INFOCHANGE

agenda

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HIV/AIDS: The Big Questions

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- What has changed for people living with HIV?
- Why are less than 50% of those who need ART getting it?
- Is transmission only about sex and drugs?
- How can interventions with high-risk groups work if they are criminalised?
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Cover: Affected children look out on an uncertain future
Photograph by Zishaan Latif

This issue has been guest-edited by Sandhya Srinivasan

Hard questions about HIV/AIDS

IN THE MORE THAN 20 YEARS since HIV infection was first identified in India, there has been a transformation in the official response to it and, as a result, the way in which the public views it. We started with denial ("it can't happen in India, we don't have sex outside marriage"), moved to fear-mongering ("AIDS kills"), added prevention programmes that targeted certain groups and promoted stigma and discrimination ("you must have done something immoral to become infected, it's up to you to protect yourself"), and included selected services such as treatment of sexually transmitted diseases. Prevention continued to be the focus of the second phase of the National AIDS Control Programme, with the prevention of mother to child transmission programme. Voluntary counselling and testing centres were introduced before there was any scope for treatment. Efforts were made to provide some kind of care and support, but without strengthening existing healthcare services. Now there is an ambitious — given the quality of existing government health services — effort to provide treatment for a fraction of those needing it.

At the same time, there has been an information overload of sorts on HIV in India. This deadens us to the subject so we don't always look for answers to important questions. Or if we have any doubts, we do not seek their clarification because we have no idea where to look or how to make sense of what is said. How significant is HIV as a public health problem? How should we tackle it? Are we going about it the right way? What hurdles do we face in this effort?

This information overload is most obvious in the numbers that are flung around, steadily climbing from 3.5 million in 1998 to 5.2 million in 2005, and now dropping to less than half that figure. India's estimated HIV burden seems to be of great importance not only to us but also to the rest of the world — despite the fact that we know the surveillance system was not designed to provide such estimates. At the same time, there is a running public tussle between NACO (National AIDS Control Organisation) and international agencies on the estimates. On what basis did the US intelligence organisation conclude that India would have 20 million people with HIV?

The focus on numbers does two things: first, it is used as a reason to increase or decrease spending on the programme. But perhaps more importantly, by being presented in isolation (and by glossing over both the range of estimates and the limitations), HIV does not get integrated into the larger health scenario. So those who speak of vulnerabilities to HIV infection and access to antiretrovirals (ARVs) are to a large extent distinct from those who speak of the socio-economic determinants of health, and of universal access to healthcare.

Related to this discussion of AIDS independent of other health issues is its discussion as a separate programme within public healthcare. Without in any way downplaying the factors that contribute to HIV transmission and the impact of HIV on already marginalised sections of society, we must ask why AIDS prevention and treatment is a separate programme. How can treatment and care for one disease be provided without proper integration into the healthcare system? Is there evidence of such integration across the country? And most important, why is there not enough focus on the health system itself?

The pressure to view HIV in this manner is directly linked to the overall pressure of international organisations to focus on individual components of health and healthcare services rather than the conditions that lead to ill health as well as the need to have a comprehensive response.

The articles in this issue of *Agenda* ask some provocative questions about HIV:

How much confidence should we have in the National Family Health Survey estimate of the HIV burden? Does the National AIDS Control Programme (NACP) represent skewed priorities for our healthcare system? Have things really changed for people living with HIV? Does the government drug programme reach the marginalised sections which are most affected, who have the least access to care? What happens when second-line drugs fail?

Do we really know the relative importance of the different means of HIV transmission? Does the focus on sexual transmission and injecting drug use shift the responsibility of prevention to individuals rather than the system? How can a prevention programme work if it is targeted at people involved in practices that are seen as illegal? Do we even know how to measure changes in HIV within a particular group, let alone explain the influences that led to these changes? How effective has the prevention of mother to child transmission programme been? Are the recent guidelines promoting provider-initiated testing for HIV justified? Should we have premarital testing for HIV? Do we need a law specific to HIV? How important is a vaccine against HIV, and where is the research going? What are the technical and ethical challenges in conducting vaccine trials?

The articles in this issue challenge conventional wisdom in order to either force a stronger justification of the current views on HIV/AIDS in India or a further examination of the alternative perspectives and their implications.

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20 million or 2 million?

In 2006, UNAIDS declared that India had 5.7 million HIV-positive people. NACO put the figure at 5.2 million. Simultaneously, others warn that by 2010 India will have 20 million positive people. Finally NFHS-3 comes along and puts the HIV burden at 2.5 million. Where do these multiple, conflicting estimates of HIV burden come from? Who has an interest in inflating — or downplaying — AIDS figures?

M PRASANNA KUMAR

ESTIMATES OF HIV IN INDIA have always been challenged, either by the government or by other agencies. In 2006, UNAIDS declared that India had an estimated 5.7 million HIV cases (range: 3.4 to 9.4 million) (1), making it the country with the largest HIV burden in the world. The National AIDS Control Organisation (NACO) quickly countered that figure, saying it was no more than 5.206 million (2). That same year, the Joint UN Programme on AIDS (UNAIDS) stated that there had been 400,000 deaths due to AIDS in India in 2005. This number too was dismissed by the government. Not too long ago, a US Central Intelligence Agency report projecting that India would have 20-25 million HIV infections by 2010 (3) was widely circulated in Indian and international publications.

On the other hand, government estimates of the HIV burden in the country have been regarded with scepticism by international agencies and AIDS activists who believed them to be underestimates.

Such wide variations baffle the average reader. How exactly are HIV estimates made? How reliable are they?

The explanation, in a nutshell, is that the various estimates are based on mostly the same data but on different calculations. NACO's calculations are made in consultation with a select team of experts including people from the World Health Organisation (WHO) and UNAIDS. However, UNAIDS uses a different modelling approach for making global estimates. Since this method is different from NACO's, it will give a different estimate when applied to India. Differences in the methodology and algorithms used lie at the root of all disputes regarding HIV estimates.

The real question may be: what drives different groups to use different methods? Do they have an interest in inflating — or downplaying — figures?

Latest controversy

In 2006, NACO calculated that there were 5.206 million people with HIV in India. This was based on the government's sentinel surveillance data collected in 2005.

Then, on June 6, 2007, a beaming Anbumani Ramadoss, Union Health Minister, released the results of the third (and latest) National Family Health Survey (NFHS-3) which arrived at an HIV burden of only 2.5 million (range: 2 to 3.1 million), half the previous year's figures (4). (By way of comparison, there are 1.5 to 2 million people with cancer [5] and 8.5 million people with TB [6] in the country at any given time.)

HIV prevalence in the 15-49 age-group is down from 0.91% to 0.28% (2). Prevalence among men is 60% more than in women, at 0.36% and 0.22% respectively (4).

What are we to make of this huge discrepancy between the earlier and latest estimates?

Sentinel surveillance and HIV trends in India

Every year since 1998, the National AIDS Control Organisation (NACO), which is under the Ministry of Health and Family Welfare, has released figures on India's HIV burden. These figures are based on data from annual rounds of sentinel surveillance in which blood samples are taken from designated sentinel groups in every state and union territory in the country: pregnant women at government hospitals, clients visiting sexually transmitted diseases (STD) clinics, and groups with high-risk behaviour such as female sex workers, men having sex with men, and injecting drug users. Most surveillance sites are in urban areas, although a certain number of rural sentinel sites are also sampled to get an idea of HIV prevalence in rural areas. A specified number of samples is collected from each sentinel site (400 from the sites of pregnant women and 250 from others) and tested for HIV. India has the largest HIV sentinel surveillance programme in the world and it is being improved and extended every year. In 2005, it was carried out at 703 sites throughout the country. That number was increased to 1,122 in 2006.

Still, not all 611 districts in India are represented in the sentinel surveillance programme. There are plans to increase the number of sites further, to ensure greater geographical representation and to include all significant risk groups in an area. This would certainly mean closer monitoring of the local epidemic, and more accurate assessments of the trend of the epidemic.

Sentinel surveillance is used along with other measures to look at trends in HIV prevalence. Information from various sources is triangulated — surveillance data, number of AIDS cases reported, number of AIDS deaths reported, age-specific mortality, blood bank data, and size of population of groups with high-risk behaviour. In any particular site, if data from multiple sources is available, it helps build a truer

picture of the local epidemic. Such triangulation also helps to limit errors in noting trends. But one should never forget that in any study of this kind, where only selected small subsets of the population are sampled and the results of the sample used to make projections for the entire country, there is bound to be some degree of uncertainty in the final estimate. This is why the methodology is constantly being refined to reduce the margin of error.

Sentinel surveillance is a good tool for noting trends in HIV prevalence, and changes over the years. It is a costly and labour-intensive exercise (over Rs 3 crore is spent every year). In India, it is well carried out and generally well supervised. Preparations for each annual round of sentinel surveillance are made months in advance, all staff involved are trained, a standard protocol of data gathering and testing in all sites is followed, and there is monitoring by observers at all levels as well as external quality assurance in the testing of samples.

Sentinel surveillance and the HIV burden

The problem arises when sentinel surveillance data is used to estimate a country's HIV burden. Sentinel surveillance is not designed to make estimates, but it has been used to provide rough estimates of the HIV burden for many years, for want of a better approach. One could ask why other methods were not used. But the problem is not so much in making rough estimates as in their dissemination and use to make a point that they cannot make.

HIV is not very prevalent among the general population in India. (The latest figures suggest that the prevalence is half of the already low prevalence of less than 1%.) The accuracy of a sample survey depends partly on the prevalence of the condition. The lower the prevalence, the higher the minimum sample needed. Also, sampling biases are worsened when the condition has a low prevalence.

Biases in the sampling process

There are various biases in the existing sampling process. However, these biases are not publicly acknowledged, as a result of which the public is misled.

For example, practically all sentinel sites are in government hospitals, whereas the majority of people use private services. We don't know the HIV prevalence among those who attend private hospitals. Estimates of the overall HIV burden are mainly based on prevalence among pregnant women attending government hospitals. This excludes those who go to private hospitals for antenatal care — and those who don't receive any healthcare at all.

Further, the samples are of pregnant women and various groups with risk behaviour. They offer no direct information on other women or on men outside these groups.

In addition, samples taken from STD clinics are intrinsically biased — they are taken from people with symptoms of a sexually transmitted disease who attend government STD clinics for treatment. These should not have been included when calculating the HIV burden of the country.

Finally, if the condition is unevenly distributed in the population, any sample taken will not be representative of the population. Representative samples are necessary in order to make projections or estimates, or else the results will be unreliable.

To illustrate, each state provides 400 samples each for the annual surveillance, from several antenatal clinics. Just two or three positive samples among them could skew the overall results. In Uttar Pradesh, in 2003, at least eight of the 17 antenatal clinics did not have a single positive sample.

By contrast, in South Africa, the antenatal prevalence in 2003 was 28%. If they had used the same system as ours, they would have had 112 positive samples out of 400 samples at a single site.

The only way to get an accurate picture of the HIV burden is through a head count — that is, testing everyone — which obviously is not possible. One therefore has to be satisfied with the limitations of using sentinel surveillance data, and now the NFHS data which is likely to be more accurate.

Assumptions behind the NACO algorithm

When NACO mentions an increase in HIV burden, it is referring to an estimated number based on a calculation. These estimates are affected by sampling errors and the number in a particular year does not tell you much. The numbers are useful only when one wants to look at trends over time, to assess the rate of growth of the epidemic.

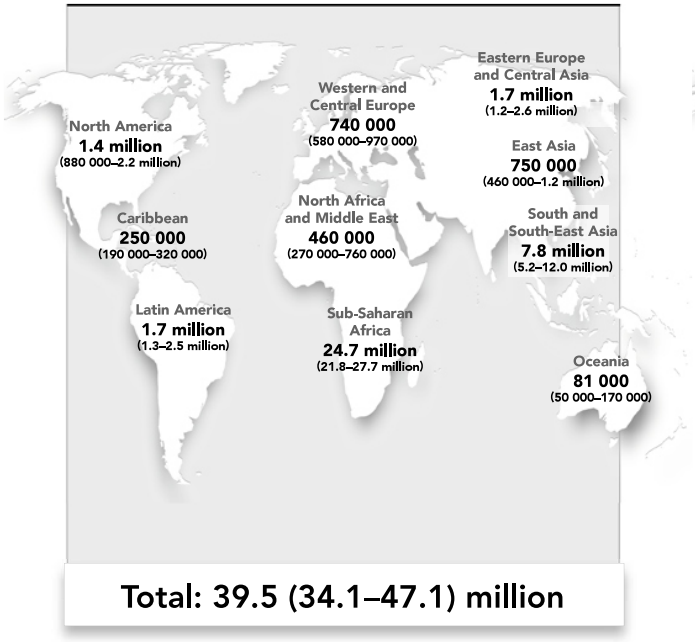
Even here, there are questions. This is illustrated by looking at the estimates from 1998 to 2005, given in the table.

Year	HIV estimate in lakhs	Increase over previous year in lakhs
1998	35	-
1999	37	0.2
2000	38.6	1.6
2001	39.7	1.1
2002	45.8	6.1
2003 estimate with improved method	51.06	5.26
2004 estimate with above method	51.34	0.28
2005 estimate with above method	52.06	0.72
Source: National AIDS Control Organisation. UNGASS India report, 2005. //data.unaids.org/pub/Report/2006/2006_country_progress_report_india_en.pdf		

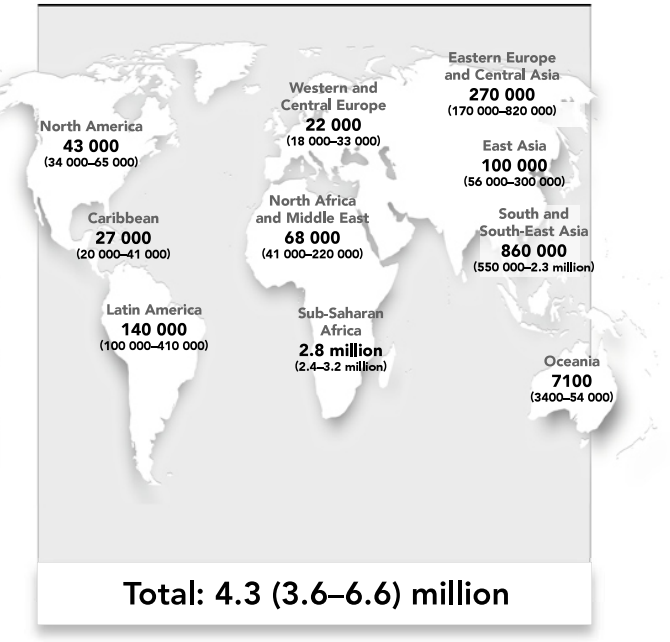
How should we understand these annual estimates?

First, these estimates are based on an algorithm used by NACO which utilises sentinel surveillance data. The algorithm in turn is based on HIV prevalence among pregnant women, prevalence among STD clinic attendees, percentage of men and women between the ages of 15 and 49 in urban and rural areas, ratio of HIV prevalence among men and women, ratio of HIV prevalence in the urban population to that of the rural population, etc. When one is

ADULTS AND CHILDREN ESTIMATED TO BE LIVING WITH HIV IN 2006



ESTIMATED NUMBER OF ADULTS AND CHILDREN NEWLY INFECTED WITH HIV DURING 2006



Source: UNAIDS/WHO 2006 AIDS epidemic update

projecting from a sample subset to the entire population, one is forced to make some assumptions or use values which seem plausible for certain parameters. However, these could result in large margins of error in the final result (7). The most critical is the one that HIV is uniformly present among the general population. This may not be true. Another important assumption is that there is a differential of 2.4:1 between the HIV prevalence in urban areas and rural areas. A third source of error is the assumed HIV prevalence differential between men and women; 1.2:1 in high-prevalence states, 2:1 in medium-prevalence states, and 3:1 in low-prevalence states. In defence, it must be said that without making these assumptions it is not possible to calculate the HIV burden of the country, when men are not sampled and the main input is that of HIV prevalence among pregnant women.

Then, from time to time, NACO also makes changes in the algorithm, taking new evidence into account to help make a better estimate. Changing the methodology or algorithm will alter the final estimates, so estimates made with different algorithms are not strictly comparable.

Is the epidemic stabilising?

In India, which has an overall low HIV prevalence and a non-uniform spread, when we make projections with only 400 samples from each site, there are bound to be uncertainties in the final estimate. No one can be sure what the margin of error actually is. But we can have some confidence in the fact that since 1998, when sentinel surveillance was first done at a national level, a number of states have registered only marginal increases in HIV prevalence and many have remained at the same level for years. Several large states such as Uttar Pradesh, Madhya Pradesh, Bihar, etc, have only 0-0.25% prevalence levels (8). Tamil Nadu has had a sustained HIV prevalence of under 0.7% and should no longer be considered a high-prevalence state. All these indicate that HIV is not spreading as rapidly as we once thought it would in our country; it is probably stabilising (9).

Are our preventive efforts paying off? Or is this just part of the long-term history of HIV infection? Will it become less virulent over time, as happened in the case of syphilis? This is something that we will not know at this stage, as HIV is a new disease. One can be really certain only if a similar slowing is seen in subsequent years as well.

Household surveys

In order to improve HIV estimates, epidemiologists have started implementing population-based surveys or household surveys, in which blood samples are taken from the male and female members of randomly selected households. About 30 countries worldwide, mostly in Africa, have conducted such population-based surveys. In most cases, this has resulted in a downward revision of earlier HIV estimates based on sentinel surveillance. Kenya, Ethiopia, Cambodia and now India are countries where the new method cut previous estimates by half. As these surveys are

accepted as being more accurate than the previous ones, the total number of HIV infected in the world is being revised downwards constantly. In 2006, UNAIDS estimated the global HIV burden to be 38.6 million, with a range of 33.4 to 46.0 million (10). Now this will shrink by 2.5 million based on the latest estimates from India.

Third National Family Health Survey

The third National Family Health Survey (NFHS) was carried out throughout India in 2006. This community-based household survey was carried out to obtain data on indicators of population, health and nutrition, according to background characteristics. Information was collected about households, and interviews conducted with women aged 15-49 years and men aged 15-54 years. Blood tests were also conducted for anaemia and HIV for a sub-population of respondents.

A community-based survey is the ideal method of finding out the HIV burden of the country because it covers men as well as women in the reproductive age-groups, both married and unmarried, and not just pregnant women. This study is far more representative than sentinel surveillance, since it represents all adults. However, such a survey is most accurate in countries with a generalised epidemic — more than 1% of adults must have HIV infection. In India, HIV infection is seen predominantly in vulnerable groups such as female sex workers, their male clients, men having sex with men, injecting drug users, their spouses and other sexual partners. Only five states have an HIV prevalence of over 1%, so it may not be true to say that India has a generalised epidemic.

