



SANKALP

A Solemn Resolve, a Commitment

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At the HIV/AIDS Frontline: The National AIDS Research Institute, Pune

BY SUBHADRA MENON

In a people's struggle against a disease, there are many factors that can reinforce a positive outcome. Institutional infrastructure, and the specialised professional strength available in these institutions are amongst the most significant of these factors. In India, where AIDS has spread to almost every part of the country in a short span of less than two decades, the National AIDS Research Institute (NARI) in Pune, Maharashtra, is one such institution.

NARI has been in the front lines of India's HIV/AIDS research on epidemiology, and effective prevention technologies, among many other aspects, and is now poised to take a leading role in AIDS vaccine studies. For this new effort, NARI hopes to build on its basic capacity and skill of having recently completed two Phase I trials of vaginal microbicides, Buffer Gel and Nonoxynol-9 (Today) in low-risk Indian women. Concerned stakeholders across the country and globally hope that this experience will be valuable when NARI moves into Phase I trials for an AIDS vaccine, late next year, as currently planned.

Established in October 1992 by the Indian Council of Medical Research (ICMR), New Delhi, NARI was – according to the Indian government – the country's response to a growing realisation that any national effort to control the spread of HIV infection would need strong support from basic research. Considering the multidimensional character of HIV/AIDS as a disease – from basic scientific detail to social and behavioural issues, besides ethical and human rights concerns – NARI's charter was clear: a focus purely on HIV/AIDS.

According to senior scientists at the institute, the focus has not blurred in the ten years since. There are six academic divisions: Epidemiology

and Biostatistics, Serology and Immunology, Clinical Sciences, Molecular Virology, Microbiology and Behavioural and Social Sciences. With partial funding from ICMR, NARI also receives almost equal funding from national and international agencies. A Scientific Advisory Committee reviews all research projects, and all these programmes are put through an Ethics Committee for approval.

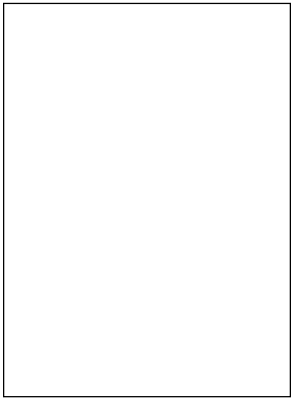
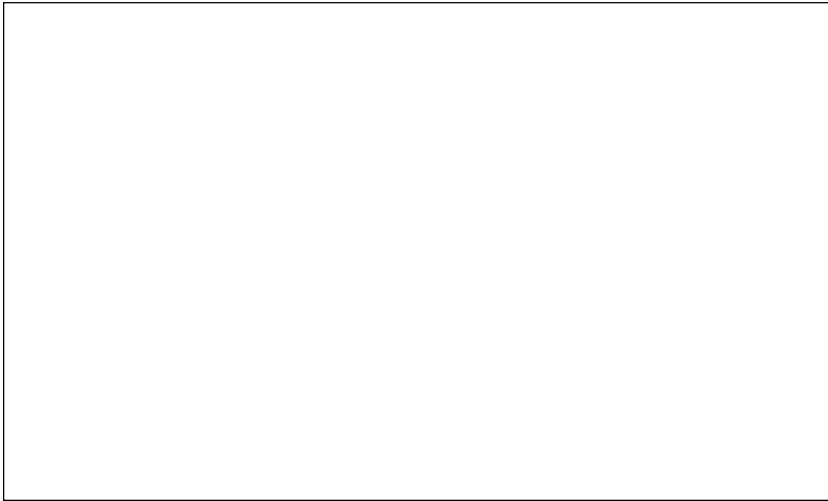
Among the first institutes to reveal formal estimates of HIV incidence in India, NARI's core competence is in the field of epidemiology. 'It's our real strength', says Dr Ramesh S Paranjape, deputy director and officer-in-charge at NARI (See full interview with Dr Paranjape in this issue, page 5). Linked to a biostatistics department, epidemiological studies at NARI have – over the years – revealed significant trends in India regarding the spread of HIV/AIDS. "NARI's studies showed how HIV infection was spreading from the core of the epidemic to its periphery," says Paranjape, explaining how the infection has moved from at-risk groups to society-at-large. This particular finding from NARI did in a sense, take the lid off HIV/AIDS in India – it showed how the infection was spreading to young, married, monogamous women through their infected spouses. These women have now become one of India's biggest challenges in tackling the epidemic effectively. According to NARI, sentinel surveillance data indicate that in at least five Indian states more than one percent of pregnant women are infected with HIV.

