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SPOTLIGHT

The AIDS Vaccine Quest: India's First Milestone

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National AIDS Research Institute: The trial site at Pune

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India began its first Phase I human clinical trial for a preventive AIDS vaccine on February 7, 2005, at the National AIDS Research Institute (NARI) in Pune. NARI is one of the country's premier HIV/AIDS research institutions, under the Indian Council of Medical Research (ICMR). With the initiation of this AIDS vaccine trial, the country has demonstrated the tangibility of its resolve in joining the global drive for an ultimate solution to end an epidemic that has infected more than 40 million people the world over. This is a significant milestone in India's multi-pronged approach towards tackling HIV/AIDS, as the Union Minister for Health and Family Welfare, Dr. Anbumani Ramadoss, said while an-

nouncing the trial: "Developing a vaccine to prevent AIDS is one of the most difficult scientific challenges of our time. It is also one of the most urgent health needs. Perseverance is the way forward, and India has a long-term commitment."

The Phase I trial in Pune is testing tgAAC09 — the technical name for the investigational vaccine based on the naturally-occurring adeno-associated virus (AAV) and genes from HIV subtype C (*see Side Bar: The Vaccine on Trial*) — to evaluate its safety by enrolling 30 men and women as volunteers. It will take roughly 15 months before the results of this trial can be known. It is a trial overseen by the

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The AIDS vaccine development programme has always placed a great deal of importance in the meaningful engagement of local communities for the transparent and ethical conduct of clinical trials, and the Indian trial is no different.

Indian government, and is being conducted under a collaborative effort by the ICMR and the National AIDS Control Organization (NACO) in partnership with the not-for-profit International AIDS Vaccine Initiative (IAVI). The trial has begun after approval from Indian regulatory authorities — the Drugs Controller General of India, the Health Ministry's Screening Committee, the Genetic Engineering Approval Committee, the NARI Scientific Committee, the NARI Ethics Committee and the National Ethics Committee.

A Multi-Country Effort

India is the third country to be part of this multi-nation trial — researchers in Germany and Belgium have been testing tgAAC09 in partnership with IAVI in university-based clinics at the Universitätsklinikum Bonn and Universitätsklinikum Hamburg-Eppendorf in Germany and hospitals in Belgium, the Centre Hospitalier Universitaire Saint-

Pierre in Brussels and SGS Biopharma SA in Antwerp. The European Phase I trial began in end-2003 after obtaining all requisite approvals from regulatory authorities in Germany and Belgium, and 50 men and women are participating in this trial as volunteers. India's participation in this trial is linked to the enormity of the public health challenge that HIV/AIDS presents for our country, 'The development of a safe and effective AIDS vaccine is becoming a global health priority and particularly in the developing world where access to antiretroviral therapy for HIV is not available to the majority of HIV infected persons' (www.nacoonline.org).

There are other compelling reasons for India's participation in AIDS vaccine research and development. As Prof. NK Ganguly, Director General of ICMR, said at the initiation of the trial in Pune: "Our country is an emerging global leader in biomedical research. With this first trial,

Indian scientists are making an important contribution that will bring the world a step closer to an AIDS vaccine."

The Pune Trial

Thirty healthy, literate, HIV-uninfected men and women are required to participate in this Phase I trial, in which a low, medium and high dose of tgAAC09 will be analysed. According to Dr. SM Mehendale, Deputy Director at NARI and Principal Investigator of the trial "some volunteers receive an injection of tgAAC09 into the upper arm, while others receive an inactive substance called a placebo. Neither the volunteers nor the clinicians working with them know who received tgAAC09 or the placebo, until after the study finishes". This is the classical double-blinded approach that has been applied to all such trials worldwide. Prof. Ganguly said that the tgAAC09 trials in Germany and Belgium have shown excellent safety results. By March, 2005, the 10th volunteer for the trial, who is also the last participant in the low-dose vaccinee group, had received the trial injection.

It is apparent that altruism is the key driving force behind the decision of these volunteers to be a part of such a research study. Dr. Mehendale revealed that social workers, regular office-goers and health workers are among the volunteers, and a good number are women. The AIDS vaccine development programme has always placed a great deal of importance in the meaningful engagement of local communities for the transparent and ethical conduct of clinical trials, and the Indian trial is no different. All the work for the trial is being coordinated through a vaccine trial clinic at NARI and a community office on Paud Road in the city of Pune. The team includes medical professionals, immunologists, laboratory technicians and community mobilisation specialists.



The immunology lab at NARI

A Community Advisory Board (CAB) has played an active role in the entire programme and offers advice and suggestions on a regular basis. The CAB is functioning as a bridge between the community and the researchers, as is generally the case. Additionally, ICMR, NACO and IAVI have been working at the national level over the last few years to increase public awareness about AIDS vaccine research. Their programme of activities has helped build national and state-level political support in the search for an AIDS vaccine and mobilised communities and different stakeholders. The programme is overseen by the National Advisory Board, comprising of persons with longstanding experience in the social, political, scientific, ethical, economic and gender-based dimensions of AIDS prevention and care and representatives of various sections of civil society, especially Persons Living with HIV/AIDS.