Limitations of the NFHS

While the NFHS-3 estimate is believed to be more accurate than the annual estimates provided by NACO, we must remember that it too has certain limitations.

A community-based study may also introduce errors of various kinds. One is that as only members of households are sampled, people on the move, migrants, those who have no regular living place such as sex workers and similar groups at higher risk are excluded. In this survey, the sample sizes for the four high-prevalence states of Maharashtra, Karnataka, Andhra Pradesh and Manipur and the low-prevalence but high-population state of Uttar Pradesh, were adequate to provide state-level HIV estimates.

In the other 22 states, the sample size was good enough to provide HIV estimates at the national level but inadequate to provide state-level estimates.

In low-prevalence states, a very large number of samples are required to provide accurate HIV-prevalence estimates. This measure, no doubt enforced by the need to keep costs down, reduces the validity of the study.

An advantage of sentinel surveillance is that it provides state-specific estimates. More than 100,000 blood samples were collected in the NFHS-3 survey. In contrast, 225,000 samples were collected in the 2005 sentinel surveillance round, and with half as many centres as in the 2006 round, many more samples were collected.

Another possible source of error in any community-based survey is the need to link blood samples to personal interviews and household surveys. NFHS-3 used the Linked Anonymous method: individual interview data can be linked to his or her HIV result. After the interview, which included sexual history-taking, every participant was informed about the purpose of blood testing and was asked to sign a consent form. Blood was drawn only from individuals consenting to participate.

Linked surveys underestimate HIV prevalence. People who know they are HIV-positive or suspect they may be infected may refuse to provide a blood sample. Non-participation of infected individuals aggravates the error in low-HIV-prevalence situations. Most low-prevalence states have an HIV prevalence of 0.1% to 0.3% which means that among 1,000 individuals only one to three individuals may be positive. Even if a few such positive individuals do not participate in the survey, the estimate is thrown off considerably. By contrast, sentinel surveillance employs the Unlinked Anonymous method, in which HIV testing is done in blood samples which are routinely collected for other purposes, and participation error is minimised.

It was speculated for some time that India's HIV burden was overestimated. AIDS was not very visible in large parts of the country with low numbers of reported AIDS cases and AIDS deaths. When antiretroviral therapy was initiated, the uptake was remarkably low and the expected hordes of AIDS patients demanding ART did not materialise. The algorithm used for estimating the HIV burden had a lot of unvalidated assumptions. In a landmark study, Lalit Dandona *et al* (11) did a population-based HIV prevalence survey in the high-prevalence district of Guntur in Andhra Pradesh. They demonstrated that the sentinel surveillance methodology and the algorithm used for estimating HIV burden were overestimating the infected population.

The NFHS-3 study has provided valuable information on the state of the epidemic in the country. It provides a more accurate figure than previous estimates but it needs further refinement. While there is no doubt about the usefulness of the study, its limitations have to be addressed so that it is more informative and reliable.

What do we make of the different estimates?

Coming back to the question we started with, why do we have conflicting estimates?

One reason is that different organisations use different models and algorithms when arriving at estimates, even though they might use the same data.

One example is the estimate of AIDS-related deaths. Recording of AIDS deaths is important because they indicate the mortality toll of the disease. Historically, reported AIDS deaths were used to estimate HIV prevalence using

the 'back calculation' approach.

UNAIDS's estimate of AIDS deaths uses a projection method based on HIV prevalence data. This method, when used in low-prevalence regions where the epidemic mostly involves some vulnerable groups, can only provide death estimates with very wide margins of error (12). On the other hand, NACO does not make an estimate but gives the actual number of reported AIDS deaths in the country; only 8,097 AIDS deaths were reported till the end of 2005 (13). If the cause of death reporting is nearly complete, reported AIDS deaths do give an indication of the state of the epidemic in the area. However, AIDS death reporting is insisted on but rarely followed even by hospitals in India, with the result that only a tiny fraction of those with HIV infection are ever recorded to have died of the disease.

One must also remember that all groups concerned — whether government, international organisations or civil society organisations — may have their own biases as well as their own interests in projecting a particular number.

When we hear civil society organisations claiming that the country's HIV burden is much higher than NACO's estimate, we must also remember that many civil society organisations see only a small part of the whole picture. They tend to see people who are symptomatic or have AIDS. The number of symptomatic people and people with AIDS is certainly increasing, since those infected years ago are now developing symptoms/AIDS.

There is no doubt that doctors and civil society organisations are seeing more people who need care. But a spate of AIDS cases does not mean an absolute increase in the number of people infected. All it means is that the epidemic is becoming more visible as the proportion of symptomatic patients increases.

There is another factor as well. With the global interest in AIDS, institutions of all kinds could have an interest in high estimates. If surveillance and other data show that the HIV epidemic is not increasing as rapidly as was expected, it would also mean a cut in funding. In 2004, Richard Feacham, Head of the Global Fund for AIDS, TB and Malaria, declared that official NACO HIV estimates were conservative and that "the HIV/AIDS epidemic in India is extremely grave… a ticking time-bomb" (14). UNAIDS has been accused, most notably by Dr James Chin, former Chief Epidemiologist of the Global Programme on AIDS, of consistently overestimating HIV caseloads of not just India, but countries around the world, and not being prompt enough to adopt more accurate methods of estimation. This, some say, has resulted in the AIDS programme getting a greater share of the limited funds available for international health. The Global Programme on AIDS had projected earlier that if the HIV epidemic was not contained early, the cost of human life and economic devastation would be on a massive scale. This could explain why the HIV epidemic was able to attract funding, though by many estimates it is still far short of what is necessary.

The implications of low figures are two-fold, depending on how they are used. First, they could suggest that the problem is not as grave as was believed. Second, they could be used to argue that prevention programmes are making a difference, and therefore gain support for future funding.

My belief is that prevention programmes are working, as shown by steep sustained falls in HIV prevalence among sex workers especially and among pregnant women in several states such as Tamil Nadu, Karnataka and Maharashtra, to some extent.

At the end of the day, do we have a better sense of how AIDS has affected the country? Are the latest numbers more accurate? The answer: the latest calculations give us a better picture of the problem, but they too have their limitations. Maybe we shouldn't take all these numbers too seriously.

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Is HIV/AIDS skewing public health priorities?

The bulk of health problems facing Indian people are simple — malnutrition, malaria, etc — and they require simple solutions. But the government increasingly focuses on vertical programmes to tackle each disease instead of comprehensive healthcare. The AIDS control programme is another vertical programme that reinforces our misplaced priorities and puts more pressure on an already crumbling public health infrastructure

T K RAJALAKSHMI

THE YEAR 2008 will mark the 30th anniversary of the World Health Organisation's declaration at Alma Ata, then in the USSR. Many governments including the Indian government promised to provide Health for All, setting a date for this, the year 2000. This was not only an expression of intent; it was a slogan reiterating a serious commitment to health issues.

Health was defined as a state of complete physical, mental and social wellbeing, not merely the absence of disease and infirmity. Health was a fundamental human right and the attainment of the highest possible level of health was an important social goal whose realisation required the action of the health sector as well as many other social and economic sectors.

The Alma Ata declaration was made just as the global health divide between rich and poor countries reached a flashpoint. Thirty years down the line, there is an increasing awareness that the economic divides within countries and between countries have worsened. Health priorities are no longer set by countries themselves; they are often dictated by international funders and agencies.

What are our health concerns?

Despite attaining a certain degree of wellbeing, as reflected in their growth rates, much of South Asia and Africa continue to grapple with simple health issues even today. In a country of 1.1 billion we don't even have public urinals for women (the Indian census also notes the abysmal lack of such facilities in most rural Indian homes). And without clean water, women are especially vulnerable to genital and reproductive tract infections. Such important issues are glossed over because in some South Asian countries, especially India, the health agenda is set by the well-off and endorsed by the government.

The growing emphasis on lifestyle-related diseases and the new priority given to health tourism do not recognise the ground realities today, 30 years after the Alma Ata declaration and 60 years after Independence. Every seven minutes one woman in India dies from pregnancy-related causes. According to the third (latest) National Family Health Survey (NFHS-3) (2005-06), one-third of Indian women have a lower-than-normal body mass index; more than 56% of all women and more than 58% of rural women suffer from anaemia. Worse still, there has been an 8% increase in the prevalence of anaemia among pregnant women over the last decade, since NFHS-2 (1998-1999). Fifty children below the age of five die every half-hour. A shocking 79.2% of infants (6-35 months) are underweight, an increase of 5 percentage points since NFHS-2. Barely 26% of the millions of children under three who suffer from diarrhoea receive something as basic as oral rehydration.

In essence, the promises made 30 years ago at Alma Ata remain unfulfilled. Despite official declarations of a paradigm shift in health to holistic healthcare, health programmes are becoming increasingly vertical.

The AIDS programme is one such vertical programme. It is also an instance of misplaced priorities at the national and international levels.

Rather than view healthcare as part of a holistic package of treatment that includes improving people's nutritional status — which itself is a function of both their purchasing power and the extent of help extended by health agencies — the approach has focused on the problem as one of 'access to treatment' alone.

The burden of communicable diseases

The government does not seem to be terribly bothered about the continuing burden of other communicable diseases.

According to the WHO, approximately 988,000 Indians die of all causes, annually. About 462,000 of these die from communicable, maternal and perinatal diseases. An estimated 34,000 die of AIDS according to this report (though the source of this estimate may be debated). Respiratory infections account for 107,000 deaths.

Take the example of tuberculosis. India ranks first among the 22 high-burden countries in the world, with some 364,000 deaths annually. According to the WHO's Global TB Report 2006, there were 1.8 million new cases in 2004, of which 5% were in people with HIV and 2.4% were multi-drug resistant (MDR) requiring very expensive treatment. The government's revised national tuberculosis programme does not provide free treatment for MDR TB.

More than one-fifth of the burden of communicable disease is related to the basic problem of clean drinking water. Look at the impact of diarrhoea which, the WHO estimates, killed

an estimated 700,000 Indians in 1999 — over 1,600 deaths each day.

Such diseases are mainly an outcome of an inaccessible and unaffordable health system and a debilitating socio-economic environment. But these diseases are not on the international radar of any funding agency or government.

There were 1.8 million reported cases of malaria last year. And this is an underestimation, as blood tests were carried out on less than 10% of people with suspected malaria. It is estimated that four people die due to malaria every day in the country. There are also the scourges of Japanese encephalitis, chikungunya and dengue. As many as 1,000 children died from Japanese encephalitis in Uttar Pradesh in two years, but these figures did not make the headlines or grab national or international attention in the way HIV/AIDS does.

While the figures for encephalitis, dengue, etc, seem irrelevant compared to tuberculosis and diarrhoea, they are important because they represent the impact of massive development programmes such as dams, which create the conditions for such outbreaks, as well as an ineffective disease control programme.

Finally, what can any health programme do when people are starving? People's resistance to any illness depends on their immunity as well as their access to healthcare. There is enough evidence to show that the poor have less food to eat, and that the public distribution system has steadily reduced the distribution of grain per household.

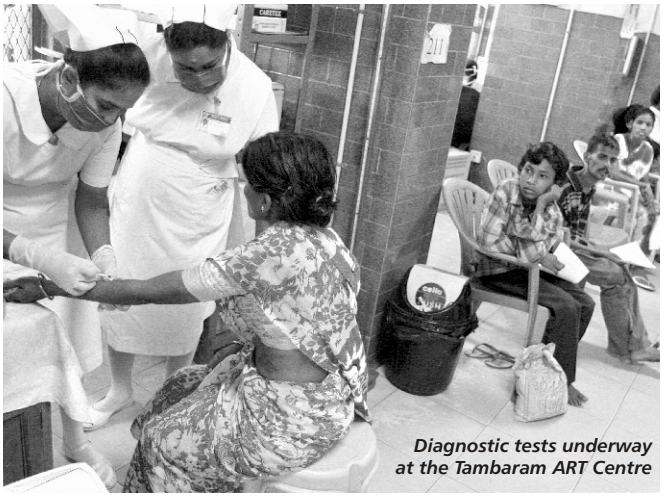
Can the government provide second-line treatment?

Apart from a resurgence of many preventable diseases, the government also gets a lot of flak for refusing to guarantee second-line antiretroviral therapy (ART) to people with AIDS. Already there are reports that between 3,000 and 5,000 of those receiving ART under the National AIDS Control Programme (NACP) have become resistant to treatment.

The problem is that the government may not be entirely wrong, especially as the National AIDS Control Organisation (NACO) itself has clarified to the parliamentary committee that providing second-line ART is fraught with a number of operational difficulties and technical problems. Given the considerable difficulties encountered in reaching first-line ART to 60,000 patients, NACO felt that second-line treatment would require a far more intensive effort. It was therefore decided that second-line ART would be considered only after 100,000 people were covered under first-line ART.

Ambitious plans

The diffidence of the apex AIDS control body is understandable given the present conditions of the health system. In 2007-08, among the NACP's priorities are: expansion of care and support and ART to cover the entire country; expansion of ART services through hospitals in other sectors like the railways, army, the public sector, corporate hospitals and NGOs; upscaling the existing 96 ART centres to 120 centres by March 2007; and providing free ART to 100,000 patients by end-2007 and to 300,000 patients by 2012. In order to improve access to safe blood, 3,070 blood storage centres will be established. Equipment for these centres will be provided through the National Rural Health Mission; NACO will provide training and annual recurring grants as well as facilities for transporting blood to storage centres. There are also plans to extend integrated counselling and testing centres and basic service facilities at the community health centre (CHC) level to ensure access to the rural population.



Gary Hampton

Diagnostic tests underway at the Tambaram ART Centre

Will the National Rural Health Mission change things?

In 2004, the United Progressive Alliance government launched the National Rural Health Mission (NRHM) with a promise to undertake a paradigm shift in its approach to healthcare. The NRHM was launched in April 2005. This was preceded by feedback from, and interaction with, public health activists. The second phase of the reproductive and child health (RCH) programme, the flagship programme under the NRHM, commenced on April 1, 2005, with a focus on seven empowered action group (EAG) states and northeastern states, with a special emphasis on rural healthcare. The EAG states are those states showing weak socio-economic indicators.

Infant mortality rate (IMR) is the most significant indication or measure of the overall health and socio-economic condition of a society. But, three years after the launch of the NRHM, at least 10 states (including the seven EAG states of Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttar Pradesh as well as Assam, Haryana and Jammu and Kashmir) have not been able to achieve the goals related to IMR. Nor have they been able to reach the goals on maternal mortality rate (MMR) or total fertility rate for 2007 under the Tenth Plan.

These facts were revealed to the parliamentary standing committee on health and family welfare, in May 2007. During 2004-05, the IMR remained stagnant at 58 per 1,000 live births. The IMR in Madhya Pradesh, Orissa, Rajasthan,

Assam, Chhattisgarh, Bihar and Haryana remained higher than the national average. While the national average for institutional births is itself low, at 40.7%, in many states it hovers between 20% and 30%. Similarly, while the average number of women receiving antenatal care showed a slight improvement between NFHS-2 (1998-99) and NFHS-3 (2005-06), in many states it ranged from 30% to 40% with Bihar and Uttar Pradesh at the bottom, at 16.9% and 26.3% respectively.

The parliamentary committee observed that despite adequate funds in the RCH programme, funds to bring down the IMR during the Tenth Plan remained unspent. Most underdeveloped states (including Chhattisgarh and Orissa) and Assam have done poorly under the RCH I programme and have continued to do poorly under the RCH II programme as well. Interestingly, under the Janani Suraksha programme intended to boost institutional deliveries by giving incentives to the mother (in EAG states, Rs 1,400 is given while it is Rs 700 in other states and union territories), these incentives are given only for the first two children and not to women delivering their third child in a hospital. This is ironical given that the objective of the programme was to reduce the IMR and MMR by encouraging safe deliveries; instead, the focus has been on population control.

Infrastructure woes

The new initiatives planned under the NACP for 2007-08 are laudable, but a critical look at the present status of the National Rural Health Mission reveals that it will take some time for these initiatives to fructify as the basic infrastructure is not in place. One of the main aims of the NRHM was to strengthen the primary healthcare infrastructure and promote effective service delivery of healthcare. If one uses infrastructure norms based on 2001 population figures, there is a shortfall of 21,983 sub-centres (SCs), 4,436 primary health centres (PHCs), and 3,332 community health centres (CHCs). Many states, including some with a high prevalence of HIV, have not met the Tenth Plan targets for sub-centres, community health centres and primary health centres. At least 10 states, including the national capital Delhi, did not set up a single SC, PHC or CHC during the Tenth Plan period till March 2006.

Of the 144,988 functional sub-centres, the building status of only 144,171 was provided to the parliamentary committee. There is no information on the status of sub-centres set up in Arunachal Pradesh, Meghalaya and Delhi. Buildings are yet to be constructed for at least 68,848 sub-centres whose existence is marked only on paper. There is also a tremendous shortfall in the number of functional PHCs and CHCs. Of the 22,669 functional PHCs, the building status of 85 functional PHCs in Arunachal Pradesh was not known. Of the 3,910 functional CHCs, the status of 31 functional CHCs in Arunachal Pradesh and 126 CHCs in Punjab was not known.

According to the Rural Health Infrastructure Bulletin for 2006, 21% of sanctioned posts for doctors are vacant, 39% of PHCs have no lab technicians and 18% have no pharmacists. More than 54% of all sanctioned CHC posts were vacant. Of the sanctioned posts for specialists, 59.4% for surgeons, 45% for obstetricians and gynaecologists, 61.1% for physicians and 53.85% for paediatricians were vacant. There was a shortfall of 70.2% of specialists at the CHCs compared to the requirement for existing infrastructure on the basis of existing norms. The department of health admitted to the parliamentary committee on health that the shortage of health functionaries as well as poorly staffed primary health centres was one of the "major causes of such a baleful condition of maternal and child indicators in the EAG states". With 80% of medical colleges in the private sector, and concentrated in five states where students pay huge capitation fees for admission, health priorities can never be in favour of the poor.

Thus, with the NRHM failing to set in place even its basic objectives, one wonders how it will meet more ambitious targets such as providing equipment for blood storage centres as envisaged under the NACP.

Funding

A look at funding for HIV suggests that priorities are indeed skewed. While allocation for the National AIDS Control Programme in the 2007-08 budget is Rs 720 crore, only Rs 884 crore is allocated for all national disease control programmes (including the TB control programme, leprosy, trachoma, blindness, iodine deficiency disorder, and drug de-addiction control programme).

