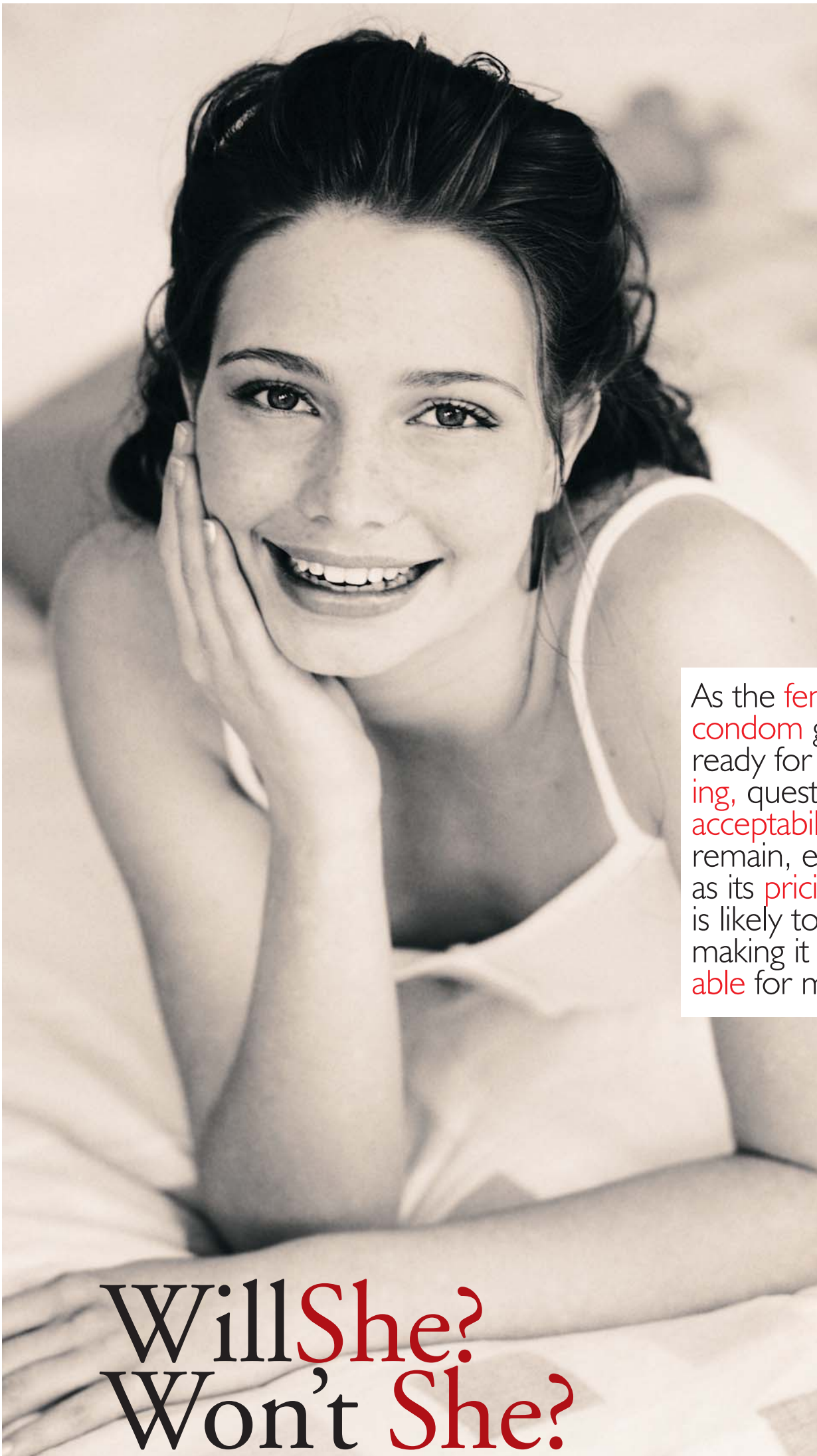


AIDS BUZZ

New Delhi June 2006

Preventive Methods Under Research



Will She? Won't She?

The first woman-initiated barrier method of HIV prevention is round the corner—any takers? By **SADHNA MOHAN** and **SHREE VENKATRAM** in New Delhi

Will the Indian woman fall for the mysterious, larger than life female condom? The proof of the pudding lies in eating and we'll know the fate of this product once it hits the market but, right now, this critical question about its potential use could be holding back its market entry.

A 'niche' product targeted at the confident woman of today, it usually appeals to women who know their bodies, want to protect their health, have used male condoms and also communicate with their partners on sexual health issues, says Patricia Weisenfeld, Asia Regional Program Manager, Female Health Foundation, an NGO established by the US headquartered Female Health Company (FHC), manufacturer of the only female health condom so far approved by the US Food and Drug Administration (FDA). Hindustan Latex Limited (HLL) made an agreement with FHC in 2001 to launch the product in India.

Does that kind of woman exist in India? Yes, says Hindustan Latex Family Planning Promotion Trust (HLFPPT), HLL's arm seeking to increase access to health products and services. And where (in women) a few gaps exist, those can be worked upon to create potential users, it adds.

So while the fiercely independent, modern, educated woman is the high-end potential customer, at the other end of the spectrum is the commercial sex worker (CSW), whose use of a self-controlled method of AIDS prevention would benefit innumerable clients and their families. Worldwide, over 5,600 women are reportedly infected with HIV every day. That works out to almost 4 women per minute, according to UNAIDS/WHO Working Group on Global HIV/AIDS and STD Surveillance.

Made of polyurethane, a clear substance that is lighter and stronger than latex, from which male condoms are made, the FHC female condom has two flexible rings; the one at the closed end is used to insert it into

the vagina. The condom lines the vagina and covers the cervix and external genitalia. It is not as constricting as the male condom and also doesn't inhibit sensation or the spread of warmth as latex does, say its promoters.

Plumping its case on the existence of potential customers, HLFPPT points out that eligible couples, CSWs and men who have sex with men (MSM) who tried the product in Andhra Pradesh, Kerala and Maharashtra in 2003 gave it a vote of confidence. An overwhelming number continued using the condom over a two-month period, the least discontinuation being reported by eligible couples, followed by MSM. Sex workers (69 per cent of them) liked using it with clients who refused the male condom or were drunk. MSM found it to be better lubricated and thicker than the male condom and therefore less prone to breakages. Apprehension and discomfort relating to its size and the process of insertion decreased with use over the trial period.

The studies brought home the importance of seeing the female condom as a programme and not a mere product. Well-trained and dedicated outreach workers who'd familiarise women with its use were going to be vital because the product's acceptability was found to be directly related to the interest the outreach workers took in the programme.

continued on page 2

As the female condom gets ready for marketing, questions of acceptability remain, especially as its pricing is likely to be high, making it unaffordable for many



Will She? Won't She?



HONEYMOON DAYS FOR FEMALE CONDOM

'Passion Ring', the suggested name for the premium-end FHC female condom, might be sold along with the male condom in 'honeymoon packs' to play up its image as a pleasure enhancer.

The plan is to promote the condom as a modern woman's accessory, a lifestyle product that she carries in her bag 'just in case'. It will be sold at beauty parlours, at women-only gyms and across cosmetic counters in supermarkets. Women will be guided on its use in a private area. On the retail shelf, it is expected to cost Rs 100 or more per piece. An aggressive ad campaign, stockists' commissions and customer 'education', etc. would hike up the price.

The Indian woman's reluctance to put things inside the body (tampons are not popular here) and poor knowledge about her body are critical issues that condom guides at retail outlets will address. Even modern, degree-holding women are not able to identify and locate the vagina or differentiate between the vagina and the urethra.