In keeping with international norms of human clinical trials, the Pune trial too is based on total informed consent from the volunteer. The informed consent forms for this trial have been developed through an intense process of review by a Consent Form Review Panel comprising scientists, researchers, lawyers, community representatives, experts in biomedical ethics, and academicians. The panel met over three day-long consultations to finalise these forms. Built into the trial process is a system of careful monitoring. A volunteer is totally free to leave the trial at any time for any reason and all information about a volunteer is kept completely confidential. The study involves a detailed screening and enrolment process and a 12-month follow-up with 10 scheduled visits to the clinic and two additional meetings. Blood samples are collected during six of these visits for regular analysis as part of the research design. Beyond the schedule, participants are free to seek clarifications or clear any doubts they may have by getting in touch with the trial team at any point of time during the trial.



The Pune Vaccine Trial Clinic

“This is a marathon, not a sprint”

An AIDS vaccine is a clear scientific possibility, but one that is enormously challenged by HIV's relentless mutability. For researchers in many labs across the world, the only reasonable way to address this challenge has been to ensure that various investigational vaccine candidates are tried in human clinical trials simultaneously. Since 1987, more than 40 different AIDS vaccine candidates have been tested in over a 100 clinical trials across many countries like Australia, Belgium, Botswana, Brazil, Canada, China, Cuba, Finland, France, Germany, Haiti, Kenya, Malawi, Peru, Puerto Rico, South Africa, Switzerland, Thailand, Trinidad and Tobago, the United Kingdom, the Netherlands, Uganda and USA.

At the initiation of the Pune trial, Dr. Seth Berkley, President and CEO of IAVI, mentioned that the search for an AIDS vaccine is “a marathon, and not a sprint”. The Pune trial is just the first step in the attempt to determine whether tgAAC09 will work

for India, where HIV subtype C is the most prevalent. It is an experiment designed to find out if this investigational vaccine is safe. Will this vaccine emerge as a clear public health tool against the biggest pandemic of recent times? The jury will remain out on that question till tgAAC09 goes through a series of larger trials that would continue to evaluate safety and also assess the level of immune response that the vaccine elicits in trial participants. It is highly likely that a “funnel” process will be necessary – testing several candidate vaccines in human clinical trials, moving only the best candidates emerging from Phase I trials to Phase II and the best of Phase II to Phase III efficacy trials. Experts believe it will take at least 10 years for a safe and effective AIDS vaccine to be available.

That is why partnerships are becoming vital to the global search for an AIDS vaccine, for it is really too mammoth a task. In fact, the coming years will see how strongly this quest will be fuelled by these critical alliances. Recent Government of

It is highly likely that a “funnel” process will be necessary – testing several candidate vaccines in human clinical trials, moving only the best candidates emerging from Phase I trials to Phase II and the best of Phase II to Phase III efficacy trials.

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Announcing India's first AIDS vaccine trial (From L to R: Dr. SY Quraishi, Mr. Kapil Sibal, Dr. Anbumani Ramadoss, Prof. NK Ganguly)

“The IAVI partnership with India is an example of the kind of international collaboration that is critical to the quest for a vaccine. We must work together to mobilise the best science in the fight against the epidemic.”

- Dr. Seth Berkley

India initiatives are evidence of this understanding. From the late nineties, when discussions for the need to focus on the search for an AIDS vaccine were initiated, to the beginning of the first Indian AIDS vaccine trial in 2005, partnerships have been at the core of the AIDS vaccine programme. “The IAVI partnership with India is an example of the kind of international collaboration that is critical to the quest for a vaccine. We must work together to mobilise the best science in the fight against the epidemic”, said Dr. Berkley. There are also internal synergies being built within India to achieve these goals. As Minister of State (Independent Charge), Science and Technology, Mr. Kapil Sibal, also on the Board of Directors of IAVI, said: “Vaccine research is so critical that the Ministry for Health and Family Welfare and the Ministry of Science and Technology have joined hands to provide the effort the support it needs.”