Table 1 shows the declining expenditure and budgetary allocation to some programmes as compared to the National AIDS Control Programme. For example, the National Integrated Disease Surveillance Programme provides for the surveillance of communicable diseases. Here the allocation for the year 2007-08 has actually gone down. A very marginal increase is also visible in the allocation to the overall National Disease Control Programme. Comparatively, funding for the NACP has risen steeply from the 2004-05 budget period till 2007-08. Again, not only has the expenditure for routine immunisation (this includes vaccination for six vaccine-preventable diseases — tuberculosis, pertussis, diphtheria, polio, tetanus and measles — to children in the 0-5 age-group and to pregnant women) gone down, but the budget allocation itself for 2007-08 has been reduced drastically as compared to the 2005-06 allocation. In contrast, the allocation for pulse polio has been increased rather disproportionately.

According to the district-level household survey of 2002-03, only 47.6% of children and pregnant women received all six vaccines. According to NFHS-3 data, the all-India average for immunisation coverage is 43.5%, a nominal improvement from 42% in 1998-99 (NFHS-2). On the other hand, the oral polio vaccine for polio eradication has been given overwhelming importance at the cost of the immunisation

TABLE 1

Selected heads of expenditure of central government (department of health and family welfare) in crores

	2004-05		2005-06		2006-07		2007-08
	Budget	Revised	Budget	Revised	Budget	Revised	Budget
National AIDS Control Programme	**232**	**422**	**476.5**	**476.5**	**636.7**	**636.7**	**719.5**
National Mental Health Programme	**30**	**30**	**36**	**36**	**45**	**40**	**58**
Public Health Education	**-**	**-**	**12.51**	**12.51**	**16.46**	**18.79**	**19.05**
	NATIONAL RURAL HEALTH MISSION						
National Disease Control Programmes							
National Vector-Borne Disease Control Programme	**242.45**	**265.45**	**319.16**	**309.38**	**345.22**	**352.95**	**368.4**
National TB Control Programme	**115**	**129**	**166.39**	**166.39**	**184.17**	**206.5**	**249**
National Leprosy Control Programme	**53**	**40.84**	**38.57**	**25.82**	**38.25**	**35.41**	**34.65**
National Trachoma and Blindness Control Programme	**85**	**85**	**86**	**86**	**81**	**98.39**	**126**
National Iodine Deficiency Disorders Control Programme	**7.5**	**7.5**	**11**	**11**	**14**	**14.17**	**24**
National Integrated Disease Surveillance Programme			**80**	**50**	**93**	**33.36**	**72.01**
National Drug De-addiction Control Programme	**-**	**-**	**-**	**-**	**-**	**-**	**10**
Total (National Disease Control Programmes)	-	-	701.12	648.59	755.64	740.78	884.06
Reproductive and Child Health Project	**-**	**-**	**267.25**	**32.85**	**235.88**	**5.27**	**196**
Routine Immunisation	**-**	**-**	**472.6**	**155.82**	**326.5**	**266**	**300.5**
Pulse Polio Immunisation	**-**	**-**	**832**	**806.83**	**1,004**	**1,006.72**	**1,289.38**
Total (National Rural Health Mission)	-	-	6,508.05	6,075.17	8,141.9	7,190.37	9,839.08

Source: Expenditure Budget, Volume II (2005-06, 2006-07, 2007-08)

programme for other diseases. While only Rs 300 crore is allocated for routine immunisation in this year's budget, a whopping Rs 1,289 crore has been given to the pulse polio programme. In sum, there has been no significant improvement in the percentage of complete immunisation figures, and this is true across the country. In the case of Maharashtra, Gujarat and Punjab, NFHS-3 figures show a regression over NFHS-2 levels; states like Uttar Pradesh, Bihar, Jharkhand, Rajasthan, Nagaland and Arunachal Pradesh hover at between 20-35% of full immunisation levels.

While the allocation for routine immunisation has been going down, even these reduced allocations are not utilised. Personnel vacancies for auxiliary nurse midwives and district immunisation officers add to the problems of an inadequate infrastructure and are important reasons for the low rates of immunisation.

Certainly one can argue that, parallel to the increase in interest in and funding for the HIV/AIDS programme, there has been a decline in the attention and funding given to other diseases. It may also be reasonable to argue that the latter trend is a result of the former trend. Public health professionals working in the area of immunisation have conceded that the single-minded focus on the vertical programme of polio eradication through the pulse polio campaign, using the oral polio vaccine, has had an impact on immunisation levels of other vaccine-preventable diseases. One obvious reason for this is that the entire immunisation programme focuses on polio alone, and there are anecdotes of parents in remote areas who are aware of polio immunisation but whose children have not received other vaccines that could save them from disability and death.

In a similar manner, the single-minded focus on HIV/AIDS as a vertical programme has its impact on the availability of healthcare for other illnesses. This is not only because of the reduced funding for other diseases but also because the public health infrastructure that has been weakened over the years is unable to implement the AIDS programme while also doing the little that it can to prevent and treat other illnesses. So, for example, district hospitals are given the job of providing antiretroviral drugs, but without the additional personnel. Sometimes, antiretroviral drugs may be available, even as basic antibiotics, anti-rabies vaccines and snake venom antidotes are unavailable at primary health centres.

Conclusion

While HIV/AIDS is certainly a concern for us, it is not our *only* priority and we cannot focus on it at the cost of other visible challenges to public health. For the silent majority, healthcare is still about clean drinking water, adequate nutrition, proper sanitation and a secure income. Their main aspiration is to lead the bare minimum of what constitutes a decent existence.

T K Rajalakshmi is a correspondent for the Indian newsmagazine Frontline

What has changed for people living with HIV?

Many experts feel that it's time we moved beyond HIV/AIDS awareness campaigns and began seriously tackling the practical considerations of getting medicines to patients. Awareness is important, but it's useless if we cannot provide the medicines

RANJITA BISWAS

IT'S BEEN 21 YEARS since India's first HIV cases were diagnosed among sex workers in Chennai, Tamil Nadu, in 1986. And exactly two decades since the National AIDS Control Programme, now NACO, was launched. Since then, India has been in the news for its rising HIV/AIDS graph, although NACO has hotly debated the number (5.4 million) projected by international agencies. This year, 2007, using a more effective surveillance system, UNAIDS and NACO agreed on a new estimate — there are between 2 million and 3.6 million people living with HIV in India, placing the country behind South Africa and Nigeria.

While experiencing relief and even a little elation at this scaling down of numbers, there is also apprehension that some of the real issues may be overshadowed. For example, have things changed over the years for people living with HIV? What about treatment? Are affected people getting adequate support from the government and NGOs working in the area? Why is there still so much stigma and discrimination even among the medical fraternity, let alone the general public, when crores of rupees have been spent on awareness campaigns? Are these problems being addressed? If not, what are the hurdles in the way of change?

It's best to listen to people who have firsthand experience through their work in the field.

Treatment and availability

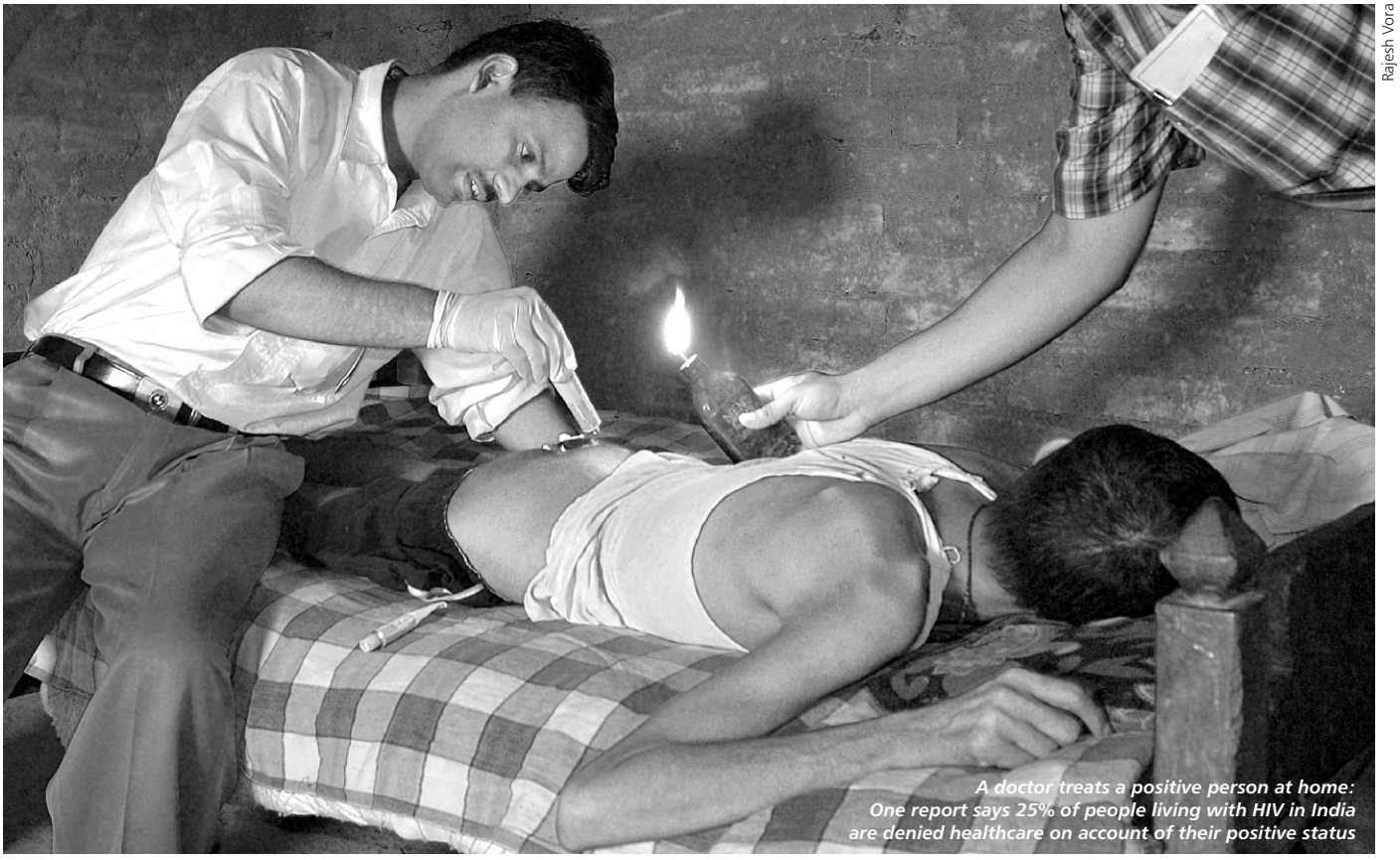
Dr Jack Preger, who founded the healthcare NGO Calcutta Rescue and is often referred to as the 'footpath doctor' (that's how he began treating the poorest of the poor — on the footpaths of Kolkata), also heads the only centre in West Bengal that provides second-line ARVs free of cost. Patients are referred to him by the School of Tropical Medicine (STM) and Calcutta Medical College and Hospital. Both provide first-line ARVs to affected people from the vast hinterland of districts in West Bengal.

Whilst admitting that there has been a definite change from the old days, in that many more people now receive free treatment, Preger highlights the problems patients face in receiving medication: "To get free medicines, patients have to produce a below the poverty line (BPL) certificate endorsed by the local panchayat. This has some inherent problems; plus, many of them are not actually from the BPL segment." Another problem is the distances patients have to travel from village to city to get medicines. For some, because of logistical and other reasons, there is a gap in treatment, which could lead to them developing resistance to the medicine.

Tarit Chakraborty, Regional Coordinator, Indian Network of Positive People (INP+) and President of the Bengal Network of Positive People (BNP+) (West Bengal), which has around 4,000 members, also believes there are many gaps in access to treatment, although the situation is better today compared to a few years ago. People are getting medicines, or they are available in the market to those who can afford to buy them. But quality treatment is still missing. "It's not available at an easy access point," he says, adding that many patients are daily wage earners who cannot afford to miss out on a day's wages, not to mention the travel costs. They also have to pay for certain clinical tests. These "hidden costs" sometimes dissuade an infected person from taking treatment. "Why aren't medicines made available at the district hospital or even at primary health centres," asks Chakraborty.

Dr Santanu K Triparthi, Head of the department of pharmacology, Nil Ratan Sarkar Medical College and Hospital in Kolkata, agrees: "We should look more at ways of providing medicines at easily accessible places, rather than expect them (patients) to travel all the way (for them). This can be done only at the government level. It (the government) should take the initiative to clearly identify to what level the agency can provide ARVs and then formulate a public-private partnership strategy with achievable goals. It's time that we talked about the practical considerations of getting medicines to patients, and move beyond awareness campaigns. Awareness is important, but it's useless if we cannot provide the medicines."

Divya Mithel, a grassroots worker for PLHAs (people living with HIV/AIDS) in Raigad, Maharashtra, believes there have been some positive changes in the treatment regime. "The government centres are trying their best to get as many AIDS patients under the ARV umbrella, which is causing them (patients) to live longer. Women who are registered at antenatal clinics are getting the maximum benefit in terms of prevention of vertical transmission. In the last one year, children have started getting free ARVs from the government centres. Prophylactic drugs have reduced the incidence and severity of opportunistic infections."



Rajesh Vora

A doctor treats a positive person at home: One report says 25% of people living with HIV in India are denied healthcare on account of their positive status

But, says Mithel: "All the pharmaceutical companies making and marketing ARV drugs are pushing them on a war footing in the open market. There's nothing wrong with that, but ARVs are being prescribed by every medical practitioner without a thought as to whether the patient is financially 'fit' to prescribe these drugs to, let alone whether the doctor is 'fit' to prescribe the drugs."

"Not many doctors/family physicians know the correct regimen and side effects of these drugs. Our centre gets a lot of patients who are on an incorrect regimen," says Mithel.

Indrani Sinha, Founder Secretary, SANLAAP, an NGO in Kolkata that works with trafficking and women's health issues, says: "It (treatment) is not enough, and the people providing the service are not aware; they suffer from ignorance much more than many."

Pawan Dhall, Director, SAATHI, Kolkata, another NGO, concedes that NACO has set up a good protocol for Phase III, following WHO guidelines, but that "it's half-hearted on the aspect of providing second-line ARVs. NACO's stand seems to be to reach a target of 100,000 people receiving first-line ARVs and then starting with the second line". He draws attention to NACO Head Sujatha Rao's comment of a while ago that prevention was the priority now. "But what about the people who are already affected? What about their treatment? It sends a wrong signal to those people."

As one providing second-line ARVs, Jack Preger has certain views that may be considered controversial: "It's expensive; a patient's monthly bill can go up to Rs 2.6 lakh per month. We raise the funds ourselves from our well-wishers abroad; we don't take any money from the government. But I am finding it increasingly difficult to raise the money… It's unfortunate that though there are so many NGOs working in the field of HIV/AIDS care, they mostly concentrate on counselling and other services. While these are important, one must make medicines available to patients. Many of these NGOs have huge funds but they don't think of setting aside some funds for second-line ARVs."

Preger's bitterness is apparent when he says that he has, of late, refused patients referred to him by some NGOs, as they have sufficient funds to provide for the patients. "There are more needy people; they don't have any other means of getting treatment."

Stigma and discrimination

A 2006 UNDP study ('The Socio Economic Impact of HIV and AIDS in India') found that 25% of people living with HIV in India were refused medical treatment on the basis of their HIV-positive status. Evidence of stigma was rampant in the workplace, with 74% of employees not disclosing their status to their employers for fear of being discriminated against. Of the 26% who did disclose their status, 10% reported having faced prejudice as a result. It is more

pronounced among people in marginalised groups: female sex workers, hijras (transgenders) and gay men are often stigmatised not only because of their HIV status but also because they belong to socially excluded groups.

According to Preger, the stigma is very much there still. "I know of a 15-year-old boy from a BPL family who became HIV-positive due to infected blood transfusion. He can't go to the STM to collect his medicine because if anyone recognises him he'll have a problem staying enrolled in school. His parents know this. So his father goes to the STM instead."

Dhall corroborates this point: "There's been some change at the micro level but on the whole there's not been much change. Superficially, perhaps also because of political correctness, people express their awareness and acceptance, but there are so many instances where patients have faced discrimination. It's happening even at government hospitals in Kolkata; one wonders if all the money spent on sensitising healthcare professionals has gone to waste."

Mithel too believes levels of stigma and discrimination from close relatives and society remain high. "All, and I insist all, government hospitals and even private medical colleges, with their high-tech hospitals and trained staff, refuse to operate or do the necessary invasive procedures. The victim and his relatives are made to run from one centre to another in the hope of intervention until the case deteriorates so badly that it becomes inoperable, or the relatives abandon the victim, or the victim himself gives up."

Chakraborty agrees: "These days, due to sensitising programmes and perhaps for fear of getting castigated, there may be less direct discrimination. But there's indirect discrimination. Often when an HIV-positive person is sent for surgery to a hospital that has all the facilities, and his/her HIV status is mentioned, the staff say that the hospital does not have the necessary facilities. Then there are cases where a person is shifted from one hospital to another, on some pretext or the other, and ultimately doesn't get treated at all. Or, the doctor may cooperate but Group D staff may not, once the HIV status of the patient is known."

According to Dhall, there could be other instances like these that have not yet come to light. Last year, a peer educator from Manas Bangla, a network of NGOs working mainly with MSMs, in Kolkata, was denied surgical treatment and turned away by Nil Ratan Sarkar Medical College, a government hospital in the heart of the city, when he developed HIV-related complications. Ultimately, he committed suicide.

The activist throws light on a lesser-known fact about discrimination within the HIV-positive community. "There's this idea of 'good HIV' and 'bad-HIV' — the former is contracting the disease by blood transfusion, or it being sexually transmitted by a spouse/partner, etc. 'Bad HIV' is contracted through risky behaviour or 'dirty sex'. Many PLHA organisations, for example, do not invite positive members from sex worker groups, or even MSMs, to their meetings because of this. So, the whole idea of correlating HIV and sex, still a taboo subject for most people, needs to be addressed upfront," he says.

Chakraborty agrees that this kind of discrimination exists. "A housewife who contracts the virus through her husband would not like to associate with a positive CSW."

Counselling

Counselling has an important part to play in the campaign against HIV/AIDS. Says Sinha: "The fear about AIDS exists due to ignorance, and a lot needs to be done. Vulnerable families need to know much more. Proper counselling services should be provided at every level; this is not being done. In cases of trafficking, we have seen that it happens to illiterate and poor families and it is very difficult to explain such things to people who have had no education."