The pictorial guide on the use of the condom and female anatomy should go a long way in making a segment of Indian women more comfortable with their bodies and functioning, placing them on the road to true emancipation!

continued from page 1

Well-trained and dedicated outreach workers who would familiarise women with the product and its use are going to be vital for its success

A separate discussion with 45 independent women belonging to the rich and super rich segment in Bangalore, Chennai and Delhi organised by HLPPT soon after showed that the women were willing to carry their independence to the bedroom. They suggested the product's pleasure enhancing properties be highlighted, leading an ad agency to coin the term 'passion ring' to position and market the condom to women like them (See Box).

Why then has the product still not appeared on the scene despite several announcements about its launch? The first announcement about the condom making a presence on the retail shelf and as part of the government's health programme came at a national-level meeting of senior health ministry officials and others in Delhi in February 2004 but the launch got postponed to May 2005 and then to March 2006.

At Rs 45 a piece (rate at which it will be sold to the Indian Government) the price is prohibitive. Open market sales volumes probably aren't going to be large enough to make business sense, making it imperative to add volumes of the subsidised sector. This can be gauged from the fate of the male condom and the fact that only about one-eighth (227 million) of the 1.6 billion male condoms supplied in a year are commercially sold. The bulk (963 million) are given free and the rest are socially marketed (ORG retail audit data 2002). Therefore, getting the government to buy into the female condom programme is a major focus of the promoters at present.

According to estimates used for NACP III, there are 8,00,000 CSWs in the country. "If 10 per cent of them were to use the female condom with say two customers a day who refused the male condom or were drunk, this adds to 48,00,000 condoms a month," says Sanjeev Kumar, Head, Social Consulting Division, HLPPT, New Delhi.

Social marketing or free distribution of the female condom would involve a whopping subsidy of several crores of rupees—will the women actually use it or will the product

go waste and be used for blowing balloons as has often been reported with the male condom. The Government has to do some serious thinking.

During the trials, some women said they'd pay up to Rs 5 for the product. Sharing shelf space with the male condom that sells for less than a rupee, will the higher priced female condom have a chance of making a sale? critics wonder.

Future part manufacture of the foreign-made condom will bring down the cost to Rs 28 a piece, still out of reach for most Indians. Polyurethane is expensive and would be imported even when manufacturing begins here.

Meanwhile, a female condom developed by an Indian doctor, AVK Reddy, has come on the radar. It is being manufactured by MedTech Products, Ltd. in Chennai and is said to be a third the cost of the FHC product. The Reddy condom, made of latex, is shaped like a pouch. It has a triangular-shaped plastic stiffener attached at its open end. At insertion, the stiffener remains outside of the body and covers external genitalia. A polyurethane sponge is located at the closed end and serves to anchor the condom during intercourse.

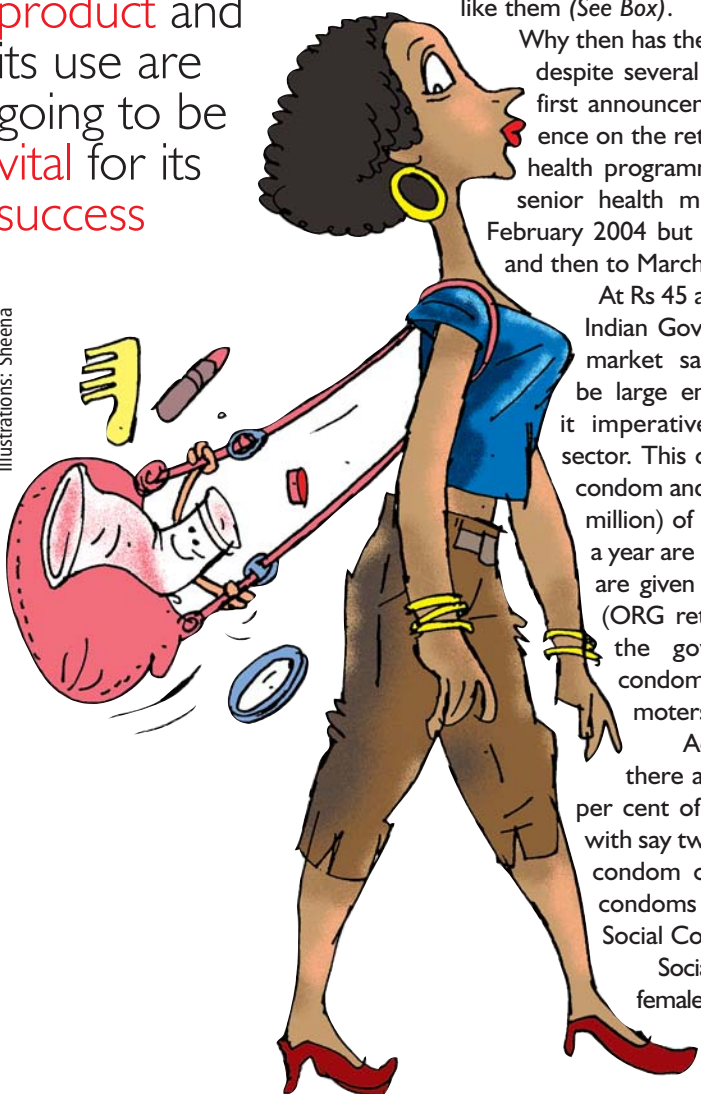
The condom has been evaluated in small studies by Contraceptive Research and Development Program (CONRAD), a cooperating agency of USAID, and Family Health International (FHI), an international NGO. DESH, an NGO in Tamil Nadu, also carried out a small pilot study among women of two slums in Chennai.

MedTech Products says the condom is being marketed in South Africa and has been approved by the Indian Drug Control Authority. Trials in the US for FDA clearance are in the final stage.

Not yet out in the Indian market, but when it is, even at Rs 12-15 a piece, it will be out of reach of middle class women. The price factor is something that will have to be addressed before the female condom takes off in the Indian market.

An order for about 5 lakh female condoms was placed with FHC by United Nations Population Fund for NACO, which will distribute the product to CSWs in four high-prevalence states, a PRNewswire-Asianet release said from Chicago on May 9, 2006.

Illustrations: Sheena



WORLD BYTES

Pope Weighs Rubber to Burn HIV

Rome: Pope Benedict XVI has asked a team of experts to prepare a statement on the use of condoms by married people who carry infectious viruses such as HIV.

Even the most cautious discussion of this subject marks an encouraging change in approach by the Vatican, which has long opposed the use of condoms under any circumstances. Although the Catholic Church opposes contraception, some liberal cardinals now argue that the fight against sexually transmitted illnesses—notably AIDS—is so pressing that the use of



condoms, in some circumstances, should not be condemned. It might be justified, for example, if the intention were not to prevent contraception but to stop the spread of a virus from husband to wife.

The Economist

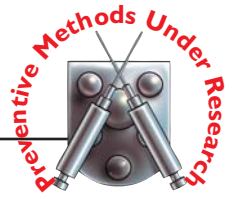
Don't Sexualise Kids: Cameron

London: David Cameron has launched an attack on High Street stores for selling 'harmful and creepy' clothes that 'sexualise' young children. The Tory leader said retailers selling high-heeled shoes, 'boob tubes', padded bras and mini skirts to girls as