Cross-national collaboration will not just enhance the speed at which the world will find an AIDS vaccine that works, it is also perhaps the only way ahead. Dr. SY Quraishi, Director General of NACO said: “The trial initiation is a great culmination of the tripartite partnership among ICMR, NACO and IAVI. We expect to test other vaccine candidates in the coming years under this partnership.” On NACO's official website, one of the key priorities for the Phase II of the National AIDS Control Programme (NACP) listed is – ‘increasing the country's research and development capacity to be able to pilot efforts to develop an AIDS vaccine’. India, with its high level of political commitment and world class research and development capacities, is a front-liner in the AIDS vaccine quest, and the NACP priority is certainly not an unachievable goal. It is however, a long road home. ■

The Vaccine on Trial

The Pune trial is testing tgAAC09 – a vaccine candidate based on the adeno-associated virus (rAAV), a naturally occurring virus not known to cause any disease in humans. Designed by the Targeted Genetics Corporation, based in Seattle, Washington, and the Columbus Children's Research Institute in Columbus, Ohio in partnership with IAVI, tgAAC09 has an AAV capsid (a protein coat that covers the viral DNA) that is used to deliver carefully selected genes of HIV subtype C (gag and pro genes and a portion of HIV's reverse transcriptase gene).

The rationale of testing tgAAC09 as a preventive AIDS vaccine candidate is to find out whether it can prevent the development of AIDS in people who are not infected with HIV. Preclinical studies using animal models have been promising, demonstrating that tgAAC09 is well tolerated at all dose levels tested. Primate-based tests of AAV-based vaccines on monkeys have shown how they are able to elicit strong B-cell and T-cell responses against an HIV-like virus called the Simian Immunodeficiency Virus (SIV) that infects monkeys and causes an AIDS-like disease in some species. B-cells are white blood cells of the immune system and produce antibodies against infectious agents. T-cells actually destroy cells that carry the infectious agent. Getting an investigational AIDS vaccine to stimulate both these kinds of cells of the immune system is one of the biggest challenges of AIDS vaccine research today.

The manufacture of the candidate vaccine (using recombinant DNA techniques) does not utilise either AAV or HIV. Original AAV genes are removed from the virus's DNA and replaced with synthetically copied portions of the HIV genome. The design of the investigational vaccine is such that tgAAC09 cannot cause HIV infection or AIDS.

IN CONVERSATION

AIDS Vaccine Research in India – Pushing the Medical Science Envelope

An Interview with Professor NK Ganguly



Prof. NK Ganguly

In the year 1998, Prof. NK Ganguly, an infectious diseases and biotechnology specialist, took over as Director General of the Indian Council of Medical Research (ICMR). He has spearheaded ICMR's wide-ranging programmes on medical research since then, across its network of 26 institutions and laboratories. A well-known academician and teacher, Prof. Ganguly headed the Department of Experimental Medicine and Biotechnology at the Post Graduate Institute for Medical Education and Research (PGIMER), Chandigarh, for over a decade. A former President of the National Academy of Medical Sciences, New Delhi, Prof. Ganguly has authored more than 530 research papers, written several books, and contributed significantly to the medical science research field in India. In this interview with Dr. Subhadra Menon and Dr. Sonali Kochhar of IAVI, he spells out the challenges that face the Indian medical research community in the search for an effective AIDS vaccine.

Q: The last few years have seen a strong surge in scientific interest towards AIDS vaccine research and development (R&D). In your opinion, has this brought change in research priorities at ICMR or research policy at the national level?

AIDS research has always been a priority in India, mainly because HIV/AIDS is something that has always had us worried. It is very heartening that the exponential rate at which AIDS numbers were expected to grow in India did not happen — so we were successful somewhere. But HIV/AIDS still throws new challenges at us, making us define new research priorities. For instance, a big challenge we faced in recent times was how to stop AIDS from spreading in the general population. When we found that 90 percent of women coming to antenatal clinics are monogamous married women and condom use in those groups is only eight percent, a new need was felt — how do you stop the spread? In this context, we felt that microbicide research for personal safety measures is important. Another challenge has been mother-to-child transmission, how can you get better results, how can you expand interventions? New breast feeding practices, regime changes and nutrition maintenance have all been introduced. There is also the challenge of saving the mothers and helping avoid children becoming orphans. So the government started an anti-retro viral drugs (ARV) policy for mothers. Meanwhile, ARVs have become cheaper, more affordable, and new ARVs are being made available. In this scenario, it was important to identify new research priorities. Research has been initiated on studying new resistance patterns, better and cheaper drug combination regimes, finding better ways of administering ARVs, and investigating the viral load and immune status of the population.

Another research priority is the need to have a vaccine that would be useful for us in India against clade C at least. As you are aware, the first vaccine trial has been initiated, and the sec-

ond vaccine candidate will soon be moving. Meanwhile, more vaccines may come up. Ultimately, India will be in step with the world in introducing a vaccine for HIV/AIDS.

There are some challenges yet to be addressed — saving injecting drug users; the TB-HIV challenge; tackling other concomitant viral infections like hepatitis and HIV/AIDS, leishmaniasis and HIV/AIDS. Some populations remain enigmas like migrant populations and high risk groups whose total demography is changing, as they cannot be found in defined areas. Trafficking is another problem. All these issues need very good research to address them.