Chakraborty points out that what is important is "quality" counselling. "A patient is more comfortable with counsellors who empathise with him." He believes the number of peer counsellors should be increased. "From our experience we have seen that it's more difficult to convince so-called educated people in urban areas than villagers. In rural areas, people do not have enough information, so they are ignorant. But once you make them understand and explain things to them they are more willing to accept a person who is HIV-positive." As an example, Chakraborty reveals an instance where a woman from Arambagh area who contracted the virus from her husband was put almost under house arrest when people learned of her status. The Network's Hooghly district representatives went to the village and had a meeting with panchayat members and the community who said they had acted that way because they did not know much about the disease; they subsequently lifted the ban on the woman, who has since died.

The hurdles

Different people react differently to the point about hurdles in the fight against HIV/AIDS. For example, Preger has reservations about the method of the sample survey. While the scaled-down number of people affected by HIV/AIDS in India is a good sign, he says: "Sample surveys may have unrepresented sections. How many people really go door-to door? Even if they do, do they get the correct information? Usually, they visit households during the day; as we know, most householders are at work during the day. The second question is about confidentiality, especially when stigma is so rampant. Will a householder talk openly about his status in a close community?"

"In my experience, the level of information about HIV and treatment has surely gone up for positive people, but information should be there for everyone, which has not happened," says Sinha. Since "each and every one of us is vulnerable to HIV," people should have access to proper information and assistance if needed. "This goal

is yet to be achieved."

Mithel encounters many young girls and women who are married to "HIV-positive crooks" because the men marry without disclosing their positive status. After the death of their husbands, these unfortunate widows are thrown out of their homes and lose their property and their inheritance, sometimes even their children. "Even if these victims do manage to get help from ART centres or shelter homes like ours, their rehabilitation remains a massive unresolved problem."

Even when HIV-positive patients stabilise with proper ARV treatment, where do they go? Their relatives do not want to keep them, and their employers don't want to take them back.

"This group, which is the newest face of all our efforts in fighting the disease, is totally ignored by the policymakers. There are no more than two to three shelter homes that can keep such people for, say, a few days, a few months, or even years. But how long can they be kept here?" Many of Mithel's patients want to go back to begging, prostitution and drugs, not by choice but because there is no alternative.

She points out that there has been no funding, by NACO or State AIDS Control Societies (SACS), for institutionalised centres that are at least making some efforts in this direction. Due to lack of adequate support and funds, these centres are desperately trying to survive against all odds; their struggle has dissuaded a lot of people from venturing into the area of palliative care and support.

Dhall adds that the government's health budget is woefully inadequate. "Look at our defence budget — it keeps increasing every year. Health does not seem to be a priority."

When Preger is asked why if Brazil can provide universal treatment for HIV/AIDS, India, which produces some of the cheapest generic medicines for HIV, cannot do the same, he says: "Look at their budget and ours. India's proportion of the budget for health is pathetically low. Of late, the budget has been enhanced somewhat, but the major portion is spent on administrative and other departments, leaving little for medicine and care."

Joanne Csete, Director of the HIV/AIDS programme at Human Rights Watch, once observed: "It is a sad irony that India is one of the biggest producers of the drugs that have transformed the lives of people with AIDS in wealthy countries. But for millions of Indians, access to these medicines is a distant dream."

The road ahead

So, what can be done to ensure that HIV/AIDS patients in India get better care? Dhall is emphatic that civil society has to come together to force the government to provide the necessary care and support to HIV-positive people. "One can recall the instance of ACT-UP (AIDS Coalition to Unleash Power) of the '80s in the US that aimed at fighting government apathy towards gay civil rights. It was hugely successful." ACT-UP and other groups organised hundreds of civil disobedience actions across the country, focusing not only on AIDS but on the increasing climate of homophobia and attacks on lesbians and gay men.

Through their activism, and using the media and other sources, the civil disobedience actions brought the AIDS care issue to the forefront. Dhall says: "We are not equipped to do something on the medical side of the disease, but we can raise the issue through concerted action." For example, NACO's Phase III programme "is good, but it's the responsibility of civil society to see that the government delivers". Sinha says: "The problem is being addressed, but mostly by civil society groups and not the government."

According to Dhall, good practices must be replicated by others in the field. For example in Tamil Nadu, compared to West Bengal, reproductive rights, sexual behaviour and sexuality are discussed more openly, and there is greater awareness and action. He uses some of SAATHI's (Chennai) flip-charts in his office in Kolkata.

Dhall believes that sex education in schools, even for adults, is a must. "They can be planned age-wise, culture-specific-wise, etc. Even parents need counselling. Denying its introduction in schools puts the vulnerable young population at risk."

Why don't NGOs bond as a network to tackle some of these vital issues? In Kolkata, some effort has been made through the Treatment Action Campaign (TAC) in West Bengal, initiated by BNP+ and positive people's organisations and NGOs. "We need to start a coalition-based campaign to ensure that treatment is made available to those in need. The government must make us partners, and civil society has to come together," says Dhall.

Chakraborty agrees that a collaborative network is a good idea. He refers to GIPA (Greater Involvement of People Living with HIV/AIDS), which was adopted as a principle at the Paris AIDS Summit in 1994, by saying that the personal experiences of positive people could and should be translated into helping shape a response to the AIDS epidemic.

Meanwhile, NACO's immediate task, says Chakraborty, should be to provide second-line ARV treatment. "So much money is spent on prevention; some of it should be spent on positive prevention too, that is, focus on people who are into needle-sharing or into other risky behaviour."

He also suggests that images of positive people be used in ad campaigns (if they are willing). In West Bengal, the WBSAPC Buladi campaign that uses an understanding woman-next-door image to send a safe sex message is extremely popular. "That's fine, but I feel that if a positive person had said, 'Yes, I am a positive person but I lead a normal life, I am not sick or dying', it would have cleared away misconceptions about the disease more effectively."

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Zarina: 'We need more than information'

Zarina is just one of thousands of HIV-positive people caught between a government that cannot provide care and treatment to all, a private sector that is expensive and swarming with quacks, and NGOs that are driven by their own agendas.
Photographs by Sudharak Olwe

MANJIMA BHATTACHARJYA

ZARINA IS ONE AMONGST the thousands around us who are silently living with HIV. One of the many milling around us in malls window-shopping on a day out, rushing past us in railway stations to get home in time to cook for the family, or bargaining with the vegetable vendor while buying supplies for the week. Ordinary people living ordinary lives, and taking their HIV-positive status in their stride.

Twenty-five-year-old Zarina's story is however a little more than ordinary. At the age of 15, Mallika, as she was then called, ran away from her village in the hills of Nepal — away from a negligent father, stepmother and backbreaking hours of work in the fields — with a distant relative to take her chances with the world out there. Like many other girls before and after her, she ended up in Kamathipura, Mumbai's red-light district, after being smuggled across the border. She remembers that night vividly: "I was given two pills that knocked me out. When I woke up I saw an incredible sight. A big monument and what I thought was a huge river. It was Haji Ali."

After a few days in imprisonment in a room in Walkeshwar and a frightening encounter with police, goons, *gharwalis* and all sorts of characters, a shivering Mallika, who knew neither where she was nor understood the language around her, was taken to a new place that was to be her home for the next few years. A *kothi* (brothel) in Kamathipura. And thus began her new life, complete with a new name given by the *gharwali*. Zarina.

Life in red

It took time for this sudden turn of events to sink in. Moreover, the red-light area wasn't quite what she expected it to be. She says: "I saw a young girl cutting vegetables and another blowing a *chulha*. No gaudily dressed ladies of the night, no garish make-up. I could not believe it."

"I tried to run away many times, I really did," she remembers. "The *gharwali* told me I would have to pay her Rs 40,000 if I wanted to leave. Or I could work there for three years in which time my debt to her would be repaid. I had no choice. I didn't see any sunlight for two years. That became my life."

Ek chhoti si love story

The next dramatic turn in Zarina's life came when she fell in love with a young man from the neighbourhood. They shared a love for the silver screen, and as the young man

began to take the beauteous Zarina for many matinees, their own love story began. It was accelerated by a chance discovery, after Zarina fell ill, that she was HIV-positive.

The doctor, who was personally known to the young man, told him that Zarina would not survive for more than a month if she continued in the brothel. The young man pulled all the strings he had — a contact with a hotel owner in the area who had contacts in the media, a photographer, and a social worker — and made a plan to run away with Zarina and marry her. To make sure that there would be no immediate backlash in the form of a police complaint by the *gharwali*, his contacts got the deputy commissioner of police himself to call the local police and ask them to ignore any such complaints. Had things gone according to plan, Zarina and the young man would have been married on Valentine's Day. But romance took a backseat to paperwork, and it was only on February 17 that a *nikaah* was performed. Soon after, not wanting to invite trouble by staying in the same area, Zarina and her husband moved to Navi Mumbai. They sold a gold chain to pay for a deposit to rent a small room in which they set up their new home.

Living with HIV

Meanwhile, Zarina's illness was beginning to take its toll. Every month during her period she crumbled under a bodyache that reduced her to tears, a swollen abdomen and inexplicable white discharge. Often, it would be as frequent as once a week.

It was when she had to undergo an operation in the third month of an ectopic pregnancy a while ago that she encountered in some way the real meaning of her HIV status. Doctors at the hospital were hesitant to operate upon her when they found out her HIV status but had to do the operation. Various tests were done at this stage, including the CD4 and CD8. This was a government hospital where they considered enrolling for free treatment for HIV. However, they found that Zarina was not eligible for free treatment. According to the fine print, only patients with a CD4 count below 200 are eligible for free treatment; those with a count above 200 have to pay for their treatment, the cost of which is about Rs 35,000 for six months. Why this differentiation amongst HIV patients? Just government policy, said the hospital. Those in the worse stages are given first preference for medicines.

With no way to challenge this logic, the couple turned to the private sector. An ayurvedic hospital in Worli was offering free medical treatment. But 'free' once again did not really mean they could afford it. Even though they were giving the medicines free, they were required to go twice a week. Going from Navi Mumbai to Worli twice a week was not sustainable for the couple, and was not always possible given the young man's job. The medicines also seemed to have little or no effect. Instead, Zarina felt her body heated up, and she felt nauseous. After two weeks, the hospital wrote a prescription for the medication, saying that they had run out of stocks at the hospital and the patient would have to buy the medication from elsewhere with the prescription, the cost of which was Rs 600-Rs 700. When this was repeated, they stopped going.

Misplaced priorities

Disillusioned with the government and then the private hospital, Zarina approached a big NGO to help her with the treatment. That one time that Zarina approached an organisation, she realised that they were after something else altogether and did not see her real requirement.

Instead, the director of the NGO was more interested in finding out who had trafficked her 10 years ago. She told Zarina: "Let's find the trafficker and put him behind bars." How will that help me, wondered Zarina. "Why should I go back to my village after all these years? My family thinks I am dead anyway; they will say, why has she come back to give us a bad name?"

Her husband is suspicious of what NGOs do with the millions of dollars worth of aid entering the country for HIV work. He says: "They get so many donations from abroad

but they spend it on advertisements and travel. These NGOs will only give you information, nothing else. Only if you know them personally or are a relative they might help you with treatment."

The 60-rupee shot: The last resort

Zarina always wanted to have a family, a home, happiness. She says she enjoys being a housewife and waiting for her husband to come home from work, to cook for him. Today her dream is to have a small house of her own. She continues living her new life with a joy and innocence that belies her difficult past, and indeed her painful HIV condition.

Zarina and her husband feel that there is really nowhere else to go in search of treatment. They do fall for the odd herbal treatment here and there. Recently, for example, Zarina tried a bottle of a 'herbal treatment' sold to her by a lady from Nerul. Someone in the area had recommended the treatment to her, another lady who was very thin and not putting on weight. With this medicine, the appetite improved as well as sleep, leading to an overall improvement in health. Through this distributor they bought a bottle for Rs 2,500. It was a powder that had to be mixed with milk or water. Zarina tried it for a month and it did make her feel better, she says. But it was too expensive at Rs 2,500 a month and so she did not pursue it.

As of now, Zarina is not following any treatment for HIV. Instead she pays about Rs 60 to get an injection to deal with the bodyache and white discharge. She has to do this at least twice a month. Even though the doctor constantly warns her that this will harm her in the long run, and often refuses to give her the shot, she breaks down in tears and is in such visible pain that the doctor has to relent. She says that it is impossible without the injection; the pain and the swelling in her abdomen are unbearable.

Zarina is caught between a government that nit-picks about who will and will not be treated, a private sector that is expensive and swarming with quacks and alternative practitioners claiming to have found a cure for AIDS, NGOs that are more concerned about "catching the traffickers" than helping the HIV-positive. Until the system critically evaluates the imbalance towards AIDS awareness in the media as opposed to care for people living with HIV, and re-examines its policies towards HIV treatment, people like Zarina will continue to fall through the cracks and be excluded from the HIV treatment that is being made available in the country. Till then, Zarina and thousands like her will have to continue depending on dangerous 60-rupee quick-fixes for fleeting moments of relief.

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Why do less than half of those who require ART get treatment?

Despite the fact that India is a major producer of cheap generic HIV and AIDS drugs, India's ART programme is poorly conceived, implemented and monitored, with a shortage of drugs, equipment and personnel in most states. An unprepared public health system with no transparency is in no position to handle such an intensive programme

SANDHYA SRINIVASAN
T K RAJALAKSHMI

MORE THAN TWO DECADES after the detection of the first AIDS case in India, the disease is now regarded as a 'development' problem and not just a public health issue. Government policy has also moved forward, from denial to practical acceptance of AIDS. The virus has moved from a few epicentres in the southern and northeastern states to 163 districts in 20 Indian states, though the overall prevalence remains low in the general population. It is also acknowledged that women and young people are becoming increasingly vulnerable to the infection.

However, the programme's targeted intervention strategy does not meet needs like immunising the children of sex workers and providing alternative employment opportunities. Further, in analysing policy and implementation, one cannot afford to ignore the fact that AIDS does not constitute the leading cause of mortality and morbidity in the country.

Perhaps this is why public health experts argue that increased funding for a vertical AIDS prevention programme is no solution; spending that money on a holistic concept of public health and public good will help alter the landscape of morbidity and mortality, including that caused by HIV, in the country. Though the present government has increased allocations to the health sector by 21.9% in the Union budget for 2007-2008, it still remains below the World Health Organisation standard for public health expenditure, which is 5% of GDP. Moreover, a majority of the amount is to be spent on vertical programmes like polio prevention and HIV and AIDS control. In the era of economic liberalisation, stagnant public health budgets and decreasing government expenditure on public health facilities were worsened by the introduction of user charges in the public health sector.

In this scenario of low spending by the government on public health in general and increased spending on vertical programmes like AIDS, a new initiative by the government, to increase access to antiretrovirals (ARV) through the public health system has become the subject of a major debate in India.

The battle for access to medicines

The story of affordable antiretroviral drugs goes back some years, as new drugs changed the prognosis for people with AIDS. These patented drugs were out of the reach of most people even in the developed world. So, health activists and networks of HIV-positive people launched an international campaign to force governments and international organisations to recognise their right to treatment and care. Indian drug companies were, at that time, manufacturing and exporting cheaper generic versions of the branded drugs to Africa and Asia.

In February 2001, the Indian pharmaceutical company Cipla Ltd offered the three-drug 'cocktail' of first-line ARV drugs to international voluntary organisations at $ 350 per person per year — a fraction of the US price of $ 10,000-$ 15,000 per year. Other Indian companies followed Cipla's lead, bringing down prices even further.

In response to global advocacy efforts, the UN convened a special session on HIV and AIDS (UNGASS) in 2001, calling for additional funding for antiretroviral treatment (ART). Two years later, the WHO and UNAIDS declared the lack of access to therapy a "global health emergency" and launched the '3 by 5' initiative to ensure that 3 million people living in resource-limited settings were treated for HIV infection by the end of 2005.

ART roll-out in India: A dramatic announcement

On November 30, 2003, the Government of India announced a plan to provide ART through public hospitals in the country from April 1, 2004. The programme was initially to cover HIV-positive pregnant women who had access to government antenatal clinics, children under the age of 15, and adults with AIDS who went to government

Gary Hampton

Nair Hospital, Mumbai. Only 16% of positive people in Maharashtra had been treated in two years of the ART programme

hospitals for treatment. The programme would offer a fixed-dose combination of first-line drugs. The drugs would be provided by the three large generic drug manufacturers in India. The aim was to treat 100,000 people free of charge through the public sector by the end of 2005.

By December 2006, approximately 95,000 people were receiving antiretroviral treatment, including people enrolled through private facilities. Despite the fact that India is a major producer of cheap generic HIV and AIDS drugs, treatment reaches just 20% of those who need it.

In October 2007, the government finally met the target of providing 100,000 people with ART at its 127 centres across the country. From December 1, 2007, the government plans to introduce second-line antiretroviral treatment in a phased manner.

While the government spends Rs 7,500 per patient per year for first-line ART drugs, it will have to spend Rs 100,000 per patient per year for second-line drugs. The second-line treatment needs more investment and infrastructure.

A look at the ART programme in 14 states

In this report, journalists reported on the Indian government's scheme to provide ART in six high-prevalence states (Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra, Manipur and Nagaland), two medium-prevalence states (Goa and Gujarat), low-prevalence but highly vulnerable states like Punjab, West Bengal, and Uttar Pradesh and low-prevalence but vulnerable states (Himachal Pradesh, Union Territory of Chandigarh and Haryana). They looked at what it means to get ART from the government programme and outside the government's scheme.

These articles are a mix of insiders' views and journalistic insights. They contain the voices of HIV-positive people, vulnerable groups, health professionals, public health experts, government officials, industry representatives and others involved with the programme.

These interviews were conducted between December 2004 and January 2005 when the programme was initiated. The reports were updated through interviews and desk reviews. To a large extent, they reflect the situation more than two years after the programme was initiated in April 2004.

Two years after ART was launched in India, there seems to be a significant shift in the attitude of the government to providing antiretroviral treatment. While treatment was not a component in Phase II of the National AIDS Control Programme (NACP), 12.5% of the total funds will be spent on ART (11.5% on adult ART and 1.0% on paediatric ART) in the third phase. This makes funding for treatment the fourth largest allocation in NACP-III, after targeted interventions (19.7%), condom usage (17.3%) and providing a package of services such as STD treatment and counselling to 'most-at-risk groups' (12.0%). The plan of NACP-III also emphasises that first-line drugs will be made available to HIV-positive people referred from targeted interventions, seropositive women, particularly those who have participated in the PPTCT (prevention of parent to child transmission) programme, infected children and those below the poverty line. NACO recognises that to reach a target of 300,000 by the end of 2011, 250 ART centres need to be set up. NACP-III envisages building public-private partnerships free of cost to prioritised sub-populations.