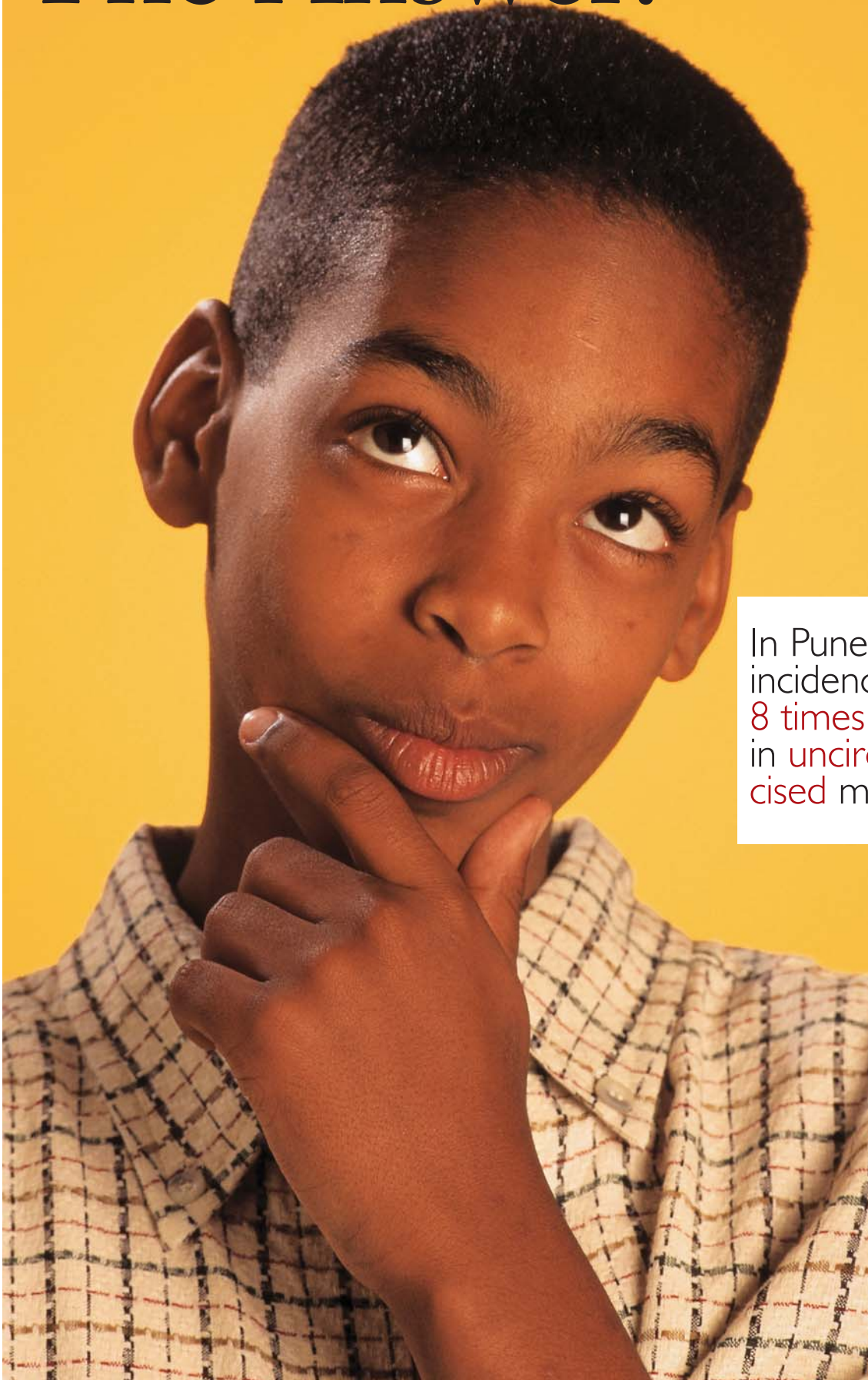


Illustrations: Sheena

Cut to Protect: Is Circumcision the Answer?



CUT TO PROTECT Is Circumcision The Answer?



In Pune, HIV incidence was 8 times higher in uncircumcised men

The case for circumcision is strong and getting stronger but will the procedure be accepted across communities, religions and races?

By **MEENA GANDHI** in New Delhi

In an outpatient department of a primary 240-bedded hospital in a rural area of Kwa Zulu Natal, South Africa, on a sleepy afternoon in 1998, I once had a conversation with a patient that went something like this:

Me: What can I do for you today?

Patient (17 year old boy): I wish to be circumcised.

Me: Why?

Patient: Because it will stop me from getting HIV infection.

Me (probably smirking): Where did you hear this? It does not protect you in this way.

Patient: It does and it will.

Me (probably irritated): Circumcision will not protect you against HIV. You can protect yourself by using condoms and being faithful.

Patient (defiant): I am not leaving this department until you give me a circumcision-I will sit here all day and I do not care what you say.

This boy was not a rich 'city-slicker', connected to the world with mobile phone and internet. Instead he came from one of the poor rural areas of Kwa Zulu Natal that had been left to decay during the apartheid years and had next to no infrastructure and an alarmingly fast rising HIV epidemic (about 15 per cent in 1998 and 42 per cent in 2002). Yet, as it turns out, the fear of this ever-advancing virus had meant that he was years ahead of me in predicting the developments to come.

The debate about circumcision and its connection to acquiring HIV started in 1986 when a Californian urologist published a paper maintaining that the foreskin 'increased infection by HIV'. Since then, numerous papers published, mainly from Africa, have explored this idea. Although appearing to show a protective effect of circumcision, most of the studies left questions unanswered or used sample sizes that were too small. Critics argued it was impossible to eliminate other reasons (confounding factors) for being susceptible to HIV, that is, was the protection due to circumcision or because the circumcised person also had less sex, drank less alcohol, did not practice risky sex and was more educated?

In 2003, Cochrane Library, well known for carrying out literature reviews on topical medical issues to provide guidance to doctors, produced a review on circumcision and HIV. The review notes "...a general failure to control all confounding factors in studies..." and concludes that "...there is insufficient evidence to recommend male circumcision to control HIV infection."

The case for circumcision has been made stronger by two recent trials—one in Pune, India, and the other in Orange Farm, South Africa. Both the trials were 'prospective', where patients were followed up over a period of time to see who developed HIV infection. Although long and expensive to carry out, this type of study is powerful in epidemiological terms.

In Pune, 2,298 men attending a sexually transmitted infection (STI) clinic, 191 of them circumcised, were followed up between 1993 and 2000. All were HIV-negative when enrolled for the study. During subsequent visits, fewer circumcised men developed HIV-1 infection. Both groups of men were similar in terms of demographics, sexual behaviour and condom use. The study concluded that the incidence rate of HIV-1 among circumcised men compared to uncircumcised

continued on page 4

young as six are harming society and robbing children of innocence.

Marketing and advertising agencies even have a name for the sexualisation—'Kids Growing Old Younger' or KGOY, he said.

The trend is blamed for contributing to Britain's soaring number of teenage pregnancies. Official figures show the number of girls aged 14 and under having abortions has topped 1,000 a year for the first time.

Daily Mail

In Tune for a Cause

New Delhi: Pakistani rock band Strings, whose song *Yeh Meri Kahani* has been a



resounding hit, has come forward in association with Indian Institute of Planning and Management's philanthropic arm "The Great Indian Dream Foundation" to promote the cause of AIDS awareness. The band recently performed in New Delhi to initiate a campaign for spreading awareness about AIDS.

Faisal Kapadia, lead vocalist of Strings, was delighted to be able to contribute to the cause and said, "We are happy to

come together for the common cause of AIDS which is a harsh reality today."

Mid-Day, New Delhi

AIDS, Now in Swahili

Mumbai: "It's not the disease that kills, it is the ignorance and stigma associated with it that do the damage," says film maker Runjiv Kapur, who has recently made a docudrama on AIDS, *Hali Halisi*—Swahili for "know the truth as it exists".

Working in Dar es Salaam in Tanzania for the past seven years as an ad film maker and photographer, Kapur has completed over 60 1-minute spots to spread the message of AIDS awareness.

DNA



Cut to Protect: Is Circumcision the Answer?

continued from page 3

men was 0.7 per cent compared to 5.5 per cent, an 8-fold difference (*Global Campaign for Microbicides News*, 3rd November 2003).

In mid 2005, a large randomised controlled trial in Orange Farm, South Africa, had to be stopped midway (after 18 months) because the compelling results showing the protective effect of circumcision made the trial no longer ethical. Over 3,000 men in this study were randomly divided into two groups, one of which was then circumcised. Both groups were similar in terms of age, religion, ethnic group, age at first sex, at-risk behaviour and many other sexual behavioural parameters.