Some of the existing laws need to be examined; we have not been able to handle our gay populations. There needs to be an appropriate policy in place so that they do not face persecution from society. HIV, meanwhile, is an enigma and challenge, and likely to remain so.

Q: So in this scenario, which would you rate as important current programmes at ICMR?

Each one of the mentioned areas is important and I have actually identified the areas that ICMR has prioritised. We also need to know more about the pathogenesis of the virus, particularly the involvement of the central nervous system. There is a need to learn about the various kinds of tropisms of viruses and their importance in causing infection; reasons why some women are refractory to the HIV virus; understanding the population

“HIV/AIDS still throws new challenges at us, making us define new research priorities. For instance, a big challenge we faced in recent times was how to stop AIDS from spreading in the general population.”

MEDIA BRIEFS

Coverage of the announcement of India's first Phase 1 AIDS vaccine trial

The Indian Express, Pune February 8, 2005

HEROES OF AIDS VACCINE TRIAL: 30 VOLUNTEERS

The tension and excitement was palpable at the vaccine trial clinic at the National AIDS Research Institute (NARI) in Bhosari here. And why not? After all, Dr. Sanjay Mehendale and his team of 20 medicos have been working since 2002 for this day.

"This is the first-ever human study of a preventive AIDS vaccine candidate in India", said the Deputy Director, senior grade, of NARI and Principal Investigator of the trial, as he explained the complicated procedure.

There are 30 volunteers who have enrolled for the Phase I trials, during which some will receive an injection of tgAACO9 – which is being developed as a preventive AIDS vaccine candidate – while others will receive an inactive substance called a placebo. Batches of 10 volunteers will be subsequently tested.

Economic Times, Pune, February 8, 2005

HUMAN TRIALS FOR AIDS VACCINE BEGIN IN PUNE

Seth Berkley, President and CEO, International AIDS Vaccine Initiative, speaking from New York, commended the Indian government's strong backing for the Phase I trial. "This human trial for the vaccine candidate is part of a trial in Europe. Different vaccines have to move simultaneously, to get a working candidate. India is crucial in the world vaccine effort since it has extraordinary scientific capabilities, with strength in pharma and biotechnology. Of all the countries we are working in, the political commitment we have received from the Indian government is the strongest. It has created a model for the rest of the world", he said.

Free Press Journal, Mumbai, February 8, 2005

INDIAN JOINS US-BASED NGO IN SEARCH FOR AIDS VACCINE

The trial initiation is a culmination of the tripartite partnership and several other vaccine candidates are expected to be tested under this partnership in future. It also showed the contribution of Indian scientists which would bring the world closer to the development of an AIDS vaccine. Dr. Anbumani Ramadoss, Union Minister for Health and Family Welfare, made the announcement about the trial, noting that the development of the vaccine was the most difficult scientific challenge and most urgent health need. Perseverance was needed and India had a long-term commitment, he reminded. According to Kapil Sibal, Minister of State (Independent Charge) for Science and Technology, who had been associated with the AIDS fight through his long stint in the Parliamentary Committee, if the tsunami had received enormous global sympathy, the fight against AIDS warranted no less. Sibal, who is also an IAVI board member, observed that the magnitude of the problem could be gauged by the fact that his ministry and the health ministry were compelled to join hands.

The Times of India, Kolkata, February 8, 2005

HUMAN AIDS TRIAL INJECTS HOPE: EXPERTS UPBEAT AT BEING PART OF MEGA PROJECT

According to Dr. Ramesh Paranjape, NARI's Officer-in-Charge, although the outcome of the trials cannot be predicted, researchers "are particularly excited about the feeling that they are part of a process which will go a long way in finding a solution to the widespread epidemic."

The Financial Express, Net Edition, February 10, 2005

VITAL TRIAL: CLINICAL TRIAL OF AIDS VACCINE OF GREAT IMPORT

Needless to say, for a country with the second highest number of HIV/AIDS affected persons in the world after South Africa – 5.1 million – the trial aimed at finding a vaccine that will prevent HIV/AIDS assumes great significance. Not merely in terms of the health of its people, but also in terms of India's socio-economic well-being. Its leadership, as evident from a statement made some weeks ago by Prime Minister Manmohan Singh, is realising that HIV/AIDS, "If not checked, can hurt our ambitions in economic development and growth very seriously."

For a country like India, where not many can afford expensive drugs, leave alone the prohibitively priced anti-retroviral drugs meant for those infected with HIV, the vaccine trial is full of possibilities. Particularly when you take into account the fact that there are 68 new cases of HIV every hour in India, according to the National Aids Control Organization. While this is merely stage one of the trial and a vaccine itself is estimated to be some eight to 10 years away, at least a beginning has been made.

We also need to welcome the trial, as it is an important milestone in the field of bio-medical research in India.