When the programme was announced in 2003, NACO had stated that children would be a priority for ART. Yet, for two years, ARV was only available in adult doses for children under nine, leading to problems in physically administering drugs to children and fears of drug resistance. To fill this gap, NACO launched the National Paediatric HIV and AIDS Initiative which — for the first time in the country — allowed children under the age of 18 months to be diagnosed and provided free child-specific dosages of ARV.

A major criterion for enrolment under the ART programme is the CD4 count (NACO guidelines state that those with a CD4 count below 200 should be enrolled for treatment). Though ART itself is free, people had to spend an amount ranging from between Rs 500 and Rs 1,500 to get a CD4 test done. To reduce the cost, NACO sent an order to all states in January 2007 to waive fees for CD4 tests at government centres.

Some positive changes can be discerned. The most obvious one is that the number of people on treatment has increased. There are more public-private partnerships, which have helped scale up treatment and improve quality of service.

Management systems are being streamlined as well. When the programme started in 2004, there was just one ART consultant in NACO. The year 2006 saw ART consultants being appointed to manage the roll-out in all states. Currently, each high-prevalence state has an ART consultant, while a group of three or four low or medium-prevalence states share one ART consultant, depending on the number of centres.

The participation of HIV-positive people in programme implementation has increased considerably though their voices are still not really heard in planning fora. Today, HIV-positive groups across the country are involved in patient referrals and follow-up.

Basic infrastructure in some centres has improved. For example, in Sangli, the programme was started in 2004 without any NACO-deputed staff or equipment. The already overworked hospital staff had to do the data entry, and provide counselling and treatment. In the absence of a CD4 machine, they used total lymphocyte counts. There was not even an ink pad to take thumb impressions before obtaining informed consent from illiterate patients. So, the doctor coloured the person's thumb with a ballpoint pen and pressed it to the form to obtain a thumbprint. Two years later, the situation has improved. Now there is a CD4 machine and trained staff deputed by NACO.

However, a look at the programme in 14 states over a period

Gary Hampton

A woman collects medicines from an ART centre: In October 2007 the government met the 2005 target of providing 100,000 people with ART

of two years makes it clear that the ART programme is poorly conceived, implemented and monitored, raising questions as to the validity of the government's claim of a "96.1%" treatment adherence. Shortage of drugs, equipment and personnel continue to be a reality. An unprepared public health system with no transparency is in no position to handle such an intensive programme. Communication and counselling are the weakest links in the programme. Access for vulnerable groups such as sex workers, men who have sex with men, and transgenders as well as those living in rural areas is extremely limited.

There is also limited involvement of those affected by HIV and AIDS, especially in planning. Further, inadequate prevention services, stigma and discrimination are also hindering successful implementation.

The government's target is limited to a small fraction of those who need treatment. Reports point to only 20% of those who require treatment getting it.

There are several complaints about the availability of health personnel and equipment.

Counselling remains the weakest component in the ART programme. Several interviews with those on treatment point to treatment being started without proper counselling on side-effects, the possibility of drug resistance eventually requiring second-line treatment, and the need to take the drugs regularly for life.

Drug shortages are a great cause for concern as they affect adherence and further chances of drug resistance. The original draft programme does not spell out procurement plans and journalists' reports point to many gaps in the procurement process. NACO officials admit that initially drug shortages were common, but claim the system has now been streamlined.

Paediatric formulations were not available for two years after the scheme started, though NACO's guidelines specifically state that children will have priority for ART. Similarly, the drug combination with Efavirenz, suitable for people with hepatitis B or concurrent TB treatment, was made available only several months after the programme started. Even so, there have been frequent shortages, apparently because of procurement issues.

Though NACO has started responding to the complaints on drug shortages, even today information about drug stocks and possible shortages is not in the public domain.

Second-line treatment is already becoming a concern in some parts of the country where ART has been available for a longer period and patients have developed drug resistance. A YRG Care study found that 20% of their drug-naïve

patients were infected with resistant forms of the virus, requiring second-line treatment. Indian AIDS patients have been lobbying for the national programme to include second-line drugs, for which cheap, generic versions are not yet available.

However, experts caution against scaling up the ART programme until monitoring systems are strengthened.

Training for healthcare staff involved in the roll-out is inadequate to implement and monitor a relatively complex drug regimen. Though all the drugs have toxic side-effects, the programme gives drug toxicity a go-by. Training is currently limited to doctors in government hospitals providing ART.

There are fears too that a poorly monitored treatment programme will contribute to an increase in cases of drug resistance.

There are complaints that by limiting ART to those with a CD4 count of 200 or less, the government is effectively making people wait until they are ill enough to qualify for treatment.

The majority of people — even the poor — depend on private healthcare for treatment. Even with the expansion of ART roll-out, people depend entirely on an unregulated private sector because of fears of breach of confidentiality or in the hope of quality services. The private sector is known to be profit-driven, promoting expensive and sometimes irrational treatments.

NGOs and HIV-positive people seem to be poorly represented in discussions, with their involvement often confined to a token presence on committees. Some HIV-positive people suggest that the leadership of some of their organisations is not always concerned with the needs of the poor and uneducated among them, who largely look to the networks for support.

There is no material in local languages for HIV-positive people on where ART is available, enrolment procedures, drugs, possible side-effects and the importance of treatment adherence. A study concluded in 2007 pointed out that 41% of respondents did not take ART because of lack of knowledge about the treatment. More than half of all public and private patients had not heard of CD4 (57%) or viral load testing (80%).

ART is still beyond the reach of the marginalised. Though in some states like Goa, sex workers and migrant workers report being treated as "any other patient", in other states like Tamil Nadu and Maharashtra, marginalised groups such as men who have sex with men or commercial sex workers report avoiding public hospitals, having experienced discrimination. Further, some selection criteria for enrolment in the treatment roll-out effectively deny ART to those who need it the most.

NGO workers in West Bengal report that ART is still inaccessible to those in rural areas or those not within the reach of NGO programmes. All state reports point out that HIV and AIDS prevention and treatment services are urban-centric. Quality as well as quantity of services start reducing as one moves from the cities to the villages.

The training programme for doctors ignores the special skills needed to communicate with children. Though women make up about 40% of HIV-positive people, they make up less than 33% of the total number of people on treatment. It has been argued that women are at an earlier stage in the epidemic, so their CD4 counts are less likely to be low enough to qualify. These numbers need to be tracked closely in future to understand the true picture.

Despite ramping up voluntary counselling and testing services, marginalised groups still cannot access them. Awareness programmes still do not reach rural women and

In Sangli, the programme was started in 2004. The already overworked hospital staff had to do the data entry, and provide counselling and treatment. In the absence of a CD4 machine, they used total lymphocyte counts. There was not even an ink pad to take thumb impressions before obtaining informed consent from illiterate patients. So, the doctor coloured the person's thumb with a ballpoint pen and pressed it to the form to obtain a thumbprint. Two years later, the situation has improved. Now there is a CD4 machine and trained staff deputed by NACO

marginalised groups. Drugs for opportunistic infections and treatment of sexually transmitted diseases are unavailable in many public hospitals.

Beyond ART

Several people expressed the need for nutritional support as part of the ART programme, as well as care in general. Good nutrition does not mean high-cost nutrition. Some NGOs have developed inexpensive indigenous diets, and also organised sponsorship for those in need. Nutritional counselling and information on nutrition needs to be an integral part of the campaign. Despite the strong need, however, there are no plans for overall nutritional support within the government's ART roll-out programme. Recently, the government has announced the provision of nutritional supplements to take care of 60% of the calorie, protein and micronutrient needs per day of over 3,000 children currently under the ART regime.

Though ART and CD4 tests are free, patients have to incur travel costs to reach the centres. Some states like Tamil Nadu have waived travel costs in public transport for HIV-positive people. However, various other diagnostic tests are not free till the patient is enrolled for treatment.

The programme needs to look beyond ART — at ways of improving literacy among women, lowering rural indebtedness, food security, and improving access to quality low-cost healthcare.

ART vs public health

Numerous reports point to problems with the public health infrastructure in general, leaving aside ART. Public hospitals today are often under-staffed and under-stocked. Indeed, the quality of the ART programme in a state seems to depend, at least partly, on the quality of its healthcare system. In this regard, Tamil Nadu's HIV management is far ahead of most other states in the country, though much remains to be achieved. At the same time, the abysmal public health infrastructure of states like Uttar Pradesh raises questions about both surveillance and the system's ability to provide care.

The public health infrastructure must be strengthened not only in public hospitals, but at all levels down to the village community. In order for people to be referred to a hospital for ART, health centres at the primary level must be able to refer people for more advanced treatment. Public health is a state subject, while national programmes — such as AIDS treatment — are funded by the central government. Government funding has remained stagnant in the last three decades. The weakening of public health systems is linked to the increased reliance on market mechanisms to address welfare needs. But there are also variations in states' commitment to social expenditure on health, education and welfare. Kerala, which has a history of state-supported services, continues to spend more on health compared to other states, despite cut-backs since the 1980s. The state announced its own ART scheme, the 'Trissur model', which integrates itself into the health system, providing comprehensive out-patient and in-patient care for about 800 people. Using funds from the state government and the Kerala State AIDS Control Society, it also provides ART for 200 people. However the question of sustainability is an issue, as the state government is starved of funds.

The NACP-III plan lays down a financial requirement of approximately Rs 134 crore for ART roll-out over a period of five years. The budget for paediatric ART is Rs 11.1 crore and Rs 1.56 crore for setting up paediatric centres of excellence. It is not clear where this money is coming from. Comprehensive information on the programme's financing and disbursal of finances is not easily accessible. Some guidelines and statements mention provision of treatment for five years. This casts doubts as to whether the programme will ever be comprehensive and sustainable.

The Patents (Amendment) Bill 2005, passed on March 23, 2005, is expected to have serious implications for access to affordable essential drugs. This amendment to the Patents Act of 1970 was made to fulfil the government's obligations on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a member of the World Trade Organisation (WTO). India now recognises patents retrospectively from 1995; formulations developed since then may be manufactured only with the consent of the patent holder and on payment of royalty. Health networks lobbied hard for modifications to the original Bill and managed to include clauses enabling the manufacture of essential drugs, including compulsory licensing of essential drugs. Still, it is felt that the Act is more restrictive than required by TRIPS, and the clauses difficult to implement.

First-line drugs currently in the ART programme date back to before 1995 and will not be affected by changes in the Patents Act, if any, and second-line antiretrovirals that are out of patent, such as Tenofovir, will not be covered either. Some new applications on Tenofovir are pending; if accepted, this would prevent off-patent production of the drug. Activists have challenged these applications.

Indian companies have not used compulsory licensing so far. However, the Indian health minister recently said that India may be forced to overrule patents and issue licences for firms to produce vital drugs. Much depends on mobilisation of public opinion.

We must strengthen our healthcare system so that it can meet the needs of people with HIV and AIDS, just as it must meet the needs of all people needing treatment for any illness. The ART roll-out must be seen as an opportunity to demand a better and more responsive healthcare system for all.

Excerpted from 'Antiretroviral drugs for all? Obstacles in accessing treatment: Lessons from India', Panos, March 2007

Is it just about sex and drugs?

Do we really know what the various forces driving India's epidemic are? The WHO estimated that unsterile medical injections accounted for 24% of HIV transmission in India in 2000. But India has focused almost exclusively on the sexual route of transmission. Very little space is left for non-sexual routes of transmission. This has important implications for the prevention programme

MARIETTE CORREA

THE CONTRIBUTION of different routes of transmission to HIV infection in India is rather uncertain. Very early in the epidemic, with a few sex workers infected and drawing on parallels with Africa, the government programme started functioning on the premise that heterosexual sex was the main cause of HIV spread in the country. Accordingly, sentinel surveillance included groups that were perceived to be at risk — sex workers, people visiting clinics for treatment of sexually transmitted diseases (STDs), injecting drug users (IDUs), and men who have sex with men (MSM). The focus of the prevention programme has been on these vulnerable groups that are at greater risk of HIV infection.

While sentinel surveys do show high prevalence among these populations, calculations of prevalence in each of these populations suggest that the number of infections in all the groups at risk is not large enough to account for anywhere near the majority of estimated cases in the country (1, 2). Unsafe healthcare practices such as unsterile injections and tattooing may be responsible for a significant number of HIV infections, and prevention efforts should address this risk as well.

Determining routes of transmission in India

The National AIDS Control Organisation's (NACO's) attribution of cases to different routes of transmission is based entirely on AIDS case surveillance. To get these figures, hospitals and institutions across the country assess and record the route of HIV acquisition for in-patients with AIDS. These institutions report to the relevant State AIDS Control Societies (SACS), which report to NACO. NACO consolidates this data at the national level. To obtain data from the states, NACO develops monthly AIDS case surveillance reporting formats, which the SACS distribute to hospitals reporting AIDS cases. Within hospitals, hospital authorities are responsible for deciding how to collect information for AIDS case reporting.

Reliability of information gathered

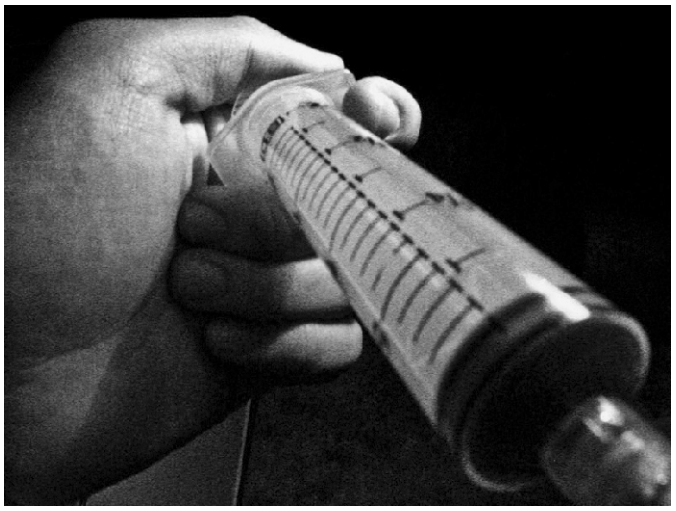
As AIDS case reporting is not mandatory, the SACS collect information from only those institutions that cooperate. AIDS cases are both grossly undiagnosed and underreported. Even in the few states in the country where AIDS is notifiable, most doctors do not report AIDS but the underlying disease. Reluctance to report a case as AIDS is partly due to the social and personal implications of identifying HIV-positive individuals, despite the fact that public health surveillance is not meant to identify or track specific cases. In many districts, only one or two government hospitals submit reports. There is minimal reporting, if at all, from the private sector; in fact, very little effort is made to get the private sector to report. Data on AIDS cases is therefore unusable in any meaningful way.

In fact, the conclusion that sex was driving India's epidemic came in the late-1980s, though up to September 1991, only 96 AIDS cases (including 13 foreigners) had been reported from across the country (3). As of January 1999, 13 years after the first case was discovered, only 6,703 AIDS cases had been reported, of which three-fourths were from Maharashtra and Tamil Nadu (4). Through end-July 2005, a cumulative total of 111,608 AIDS cases had been reported; 70% of these were from Tamil Nadu, Maharashtra and Andhra Pradesh which in no way can give a national estimate of the source of people's infections.

Given the assumption that sex was almost the sole cause of the spread of HIV, surveillance systems have been geared to perpetuate this fallacy. This has resulted in national estimates that leave very little space for non-sexual routes of HIV transmission. NACO's figures for cumulative AIDS cases through July 2005 report that 86% of HIV infections in AIDS cases have been from sexual exposure, 2.4% from IDU, 2.0% from transfusion of contaminated blood and blood products, 3.6% from mother to child transmission, and 6.0% from other or not specified risks (5). It gives no estimates for medical injections, or other blood exposures. (Sexual transmission as a category in the formats often, though not always, includes sex between men [5].)

Categories at risk

NACO designs forms for hospitals to use for monthly AIDS case reports. The current form asks hospitals to assign adults with AIDS into one of five 'risk/transmission' categories: 'sexual route', 'through blood and blood products', 'through infected syringes and needles', 'others', and 'not specified'. Categories for children up to 14 years are 'perinatal', 'through blood and blood products', 'others', and 'not specified'. The form does not mention other invasive procedures in healthcare and cosmetic services (such as dental care and tattooing). Moreover, there is no space on the forms to facilitate probing the category



'others'. Therefore, while doctors sometimes suspect that someone has acquired an HIV infection through another specific exposure, like dental treatment, they have no place to report this information. The category 'others' may include an important proportion of cases; at the national level, the joint category for 'others' and 'not specified' is 6%, larger than any other category except sex.

The guessing game of risk assignment

In asking hospitals to assign AIDS cases to risk/transmission (which involves the doctor trying to identify what must have been the actual risk of the person's HIV infection) rather than to exposure categories (based on transmission efficiencies and probabilities of becoming infected through each exposure in India), NACO in effect asks doctors and counsellors to report their best guess about the source of someone's HIV infection rather than report objectively what they learn about the risks. NACO provides no guidelines on how to classify cases with several risks.

AIDS case surveillance in India does not distinguish between high and low risks. The sexual category includes not only people with high-risk sexual exposures (for example, men who have sex with men and people with known HIV-positive partners), but also cases with lower risks, such as one to several extramarital sexual encounters — even with condoms — with a neighbour. Hence, cases with high-risk exposures are 'lost' in a large and non-specific category. Similarly, the category 'through infected syringes and needles', refers ambiguously to IDU and to medical injections. NACO's forms do not offer this as a risk category for children, implying that the category for adults is specific to IDUs.

Compare this with surveillance systems in countries like the USA and Canada where they report AIDS cases according to 'exposure categories', letting readers consider whether the number of cases assigned to a category reflects its contribution to HIV transmission.

In many countries, surveillance systems report cases according to a hierarchy of risks reflecting rates of HIV prevalence within groups defined by each risk. For example, in the US (6), Canada (7), Australia (8), and Europe (composite reporting for 52 countries by the European Centre for Epidemiological Monitoring of AIDS [EuroHIV]) (9), the first three categories for adults are: [1] MSM, [2] men and women who report IDU, and [3] men who report both MSM and IDU risks. Thereafter, receipt of blood or blood products (or coagulation disorder) and heterosexual contact are ranked fourth and fifth. In fact, in the US, AIDS cases are assigned to the category 'heterosexual contact' only if they "report specific heterosexual contact with a person with, or at increased risk of HIV infection" and have no other risk that is higher in the hierarchy, such as IDU (6).

Little or no effort has gone into training those responsible for AIDS case surveillance on how to collect information on risks, as the formats are seen as self-explanatory. Since the categories are mentioned on the forms, SACS officials do not feel the need to train doctors and counsellors on reporting routes of transmission. Further, NACO training focuses on detection and clinical diagnosis of AIDS cases.