Results showed a 60 per cent protective effect of circumcision, that is, the intervention group's chances of getting HIV were 60 per cent less than those of the non-intervention group. In all, 1.3 per cent (20 out of 1,546) and 3.1 per cent (49 out of 1,582) of those in the circumcised and non-circumcised groups, respectively, developed HIV. The authors suggest that circumcision should be considered as almost a 'vaccine' against HIV (Auvert B, *et al.* ANRS 1265

Illustrations: Sheena



Trial. *PLOS Medicine* 2005; 2: 1112-1122). The evidence is thus strong and getting stronger.

The biological explanations of this phenomenon include the fact that circumcision removes the prime site of HIV entry into the body as the foreskin has a particularly high concentration of cells susceptible to the virus (Langerhan's Target Cells). It also 'toughens' the skin at the tip of the penis, making it more resistant to HIV.

Questions still remain: will the effects be the same if people are circumcised in childhood and will this evidence lead to a rise in 'backstreet' circumcisions with their own complications? One big worry for those working in HIV is that circumcision might be seen as the answer to the entire HIV problem, leading to an increase in high risk sexual behaviour.

Long-term physical complications following circumcision have also been documented, including discomfort or pain during erections and at the scar site. Some studies report progressive sensory loss after circumcision, leading to erectile problems and difficulty with adequate stimulation during vaginal intercourse. They even suggest psychological trauma in the form of rage, resentment, depression and dependence on alcohol, drugs, food and sex.

There are some unanswered puzzles too in this story. A map of the world showing countries with their circumcision and HIV rates side by side, would quickly reveal that the two tend to go together. Countries with high circumcision rates, namely, Bangladesh and Senegal, also have remarkably low HIV rates. However, Ethiopia, which practices almost universal circumcision for men, has a rapidly spreading HIV epidemic.

Finally, the real problems may lie in the practice not the theory. Circumcision is essentially a religious ritual performed largely by Muslims and Jews. Will the practice be accepted widely in India by people of all religions? The most 'comfortable' and safest time to circumcise is in the first few weeks of life—will the whole nation be willing to carry this out on its boys to protect them much later in life?

Carrying out simple behaviour change communication can be quite complicated—is there, therefore, a hope for presenting the case for circumcision? And could it be simply a question of getting used to the idea? In the same way we've had to get used to the idea that smoking causes lung cancer and flossing teeth is a way to prevent dental caries, maybe in 20 years' time, circumcision will be as routine as getting your first polio drop when you are a few weeks old.

— with inputs from Dr Anupam Pathni

SECOND AIDS VACCINE TRIAL Begins in India

India is taking the first few steps towards developing an HIV vaccine to protect its own people. By **JAYA SHREEDHAR** in Chennai

A crumbling edifice dating back to pre-independence days greets visitors to the campus of Tuberculosis Research Centre (TRC) of Indian Council for Medical Research (ICMR), in Chennai, Tamil Nadu.

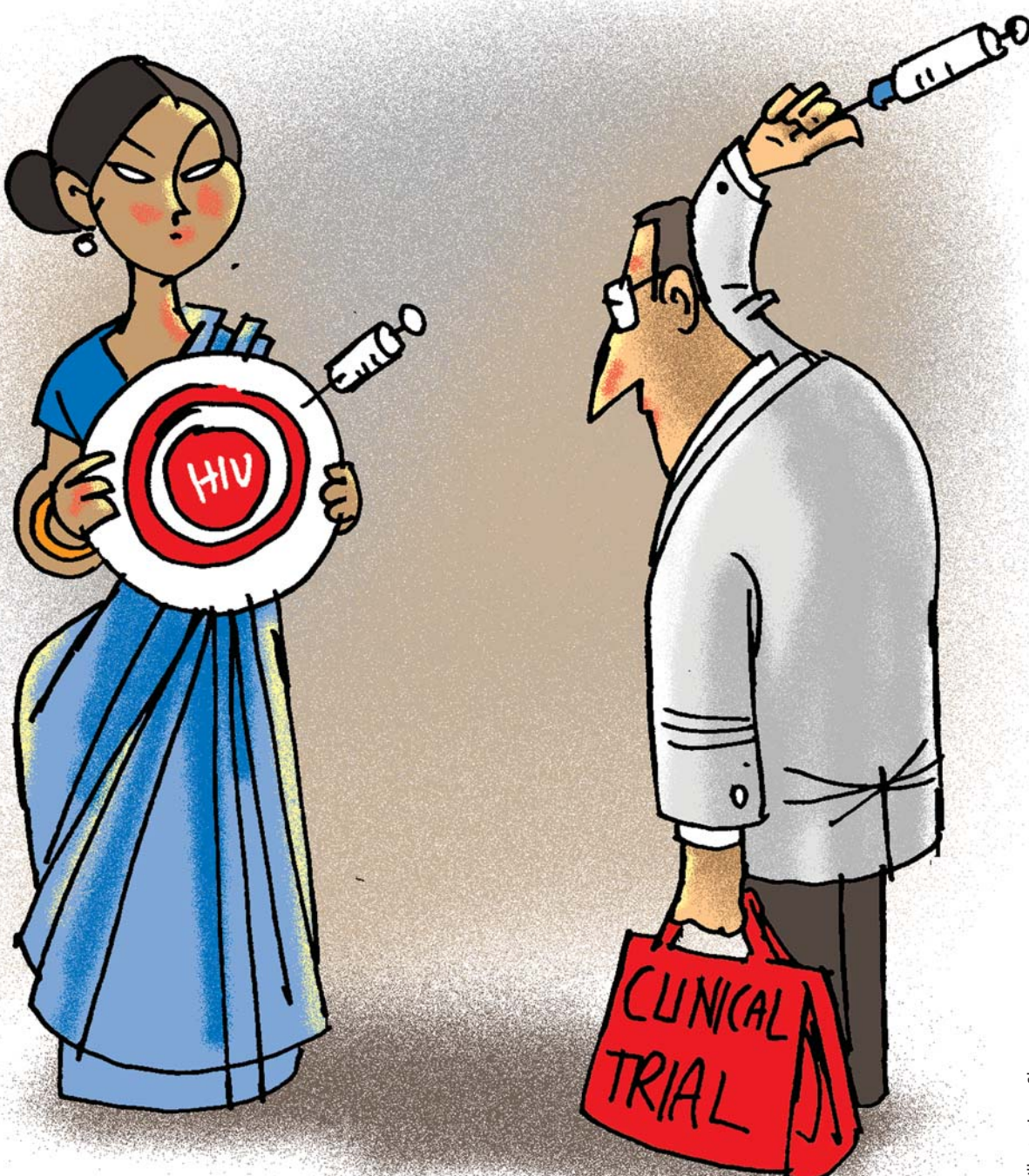
The dim quiet of its worn marble interiors is delusive. The historical contributions made by this former Institute of Thoracic Medicine and ICMR — its occupant since the past 50 years — to TB diagnosis and control worldwide have made the campus the hallowed ground of path breaking research in public health. That this reputation endures is evident from the \$2.5 million US National Institute of Health-funded spanking new centre of excellence for research. Nearby, the old building that housed the animal laboratory has been similarly transformed. It now boasts a new International AIDS Vaccine Initiative (IAVI)-funded facility which at present is conducting a trial on human volunteers with the TBC-M4 MVA vaccine, a possible new HIV preventive vaccine to protect people against infection with the HIV-1 subtype C, the variety most in circulation in India.

The TBC-M4 MVA vaccine trial on humans is the second such in the country. The first was carried out in 2005 by National AIDS Research Institute in Pune using an Adeno Associated Virus (AAV) vaccine. The volunteers who received AAV last year continue to be under observation.

