transmission probability of HSV-2 two-and-a-half times (relative risk of 2.5; 95% CI: 1.1–6.3).⁵ The study also demonstrated that male circumcision significantly decreased the relative risks of HIV transmission (relative risk of 0.24; 95% CI: 0.11–0.44) and of HSV-2 transmission (relative risk of 0.59; 95% CI: 0.36–0.91) among young men. Another analysis of the Orange Farm, South Africa data indicated that HSV-2 infection enhanced and was responsible for about 25% of new HIV infections among young men.⁶

The effect of male circumcision on transmission of other STIs is less clear. Analysis of the Orange Farm, South Africa data show that male circumcision reduces *Trichomonas vaginalis* infection among men, but not *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.⁷ However, male circumcision appeared to have no effect on the incidences of *N gonorrhoeae*, *C trachomatis*, or *T vaginalis* infection among men in the Kenya circumcision trial.⁸

Data on the effect of male circumcision on female partners and their risks of STIs are also mixed. Previous studies have indicated that male circumcision decreases the rate of cervical cancer in female partners. Pooled data from 1913 couples showed that cervical cancer was less than half as common among monogamous women with circumcised, non-monogamous male partners than among women whose non-monogamous partners were uncircumcised.⁹ Analysis of data from three observational studies in Uganda, Zimbabwe, and Thailand found that male circumcision was not associated with women's risks of acquiring *N gonorrhoeae*, *C trachomatis* or *T vaginalis*.¹⁰ However, the female partners of circumcised men in the Rakai, Uganda male circumcision trial had reduced risks of genital ulcer disease, trichomonas, and bacterial vaginosis.¹¹ Female partners of men in the intervention group (circumcision group) reported lower rates of genital ulceration (12.8%) than female partners of men in the control group (non-

circumcised) (16.8%). Prevalence of trichomonas was also lower among women with circumcised partners (5.9%) than among women with uncircumcised partners (11.2%). Bacterial vaginosis was found in 40.3% of women with circumcised partners and 50.6% in those with uncircumcised partners.

While these studies show that male circumcision decreases risk on the individual level, it is not known what level of protection is provided at a population level.¹² Where heterosexual transmission of HIV is high, there are clear benefits to expanded access to safe male circumcision services. In other cases, especially where safe male circumcision services are not feasible and where heterosexual transmission of HIV is lower, the relative costs, risks, and benefits need to be evaluated. In terms of HPV, the data clearly show that male circumcision protects men from high-risk HPV infection, and further study of the Ugandan male circumcision data should provide better information on whether that translates into reduced HPV infection among primary female partners.¹³ The data on the impact of male circumcision on HPV are useful in the development of cervical cancer prevention programmes. Male circumcision may be a useful component of HPV prevention efforts, especially where HPV vaccines are not available, and to provide some protection against HPV genotypes not prevented by the vaccines.

There is still much to learn about the biological mechanisms of protection conferred by male circumcision against specific infections, the specific effects on female partners, and the resulting population levels of protection. The growing body of data confirm the protective effects of male circumcision on HIV transmission. The apparent protection against ulcerative sexually transmitted infections, and potential reductions in cervical cancer increase the public health benefits of male circumcision.

Many southern and eastern African countries are scaling up programmes to offer male circumcision. Kenya has formally adopted national policy guidelines on male circumcision, while Lesotho, Namibia, South Africa, Swaziland, and Zimbabwe all have draft policies. Botswana and Kenya have officially launched national strategies, while Swaziland, Zambia, and Zimbabwe are developing implementation plans. In Botswana, the government, has trained medical teams to do circumcisions in all its public hospitals and hopes by 2018 to have circumcised 470 000 males, or 80% of males under age 50.¹⁴

However, demand has outstripped some countries' ability to provide male circumcision procedures due to human resource shortages and lack of funding. The demand for circumcision is likely to increase and it is important to ensure the availability of safe male circumcision services, along with appropriate risk reduction counselling. As male circumcision increases, quantifying the effect on the incidence of STIs and their interactions will be crucial to STI prevention programmes in the future.

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Public Health Review

Behavioural issues in HIV/AIDS control

The HIV/AIDS epidemic is well into its third decade, and while progress has been made in treatment, the lack of a promising vaccine candidate means that for prevention we must still rely primarily on changes in human behaviour. We continue to learn lessons about individual and social behaviour as it relates to the prevention and control of HIV, as seen in recently published articles that consider factors that influence HIV-related behaviour and communication strategies that might address these factors.

Rimal et al¹ tested a conceptual model of risk perceptions on two behaviours – use of condoms and remaining monogamous. They hoped to identify perceptions that could not only influence these two behaviours, but also might be modified through health education to enhance prevention. The researchers interviewed people in Malawi, a country of 14 million people where approximately 14% of the adult population is infected with HIV. In their literature review they make it clear that previous research has not found a definite positive link in all cases between whether people think they are at risk of contracting HIV and their adopting recommended preventive behaviours. In their model they explain that we must also consider ‘efficacy beliefs,’ that is a person’s perception and confidence that he/she can actually do what is necessary to prevent the problem.