How hospitals report

Within reporting hospitals, hospital authorities are responsible for deciding how to collect information. There are indications that hospitals have interests that compete or conflict with accurate reporting. Private hospitals may be unwilling to question paying customers about risks. Nosocomial (caused by a medical procedure) and unexplained cases present hospital administrators with a potential conflict of interest. HIV cases that cannot be explained may not be investigated as the hospital may be implicated.

There are also pressures to conform, with hospitals/doctors believing that the reports are just something that they have to routinely send to the SACS. Characteristically, the sexual route is the default category for adults. Despite these reports, counsellors and doctors in virtually every hospital acknowledge that they have come across cases for which they could not explain the route of transmission, or for which they suspected nosocomial transmission.

In the hospital setting, collecting information from patients about risks for HIV is subject to some practical difficulties. Crowded wards limit privacy, and illness weakens memories of exposure many years in the past. Doctors and counsellors understand that they are to identify and report the mode of transmission rather than risk exposures, little appreciating the speculative leap involved in going from information on risks to saying a specific risk was the source of someone's HIV infection.

Further, they believe that since the sexual route is already firmly established as responsible for the spread of HIV in the country, they do not need to question the clients much. Even when reported sexual behaviour provides no chance for sexual exposure to HIV, doctors may nevertheless attribute

cases to the sexual route on the basis of suspected but unreported behaviours. Moral judgements compound the bias towards attribution of cases to the sexual route.

Finally, they underestimate the ability of HIV to survive outside the body and to transmit through parenteral (intravenous or intramuscular injection) exposures, which undermines their attention to parenteral risks. Therefore, while doctors and counsellors often ask about blood transfusions, they ask less often about major or minor surgery or other blood exposures, particularly if a sexual risk has been reported or suspected. NACO provides no clear guidelines about when to report blood exposures. Blood exposures (other than IDU and blood transfusion) are neither included in the formats nor is training given to doctors. Even AIDS cases with blood transfusions and lower-risk heterosexual exposures may be allocated to the category 'sexual route'.

Reporting from surveillance data

Current practices to compile and report data from AIDS case surveillance are confusing. Specifically, NACO's national summaries do not include a category for 'syringes and needles', as in hospital reporting forms, but instead have a category for 'injection drug user'. The cases reported in that category at the national level apparently come from the category 'syringes and needles' in hospital reporting forms, which includes cases attributed to medical injections.

Why should non-sexual routes be considered?

First, none of the leading AIDS agencies have been able to demonstrate differences in sexual risks that could explain how heterosexual HIV transmission could be so much faster in countries with generalised epidemics versus countries with concentrated epidemics. In the US and Western Europe, despite high-risk heterosexual behaviour on the part of many IDUs and bisexual males, heterosexual transmission has not been sufficient in itself to sustain stable numbers of infections, much less drive epidemic growth.

Second, in India, the distribution of HIV infections across states and communities does not fit the assumption that sexual transmission explains most infections. How do we explain why people in many rural districts in the south are 10 times more likely to be infected with HIV than urban or rural residents in many northern states? For example, a 2003 random sample survey in Bagalkot district, Karnataka, found 6.2% of agricultural labourers — equal percentages for both men and women — HIV-positive, compared to 2.9% for all adults in the district (10). Notably, a 2004 survey of sex workers in Chennai found only 4.0% to be HIV-positive, less than among agricultural labourers in Karnataka (11) .

Third, we cannot assume that all HIV infections in high-risk groups are from personal risk behaviours. Why do sex workers in different parts of the country have such a variance in HIV prevalence? Why are sex workers many times more likely to be HIV-positive if they work in Mumbai or Goa than in Chennai or Kolkata? On the other hand, there is a lot of evidence to show that sex workers in developing countries are exposed to unsterile blood exposures and receive injections to prevent and treat STDs, which may account for many of their HIV infections. Hence, the fact that many sex workers are infected in some — but not all — communities says nothing about the relative importance of sexual and blood exposures in India's HIV epidemic.

How significant could the 'blood' routes be?

There is much evidence for HIV transmission through blood exposures in India. An incidence study done in Pune from 1993 to 2000 found that STD clinic attendees who received medical injections or tattoos were more likely to become HIV infected (12). A nation-wide study on injection practices conducted by the All India Institute of Medical Sciences in 2003 reported that 23.5% of medical injections reused unsterile or unreliably sterile syringes or needles. Injections were therefore an important risk in transmitting HIV (13). The WHO, in fact, estimates that unsterile medical injections accounted for 24% of HIV transmissions in India in 2000 (14).

Hundreds of HIV infections in India have been reported in children with HIV-negative mothers, and in men and women with no reported sexual exposure to HIV (15) including outbreaks in Pune in 1989 (16) and Mumbai in 1996 (17).

With insufficient attention paid to the nosocomial routes of HIV transmission, the contribution of these routes to HIV prevalence in the country becomes difficult to ascertain. While the evidence points to this contribution being significant, it is surprising that surveillance systems record not a single case in the country through unsafe medical care (except blood transfusions).

Underlying vulnerabilities to the spread of HIV

Acknowledging the contribution of unsafe blood exposures to India's epidemic should in no way detract from the efforts being made to stop HIV transmission through unsafe sex and through drug injecting behaviour. It only means we need to be aware of *all* the routes of HIV transmission so that we can work to block all of them.

We are far from understanding the relative strengths of the various forces driving India's epidemic. There are, in fact, various factors of vulnerability which we need to consider. While poverty has been assumed to be a factor creating vulnerability to HIV, the recent NFHS-3 data specifically states that HIV cannot be equated with poverty (18). It is the fourth quintile of the wealth index that has the highest HIV prevalence — the category that will approach healthcare, but of the kind most likely to have unsafe injections. We therefore need to avoid direct correlations between poverty and the spread of HIV. While there seem to be links between poverty and HIV transmission among specific marginalised groups, this may not be the case for the general population. That is probably why the more developed states in the country have greater HIV prevalence. Also, HIV in some African countries seems related more to wealth than to poverty.

Migration is another factor that is seen as creating vulnerability to HIV. This could be because of the status of migrants, separation from spouses, and poor access to safe healthcare. Again, NFHS-3 data refutes this assumption.

Human trafficking, powerlessness of marginalised groups, drug use and trafficking, gender disparities and discrimination, illiteracy, and lack of political will could all create underlying vulnerabilities to the spread of HIV.

There are many groups that are considered vulnerable to HIV because of their sexual behaviour — women in sex work, men who have sex with men, truckers, etc. These are the very groups that have additional exposure to unsafe blood. For example, malaria lancets are reused on sex workers, truck drivers are routinely injected with penicillin as a prophylaxis against STDs, the same needles are reused for tattooing sex workers while they wait in long queues at festivals, and due to their stigmatised status, sex workers cannot negotiate for safe healthcare even when they are aware that the doctor may be reusing equipment.

Why underplay non-sexual routes of transmission?

There are various reasons why the contribution of unsafe healthcare to the spread of HIV is ignored. One, spouted by senior AIDS experts, is that people are confused with more than one message, and giving information about safe healthcare might detract from safe sex messages. This ignores the fact that people are bombarded with all sorts of messages by the media and are definitely able to absorb more than one message on HIV. A parallel concern is that a broader focus of HIV messages (read: a complete message) might take resources away from prevention messages on safe sex. Another concern is that people may stay away from healthcare, especially immunisation programmes, if they are scared of getting infected with HIV. This argument leaves people with a choice between unsafe healthcare and no healthcare. Denying people the information that unsafe healthcare can lead to HIV infection violates their right to safe healthcare — by denying them accurate information on which they can make informed choices.

The insufficient attention given to ensuring safe healthcare is excused by arguments that there is no evidence linking healthcare to HIV infection. This is strange, considering that everyone associated with healthcare in India acknowledges that unsterile practices are common in both the public and private sectors. There is adequate evidence linking unsafe healthcare with HIV infections. India's increasing reliance on an unregulated private healthcare sector is likely to strengthen this link.

One big hurdle in ensuring the absolute safety of healthcare services is the low perception of risks associated with unsafe blood exposures. This is due to misinformation perpetuated among medical professionals and the general public alike on the survival of HIV outside the human body and transmission efficiency through injections and invasive procedures.

Difficulty in getting attention to the potential of blood transmission is also due to convenience. The sexual and drug injecting routes place the full responsibility on the HIV-positive person, or someone close to him or her, making it to a large extent a moral issue. Addressing the blood exposure route increases the accountability of the government and international agencies. Recognising the contribution of unsafe healthcare to HIV epidemics would mean acknowledging State responsibility for inadequacies in the systems, and revamping them accordingly.

It is not that the risks of unsafe healthcare to HIV transmission have gone unrecognised. Soon after AIDS was recognised as resulting from a bloodborne virus in the early-1980s, healthcare managers in developed countries, responding to public pressure, cleaned up healthcare systems to protect patients and staff. Even now, UN agencies advise their employees to carry their own syringes and needles with them when they are sent out to work in developing countries.

While in the developed world iatrogenesis as a cause of HIV transmission is completely unacceptable, the same standards are not followed for poorer countries. The inadequate efforts made by international agencies and donors as well as national governments of developing countries themselves to ensure safe healthcare as a fundamental right suggest a "tacit, widespread acceptance of a two-tiered health system: healthcare must observe the highest standards in wealthy countries, but not necessarily in poorer countries" (18).

Suggestions for improving data on routes of transmission

Despite its limitations, experts and the general public will continue to look first to AIDS case surveillance for information about the contribution of various risks to India's HIV epidemic. NACO needs to urgently review the AIDS case surveillance system to identify weaknesses and take the necessary corrective measures.

AIDS case surveillance should collect and report objective information on risks rather than subjective opinions on suspected routes of transmission. NACO forms should ask reporting hospitals to assign AIDS cases to 'risk exposure' categories rather than to the current 'risk/transmission' categories. Forms should present a hierarchy of categories, from higher to lower risk. NACO should provide questionnaires and training to guide doctors and counsellors to ask the necessary questions and to know what evidence is required to classify each case in one category or another.

The current sexual category should be divided into categories for people with specific risks, one high-risk category for MSM and another for high-risk heterosexual exposures (those who have paid or received money for sex, and those who have an identified HIV-positive heterosexual partner). Lower-risk heterosexual behaviour (any non-

commercial sexual partners with unknown HIV status) should be recognised in a separate exposure category.

To improve the sensitivity of AIDS case surveillance, formats should be revised to include all the relevant risks. Specifically, the current category for syringes and needles should be renamed 'skin-piercing exposures' so as to explicitly recognise all potentially risky invasive procedures in healthcare and cosmetic services (except for receipt of blood and blood products, which remains a separate category). To identify these risks, doctors or counsellors should ask if people have received injections, tattoos, dental care, or other skin-piercing procedures with equipment that may have been reused without sterilisation.

NACO should provide doctors and counsellors with accurate information about the survival of HIV outside the body and about HIV transmission efficiency through skin-piercing procedures. Because invasive procedures are common, HIV prevalence in people with these exposures would not be much greater than in the general population. Hence, this exposure category is low in the hierarchy. AIDS cases with both skin-piercing exposures and another risk ranked higher in the hierarchy would be reported according to the higher-ranked risk.

Conclusion

Currently, AIDS case surveillance collects information from inpatients, which has its difficulties. To improve the reliability of information on risks, surveillance may be extended to outpatients receiving antiretroviral treatment, because health staff have an opportunity to build a rapport with them before asking about risks. It is believed that NACO is currently trying this out and has commissioned a pilot study to gauge the effectiveness of ARV centres as sources of information on routes of HIV transmission.

The enforcement of standard precautions in western countries means that HIV transmission through blood exposures such as medical injections and tattooing is so rare that it can be ignored. Because standard precautions are not standard in India, there cannot be a similar logic for ignoring invasive medical and cosmetic procedures.

When people with HIV infections have had multiple possible exposures to HIV, several research designs are available to estimate percentages of HIV infections from each route. In the ultimate analysis, the need for efficient, objective surveillance systems is imperative to understand the contribution of various factors driving HIV epidemics and the risk exposures that people have, in order to plan interventions that reduce people's risks and contain the epidemic.

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This article is based mainly on a study conducted in 2005 to assess the reliability of AIDS case reporting in determining routes of HIV transmission: 'Routes of HIV transmission in India: Assessing the reliability of information from AIDS case surveillance' by Correa Mariette and Gisselquist David. International Journal of STD & AIDS *2006; 17: 731-735*

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Criminalising high-risk groups such as MSM

All three core groups affected and infected in the HIV epidemic — men having sex with men, sex workers and injecting drug users — are criminalised in India. How can any intervention work amongst groups whose behaviour is criminalised? Basic structural changes are called for, including the deletion, or at least reading down, of Section 377 of the Indian Penal Code on sodomy

ASHOK ROW KAVI

UNLIKE THE OTHER HEALTH PROGRAMMES of the Government of India, the National AIDS Control Programme (NACP) deals with three deeply stigmatised and invisible core populations: intravenous drug users (IDUs), male and female sex workers (SWs) and men having sex with men (MSM). All these three "infected and affected" core populations were not just invisible to the health infrastructure; they were stigmatised and criminalised under Indian law. So the government had to "search and hunt" for these populations. It also had to face the demand for recognition from these communities.

In India, only in the third stage of the NACP did the National AIDS Control Organisation (NACO) acknowledge that MSM populations were not just "highly infected and affected" by HIV but were also a core group that required urgent attention. This was based on evidence from its sentinel surveillance data.

All over the world, men who have sex with men (MSM) have unprotected anal sex, because it is not seen as high-risk. In the Indian cultural context, anal sex is not seen as sex at all; it is called 'masti'. So the situation among Indian MSM is more serious. However, in India, MSM are not seen as a high-risk group. Such men have poor visibility and they don't form part of the social landscape.

MSM in India are at significant risk of HIV infection because:

- They have frequent anal sex (45-55% of MSM in India practise anal sex).
- Only between 5% and 20% of MSM use condoms for anal sex.
- They have a large number of partners, reportedly between 11 and 28 casual partners per month.
- They have poor health-seeking behaviour, with only 20-30% of MSM going for STI check-ups.

The invisibility of MSM was driven home to me recently when the Project Director of NACO, Sujatha Rao, asked me to present operational guidelines for MSM interventions to the project directors of State AIDS Control Societies (SACS). "Start," she ordered, "with telling them who MSM are."

That's when it struck me how far down the road some of us activists have reached and how far behind we have left our health administrators. It was also an indication of how difficult the HIV and AIDS prevention programme is, and the roadblocks the National AIDS Control Organisation faces.

Recently I had the experience of sensitising judges of the various state high courts of India. Here, I was confronted with an incredibly high wall of homophobia and a lack of understanding of issues around sex, sexuality and gender in the highest echelons of the judiciary.

The problem is gargantuan because the issues are problematic. Not only is there no understanding of the populations involved, the approach is also very simplistic.

For example, it seems to be easier to conflate identity with risk behaviours. Thus, instead of talking about

> After starting with a denial of a large behaviourally homosexual population, the Indian health infrastructure is beginning to face some bitter facts — not only is there a large population of men having sex with men, but totally new ways would have to be devised to reach out to them

In the first year of NACP-III, there would be a scale-up in the number of targeted interventions (each reaching out to 1,000 key populations) for MSM, from 30 in NACP-II to 230 in NACP-III

"unprotected anal sex between men having sex with men," all men having sex with men are identified as a high-risk group. All sex workers are not at equal risk; those who are most marginalised, such as street-based women in prostitution, face greater risks. Likewise, in the MSM sector, NACO seems obsessed with 'kothis' or effeminate men.

Such a simplistic approach is easier for our health administrators but it is certainly not how HIV prevention programmes should be planned. This is one of the most complex situations the HIV programme confronts today.

Need to focus on risk behaviour

In Humsafar Trust prevention programmes, for example, we discovered that conflating gender and identity to fit into a particular kind of risk behaviour did not work. While effeminate homosexual men, or kothis, were said to be at the highest risk, we found from our grassroots work that, behaviourally, homosexual men who had furtive sex in public toilets, parks and beaches were as much at risk as castrated hijras in sex work. Even among hijras, the Humsafar Trust street outreach programme indicated that nearly 75% of cross-dressing males were not castrated; they were fully functional males who also penetrated other males if offered adequate monetary incentives ('dhoruu-kothis').

Such subtleties are lost in a cookie-cutter, 'one-size-fits-all' system which does not involve community-based organisations (CBOs). Gay CBOs have sometimes been bypassed in favour of organisations with no experience in work with homosexuals.

Initial prevalence studies provided startling figures. In 2006, the first sentinel surveillance among hijras was done at Mumbai's Sion Hospital. Samples from 250 hijras (anonymous, unlinked to the source of the sample) were tested and a shocking 26% of them were HIV-positive. In Delhi, the sentinel surveillance among hijras at the NGO Sahara found that 43% were positive. In 1999-2000, Humsafar Trust found that 13.8% of all samples collected as part of a baseline survey of six sex sites were positive. In fact, HIV prevalence in various surveys has rarely been less than 10%. Given that any prevalence above 5% is seen as 'hyper-endemic', this was a public health disaster.

After starting with a denial of a large behaviourally homosexual population, the Indian health infrastructure is beginning to face some bitter facts — not only is there a large population of men having sex with men, but totally new ways would have to be devised to reach out to them.

Bridge population

Unlike the other two core groups (IDUs and SWs) MSM include bisexuals, a huge bridge population or link between a sub-population with very high infection rates and a sub-population with much lower infection rates. In this case, the bridge is between high-risk multi-partner homosexuals having unprotected sex, and married women who are immobile, have no negotiation powers and generally do not have multi-partner sex. The bridge population of bisexual men is not only into high-risk unprotected sex, it is also mobile, extremely diverse and reaches across every social status and age-group.

If 'large', how many are they?

The first estimations of the size of the MSM population were attempted by using culturally inappropriate models like the Kinsey Scale which gave very high figures; apparently, over 35% of American adult males were having occasional, frequent or consistent sex with other males for at least five to 10 years of their sexually active lives. But nobody would extrapolate those figures to India. Some activists who conducted qualitative studies found that men in India had more sex with their own gender because of various cultural factors. However, there were few quantitative studies for the government to plan its public health budgets.

New estimates lead to expanded interventions

The first such estimate was attempted recently, during the planning exercise for the third stage of the National AIDS Control Programme. First, a literature search was conducted on all the research available on how many men who had sex with other men were also into anal sex. Not all MSM were into frequent anal sex and it was important to narrow the focus down to only those MSM who were having frequent anal sex. The figures ranged from 6% to over 11% in various sexually active male populations in the country. The group arrived at the conservative, lower estimate of 5% of sexually active adult (aged 18 and above) males in the country.