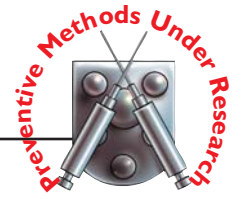
Both vaccine candidates are expected to inspire a cell mediated immune response, that is, get that part of the immune system that is programmed to act against human cells infected with a germ to act effectively against human cells carrying HIV. Both these trials mark the first few steps India is taking towards developing an HIV vaccine that will protect its own people. It may take 10 years or more for a successful vaccine to reach the market.

The Chennai trial is a joint initiative of ICMR, National AIDS Control continued on page 6

Dr Sekar Chakraborti collaborated with Therion to design TBC-M4



Illustrations: Sheena



AIDS is affecting young lives dramatically in more ways than one. Sexual lives, marriage, having babies and a family are vital aspects of a person's life; none remains as it was a decade or two ago.

If only there was a way of preventing HIV that did not call for monumental lifestyle changes! The present arsenal of prevention is low-powered. Abstain, be faithful, or use condoms—these are the only choices if HIV is to be avoided. Each requires immense behavioural change for some of us, which is pretty hard to accomplish.

Scientists, global and Indian, are working to enhance the array of preventive methods at hand. There is hope of having a microbicide available by the end of the decade. This product would, in all likelihood, enable people to have barrier-free sex and babies without fear of developing HIV infection.

Work on a preventive vaccine is ongoing in Pune and Chennai. A female condom is about to make its presence in India too following a purchase order placed by United Nations Population Fund for the product. There is news of circumcision too having a protective effect against HIV in trials in India and abroad.

Preventive methods under research — this issue of **AIDS BUZZ** brings you face-to-face with these as they are developing or planning to be used in India.

AIDS BUZZ brings you a flavour of what's new and happening in the AIDS field. Trends in the making, practices to be watched and learned from and strategies that merit a second look—all the 'vitals' an AIDS programme should reckon with are presented in this newsletter that hopes to provide a space linking key stakeholders fighting the AIDS epidemic in India.

It is our endeavour to bring you news from the field that you can use. The key stakeholders we are reaching out to initially are state AIDS control societies (SACS) and their NGO partners, government institutions, academic institutions and individuals active in the AIDS arena.

AIDS BUZZ hopes to provoke you to think anew and take stock of relevant information. It exposes you to interesting on-the-ground initiatives all over the country and the world. At present, Indian states, as large as entire European countries, aren't really in the know of what works or does not work in their adjacent states. Unique approaches or processes that have yielded good results in a state are not known about in another.

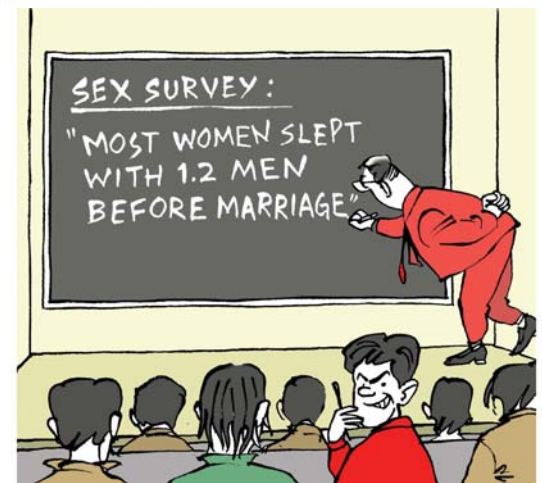
We are focusing on documenting state-level work, as well as initiatives at NACO. In a sense, the newsletter seeks to be the interface between NACO, SACS, NGOs and various stakeholders so that all are better informed about one another. It strives to be the channel that links information to key players, bringing stories of action from one place to another.

We invite you to write in about developments you'd like us to take notice of. Feel free to contribute to **AIDS BUZZ**, a melting pot of thought aiming to stimulate an informed response to AIDS.

Sadhna Motan
Editor-in-Chief



FOOTLOOSE



One must've been a midget!

Illustration: Dhir

LETTERS

Thank you for sending us a copy of **AIDS BUZZ**. We would like to congratulate you for bringing out this high quality and very informative newsletter. We have shared this with the Project Officer for HIV/AIDS in our office.

Michel Saint-Lot
UNICEF Representative for the states of A P & Karnataka
United Nations Children's Fund, Hyderabad Field Office,
H. No. 3-6-15/2, Himayathnagar, Hyderabad- 500029, A P

I read your esteemed bulletin **AIDS BUZZ** while I was at National Institute of Health and Family Welfare, New Delhi, for a training course. This publication is of immense use to researchers, postgraduate and undergraduate students. It is therefore requested to include my name for the subscription of **AIDS BUZZ**, which will be circulated to the departmental faculty and students. We hold training workshops for doctors and paramedics of our institution as per NACO's guidelines.

Dr R K Sori
Associate Professor, Department of Community Medicine,
Dayanand Medical College and Hospital Old Campus,
Civil Lines, Ludhiana-141001, Punjab

I came across **AIDS BUZZ**, the journal published by your organisation, and found it extremely useful in sharing information on HIV/AIDS. The journal would be of great use to the students of social work working in the area of AIDS. Hence, I request you to include us in your subscription list. The journal could be addressed to the Head, Dept. of Social Work, at the following address:

P V Baiju
Lecturer in Social Work, Sree Sankaracharya University of Sanskrit
Regional Centre, Tirur 676 101

Just got a copy of the new Orissa issue of **AIDS BUZZ**. It's fantastic!

Devashish Dutta
HIV Programme Officer, UNICEF, Chennai

We are in the process of developing a Resource Centre at our RCHS in Dewas, which will go a long way in increasing the knowledge of our own health team as well as of other field health workers in this area. In this regard, we would like to know about the different types of literature on sexual health and HIV/AIDS available with you and whether they are for sale/subscription. We would also like to get a copy of **AIDS BUZZ** regularly. We would be thankful if you could mail it to our office address.

Dr Rizwan
RCHS, c/o Ranbaxy Laboratories Ltd.
Industrial Area # 3, A.B Road, Dewas-455 001,
Madhya Pradesh

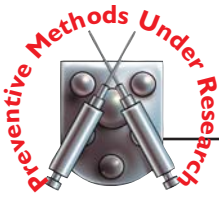
We are a grass roots organisation working on HIV/AIDS in Bhadrak district, Orissa. We are very keen to know more about the AIDS issue. I hope your organisation can help us get the required information. We would appreciate receiving **AIDS BUZZ** at the following address.

BIJOY SAMRUDHI
c/o Purna Chadraparhi AT/PO-Guamal, Dist-Bhadrak-
756163, Orissa

Greetings from LEpra Society! Please send additional copies of **AIDS BUZZ** to Dr J Subbanna, Director-HIV Division, LEpra Society-Spandana, Mr B Vijaykrishnan, Director, LEpra Society Regional Office for AP and Other States and Dr P V Ranganadha Rao, Chief Executive, LEpra Society.

Dr J Subbanna
Director-HIV Division, P B No 1518, Krishnapuri Colony
West Marredpally, Secunderabad-500 026, A P





Second AIDS Vaccine Trial Begins in India

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Organisation and IAVI. The vaccine was manufactured by the Massachusetts-based biotech company Therion Biologics Corporation. Chennai-based Y R Gaitonde Centre for AIDS Research and Education (YRGCARE) is helping recruit volunteers for the trial.

Dr Sekar Chakraborti, reputed virologist from the National Institute of Cholera and Enteric Diseases, Kolkata, collaborated with Therion to design TBC-M4 by picking out six genes from HIV-1 subtype-C and piggybacking them onto a completely different virus called recombinant Modified Vaccinia Ankara (MVA), a live but weakened vaccinia-derived virus, which is not known to multiply in humans. The recombinant MVA acts like a passenger train or vector that ferries the HIV genes. TBC-M4 is incapable of establishing infection because it contains only some HIV genes, not the virus itself. "The vaccine itself is totally safe and cannot infect anyone," said Dr Vadakkupattu Devesenapati Ramanathan, the trial's principal investigator.