Following thousands of patients from STD clinics over the years, doctors and scientists at NARI have been studying the movement of the epidemic in what may be a higher-risk group – representative nevertheless – of the Indian population. This work is carried out from seven clinics in different parts of Pune city – visited by

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Dr Paranjape, at the National AIDS Research Institute, Pune.

at least 10,000 patients each year for a variety of reasons –for treatment for STIs, HIV testing or counselling, or care and support. There are two STD clinics, two HIV referral clinics, one comprehensive health care centre in the red light area of the city and two clinics attached to the district tuberculosis centres.

Realising the need to keep HIV/AIDS research away from the ivory tower phenomenon, and to allow for total community participation in trials, NARI recently set up a Community Advisory Board (CAB) to allow an active interface between its researchers and the community. The CAB has had about ten meetings in the last two years, and these interactions have helped NARI achieve active community participation in various issues related to research carried out at NARI. Community outreach through these representatives of the community has become central to NARI’s preparations for vaccine trials. As Paranjape often says: “The community should be involved from the beginning of the trials rather than getting them in midway”.

Research to find ways of preventing new HIV infections in the community, to help control the spread of HIV, and to provide care and support to HIV positive people – NARI has a large canvas. Some scientists are working on the descriptive epidemiology of HIV/AIDS, others

NARI maintains India’s HIV virus bank.

are looking for new vaginal microbicides and candidate vaccines, yet others are developing and executing training modules for professionals in behavioural and social science, among many other things. NARI is one of the 12 National Reference Centres supported by NACO for HIV testing in the country.

Studying affected people in the Jamkhed taluka of Ahmednagar district of Maharashtra, scientists at NARI have extensively observed HIV infection in rural areas of Maharashtra. There has also been an effort over the years to develop a cohort of HIV-negative STD patients. The idea behind this was to study biological and behavioural risk factors associated with HIV acquisition. Studies first under the Prevention for AIDS Vaccine Evaluation (PAVE) network and the HIV Network for Prevention Trials (HIVNET) are now under the HIV Prevention Trial Network (HPTN) (*Watch out for more details on these studies in forthcoming issues of Sankalp*). Cohorts developed for these studies, NARI hopes, will become a major strength in making available an AIDS vaccine for India. One vaccine that is currently in the pipeline is a candidate modified Vaccinia ankara based on HIV C being developed under a Memorandum of Understanding between the Indian government and IAVI.

NARI’s Phase I microbicide trials are being termed as successful. Dr Sanjay Mehendale, Deputy Director at NARI and chief of epidemiology says of these trials: “We found both products (Buffer Gel and Nonoxynol-9) to be safe. The only adverse events were reversible local pathologies not requiring stoppage of product use except in one woman, who had to be withdrawn from the study. Women approved of the physical properties of the products. They were generally willing to use the same in future if they were found to be efficacious against HIV and STDs”.

Scientists at the institute are also conducting virological studies to clone and sequence HIV from recently infected persons, as a way of characterizing the local strains now in circulation. In addition, they are conducting immunological studies in infected people to identify the repertoire of epitopes (parts of the virus that stimulate immunity) that the immune system, specifically, the cytotoxic T-cells, respond to. Today, NARI maintains India’s HIV virus bank of 110 HIV-1 strains and 20 HIV-2 strains isolated and characterised from all over the country. But Paranjape will only say there is still a long way to go: “The country needs much more basic and clinical research, and we need to work hard to develop interventions so as to stem the epidemic”. ■

NARI: Salient Achievements of a Decade

- Documentation of the rate at which new HIV infections occur in at-risk populations and of the spread of HIV to persons with low risk.
- First report of isolation and characterisation of HIV-2 in India.
- Development of a virus repository of HIV-1 and HIV-2 strains as a national virus bank.
- First report of HIV-1 A and C recombinant strain from India.
- Establishment of reference ranges for CD4 and CD8 counts in normal healthy adults in India.