Data from the census and the National Family Health Survey (NFHS) of 1998-99 was used to calculate that there were approximately 2.35 million vulnerable MSM who had predominantly anal sex. Of these, it was judged that just 20% were to be found in public sex sites in the country. And of these, a minimum of 10% were male sex workers (MSWs).

Epidemiologists from NACO and other researchers

Zishaan Latif

determined that it would be very difficult to distinguish between MSM and MSWs in public sex sites. Except — possibly — for some difference in the level of negotiation skills, both had the same vulnerabilities. They had the same number of partners and low condom use. It was therefore decided that in the first year of NACP-III, there would be a scale-up in the number of targeted interventions (each reaching out to 1,000 key populations) for MSM, from 30 in NACP-II to 230 in NACP-III.

Thus the behaviourally homosexual population has finally been identified as a core segment with which national health programmes have to engage seriously if NACP-III is to have a modicum of success.

Continuing challenges for the programme

The programme is yet to address some major difficulties in providing support services to MSM. As pointed out earlier, there is no sensitivity to MSM issues. STI clinics directed at oral or anal sex services do not exist, and STI doctors are not culturally sensitised to MSM issues. Further, MSM community-based organisations are not encouraged to take up health issues which directly affect their communities.

Without the active cooperation of non-governmental organisations and community-based organisations, the government HIV/AIDS prevention programme cannot go forward. Government health facilities to access these communities have to be sensitised and trained. Presently, none of the three core groups can even access public health facilities, let alone use them.

Perhaps most important is the question of how the programme can conduct interventions among a group whose behaviour is criminalised.

All three core groups affected and infected in this epidemic are criminalised. Basic structural changes are necessary for health programmes to be effective. These include deletion or reading down of Section 377 of the Indian Penal Code on sodomy, decriminalising sex work and changing the approach to narcotics control by tightening up on trafficking and not punishing end-users. Only then can we openly talk about stigmatised behaviours like anal sex, intravenous drug use and sex work, and engage these groups.

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Sex workers continue to be treated as vectors of disease

Female sex workers constitute less than 1% of the infected female population in India. Yet, they are seen as a high-risk group and are the target of various HIV-related interventions. Such targeted interventions only end up further alienating communities instead of empowering them to combat HIV

MEENA SARASWATHI SESHU

WOMEN SEX WORKERS are mainly portrayed and treated in public discourse and policies as vessels of moral hazard, vectors of disease, and objects of pity. Their everyday lives are often beset by oppressive power relations and they tend to be socially excluded as their presence triggers moral panic in communities. Consequently, they find themselves at the receiving end of instrumentalist interventions because they are perceived as a public health threat to be monitored.

Ironically however, statistics show that female sex workers form less than 1% of the HIV infected female population in India. According to the National AIDS Control Organisation (NACO), in 2003 the number of women infected with HIV in India was 20 lakh, of which the number of female sex workers infected with HIV was 10,300. Every year, blood samples are collected for surveillance for HIV prevalence among the general population and various groups at risk of HIV. For female sex workers (FSWs), surveillance is done in 26 states. The number of FSW sites has gone from 42 in 2004, 83 in 2005, to 138 in 2006. Following the 2006 surveillance, it was concluded that eight states have HIV prevalence among FSWs of more than 5%: Nagaland (16.4%), Maharashtra (12.8%), Manipur (11.6%), Mizoram (12.4%) , Karnataka (9.6%), Andhra Pradesh (8.8%), West Bengal (6.58%), and Gujarat (6.4%).

We must remember two things: First, it is widely accepted that there are many limitations to the surveillance data on HIV prevalence. Second, while FSWs are much more likely to be HIV-positive than women in the general population, in absolute numbers, positive FSWs are a fraction of the total of HIV-positive women. Despite this, women in sex work have been identified in policy as a 'high-risk' group and are the target of various HIV-related interventions on the basis of this (mis)understanding.

Taking control: The SANGRAM story

Sex workers have become the focus of much bio-medical and social research and health programmes since the beginning of the HIV/AIDS pandemic. But these have not necessarily led to self-organisation or the empowerment of sex workers. However, the experience of women sex workers who are associated with SANGRAM presents a different picture. These women, who operate out of six districts across Maharashtra and Karnataka, have made considerable headway in taking control of some of the social and health threats in their lives.

The women formed a collective in 1996, and called it VAMP, in an intentional reference to the social stigma they face and in an attempt to reclaim the term 'veshya' ('whore' in local parlance). Five thousand women sex workers from western Maharashtra and southern Karnataka are now members of the VAMP collective.

Through their actions to prevent HIV/AIDS infection and help colleagues living with HIV/AIDS cope with their health and social problems, the VAMP women have challenged common perceptions of women sex workers. In particular, they challenge the notion that women sex workers are vectors of infection and are therefore to be treated as significant threats to the social fabric. They have also drawn attention to the idea of risky behaviour in HIV/AIDS infection, as opposed to high-risk groups, and focused on responsibility in sexual relations. In doing so, they have shattered the culture of silence that surrounds sexual relations and HIV/AIDS in public discourse.

The experiences of SANGRAM and the VAMP collective have also thrown up some critical issues and observations, presented below, that must be reflected on to make headway in HIV/AIDS prevention in the region.

Targeted interventions: A critique

In situations where access to treatment services for the general population is itself difficult and sporadic, a service for vulnerable groups is an almost impossible dream. The problem of addressing HIV in marginalised populations like sex workers is compounded by lacunae in the overall management of the HIV/AIDS epidemic in the region. Programmes that view women in sex work as a means to reaching the sexually active male population, rather than focusing on the sex workers themselves, are doomed from the start. Most governments in the region resort to such targeted interventions.

The targeted approach alienates communities and, in essence, continues to blame certain marginalised communities like sex workers instead of empowering them to combat HIV. In such a situation it is inevitable that the control and implementation of programmes will always remain with the implementing agencies rather than being owned by the communities.

The most effective education on HIV transmission is done by

those trusted by the community at risk. This means that sex workers have the best chance of helping other sex workers protect themselves from HIV. But peer education is not getting a fair chance in India. The police apparently do not recognise the lifesaving work done by AIDS educators, and these people face consistent abuse. Experiences of VAMP's work in Sangli, and the gay/MSM support service Naz Foundation International in Lucknow are evidence of this.

Special vulnerabilities of trafficked women

Trafficking by definition refers to the use of coercion, deception, abuse and assault to move people from one location to another across and within country borders. Undoubtedly, women who have been trafficked into the sex trade are more vulnerable to the threat of HIV and more likely to be in a situation where they are unable to control and protect themselves from HIV transmission. As illegal migrants engaged in an underground trade, they are very often subjected to sexual abuse at the hands of the authorities, including immigration and police officials, whose systematic involvement in the trafficking trade is well known and documented. Forcible detention, lack of access to redressal, police corruption, and 'invisibility' ensure that women can be violated, controlled and abused. Given the fact that HIV transmission is most efficient in situations of repression and abuse, women in trafficked situations are more vulnerable and at greater risk of contracting HIV.

However, most NGOs that work on issues of trafficking rarely include an HIV component in their programmes. In attempting HIV prevention with trafficked persons, NGOs find it difficult to build their confidence and trust. As 'Stateless' people without papers, trafficked persons prefer being invisible and underground. If they are women in prostitution and sex work, even more so because prostitution in most countries is illegal and it is almost impossible to access women who are under the 'protection' of the criminal nexus and trafficking syndicates. Fear of the police and legal repression are also major reasons why women shy away from outreach workers.

While there are many groups that work with trafficked women and illegal migrants, there are very few that actually offer services for HIV/AIDS prevention, care and support. Many women's groups in source or recipient countries provide services and support to women who are 'victims' of trafficking. But HIV/AIDS prevention and education is not part of their agenda. This gap needs to be examined.

Healthcare: Major concerns

While the 'immoral whore' image makes it very difficult for sex workers to get good medical treatment, illiteracy, ignorance and fear of the medical establishment renders them open to exploitation and extortion. Reproduced here are responses regarding healthcare by women in prostitution and sex work from West Bengal, Orissa, Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu, Kerala and the union territories of Goa and Pondicherry, from a report prepared by the National Commission for Women:

- Medical and paramedical staff at government hospitals have a callous, indifferent and often humiliating attitude. Irrelevant and embarrassing questions about sexual positions, etc, are often asked.
- Forced free sex with doctors and social workers is commonplace.
- Doctors often refuse to treat and admit women to hospital claiming they are AIDS carriers.
- In many centres, doctors make peons and attendants conduct the physical examination and only then attend to the women.

Accessing healthcare is a major concern for women in prostitution and sex work, and such gross violations of their right to healthcare demand urgent attention.

Sex workers as educators

Unfortunately the HIV/AIDS epidemic has singled out people in prostitution and sex work as 'carriers and vectors of HIV'. Apart from the stigma already attached to their work, society has further marginalised them as core transmitters of HIV infection. It fails to recognise that they are but links in the broad networks of heterosexual transmission of HIV. Today, this perception is beginning to change as it is increasingly being revealed that married women constitute the major chunk of women infected with HIV in the country.

Propagating the myth that women in prostitution and sex work are core transmitters of HIV serves the purpose of 'prostitution-bashers' who reinforce the prejudice that AIDS is an 'impure' disease that afflicts immoral and evil persons. The net result is to further target the women, which:

- Increases public and police violence against them.
- Decreases their ability to assert themselves.
- Allows customers to demand and force unsafe sex upon them.
- Increases the incidence of HIV among women, customers and the families of customers.
- Denies them access to healthcare services.

The role of women in prostitution and sex work in HIV/AIDS prevention has been slow to gain recognition. In fact, it is only now being grudgingly accepted in some circles that women in prostitution are the best educators of their male clients.

Meena Saraswathi Seshu is Director of SANGRAM, a non-governmental organisation that has worked with sex workers in Sangli, Maharashtra, since 1992. In 1996 the programme broadened into a collective of women sex workers against injustice, called VAMP (Veshya Anyay Mukti Parishad)

Moving beyond detoxification

The prevalence of HIV amongst injecting drug users in India could be more than 5%. But the only government intervention for these hidden, marginalised people is detoxification. Those who cannot obtain treatment and continue to inject drugs need other methods for reducing the risk of HIV transmission, including community outreach, the provision of new needles and syringes and drug substitution therapy

ELDRED TELLIS

ACCORDING TO THE WORLD HEALTH ORGANISATION, the sharing of HIV-contaminated injecting equipment accounts for 5-10% of all adult HIV infections worldwide and is a major driving force of the HIV and hepatitis C epidemics in some developing countries. As much as 30% of all new HIV infections are attributed to injecting in countries outside sub-Saharan Africa.

Ever since the first report of HIV infection amongst injecting drug users (IDUs) in northeast India in 1989, there has been a diffusion of HIV among IDUs in different parts of the country. In the national sentinel surveillance for 2005, HIV prevalence among IDUs was more than 5% in nine states. Hepatitis C prevalence among IDUs is alarmingly high in many places in the country: Chennai — 93%; Imphal (Manipur) — 90%; Kolkata — 80%; Mumbai — 79% (sentinel surveillance figures for 2003); and Darjeeling district of West Bengal — 48%.

Injecting drug use is a major driver of the epidemic in the northeastern states. Recent size estimation data shows that injecting drug users could constitute 1.9-2.7% of the adult population in Manipur and Nagaland. The risk of HIV transmission to sexual partners and wives of injecting drug users has been documented across India. In a sample of injecting drug users in the northeast, 75% were HIV-positive, most were under the age of 19, two-thirds were sexually active, and only 3% reported using condoms. Injecting drug users are also found in most of the major cities of India outside the northeast. The prevalence of HIV ranges between 2% and 44% in these groups. Little is known about the overlap of injecting drug users and other risk groups in states outside the northeast.

Prevention programmes gain effectiveness and sustainability when implemented in the context of a strong public health system and linkages to other programmes. Government services for STDs and basic HIV care require more resources for training and sensitisation of personnel to meet the needs of all high-risk groups which include female sex workers, men who have sex with men, injecting drug users, and people living with HIV/AIDS.

Drug treatment and HIV prevention

Drug treatment has historically been seen as abstinence, which is the most effective way of preventing HIV transmission among IDUs. Programmes based on abstinence range from detoxification to rehabilitation and from primary care to after-care. These are residential programmes and require 24-hour professional inputs which are not always possible with the available budgets. Also, as drug abuse becomes more common among the poor, residential programmes which charge high fees are out of reach for marginalised drug users.

Further, efforts at abstinence have not been very successful. While programmes promoting voluntary abstinence should be encouraged, it may not be a realistic or achievable goal for all. Relapse after detoxification is common, with relapse rates often reaching up to 90% in the Asian region.

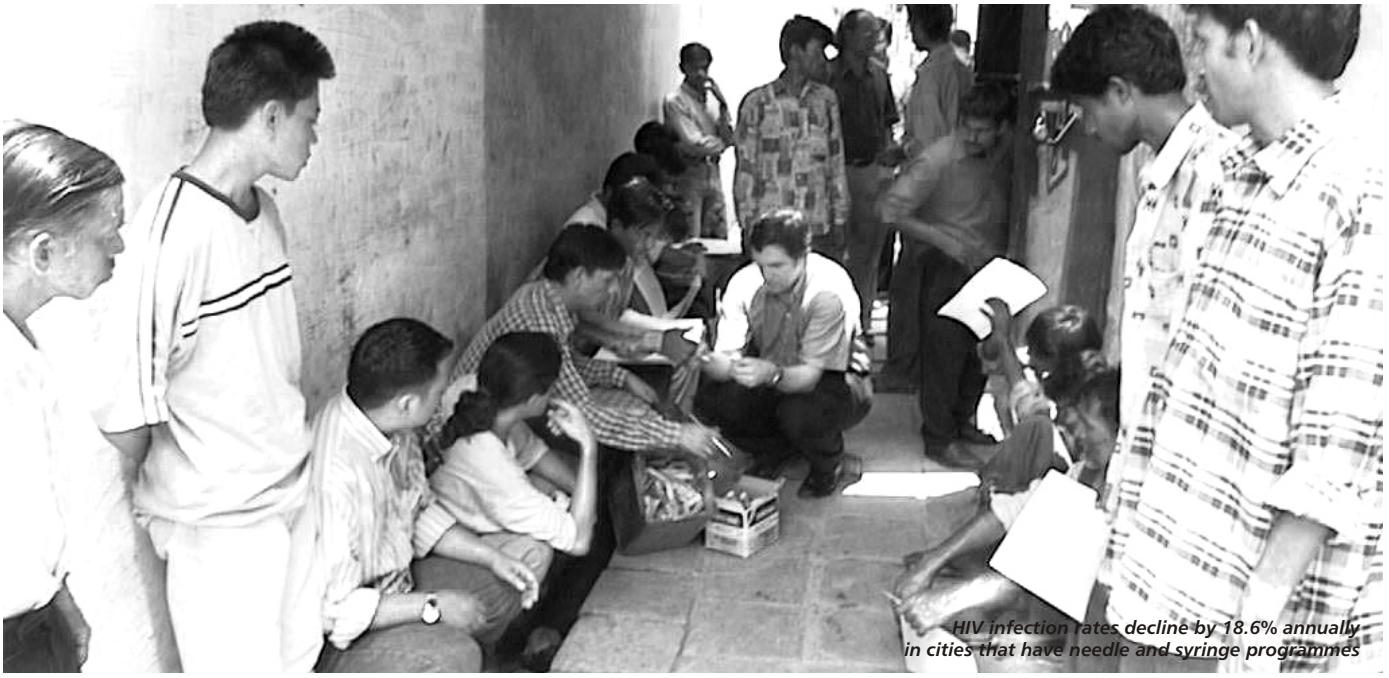
The Ministry of Social Justice and Empowerment provides grants to 400 'de-addiction centres' all over the country, providing one to two months of treatment. However, this is neither here nor there: detoxification usually needs not more than two weeks whereas rehabilitation requires about six months.

Detoxification is only the initiation into treatment and not a complete treatment for addiction. Those who cannot obtain treatment and continue to inject drugs, or those who relapse, need other methods for reducing the risk of HIV and other blood-borne virus (BBV) transmission. This is known as the harm reduction approach and incorporates activities such as community outreach, provision of new needles and syringes, condom provision accompanied with information on safer sexual practices, provision of effective drug treatment including substitution therapy such as methadone or buprenorphine, voluntary counselling and testing, and life skill programmes.

The need for needle and syringe programmes

The risk factor for HIV and other BBV transmission is not in the injecting of drugs itself, but the sharing of injecting equipment with an HIV-infected person, or the reuse of contaminated needles and syringes. For those individuals who continue to inject drugs, the provision of needles and syringes through needle and syringe programmes (NSP) reduces the need for IDUs to share injecting equipment.

A study in 2002 from 103 cities in 24 countries showed that HIV infection rates declined by an average of 18.6% annually in 36 cities with needle and syringe programmes, while it increased by an average of 8.1% annually in



HIV infection rates decline by 18.6% annually in cities that have needle and syringe programmes

67 cities that did not have NSPs.

Research from around the world has established that NSPs are effective in the prevention of HIV. They do not increase drug use, they do not recruit new IDUs or lower the age of first injecting, they do not increase the number of needles discarded in the community, and they are cost-effective.

Advocates of needle and syringe programmes highlight the fact that most injecting drug users are not in treatment. NSPs attract injecting drug users who are out of treatment to risk-reduction services, increase referrals for treatment and reduce the transmission of HIV. Thus, it is crucial to reach IDUs and provide them with risk-reduction materials and services if one is to reduce the risk of HIV to them, their sexual partners, their families and their community.

However, needle and syringe programmes need support from law enforcement officers who sometimes round up drug users who may be receiving services for prevention of HIV and force them into prisons where they may be even more vulnerable.

Opioid substitution treatment: Concept and objectives

Substitution pharmacotherapy, sometimes called 'maintenance treatment', is replacing the drug being taken with another drug or a similar drug (for example, methadone for heroin users). It may also mean using the same drug but taking it in a different way, for example, sublingual buprenorphine to replace the injecting of buprenorphine. The length of treatment can vary from six months to several years. Among the aims of drug substitution are lessening the risk of contracting or transmitting HIV/AIDS by switching from an injected to non-injected substance; to switch users from illicit drugs of indeterminate quality, purity and potency to legal drugs of known purity and potency. Opioid substitution treatment is an efficacious, safe and cost-effective modality for the management of opioid dependence and the prevention of HIV among IDUs. Provision of substitution maintenance therapy should be integrated with other HIV prevention interventions and services, as well as with those for treatment and care of people living with HIV/AIDS. A recent Cochrane review recommended that the provision of substitution treatment should be supported for opioid dependence in countries with emerging HIV and injecting drug use problems as well as in countries with established populations of injecting drug users.