The vaccine is a 'candidate' that will have to pass a Phase I trial on a small group of people, Phase II in a larger group and Phase III in thousands of people before being pronounced effective and free from side effects. "During the 18-month Phase-I trial, we aim to gather three main bits of information: whether the vaccine causes any side effects in humans, whether the human immune system reacts to it and roughly how strong a dose people would ultimately need," said Dr Soumya Swaminathan, Deputy Director, TRC. "The results will be available by mid 2008."

The volunteers will be monitored regularly over 18 months to watch for minor side effects like swelling at the injection site and to measure if they have begun to show signs of some immune action against HIV. The TBC-M4 MVA candidate, like the AAV candidate, is expected to work by priming T cells to destroy HIV, so the volunteers will have their blood drawn periodically for lab tests which will measure the level of a cytokine called gamma interferon, produced by the T cells, and also the level of neutralising antibodies, both of which can exert a lethal effect on the virus.

Sixteen volunteers will participate in the first round of the Chennai trial. Twelve of them will receive the candidate vaccine while four will get a placebo. None will know which one they've received. The vaccine in this round would be a low-dose one. The second round will have 16 more volunteers, 12 of whom will receive a stronger dose than round one and four will get placebos. The trial has already begun on a few volunteers.



IAVI laboratory in Chennai

Dr Suniti Solomon, Director of YRGCARE said, "Thousands of very special men and women the world over have participated in AIDS vaccine trials. Anyone HIV uninfected, between the age of 18 and 50 years, can participate in this trial and it's equally important for both men and women to participate."

Careful counselling that is confidential, transparent, and totally non-persuasive is underway for people who are coming forward from all socio-economic strata to volunteer in the trials. Volunteers first take an HIV test and those found infected are disqualified. More volunteers are needed to reach the magic number of 32 and YRGCARE and TRC have stepped up the recruitment drive.

"People may wonder why a healthy person who considers himself to be at low risk of getting HIV has any need to volunteer to inject himself with an HIV vaccine," says Dr Ramanathan. "I'd say because it is our basic duty to society. This is how all the drugs and vaccines we have today have been developed. Someone, at some point, volunteered and today society as a whole reaps the benefits of the contribution. Those who volunteer for this trial are doing so out of concern for future generations, in the hope of leaving behind a better world."

Dr Jaya Shreedhar is Technical Health Advisor, Internews

The trial has begun on a few people. More volunteers are needed to reach the magic number of 32

Testing Twice to Curb HIV Transmission from Mother To Child

A paper presented at the recent National Conference on Research in HIV/AIDS points to the anomaly between Government policy on ante-natal screening requiring only a single HIV test and VCTC policy prescribing repeat testing. **SADHNA MOHAN** reports

Is the Government policy on ante-natal screening of women unfair to the fairer sex? Arguing that it is, a strong case for changing the policy has been made by researchers from Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) and SAT Hospital and Medical College in Thiruvananthapuram, Kerala.

The Government policy on ante-natal screening requires a single HIV test to be performed on the mother-to-be in select government centres. A second HIV test is not conducted on those found negative by the first test.

This differs from the VCTC policy that takes the window period into account and prescribes repeat testing for a person found negative by the first test. Pointing out this anomaly in the two policies was a paper presented at the recent National Conference on Research in HIV/AIDS in New Delhi by Dr Lincoln Priyadarshi Choudhury, currently pursuing a masters in public

health at SCTIMST, V Raman Kutty, Honorary Professor at SCTIMST and Nirmala Sudhakaran, Associate Professor at SAT Hospital and Medical College.

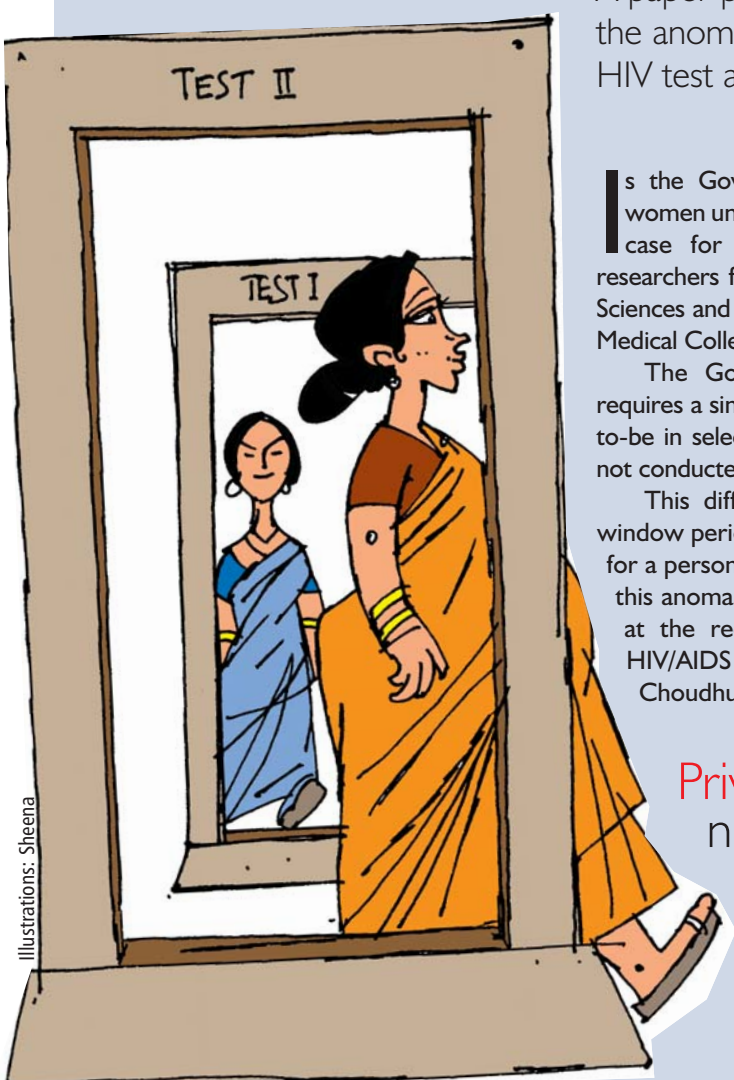
Not only does the present policy preclude a second test, it also does not involve private sector hospitals in this initiative to curb transmission of HIV from mother to child, says their study and advocates that this be rectified.

The study on obstetrics practices in two Kerala districts in the second half of 2005 found that almost 80 per cent obstetric providers (both government and private) screen for HIV during the first ante-natal visit. If the test is negative, 80 per cent of the providers do not recommend repeat testing.

Almost 100 per cent deliveries are institutional, with more than 50 per cent in private hospitals. The need to extend the policy on ante-natal screening for HIV to private hospitals in a big way is therefore pretty obvious.