Fighting with Fire: The AIDS Awareness Group, New Delhi

The public meeting was in full swing at the crowded street corner in Delhi's red light area, G. B. Road. Elizabeth was trying to hold her audience's attention on health and hygiene, safe sex as the best practice to guard against sexually-transmitted infections (STIs), including of course, AIDS, the new disease (this was 1991) with no cure. Suddenly, a young man in the crowd listening to her looked up at a woman watching from her balcony above and called out raucously, "Did you know these people are trying to put you out of business?" Unfazed, the woman replied, "Oh no! They are simply trying to protect us from the likes of you".

That was more than a decade ago, but the words still mean a lot to Elizabeth as she goes about her day's jobs running the AIDS Awareness Group (AAG), a voluntary organisation based in New Delhi, as its director. The incident revealed to her – back then – that she was on the right track. Awareness and education would become key factors for protection against HIV/AIDS, a viral wave that was just beginning its upsurge in India. Elizabeth was then teaching the children of commercial sex workers (CSWs) in a small school on G B Road under the Joint Women's Programme. Each day, she would observe the women who seemed to live on the fringes of urban Indian society. With great anguish she noted the deplorable medical services these women depended on, something that is still largely unchanged, she says. "They have no access to even the most rudimentary medical facilities, although they suffer from such a diversity of medical problems", says Elizabeth.

During those early days in the area, she happened to meet up with two like-minded souls who were then medical students in the capital's Maulana Azad Medical College doing their regular fieldwork in G B Road. The students would do the rounds each evening, after class, collecting samples, providing medical advice and medication wherever required. Elizabeth teamed up with them and the months that followed were almost scary, she says. Scary because she noticed, among the CSW population, a prevalence of all STIs imaginable, and in the most chronic of conditions. What made it worse was the fact

that the mainstream medical community was doing almost nothing to make things better.

A few years down the line, this mixed group of concerned people (doctors, activists and lawyers) 'creeping around Delhi's brothels', in Elizabeth's words, found itself a name and an identity. That was the birth of AAG – and the acronym was a happy coincidence, since it means 'fire' in Hindi. Today, AAG is working to spread awareness about HIV/AIDS in Tihar, Asia's largest jail, in New Delhi; promoting condom use among CSWs in New Delhi; operating a counselling hotline for people who have questions about HIV/AIDS, sex and sexuality that they can never seem to find answers for; running counselling services at the Sexually Transmitted Diseases (STD) centre in Safdarjung Hospital in New Delhi; and producing Information, Education and Communication (IEC) material on STDs and AIDS.

At the clean, busy AAG office, there is a happy feeling that awareness is beginning to show. Siddharth, who coordinates AAG programmes, explains how CSWs are now beginning to report discomfort and seem to be prepared to get themselves tested for HIV/AIDS. At least four days a week if not five, an AAG doctor visits the red light area to provide treatment for minor ailments and referral for major ones. AAG has also been working with the local police to sensitise them about the problems that CSWs face as part of their daily routine. The distribution of condoms is also a significant service, since to many women who live in these areas, they are simply an unaffordable luxury.