The Hindu, New Delhi, February 10, 2005

HIV VACCINES – A LONG WAY TO GO

Any vaccine must meet two daunting challenges. One is the enormous global diversity of HIV strains and their variants, and it appears probable that the genetic identities of these circulating strains will continue to evolve.....The other problem that a vaccine must successfully confront is the rapidity with which the virus evolves within an infected person and its capacity thereby to slip past the immune system. The global diversity of influenza in any given year is said to be roughly comparable to the diversity of HIV within a single infected individual.

Hindustan Times, Chandigarh, February 8, 2005

HUMAN TRIALS FOR AIDS VACCINE START IN INDIA

Phase I trials are expected to go on for a year-and-a-half. If the first phase goes well, the vaccine will be tested for effectiveness in Phase II trials for another year-and-a-half and a large Phase III trial for three to five years, before it is ready for use. "If the vaccine generates the expected immune response in humans, it should be ready for manufacturing in another 8-10 years", says Dr. NK Ganguly, Director General, Indian Council of Medical Research.

The Associated Press, February 7, 2005

INDIA TESTS ANTI-AIDS VACCINE

India was "essential" to the global vaccine effort because of its advanced biomedical research facilities, and its strong pharmaceutical industry would be able to deliver a cheap and effective vaccine to the millions infected with HIV, Seth Berkley (of the International AIDS Vaccine Initiative) said.

India has more than 5 million people living with HIV/AIDS, the world's second-highest number of infections after South Africa. Almost one-fourth of them are children and young people under the age of 25. However, many experts have argued that the official estimate leaves out many people in the vast country of more than 1 billion who could be carrying the virus without knowing or reporting it.

"There are 68 new cases of HIV every hour, said SY Quraishi, who heads India's National AIDS Control Organization, one of the partners in the vaccine project. "Those numbers alone should strengthen our resolve to press ahead with the vaccine project".

◀ Cont. from 5

genetics level and the evolution of the virus when it crosses geographical locations.

Q: Which are the AIDS vaccine candidates that you are exploring?

At the moment one is the Adeno-Associated Virus (AAV) vaccine which has gone into Phase I in Pune. The second is the Modified Vaccine Ankara (MVA) vaccine for which the application is going to the Drugs Controller General of India (DCGI); it will probably undergo trials in Chennai very soon. Another promising vaccine on the horizon is from Merck, but complete information is still trickling in.

Q: What do you feel are the big hurdles that you have had to face in AIDS vaccine development in India?

The hurdles are very many. There are huge Intellectual Property Rights (IPR) issues which need to be addressed. Another hurdle is being able to expand laboratory technology and convert it into a product through formulation. Others include tackling ethics issues, dealing with the needs of communities, journalists and politicians – each requiring a different approach. Protecting the interests of people involved in the research was important – in fact, even coming to a decision of conducting a vaccine trial was difficult.

Q: Linked to this is the issue of building AIDS vaccine R&D capacity in India.

That we will do. Whatever vaccine goes to trial in India, we would like it to be manufactured by an Indian company so that our vaccine R&D capacity develops as well as the price of the vaccine remains manageable.

Q: But if you were to address the earlier step, which is developing investigational candidates.

Investigational candidates are being developed. India has never lacked that expertise. But investigational candidates do not become vaccine candidates because IPRs have not been addressed and industry participation with scientists was low. Moreover, there is the huge cost of clinical trials and tackling regulatory activities. Things are becoming better now, Indian companies are improving. In the past too, until and unless there were partnerships, it was difficult. So, partnerships are very important even today. There are different kinds of partners with different responsibilities.

“Protecting the interests of people involved in the research was important – in fact, even coming to a decision of conducting a vaccine trial was difficult.”

Q: How about setting up other trials sites and laboratories that are compliant with Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP)?

At the moment two vaccine candidates are being tried at two sites (National AIDS Research Institute, Pune and Tuberculosis Research Centre, Chennai). A third site has been evaluated at Kolkata, so if there is any new vaccine candidate that has to be evaluated, we will see if it can be done there or not.

Q: And smoothening out of the regulatory process in the context of AIDS vaccine trials?

When ICMR is a partner, the regulatory process automatically becomes smooth.

Q: But having been at the helm of affairs for so many years, have you seen change in the regulatory system?

The regulatory system is becoming more sensitive to research needs, it is taking less time. All this is a part of larger change.

Q: Having begun this first Phase I trial, do you see a blueprint emerging for ICMR for vaccine development?

Yes. We have been able to move very fast because of our partnerships. The time taken for the whole process was much less. The new blueprint is factoring all these things and ultimate product development is becoming much smoother than it was before.

Q: At the First National Conference of the AIDS Society of India in April 2005, you spoke about the importance of such partnerships. Is ICMR then addressing this approach in a big way, or has it always been like this?

A very good model of collaboration is the AIDS vaccine partnership between the Government of India and IAVI. I don't think we have ever seen a better partnership model than this one. So, if models like this could be replicated, it would be quite useful.