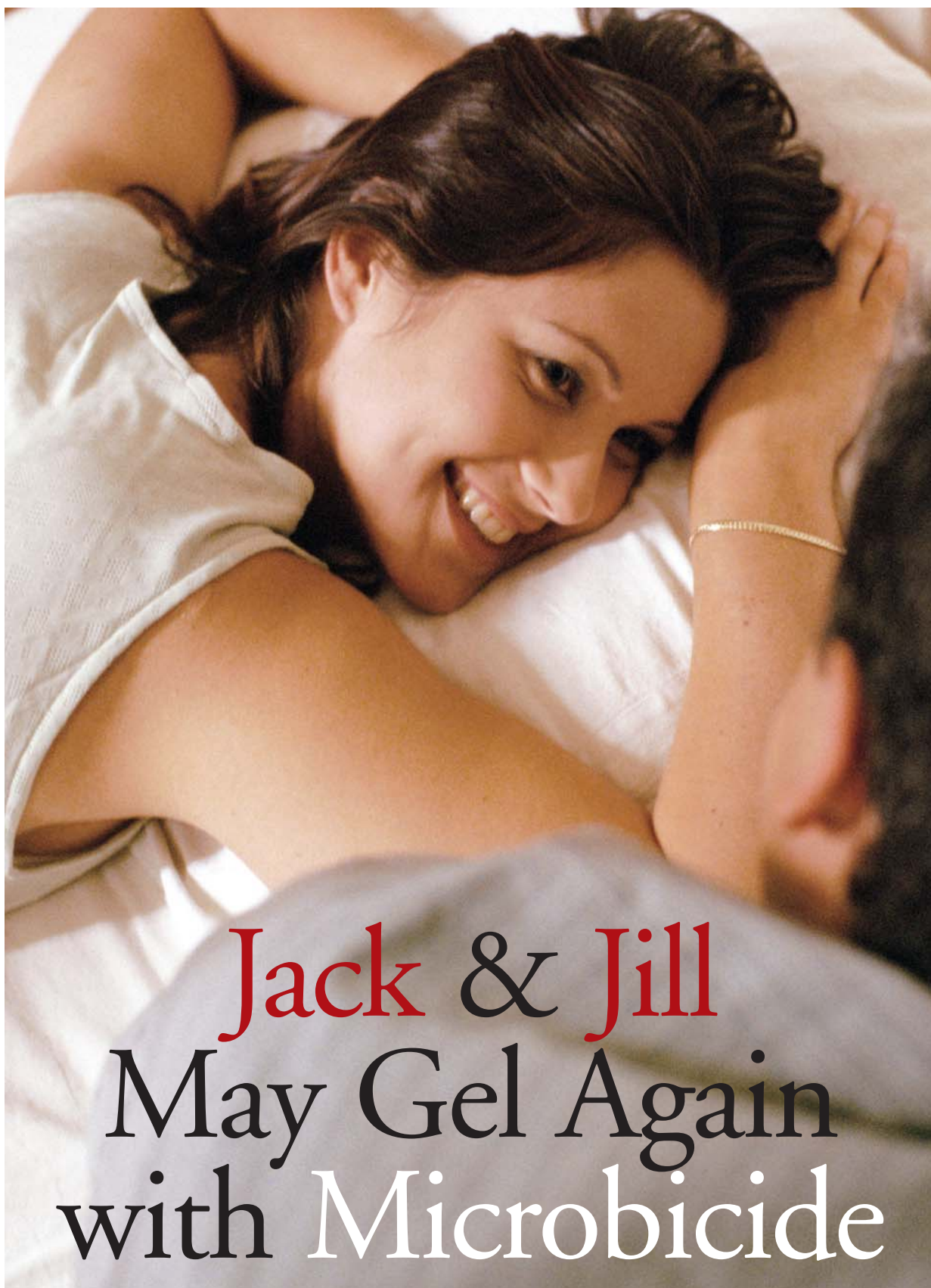
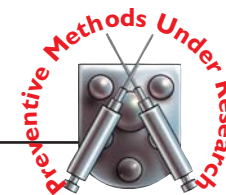
Per sentinel surveillance data (0.4 per cent of general population estimated to have HIV), 828 pregnant women (out of a total of 5 lakh deliveries a year) would have tested positive for HIV in the first half of 2005 all over the state, more than 400 of them in the private sector, says the study. Ironically, however, only 23 positive women were identified under the Prevention of Parent to Child Transmission programme in the entire state and none of them was from a private sector hospital.

Private sector hospitals need to be involved in this initiative to curb transmission of HIV from mother to child



Illustrations: Sheena

Jack & Jill May Gel Again with Microbicide



Jack & Jill May Gel Again with Microbicide

Microbicides, vaginal and anal, may become available by the end of the decade, offering safe and pleasurable sex. By **SHREE VENKATRAM** in New Delhi

For all those who complain that condoms are a 'barrier' to pleasurable sex but worry about catching HIV, a microbicide may provide the solution. It would ensure safe and enjoyable sex — something that's not been possible ever since HIV came on the scene.

Microbicides may or may not have spermicidal properties; if they don't have these properties they'll enable women to conceive from an HIV-positive partner while remaining HIV-free themselves.

Said to be in the final stages of development, microbicides that destroy disease causing organisms could be in the form of a gel, cream, foam or tablet used within (applied in) the vagina. They are expected to be available by the end of this decade.

Currently, over 50 microbicide candidates are at the pre-clinical stage of development in the world. Ten others are in or nearing human trials. PRO 2000, Cellulose Sulphate, Savvy and Carraguard and the Praneem Polyherbal tablet, which is being evaluated for safety and efficacy in a Phase II trial at National AIDS Research Institute (NARI), Pune, are said to be among the most promising candidates. Apart from Praneem Polyherbal, seven indigenous microbicides are being investigated in India — most of them at the pre-clinical stage.

A microbicide will enable a woman to protect herself. Work to find a suitable microbicide began over a decade and a half ago. Nonoxynol-9 (N-9), emerged as a very promising frontrunner for a while, it killed HIV in

test tubes and some health professionals began recommending this spermicide in addition to condoms to prevent HIV infection.

But at the 13th World AIDS Conference in Durban, researchers from the Joint United Nations Programme on AIDS informed that tests on a large group of sex workers in Africa showed that those who used N-9 gel

Study Phases

Pre-clinical—Test for safety and efficacy in labs on animals.

Human clinical testing

- Phase I trials—The new drug or treatment is tested on about 20 to 80 healthy, HIV-negative volunteers who are at low risk to HIV exposure, to evaluate safety, determine a safe dosage range and identify side effects.
- Phase II trials—Tested on 100-300 people to check efficacy and to further evaluate safety. Some microbicide testing is being done on volunteers who have abnormal vaginal discharge.
- Phase III trials—Tested on 1,000-3,000 people to confirm effectiveness, monitor side effects, compare with commonly used treatments and collect information that will allow use of the product. Microbicide trials (as per international norms) are being carried out among women at high risk of getting HIV, living in a community that has an over 2 per cent HIV infection rate. Some microbicides are being tested in two or more countries simultaneously.

Microbicide studies in India are at present being conducted on sex workers but researchers are keen to include women whose husbands are HIV-positive in the trials.

got HIV 50 per cent more often than those who used a placebo gel. The reason: N-9 irritates the vagina when used frequently, damaging the cervical cells and making the entry of the virus easier into the bloodstream. As a result suitable steps are being taken to see that the newer substances investigated are gentler.

Research in India is being carried out by Indian Council of Medical Research (ICMR) and its affiliated institutions. Among the products being evaluated here are three herbal-based microbicides: Basant from curcumin, at the National Institute for Research in Reproductive Health, Mumbai, Nim-76 from neem at the Defence Institute of Physiology and Applied Sciences, Delhi and the Praneem Polyherbal tablet, also from neem.

Two international microbicide candidates, Cellulose Sulphate and Tenofovir Gel, are being tested in India. Cellulose Sulphate is undergoing multi-site Phase III trials at St John's Medical College, Bangalore and YRG CARE, Chennai. Phase III trials are conducted amongst populations with a high HIV incidence rate of over 3 per cent. A Phase II study on Tenofovir Gel is ongoing. (See Box 'Study Phases'.)

Microbicides act in different ways. Some enhance vaginal acidity or natural vaginal bacteria. Others break down the outer coats of bacteria or viruses. Still others prevent various STD-causing microbes, including HIV, from entering cells. Yet others work by stopping the replication of HIV.