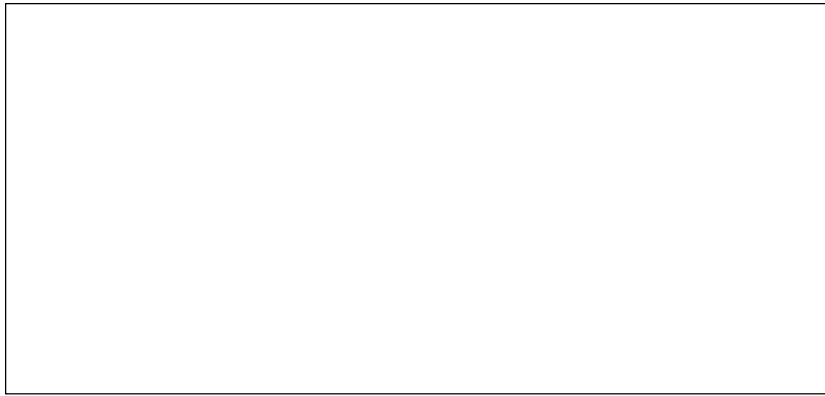
By SUBHADRA MENON

At Tihar, homosexuality is a big problem, specially considering the need to make inmates more aware of the HIV/AIDS risk.

— Elizabeth, AAG

*Working towards greater awareness among the less privileged, Delhi.
(Picture courtesy: AAG)*

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Elizabeth, Director, AAG.
(Picture courtesy: AAG)

At Tihar, AAG is working at two levels – one is to continue HIV/AIDS awareness work and the other is to offer free, legal advice. AAG holds sessions in different wings of Tihar once a week. Says Elizabeth, “At Tihar, homosexuality is a big problem, specially considering the need to make inmates more aware of the HIV/AIDS risk”. Another challenge, Elizabeth says, is that “jail doctors who attend to patients are mostly unmotivated. They really don’t care either way”. AAG has worked through screening films, doing street plays and putting up posters to bring prison inmates face to face with the reality of HIV infection and the threat of AIDS as a disease with no cure.

In the slums of New Delhi too, there lives a huge, fringe population of people cut off from most urban amenities, and AAG has found its way to three slums – Dhapo camp, Hanuman camp and Saraswati camp. The idea is to try and bring these people face to face with HIV/AIDS, and what they can possibly do to protect themselves from the disease. There are fixed days of the week when an AAG doctor attends to slum dwellers’ needs for medical care and support; there are also campaigns to help women become more aware of health and well being.

For Elizabeth, Siddharth and their small devoted team, this is compelling work. The challenges they face are many – funding for projects is always hard to come by, collecting condoms for free distribution is a problem too. There is always a pressing need to ensure no single vulnerable group of people at-risk is targeted by authorities, and safeguarding basic human rights of people tops the priority list. Yet, there are big plans – an AIDS hospice, training people for home-based care of AIDS patients, improving health care, legal aid and education in the red light area, advocacy for the human rights of PLWHAs and prisoners, among others. Tall order, but with an ‘aag’ in the right place, it just might happen. ■

Barcelona 2002: A Retrospective – and a Look Ahead BY PATRICIA KAHN

“In Barcelona, people were coming to realize that there are no magic bullets in this epidemic,” said Jose Esparza, who heads the WHO/UNAIDS HIV vaccine unit. “We have to accept that there are no ideal interventions, and use what is in our hands.”

This time around, the world’s largest AIDS conference had a very different tone than its predecessor. While Durban 2000 was a turning point in galvanizing global momentum for an all-out response to the epidemic, Barcelona was permeated with the hard reality that the world has not yet risen to that bold challenge, either in terms of political will or committed funding. So once again, this bi-annual gathering was focused on the epidemic’s unrelenting spread and the world’s woefully inadequate response. Yet at the same time, the conference spelled out plainly what can be achieved now, by using proven prevention measures and tackling prevention and treatment together rather than pitting them against each other.

“We’re still hearing a lot of words, but not the scale,” Columbia University economist Jeffrey Sachs told the audience. “The scale of what’s needed has never been more clearly understood. The number of deaths on the line has never been clearer.”

“In Barcelona, people were coming to realize that there are no magic bullets in this epidemic,” said Jose Esparza, who heads the

WHO/UNAIDS HIV vaccine unit. “We have to accept that there are no ideal interventions, and use what is in our hands.”