Q: Are you exploring any other partnerships?

In HIV related areas, at the moment, we have a partnership in microbicides research with Conrad (Contraceptive Research and Development Programme), the World Health Organization and the Medical Research Council (United Kingdom). Some other partnerships include those in areas like Hib vaccines (*Haemophilus influenzae*) and also with the Global Alliance for Vaccines and Immunisation (GAVI), Johns Hopkins University, USAID and the Government of India.

Q: The systems put in place for informed consent, medical insurance, for care and treatment – do you envisage that they would need to be followed for future trials?

Yes, these systems have provided us with very useful lessons for vaccine trials. ■

IN FOCUS

Popular Indian Science Meet discusses AIDS Vaccines

By Subhadra Menon in Ahmedabad



“Let us make an AIDS vaccine and plan for its production”

– The President of India, Shri APJ Abdul Kalam, speaking at the 92nd Indian National Science Congress, January 2005, Ahmedabad

The remarkable and tangible power of scientific progress in helping a country and its people meet basic needs such as food, clean water and health is globally recognised. Within this broad framework, the contribution of cutting-edge scientific discovery and research in building and strengthening health care systems, especially in developing nations, is of particular significance.

The Indian Science Congress (ISC) is a popular forum that has played an important role in the promotion of science in India since it was first held in 1914. The focus of the 92nd meeting of the ISC, held in January 2005 in the city of Ahmedabad, Gujarat was on *Health Technology as a Fulcrum for the Development of the Nation*, acknowledging how essential it is for science to contribute to improving health systems for civil society.

The Government of India has always been committed to strengthening the role of science in improving life in India, and this was reaffirmed by Prime Minister Shri Manmohan Singh when he inaugurated the week-long meeting. He shared with the delegates his government’s allegiance to the development of basic science, to rebuilding the science base in universities, promoting public private partnerships to increase funding for frontier areas of scientific and technological research, de-bureaucratising science and technology institutions and creating

exciting career opportunities for scientists in India.

Partnerships are critical to advancement of knowledge in every field, and this came through at the January 2005 ISC. According to Prof. NK Ganguly, President of the Congress for this year and Director General of the Indian Council of Medical Research, “international cooperation in science and technology in cutting-edge research areas is required”. This cooperation through effective global partnerships is all the more necessary in areas such as the prevention and elimination of infections like HIV/AIDS, where the world is still searching for an effective AIDS vaccine. “The search for an AIDS vaccine is just entering the enterprise zone” and the stress has to be on “cooperation, collaboration and transparency” said Dr. Margaret I. (Peggy) Johnston, Assistant Director for HIV/AIDS Vaccines, the US’s National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, Maryland. She was speaking at a special Parallel Health Science Summit as part of the ISC. She highlighted that the core of the worldwide AIDS vaccine search was to address the rate limiting step in the search, which is “the scientific challenge” and how important it was to “continue research so as to find a vaccine that will work”.

Several scientists and specialists at the Congress referred to the continuing chal-

lenge of expanding the vaccine pipeline – testing and trying more and more approaches. Dr. Renu B Lal, a consultant with the Centers for Disease Control in India shared her concerns about how “the genetic diversity of HIV 1 is like a moving target, there are 16 published Circulating Recombinant Forms (CRFs) and the list is growing”. Dr. Renu Lal also feels that scientists need to address “the impact and the challenges of this viral diversity on vaccine strategies”.

Today, the world does acknowledge that AIDS vaccine research is important, in recognition of a grave public health need to end HIV/AIDS. The clear understanding that cracking the science of a functional AIDS vaccine is going to be very tough has only strengthened the resolve of numerous scientific institutions and groups across the world. A safe and effective AIDS vaccine remains a strong scientific possibility and there have been many public expressions of this confidence in the last decade or so. The ISC congregation of scientists was no different. In a plenary lecture, Dr. Richard Klausner, Executive Director, Global Health, the Bill and Melinda Gates Foundation spoke about *Global Health: The 21st century challenge for Science, Technology and Society* and said: “There are few single medical technologies that would have as profound an impact on global health as an effective HIV vaccine.