Connected with microbicide development are a range of issues relating to gender and power. Will women have the power to decide upon its use or will they need their partner's permission? What will be the repercussions for a woman whose partner 'detects' her having used the product? How will women store and use it in settings where there is little privacy? Help from social scientists is being sought and these issues are now forming an important part of the study design. In India, not much

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Indigenous Microbicides Being Developed in India

Microbicide	Institute where it is being developed
Nisin	National Institute for Research in Reproductive Health, Mumbai
Meganin	National Institute for Research in Reproductive Health, Mumbai
From the haemolymph of the Indian mud crab	National Institute for Research in Reproductive Health, Mumbai
Sapindus mukosrossi and extracts from the marine fauna	Central Defence Research Institute, Lucknow
Aspartic protease inhibitor derived from extremophilic bacteria	National Chemical Laboratories, Pune
Basant – herbal based, from curcumin	National Institute for Research in Reproductive Health, Mumbai
Nim-79 – herbal based	Defence Institute of Physiology and Applied Sciences, Delhi
Praneem Polyherbal tablet – herbal based	National AIDS Research Institute
There could be more products in the pipeline.	



News Punch

HIV Figure in India Pegged at 5.2 million

New Delhi: The number of people living with HIV/AIDS has increased. The latest figures compiled by National AIDS Control Organisation (NACO), using an improved data collection strategy, show that an estimated 5.21 million adults in India are living with HIV.

The previous figures, compiled in 2004, had shown that India had 5.13 million people infected by the virus. Of the estimated adults living with HIV in India, over 38 per cent are females and 57 per cent are of rural background. Besides, 90 per cent of the infected people do not know that they are carrying the infection.

HIV prevalence is more than one per cent among ante-natal mothers in 95 districts, including nine districts in low-prevalence states. Also, HIV prevalence is more



Illustrations: Sheena

than 10 per cent in 34 sexually transmitted infection clinic sites across the country.

“According to the latest figures available with us, 5,206 million adult people are HIV-infected. The adult prevalence is still less than 1 per cent, at 0.91 per cent, in the country,” K Sujatha Rao, Director General, NACO, said. To get a better picture of HIV prevalence in the country, NACO plans to set up 400 new sentinel surveillance sites in the country, bringing their total number to 1,150 from 750 at present. The proposed additional centres will come up primarily in Bihar, UP, Chhattisgarh, Rajasthan, Orissa, MP and Jharkhand, considered to be highly vulnerable.

The Times of India, New Delhi

Jack and Jill May Gel Again with Microbicide

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social research exists in the field of sexuality and how women negotiate sexual matters. Recently, researchers and social scientists involved in the trials in India, Africa and the US got together under the aegis of ICMR and Microbicide Development Programme (MDP) of Medical Research Council (MRC), UK, to share experiences on methodologies being followed for data collection and identify priority areas of research.

The look, feel and smell of the microbicide will have a direct bearing on its use. Its lubricating qualities, for example, can affect whether women believe they will be able to use it clandestinely or not. Studies so far have revealed that clandestine use would be impossible because of the “wetness” or “messiness” of some of the trial products. Researchers plan to see how these products would fare as anal microbicides to provide safety to men who have sex with men.

Making a microbicide is an expensive and lengthy business. A drug is tested to see if it cures. But as microbicides are preventive, researchers have to measure the continued absence of disease over several years to confirm their efficacy. It is estimated that it would cost almost \$57 million to see a microbicide through pre-clinical development, clinical trials and into commercial production. But the effort is severely underfunded despite the public health potential.

At the end of it all, a microbicide is not expected to have 100 per cent efficacy. But scientists tell us that even a 60 per cent effective microbicide could prevent 2.5 million new HIV infections in the next three years even if it is used by just 20 per cent of the population reachable by existing services and used in 50 per cent of sex acts where condoms are not used. And with the HIV vaccine still not on the horizon, it is imperative that research goes on full swing to find an affordable microbicide.

Announcement

The Indian Association for the Study of Sexually Transmitted Diseases and AIDS (IASSTD & AIDS) in collaboration with COTTISA and RCSHA is holding an STI & HIV Certificate Course for medical practitioners in Chennai from 1st to 9th July.

For details, visit the IASSTD & AIDS web site www.iasstdaids.org



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AIDS No Bar as Awareness Ties Couples

New Delhi: When it comes to HIV/AIDS, being ‘discordant’ is good news. Discordant couples where one spouse is HIV-positive and the other is HIV-negative are not as rare as they were a decade ago, say experts. For this, one can thank the government’s AIDS drugs programme and the increasing awareness on HIV/AIDS.

Over 25 per cent of the spouses of people getting treated for HIV/AIDS in Mumbai’s J J Hospital have tested negative for HIV infection. This indicates that patients are successfully using protection to stop the spread of infection to their spouses.

“Most of the patients are in the 26-45 age group and they would have got the infection 10 years earlier on,” says Dr Alaka Deshpande, Professor and Head of Department of Medicine, Grant Medical College & J J Hospital. “The fact that many of them have sero-negative spouses shows they are using condoms — and successfully so — while getting treated with anti-retroviral drugs that further cut down the risk of HIV transmission,” explains Dr Deshpande, who presented the data at the National AIDS Control Organisation’s first National Conference on Research in HIV and AIDS.

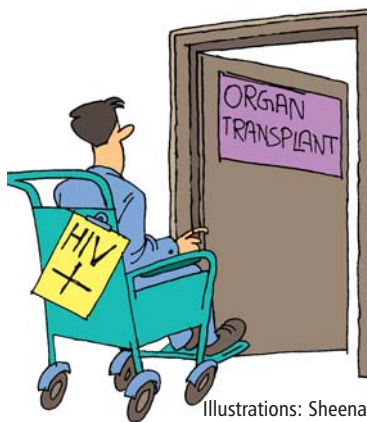


Illustrations: Sheena

The Hindustan Times, New Delhi

Hope for HIV-Infected

New Delhi: In a first of its kind surgery in the country, doctors at All India Institute of Medical Sciences will soon be performing a kidney transplant on an HIV-infected patient. Till now most transplant units have excluded patients with HIV infection from consideration for solid organ transplantation as their chances of survival are minimal. “However, after recent successes in the USA, we have decided to give it a try. We feel that donating an organ to an HIV-infected person does not



Illustrations: Sheena

waste a scarce resource, rather it prolongs the survival chances of the patient,” said Dr Sandeep Guleria, Additional Professor, Department of Surgery, AIIMS, who is monitoring the process. The patient has been selected as he is in his early 20s. “This organ transplant is for carefully selected patients who are being administered the highly active anti-retroviral

therapy which improves their chances of survival,” added Dr Guleria, explaining that the patient’s CD4 count must be more than 200 cell/mm as these cells fight infections in the body. The surgery is a complicated affair as the doctors have to continuously monitor the patient’s immune level and acceptance of the new organ. “In a normal patient, we give medicines to kill his immune capacity. But in an HIV-infected person we don’t need to suppress the immune system as it is already at an all-time low. We give small dosage of medicines so that the body accepts newly-introduced organ,” explained Dr Guleria. Though the process of surgery has been initiated it can take a couple of months. “We will need to carefully monitor both the patient as well as the donor over a period of time to make the surgery a success,” he added.

The Statesman, New Delhi

India to Get Tools to Detect HIV in Kids

New Delhi: India is procuring 19 Qualitative Polymerase Chain Reaction machines (PCR), the only diagnostic tool in the world to accurately detect the presence of HIV among children aged below 18 months. Costing National AIDS Control Organisation (NACO) nearly Rs 2 crore, the machines will be installed in medical colleges of six high-prevalence states – Maharashtra, Karnataka, Andhra Pradesh, Tamil Nadu, Manipur and Nagaland.



Until now, paediatricians in India, on detection of HIV antibodies in children below 18 months, could not tell for sure whether they were actually infected or had simply got the antibodies from their mothers.

Therefore, doctors couldn’t put them on anti-retroviral treatment – the only effective way to treat HIV.

According to NACO, 33,000 new infants are identified with the infection each year. According to UNICEF’s senior programme advisor on HIV, Chewe Luo, 50 per cent of these children died within two years of birth while 80 per cent of them died within five years of birth. NACO is also ready with the country’s first national treatment protocol for paediatric HIV, prepared along with the Indian Association of Paediatricians.

The Times of India, New Delhi