Barcelona also marked the debut of Richard Feachem at the helm of the Global Fund on HIV/AIDS, Tuberculosis and Malaria, on which many hopes are pinned. In a much-anticipated speech, Feachem vowed to fight for a “massive increase” in donations, to support treatment as well as prevention, and to run the Fund in an accountable manner with built-in outcome measurements. He also expects to release multi-year projections of resources needed and anticipated rates of expenditure following the Fund’s Board of Directors meeting in October.

On the vaccine front, many speakers focused less on recapping progress than on mapping the way forward, identifying gaps and proposing solutions to some of the thorny challenges ahead – topics that provided the meat of a one-day vaccine satellite meeting. The main conference offered updates of ongoing clinical trials, reports on newer vaccines in the pipeline and presentations on the difficult task of designing efficacy trials for candidates that may be only partially effective.

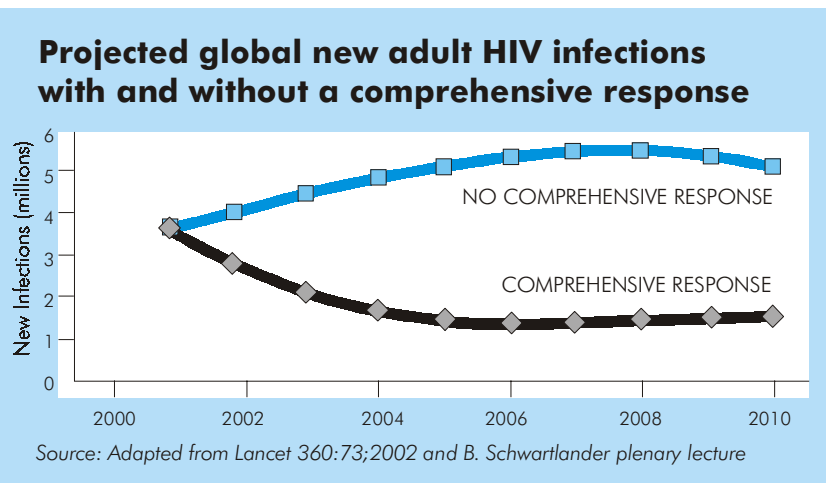
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Underscoring the growing recognition of links between prevention and treatment, it was striking that some of the most provocative talks for vaccine developers focused on infected people or animals. Topping the list was Dr. Bruce Walker's report (Massachusetts General Hospital, Boston) of an HIV-positive man who became "superinfected" with a second HIV strain, despite an immune response that controlled the first virus – a finding widely portrayed in the press as a major blow for vaccines.

The Epidemic's Future: Two Scenarios

The international AIDS conferences traditionally begin with an update on the global epidemic, and Barcelona was no exception. But there was a difference: This year, Bernhard Schwartländer (WHO, Geneva) also presented a study on projected numbers of new infections, but with two sets of predictions: one, if the global response remains at today's levels, and another, if it scales up to meet the targets set at the United Nations General Assembly Special Session on HIV/AIDS in June 2001. The analysis was based on reviewing the impact of prevention activities in 126 middle- and low-income countries, while the comprehensive response assumed a package of proven prevention and treatment interventions costing about \$9.2 billion yearly by 2005. (The study was published in *Lancet* 360:73;2002.)

The result was stark and simple (see figure above): without a comprehensive response,



another 45 million people will become infected by 2010; with it, 29 million of these infections (nearly two-thirds) can be prevented. The analysis also found that a one-year delay in mobilizing a response will cost 5 million of these preventable infections; a three-year delay, half of them.

Other speakers referred repeatedly to this blunt message. For example, Helene Gayle of the Bill and Melinda Gates Foundation, pointed to a 1993 WHO projection that spending \$1.5 billion on prevention could halve the number of new infections by 2000 and save \$90 billion in related costs. "Will we continue to wait until the cost has doubled, tripled, quadrupled and tens of millions more lives are lost?" she asked. "Ultimately, we will pay now or pay later." ■

(Reproduced from the IAVI Report, July-September, 2002)

An Interview with Dr Ramesh S Paranjape, Officer-in-Charge, NARI

Dr Ramesh S Paranjape is an immunologist who heads the only scientific institution in India devoted exclusively to research on HIV/AIDS. After spending many years at the Chennai-based Tuberculosis Research Institute, Dr Paranjape, is now spearheading HIV/AIDS research from NARI in Pune.