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EVENTS UPDATE

ASICON 2005: The Big Five

India's five big challenges in confronting HIV/AIDS were spelt out by the Union Minister for Health and Family Welfare, Dr. Anbumani Ramadoss, at ASICON 2005, the first National Conference of the AIDS Society of India (April 2-4, 2005) in New Delhi. The AIDS Society of India (ASI) is an affiliate of the International



Dr. Anbumani Ramadoss

AIDS Society (IAS), and the chairpersons of the conference were Dr. IS Gilada and Dr. Suniti Solomon of YRG Care, Chennai. Dr. Ramadoss's five big challenges are:

- ♦ **Challenge # 1:** Addressing the scale and diversity of responses required in prevention, care and support. Especially addressing the needs of young people and working with the Human Resources Development ministry to ensure a new and vigorous health education programme as part of formal education curricula.
- ♦ **Challenge # 2:** Strengthening the response from the private sector: involving the private sector through public-private partnerships, particularly for workplace interventions.
- ♦ **Challenge # 3:** Improving the quality and capacity of health systems to ensure uniformity in the service.
- ♦ **Challenge # 4:** Accreditation of blood banks and laboratory facilities to create stringent measures for protection from HIV.
- ♦ **Challenge # 5:** Strengthening the government's programme on anti-retroviral (ARVs) drugs by increasing the number of hospitals providing free ARVs from the current 25 to 100.

Underscoring the importance of partnership, Prof. NK Ganguly, Director General of the Indian Council for Medical Research, highlighted the example of the Indian government's partnership with the International AIDS Vaccine Initiative for AIDS vaccine development in the country as an excellent model of a "thorough" approach. In this partnership, every thing had been taken care of - right from stakeholder and community involvement to the collaborative approach taken for the scientific aspects of the programme.

Focusing on the Young: "The Wonder Years?"

How do you meet the health and social challenges of very young adolescents? A two-day national conference *Tomorrow's Youth Today: Very Young Adolescents (10-14 years) in Sexual and*



Mr. PK Hota

Reproductive Health organised by the Family Planning Association of India (February, 2005, New Delhi) tried to knit together existing experiences of working with these very young adolescents

New vaccine trial enrolling in New York

(Source: HIV/AIDS VAX 3(2), February 2005, an IAVI Report Bulletin)

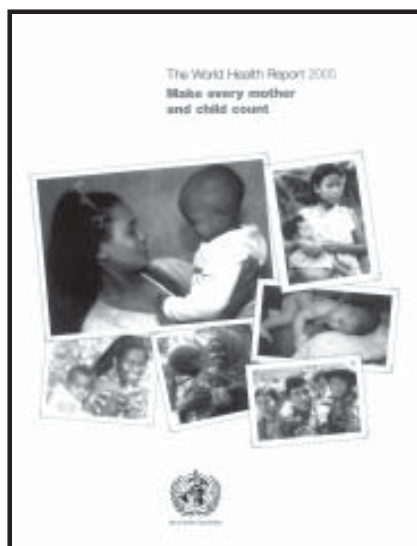
The Aaron Diamond AIDS Research Centre (ADARC) in New York City and University of Rochester Medical Centre at Rochester, NY recently began enrolling volunteers for a Phase I vaccine trial. The trial will test the safety and immunogenicity of a vaccine candidate in 48 healthy volunteers. The vaccine candidate is called ADMVA and is based on a Modified Vaccinia Ankara (MVA) viral vector. This vector is developed from a virus that is similar to the virus used for the smallpox vaccine.

This vaccine candidate was developed at ADARC and contains genes from clade C HIV, which is prevalent in China, India and sub-Saharan Africa. "We're particularly excited about this. The epidemic in China is burgeoning and really the only hope for some people is a vaccine," says Dr. Sarah Schlesinger, a Research Associate Professor at ADARC, a partner of IAVI and Rockefeller University.

and also tried to formulate what could be done to make things better.

Mr. PK Hota, Secretary, Ministry of Health and Family Welfare, speaking at the inaugural session, said: "These are the wonder years, when young people are vulnerable to wrong information and when the peer group often gives out half-hearted and dubious information". The conference sessions were aimed at addressing several concerns including what was voiced by Mr. Hota, such as listing out the health and social challenges youngsters face, child abuse, organising sexual and reproductive health services in the public sector, imparting sexuality education and addressing strategies for action – with communications, education and advocacy. Mr. Hota promised a "careful follow-up of what emerges from this conference".

World Health Report 2005 released in New Delhi



On April 7, 2005, WHO released The World Health Report 2005 – *Make Every Mother and Child Count* – through a launch in New Delhi, with related events in many countries. Across the world, 'hun-

dreds of millions of women and children have no access to potentially life-saving care with often fatal results', says the report. It highlights the fact that there can be a significant and sharp reduction in the resulting loss of life if only key interventions that already exist were used more widely.

According to the report, around 2.2 million women with HIV infection give birth each year; nine percent of children under 15 years of age in 40 countries in sub-Saharan Africa have lost a parent, and one percent have lost both. Last year, 3.1 million people succumbed to AIDS, of which 510,000 were children.

Now, A National Council on AIDS

In an effort to mainstream HIV/AIDS related issues across government ministries and departments, on January 5, 2005, the government announced the formation of a National Council on AIDS. The National Common Minimum Programme of the United Progressive Alliance had committed itself to the same. The Council – for which terms of reference and guidelines are still being worked out – is to be chaired by the Prime Minister Shri Manmohan Singh and co-chaired by the Union Minister for Health and Family Welfare, Dr. Anbumani Ramadoss.