The combination of risk perceptions and efficacy beliefs creates the risk perception attitude (RPA) framework leading to four possible situations listed below:

1. high-risk perceptions coupled with strong efficacy beliefs means people are *motivated* and able to engage in self-protective behaviours;
2. risk perceptions and efficacy beliefs are both weak,

where people are described as holding *indifferent* attitudes – not motivated to take action and not feeling action would make a difference;

3. low-risk perception but strong efficacy beliefs describes people who hold a *proactive* attitude – they know they can do something, but may not if they do not see a real risk;
4. high-risk perceptions and weak efficacy beliefs describe people who hold *avoidance* attitudes and consequently do not take action.

The group’s research in Malawi wanted to add another dimension to this framework, ‘behavioural intentions.’ They draw on behavioural research that says people’s intentions are a good predictor for their actual, later performance of that behaviour. Understanding such intentions can be helpful in designing health education interventions. Therefore the key research question here was whether efficacy beliefs would have a moderating effect on risk perceptions and thus influence intentions to engage in the two preventive behaviours – condom use and monogamous relationships.

Their study found that a direct relationship between risk perception and behavioural intentions was not significant, but those between efficacy beliefs and behavioural intentions were. Furthermore, efficacy beliefs themselves were able to moderate the relationship between risk perception and intentions to remain monogamous, but not between risk perceptions and intentions to use condoms.

Much of health education focuses on increasing people’s perceptions of risk, and one might even say that health workers even try to scare the public. We can see here that perception of risk alone will not help change behaviour, and fear may even result in avoidance, hiding, or denial. The key element is providing people with the confidence that they can actually do something about the risk, and that what they may do will actually work. In this case a further important lesson is that not all behaviours are the same. Confidence and risk perception together in the Malawi context can potentially lead to modifying relationship behaviour but not so easily condom use behaviour.

The authors did find that there were key gender differences concerning condom use efficacy beliefs. Men felt more confident in their intentions to use condoms, while women did not. There are clearly power issues in relationships that must be accounted for. Overall this study helps us see that health education and communication programmes must do more than instill fear or risk beliefs. Such programmes also must be tailored to different groups such as men and women.

Health education and communication efforts often rely on the mass media, although such efforts may do more to stimulate dialogue that directly change individual behaviour. Bastien² has taken a somewhat different approach in looking at mass media, particularly popular music, as it relates to HIV communication in Tanzania. Instead of studying programmes that intentionally designed music to convey a HIV/AIDS message, she let community members help her identify popular songs that they perceived as having HIV/AIDS messages and meaning. These songs may or may not

have been stimulated by health programme planners or could have arisen from the creative impulses of the singers themselves. What was important was that young people identified the songs and described what they felt. Several key metaphors used to describe the HIV/AIDS experience include:

- electricity – people have been zapped, fallen on a wire, played with fire;
- accident – fatalism, though some singers point out that this belief is contrary to reality;
- drum–ceremonies, dance and sexual risk, a beat rippling through and infecting the population;
- insect – insidiously invading and destroying.

The lesson from Bastien's work is that health workers need to pay attention to popular culture including such metaphors used to speak and sing about HIV/AIDS. Musicians do have a wider reach than health workers when it comes to the age groups most at risk of contracting HIV. While the messages in popular songs may not always be 'medically correct,' they do represent the current dialogue where social attitudes and even individual perceptions may be shaped. Understanding how musicians talk/sing about AIDS can provide us with the metaphors that people will understand, even if we eventually modify the message conveyed through those metaphors to help protect young people.

Green and colleagues³ explain that the pattern of the HIV/AIDS epidemic reflects the nature of sexual relationships in a given setting. Understanding those relationships can help us better communicate with people about what they can do to protect themselves. They have identified five types of partnerships in southern and eastern Africa that are not necessarily discrete categories, but give us a handle on how people behave. These are listed below in relative order of increasing risk.

- Long-term mutually monogamous partnerships.
- Serial mutually monogamous partnerships.
- Regular partnerships, with one or both partners having occasional casual partners.
- Regular partnerships, with one or both partners having regular concurrent partners when this pattern is not common in the wider society.
- Regular partnerships, with one or both partners having regular concurrent partners when this pattern is common in the wider society.

The authors warn us that, 'Each of these types of partnerships requires a different type of prevention message, and effective messages must take into account the social, cultural, and economic contexts within which the partnerships exist.' For example, they point out that when ever a regular relationship exists together with other concurrent or casual relationships, it is difficult to promote condom use within the regular relationship. The authors also note that it is more difficult to end a relationship that has been going for some years than in preventing new casual relationships. We may see here the some of the factors that relate of Rimal and colleagues¹ conclusions on the potential difficulty of influencing condom use intentions.

It is also important to tie these relationship issues into the findings of Bastien's study² of popular music.

Relationships are a key theme in many popular songs. One such theme in one popular song that Bastien found was the pursuit of luxury goods and multiple partners as a way that HIV spreads.

These three studies show us that after many years we have a lot to learn in order to prevent HIV. What they emphasise is the need to learn from the community, from our clients about their perceptions, their beliefs, their relationships, and their popular culture. We must begin our health communications as a dialogue grounded in what people actually think and do. Medical knowledge about HIV/AIDS is not enough to control the epidemic.

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Africa HEALTH CPD Challenge
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