If you were to assess India's position on the AIDS research map of the world, where would you place the country?

AIDS research has essentially to be looked at from different aspects – basic biological research, the behavioural and social aspect, epidemiology, and clinical management and interventions. We have considerable data on the epidemiology of HIV infection and

considerable work carried out on the social and behavioural aspects. By no means is the work done enough, there is need to do much more to plug the gaps. Two areas where we have not had much activity are basic and clinical research. Interventional research should definitely take priority because we have close to four million people who are infected with HIV and their infection can be stopped now rather than when numbers increase further.

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We were the first to report various aspects of HIV epidemiology, especially in relation to high-risk STD patients. We gave the first reliable estimates of HIV incidence rates, meaning how frequently new infections occur in a population. We were also able to demonstrate for the first time that HIV is spreading from the core group to peripheral population.

What about AIDS research specific to a vaccine? Where are we in terms of trying to get a vaccine for our people?

In India the efforts started late compared with the Western world, we were required to do that because of the local HIV strains circulating in the country. Work is in preliminary stages. It is nice to see collaborative research is coming up, so that people instead of working in isolation are able to get the benefit of expertise that lies in different places.

If you were to define NARIs particular strengths as an institute, what would they be?

Let me give you a little background. NARI was established in 1992, primarily as a response to a growing epidemic and the need for generating knowledge about HIV that was indigenous, specific to our virus and our population. A nucleus was already there at the National Institute of Virology in Pune. Pooling expertise from various ICMR institutes, NARI was established. Initially, the focus was more on epidemiological studies.

We were the first to report various aspects of HIV epidemiology, especially in relation to high-risk STD patients. We gave the first reliable estimates of HIV incidence rates, meaning how frequently new infections occur in a population. We were also able to demonstrate for the first time that HIV is spreading from the core group to peripheral population. This was based on the finding that women with a single sexual partner – the husband most often or any other regular partner – were reporting positive; their only risk factor was infection from the spouse. We have also studied acute primary infection of HIV.

Today, NARI has state-of-the-art laboratories with most facilities required for HIV research. Our virology lab has a virus repository with 110 HIV-1 and more than 20 HIV-2 strains collected from different parts of the country, well characterised and expanded, and available for whoever wants to conduct research on Indian strains of HIV. Viruses are being characterised, we are also studying the nef gene of HIV C in India, and looking for recombinants. Studies related to immune response to HIV infection in Indian patients are being carried out, especially on cytotoxic C-lymphocytes (CTL) [immune cells thought to be a key component of protection against HIV]. That is a strength when we consider the vaccine trials that may be coming up. Another strength is regarding interventions, especially our studies on vaginal microbicides, female-controlled methods for prevention of HIV, the female condom. We have established our capability for carrying out Phase 1 and Phase 2 studies for vaginal microbicides (VM), we have

already reported this scientifically. This has given us sufficient experience to undertake prevention research on our own, as we are envisaging in the HIV Prevention Trial Network (HPTN) and HIV Vaccine Trial Network (HVTN) studies or in our vaccine studies with IAVI.

What about your involvement with HPTN and HVTN, what is the status of studies under these networks?

HPTN is an international network, and protocols are being developed in a multi-centre manner with inputs from all participating sites. The areas in which our institute will be participating in these trials are the anti-retroviral therapy (ART) and vaginal microbicides (VM) studies. They are being formulated, protocols are near ready, and will hopefully be launched in the near future. The ART study will have about 320 participants, VM will vary study to study, but the first being planned is a Phase I, which will be anywhere between 20-60 participants. As for HVTN, as of today we don't see any subtype C specific vaccine really available for a Phase I trial in the country.