It is expected that the Council's main role will be to provide strategic guidance and advice to the National AIDS Control Organization and enable various ministries to incorporate HIV/AIDS prevention and control programmes into their work plans. Various ministers (Finance, Home, Defence, Labour, Railways, Health and

Family Welfare and others) are to be members, along with select Chief Ministers and civil society representatives. The Council will meet once a year.

Media Rises in Support for AIDS

A Media Leaders' Summit, chaired by the Prime Minister Manmohan Singh, was held in January 2005 at the PM's residence in New Delhi. The basic idea of the summit was to get senior media leaders together to use their collective expertise in reaching out to people, especially young people, to send out as much information as possible on how to prevent HIV/AIDS.

The Prime Minister said: "While focusing attention on research for finding a

vaccine for this pandemic, we must leave no stone unturned in preventing its occurrence by using media in an intelligent and creative manner. In the absence of a vaccine, the social vaccine of education and awareness is the only preventive tool we have. It is appropriately said that prevention begins with



Dr. Manmohan Singh

information. Media, which conveys information and moulds public opinion, must remain at the heart of our campaign to help people make informed choices." This meeting was a sequel to the Global Media Initiative hosted by the United Nations Secretary General, Mr. Kofi Annan in January 2004 in New York. Hollywood star and HIV/AIDS advocate, Mr. Richard Gere said that the media leaders shared their problems in covering AIDS and the meeting tried to address these so as to allow for greater and better coverage. ■

◀ *Cont. from 9*

It is one of the most scientific and technically difficult problems ever faced." Klausner emphasised the fact that societal inequity has only grown with scientific achievement, and one effective way of changing that would be to push for new health technologies. The AIDS vaccine quest is a clear example of such innovation. The Global HIV Vaccine Enterprise has been established as an attempt to build this very innovation.

Finding new vaccines to combat communicable diseases has been a continuous process for human society. At the Health Science Summit, Dr. Stephen L. Hoffman, founder and CEO of Sanaria Incorporated, a US-based company that works on malaria vaccines, spoke about the number of malaria vaccine approaches being tried – more than 70. In India, the International Centre for Genetic Engineering and Biotechnology, New Delhi, is developing and testing investigational malaria vaccine candidates. Considering malaria is responsible for an enormous disease burden, these efforts have great significance, even urgency.

Meanwhile, there is little doubt that public health challenges in India will only grow, and Dr. Altaf Lal, Health Attaché at the US Embassy in India, said: "So what is it that 21st century public health should be looking at? Emerging and re-emerging diseases are not one country's problem, but a global one, and yet each country has different resources and expertise in handling this burden." Dr. Lal stressed on the importance of translational research – the capacity to conduct trials and to mount carefully designed epidemiological studies. The ISC also had discussions and presentations on the issue of setting priorities for research in developing countries. Professor Stephen Matlin, Executive Director of the Global Forum for Health Research, Geneva, said that "less than 10 percent of resources are spent on 90 percent of health problems" and there was a felt need for "research priorities to get vaccines for communicable diseases".

We have to "end the neglect, clear the dangers", as Dr. Lal said, referring to the multiple health challenges that face us today. The ISC was, in a sense, "a show of strength, of the commitment of scientists from all over the world to improve the quality of life and longevity, by using new and innovative health technologies", said Mr. Kapil Sibal, Minister of State (Independent Charge) for Science and Technology and Ocean Development. He also shared the government's commitment to similar goals, saying that "I assure all participants sustained and enhanced support from the Government to realise their dreams of eradicating dreaded diseases".

There was widespread expression of interest in converting concept to reality, especially in the field of big challenges like the search for an AIDS vaccine. As several delegates at the ISC observed, this interest is receiving strong support from the political leadership of India — evident from the fact that Prime Minister Shri Manmohan Singh who inaugurated the ISC and President Kalam who gave the valedictory speech both brought up the need for an AIDS vaccine. In strong recognition of what the frontiers of scientific research must do for humanity, the Prime Minister said: "new advanced health technology must help the poor and needy. Our 'best minds' in science must engage themselves in providing solutions to the problems that can make a difference to humanity. Every thirty seconds, a child dies somewhere of malaria. We can imagine the benefit to humanity if we had a good vaccine for malaria. HIV/AIDS is ravaging nations today. A new vaccine for HIV/AIDS can make a big difference. Such breakthroughs cannot occur unless our most creative brains dedicate themselves to these problems. I appeal to the very best of our scientific community to engage themselves in dealing with such challenges that are both intellectually stimulating and socially relevant". This appeal – it is hoped – will go a long way in enhancing scientific activities in the search for vital vaccines and new health technologies. ■

SANKALP

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IAVI is a scientific organisation 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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