Cross-reactivity between clades is being assessed and there appear to be significant cross-clade responses. At this point HVTN studies are focused more on building capacity. We are studying the willingness among persons with high risk to participate in such a study, understand barriers to their participation, their concerns and other issues which will be very useful in the community development studies for HVTN. The other project for HVTN is to look for the extent of cross-reactivity in CTL responses, especially in the context of different HIV subtype candidate vaccines being considered for Phase 1 trials.

NARI has been developing cohorts over a long time. What do you see ahead for NARI in terms of cohort-based research?

We had a collaborative study with Johns Hopkins University (JHU), which really allowed us to build capacity. We have scientists trained in public health at JHU, and we have developed state-of-the-art facilities that can support such studies.

One of our earlier studies was to establish a cohort of HIV-seronegative STD patients. There were problems related to follow-up, but one should understand limitations of such studies, especially when the issue of care during a study could not be addressed. This gave us the expertise and understanding related to cohort development. This is an open cohort, where patients are continuously being enrolled and followed up – we have over 11,000 patients screened for this particular cohort.

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Now, the other two studies which have really demonstrated our capability to establish and follow cohorts were the VM studies with Nonoxynol-9 and Buffer Gel – in both these studies we have close to 95% follow-up, which was very commendable. We took up another behavioural study where discordant couples were used to test novel strategies for increasing condom use, and even here we have almost 90% follow up, That gives us the confidence that we can set up cohorts and develop mechanisms for group follow-up. Another study on the immunopathogenesis of acute primary HIV infection has had follow-up of over 70% for a period of two years.

Do you feel the average Indian has a level of preparedness or acceptance for participating in an HIV vaccine trial?

Honestly there have been no studies on this. We will learn about vaccine awareness from our HVTN studies and maybe we would expand the study into the general population. The target was to enroll 500 people; we have already over 300 patients in the study. But since the study doesn't allow for interim analysis, we are not in a position to speak about it. I think these results will put us in a position to find out. Here we have two groups of patients, one that has been coming for routine follow-up, counselled a number of times and is more familiar with HIV, with our clinic and staff. But half of our volunteers are brand new. They are naïve and have received first counselling, but not beyond that. In another six months we should have results.

If you were to judge the overall AIDS situation in the country's disease, what would you say?

I think we are seeing the tip of the iceberg as far as the real impact of the epidemic on the country is concerned. The majority of patients are still in

the asymptomatic phase of the infection. Our clinics and hospitals are going to see large numbers of people with opportunistic infections. I am not sure we are geared to deal with these clinical problems. We have no conclusive studies on HIV drug therapy – which regimen is the best one, which one is associated with more relapses, or more resistance.

If you look in terms of sheer numbers, we have about 4 million cases, according to the Government of India. This is a very large number of infected people, although not as a percentage of total population. But they will impact our healthcare system. We are really at a cross road – are we going the Africa way? We really do not know at this stage. But there is a silver lining. There is a lot of awareness among people now, although we don't know what impact this will have on the epidemic.

We have to look at two aspects. One is care and support for patients – access to drugs, bringing down costs – which may not be within the financial powers of the government, but it should be at the back of the mind that this needs to be considered. The other is intervention and research that can cut down numbers of new infections. That will include studies like the one on vaginal microbicides, studies related to a vaccine and behavioural studies.

More and more women are getting infected. In the initial stages, the ratio of infected men to women was very low compared to what it is today. We need to increase women's awareness, empower them to take decisions.

Another group that needs attention is adolescents. They are the future of the country and have urges to explore new areas like sexual relations, so they must be empowered with knowledge on HIV/AIDS, and how to protect themselves. ■

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IAVI India's Advisory Board Discusses Sub-Group Formation

The Advisory Board of IAVI India met for a second time on September 2, 2002. Presentations at the meeting ranged from India's initiatives for an AIDS vaccine (Ms Meenakshi Datta-Ghosh, Project Director, National AIDS Control Organisation), the global scenario on research and development of the vaccine (Dr Jean-Louis Excler, Medical Director, IAVI, India), the Thailand experience with vaccine trials (Dr Punnee Pitisuttithum, Deputy Head, Vaccine Trial Centre, Mahidol University, Thailand), the India Programme update (Prof N K Ganguly, Director General, Indian Council of Medical Research, and infrastructure and recruitment issues (Dr Ramesh Paranjape, Officer-in-charge, National AIDS Research Institute, Pune).

The Advisory Board brought up many of their own concerns regarding the development and deployment of an AIDS vaccine in India. There were concerns regarding the vaccine per se:

1. How effective will the vaccine be against HIV sub-types prevalent in India
2. What about technology transfer of the science of developing the vaccine?
3. Who will own rights to this technology, and the intellectual property so generated?

There were also issues of concern regarding trials and volunteering for trials:

1. How prepared is the Indian community to conduct and participate in trials for an AIDS vaccine?
2. Who gets recruited for a trial – low or high-risk groups, males or females; are certain groups to be excluded from the trial?
3. What is the dissemination strategy to enlist volunteers and how do you motivate volunteers to get involved in a trial?
4. What is to be done to make sure volunteers understand the process of recruitment for trials?
5. What about dealing with stigma and social harm, compensation, care and support to volunteers who may get infected during a trial?
6. Explaining research design, the concept of an experimental and placebo dosage of the vaccine on trial, to volunteers and the community.
7. Dealing with risk behaviour among volunteers.

Since so many narrowly focused concerns and issues have emerged since the first meeting of the Advisory Board, Mr Mark Chataway, India Team Leader, IAVI, put forth a concept of dividing the Advisory Board into sub-groups. The main idea behind this meeting was to create sub-groups of the 34 members of the Board so that each group could – from the next meeting onwards – focus on a specific issue. Considering the number of specific issues and concerns, it was considered appropriate to divide the Advisory Board into these smaller groups. The following groups have been suggested:

- Advocacy and Communication
- Informed consent, management and care issues
- Local community mobilisation, recruitment of volunteers
- Access and public vaccine strategy and vaccine policy
- Manufacture and industrial planning (patents and production issues)
- Comprehensive legislation
- Epidemiology, final design and statistical guidelines

Consulting with Civil Society in Pune, Maharashtra

IAVI, in its Memorandum of Understanding with the Indian Government places great importance in the involvement of affected communities and civil society in general. This has been central to the planning and implementation of state-level programmes. Towards this end, in an effort to explain to and consult with a wide cross-section of society in Pune – where Phase 1 trials for an AIDS vaccine for India are being planned – a meeting was held with policymakers, NGOs, corporates, scientific and research organisations and the medical fraternity on September 7, 2002.

The well-attended interaction drew enthusiastic response from most participants. Chaired by Mr Kapil Sibal, Member of Parliament (MP), the interaction began with brief presentations by the Indian Council of Medical Research, the National AIDS Control Organisation, the National AIDS Research Institute and IAVI. These presentations were made to orient the gathering towards the various complex issues that one needs to address as part of the process of vaccine research, development and trials.

Important issues raised at the Pune interaction related to the science of the vaccine and trials of the vaccine. Questions surrounding the science of the vaccine included mutations and hypervariability of HIV as a virus, recombinant strains, cross-clade immunity, whether the vaccine would work in preventing Mother-to-Child Transmission of the virus and the fear of getting infected by the vaccine.

As far as vaccine trials are concerned, there are other concerns – how will the real effectiveness of a vaccine be measured when volunteers would be using other basic prevention techniques and what about the expected outcome of the various phases of trials? There is a need to know for sure that Indians are not being used as guinea pigs, that informed consent is really what it is meant to be, that strong voluntary counselling and testing systems are in place. There were also questions about intellectual property and ownership of the vaccine, and concerns about some other candidate vaccine becoming successful while trials for another candidate vaccine are still on; besides the larger question of what motivates a healthy person to enroll in a trial. The Pune meeting, while providing some answers, was also a strong indicator of interest and curiosity, among many stakeholders, about an AIDS vaccine for India. ■

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IAVI is a scientific organization founded in 1996 whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI focuses on four key areas: accelerating scientific progress; education and advocacy; ensuring vaccine access and creating a more supportive environment for industrial involvement in HIV vaccine development.

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