In India, the experience with sublingual buprenorphine indicates that the treatment is attractive to drug users, families as well as communities. Further, the treatment has the potential to retain clients in treatment as well as link them with other services including treatment for conventional drug use. The post-marketing surveillance of sublingual buprenorphine from 10 centres across India indicated fewer adverse effects, and no deaths have been reported.

We need to develop appropriate, strategic and pragmatic long-term approaches to reduce HIV transmission among drug-using populations and their sexual partners. Needle and syringe programmes and opioid substitution can have a considerable impact on HIV transmission but they need to be implemented to scale in India. We need a clear-cut policy to create an enabling environment for services to reach these hidden, marginalised populations.

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Why are AIDS drugs unaffordable in India?

The big question facing HIV-positive people in India is access to affordable antiretroviral drugs. Already, second-line drugs cost over Rs 1 lakh per person per year in India, compared to approximately Rs 50,000 in 66 other developing countries

K M GOPAKUMAR

IN FEBRUARY 2001, the Indian pharmaceuticals company Cipla made the historic announcement that it would sell a generic version of the three antiretroviral (ARV) drugs used in combination for US$ 350 per person per year (PPY), a fraction of the $ 12,000 PPY charged by multinational companies. Prices fell further as other Indian generic companies got into the production and marketing of ARVs. This also enabled national governments and non-governmental organisations to initiate free antiretroviral therapy (ART) programmes. Currently, more than 2 million people in the Global South receive ARVs.

In India, more than 100,000 people receive first-line ARVs today, through the government's free treatment programme started in April 2004. However, about 10% of people living with HIV/AIDS need treatment, and, according to the latest estimates, there are 2.5 million HIV-positive Indians. That means 250,000 Indians need the drugs but more than half of them do not get them.

There is also an urgent need for affordable second-line treatment. In the absence of official data, estimates of people who have developed resistance to first-line drugs and who need second-line drugs range from 1,800 to 35,000. These people have two options — the debt trap or the death trap. Activists have campaigned for the availability of second-line drugs in the government programme. From December 1, the government is expected to introduce second-line treatment in a phased manner.

The efforts of activists and governments are threatened by the amended Patents Act, 2005. The product patent regime has emerged as a major potential threat to the sustainability of the free treatment programme as well as affordable drugs in general. What are the implications of the new patent regime on access to ARV drugs in India, and what can we do about them?

Process patents and access to drugs

The absence of product patent protection to pharmaceutical inventions in India till 2005 contributed in three ways towards improving people's access to ARV drugs. Because the Patents Act, 1970, recognised patents on processes alone, Indian pharmaceutical companies could produce generic versions of drugs and drive down the prices of drugs from multinationals. Second, though fixed-dose combinations (FDC) are ideal for patients, multinational corporations did not wish to manufacture these by cross-licensing their patents. As Indian pharmaceutical companies had no such problems, they developed and manufactured FDCs and thereby reduced the number of pills to be taken from six to two per day. Finally, in many countries, patents covered even paediatric doses, which meant they could not be available at affordable prices. Again, Indian generic pharmaceutical companies introduced generic paediatric doses at affordable prices.

Under the new patent regime with the Patents (Amendment) Act 2005, it is not possible to introduce generic versions of drugs that are under patent protection. This will affect the availability of existing drugs — both generic drugs currently available for which patent applications are pending and new drugs for which generic versions are not yet available. It can also affect the availability of new drugs currently in research and development.

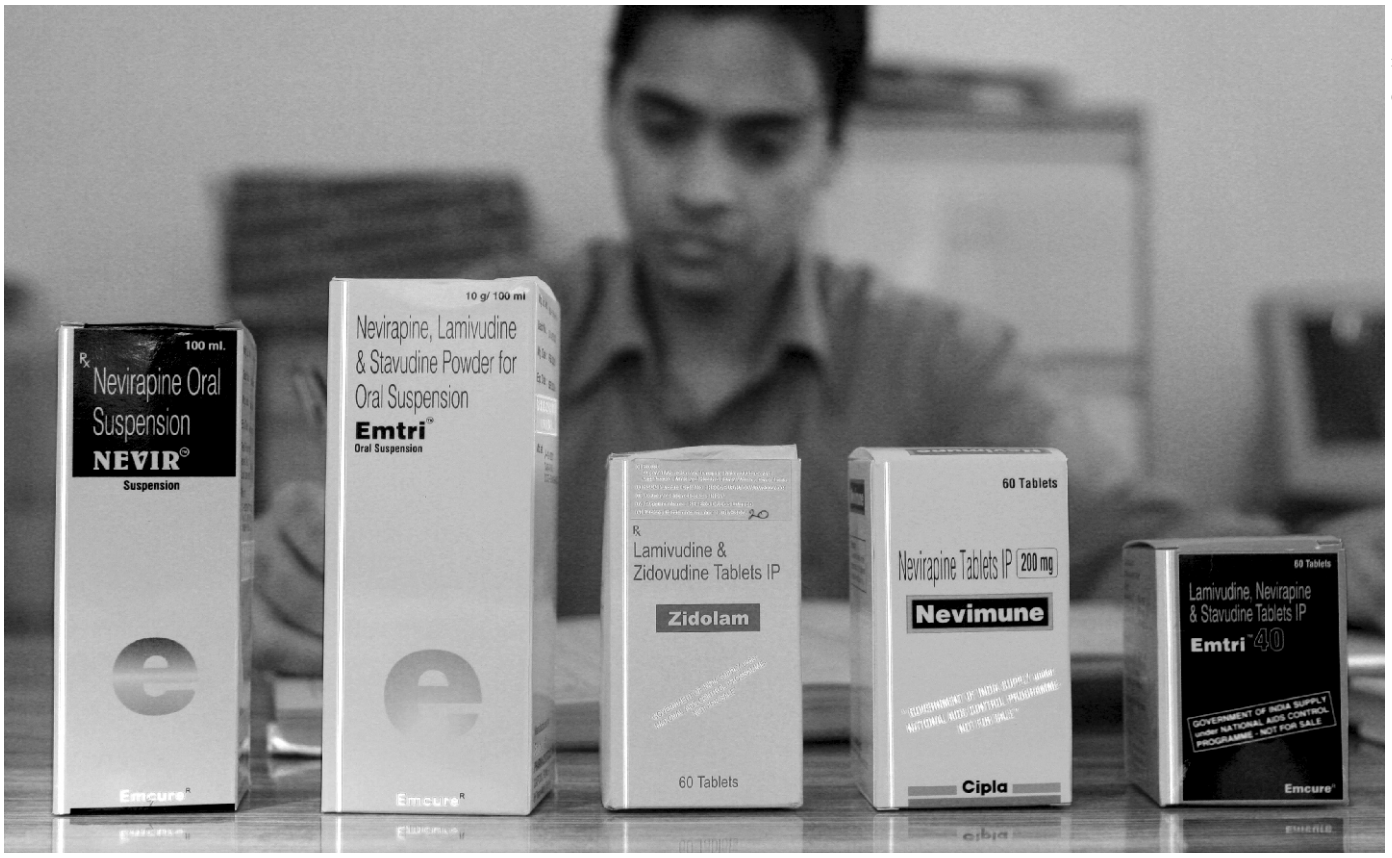
Currently there are 23 ARV drugs that have obtained marketing approval for treating AIDS. They are classified into five groups: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors and integrase inhibitors. These classifications are broadly based on the way in which these drugs contain the destruction of T4 cells. (For second-line treatment, the WHO has recommended one NNRTI and NRTI each, along with one PI for those exposed only to NRTI in the first-line treatment.)

Only two of these 23 ARV drugs are believed to be invented after 1995. The rest are not eligible for patent protection because the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provision on product patents is applicable in India only from January 1995.

Availability of existing drugs under the process patent regime

Despite the constraints of the amended Patents Act, certain provisions set limits on what can be patented as well as the action that generic manufacturers can take to prevent the granting of frivolous patents.

Pharmaceutical companies often misuse patent protection by making small modifications of a known substance and applying for a new patent to extend their monopoly even after the patent on the original molecule has expired. The



Gary Hampton

amended Act contains safeguards against this practice, known as 'evergreening' patents. Information in the United States Food and Drug Administration's 'Orange Book' (containing a list of all drugs approved for marketing in the USA) on patent expiry dates reveals that there are multiple patent applications on a single ARV drug, with different expiry dates. In other words, there are evergreening patent applications on many drugs.

In order to check the practice of evergreening, Section 3 of the amended Indian Patents Act prevents the patenting of known substances. Sixteen categories of discovery — three relevant to pharmaceutical patents — are excluded from patent protection as they are judged to be outside the definition of an invention. In an elaboration of the section in the Act on what are not considered inventions, Section 3 (d) introduced the notion of 'efficacy'. This excludes "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant". Further, "for the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

Limitations to the safeguard provided by Section 3 (d)

However, a patent can be granted if the applicant proves that the claimed invention related to the known substance results in the enhancement of the known efficacy of that substance. A patent may also be granted to a derivative if the applicant proves that it differs significantly from the existing substance with regard to efficacy. Further, the Patents Act itself does not provide any definition of the term 'efficacy'. Therefore, as Section 3 (d) adopts a case-by-case approach, it does not provide a comprehensive safeguard against evergreening.

The term 'efficacy' was recently defined by the Chennai High Court in its judgment on the Novartis petition challenging Section 3 (d). According to the court, "…What the patent applicant is expected to show is how effective the new discovery made would be in healing a disease/having a good effect on the body".

In light of this judgment, a substantial number of patent applications related to ARV drugs currently under examination will attract the scrutiny of Section 3 (d). Public interest groups and generic companies in India have already identified approximately 120 patent applications on various ARV drugs. These applications cover both first-line and second-line drugs. Table 1 is a list of some pending patent applications currently being examined by the Indian Patents

Table 1: A select list of patent applications on ARV drugs in the mailbox currently being examined by the Indian Patents Office

Substance name	Title	Indian application number	Priority date	Applicant
Lamivudine+Zidovudine	Pharmaceutical compositions	2044/CAL/1997A	31/10/1996/UK	Glaxo
Nevirapine/Hemihydrate	Pharmaceutical suspension comprising Nevirapine Hemihydrate	2485/DEL/1998A	NA	Boehringer Ingelheim
Trizivir	Antiviral combinations	1206/CAL/1997A	NA	Glaxo
Tenofovir	Nucleotide analog composition	986/DEL/2002A	25/7/97/US	Gilead
	Nucleotide analog composition	963/DEL/2002A	25/7/97/US	Gilead
	A method for preparing Form 2 or Form 4 Crystalline Adefovir Dipivoxil	989/DEL/2002A	25/7/97/US	Gilead
Lamivudine	Pharmaceutical compositions	479/CAL/1998A	24/03/1997 and 26/03/1997	Glaxo
Amprenvir+AZT+Ziagen	Antiviral combinations	1206/CAL/1997A		Glaxo
Amprenvir+AZT+3TC+FTC	Vaccine	2172/MAS/1998A	26/09/1997	SmithKline Beecham
Amprenvir	Pharmaceutical formulations	727/DEL/1997A	22/03/1996/USA	Glaxo
Abacavir	A novel salt	872/CAL/1998	17/5/97/UK	Glaxo
Lexiva Fosamprenavir Calcium	Calcium (3S)	IN/PCT/2001/00039	18/7/1998/GB	Glaxo
Lopanavir	Process and intermediates for preparing retroviral protease inhibitors	259/MUMNP/2003	31/08/2000	Abott

Source: Compilation by Leena Menghany, Medicins Sans Frontieres

Office. These applications claim patents in the form either of salts or of combinations or isomers, and therefore attract Section 3 (d) of the Indian Patents Act.

Further, a majority of the 327 new molecular entities (NME) approved between 1995 and 2005 by the US FDA would also attract Section 3 (d). Since it takes eight to 10 years from the date of patenting to marketing approval, the vast majority of these 327 NMEs were invented before 1995 and the patent applicant must prove enhanced efficacy.

It is to be noted that even the Chennai High Court judgment does not rule out the possibility of evergreening patents. For instance, a combination of two drugs may have a substantial improvement in therapeutic effect and be held patentable. Also, this judgment is a high court decision, not a law, so while it may set a precedent it is not binding.

In the final analysis, all the drugs that we are using for first-line and second-line treatment will not be eligible for patent protection in India in light of Section 3 (d). However, the effectiveness of this section depends on the skill and willingness of patent examiners to apply the law to real-life situations. The current infrastructure, including human resources, is insufficient to meet the challenges posed by the flood of evergreening applications. Public interest groups must be on guard.

Public scrutiny through pre-grant opposition

Section 25 of the Patents Act provides an opportunity for the public to scrutinise all patent applications and state their opposition before or after the grant of patent. This section provides various grounds to oppose the grant of patent. The Indian Network of Positive People (INP+) along with its associates, including the Delhi Network of Positive People (DNP+), has filed 13 patent oppositions against various evergreening applications. Table 2 provides details of these oppositions.

Public scrutiny and opposition may have an impact on MNC efforts to patent their drugs in India. Glaxo has withdrawn its patent applications on the first-line combination Combivir. Patent applications for Atazanavir and the Lopinavir/Ritonavir combination in gel form — critical for second-line treatment — are now considered to be effectively abandoned. However, the patent application for a heat-stable version of Lopinavir/Ritonavir is still under examination. The public interest group I-MAK has filed a pre-grant opposition in India arguing that the technique used for making the heat-stable version is not new and lacks inventive steps. Opposition has also been filed to the patent application for Tenofovir, another drug used for both new-generation first-line and second-line treatment.

Immunity against patent infringement

The other relevant safeguard in this context is Section 11 A of the Indian Patents Act, which provides immunity to (generic) drug manufacturers against suits alleging patent infringement under particular circumstances. Section 11 A states that [as] "a patent is granted in respect of applications made under sub-section (2) of Section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the first day of January 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises".

This means that all drugs which were in the market before the introduction of product patents — this would include all

Table 2: List of pre-grant oppositions

Name of drug	Name of company	Date and place of filing opposition	By (name of network)	Legal and communication support	Remarks
Combivir	GSK	March 30, 2006, Kolkata	MNP+ and INP+	Lawyers Collective, MSF Access Campaign	GSK claim to withdraw their patent, but no confirmation from Patents Office
Nevirapine Hemihydrate	BI	May 9, 2006, Delhi	PWN+ and INP+	I-MAK and MSF	Written response from BI, opposition hearing soon
TDF	Gilead Science	May 9, 2006, Delhi	DNP+ and INP+	Alternative Law Forum and MSF	Gilead is trying to dilute the opposition by offering voluntary licensing to Indian generic companies
TD	Gilead Science	September, Delhi	DNP+ and INP+	I-MAK and MSF	
Atazanavir	Novartis	July 27, Chennai	KNP+ and INP+	Lawyers Collective and MSF	Abandoned
Ritonavir	Abott	August 2006, Mumbai	DNP+ and INP+	I-MAK and MSF	
Lopinavir	Abott	August 2006, Mumbai	DNP+ and INP+	I-MAK and MSF	
Kaletra (soft gel)	Abott	August 2006, Mumbai	DNP+ and INP+	I-MAK and MSF	Abandoned
Amprenavir	GSK	July 13, Delhi		LC and MSF	
Abacavir	GSK	June	INP+	I-MAK and MSF	
Effavirenz	Merck	April	INP+	Lawyers Collective	

Source: Compilation by Loon Gangte, Delhi Network of Positive People (DNP+)

first-line drugs except the new-generation first-line drugs — will continue to be available in the market, but the (generic) manufacturers may have to pay a "reasonable royalty" to the patent holder. Still, even if the Patents Office grants a patent on a first-line drug this does not stop the production and marketing of those drugs in India if production started prior to December 31, 2004; it would be eligible for immunity from infringement proceedings provided under Section 11 A of the Patents Act.

However, the Act does not put a ceiling on this royalty, which means that if the patent holder sets a very high royalty, patients will have to pay higher prices for the drugs.

With the exception of Tenofovir, that too made by a single generic manufacturer, no second-line drug is eligible for this immunity. Hence there is a need to oppose these patents using pre-grant opposition as available under Section 25 of the Patents Act.

Supply of new drugs

The most important challenge in the product patent era will be to ensure access to new drugs currently in the research and development pipeline, and those that are yet to be launched in the market. Two provisions in the amended Act can be used to deal with such situations — compulsory licence and government use. However, it may be difficult to actually implement these safeguards.

Compulsory licence

Compulsory licence is a licence given by the government to a third party to use a patent without the authorisation of the patent holder. It permits a government to issue a licence to manufacture and export a patented drug "in certain exceptional circumstances". According to the Commission on Intellectual Property Rights (CIPR), an independent commission appointed by the UK government to examine the implications of intellectual property on development, "developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use". The CIPR recommended that developing countries adopt effective compulsory licensing mechanisms which include straightforward, transparent and fast procedures that do not suspend the execution of the licence. The effective and efficient issuance of compulsory licences is imperative to curb the abuse of patent rights by the patentee.

However, the compulsory licence provisions in the Indian Patents Act do not ensure the efficient issue of compulsory licences. Even though the language of Section 83 of the Patents Act reflects the spirit of Articles 7 and 8 of the TRIPS Agreement and of the Doha Declaration on Public Health and the TRIPS Agreement, the subsequent sections do not do so. With the exception of a "national emergency", "extreme emergency" or "public non-commercial use", a compulsory licence is available only three years from the date of grant of patent. Further, the legislation does not state clear grounds for the issuance of a compulsory licence. For instance, can a compulsory licence be issued when a patentee refuses to issue a voluntary licence on reasonable commercial terms? The details of anti-competitive practices are not spelt out clearly in the Patents Act or Competition Act. This leaves a gaping hole in the process that is likely to be exploited by the patent holder.

The procedural requirements to issue a compulsory licence are cumbersome and do not provide timeframes for the

conclusion of the process. This will result in extreme delays in the issuing of compulsory licences. In addition, there is no ceiling on the remuneration payable to the patent holder, which will inevitably lead to demands for excessive royalty and unnecessary litigations. Finally, the injunction remedy, optional under TRIPS with regard to compulsory licence litigations, gives extra power to the patentee to block the compulsory licence for a long period of time. All these requirements cumulatively make the compulsory licence system an unworkable option in India.

Section 92 (a) of the Patents Act permits the waiving of procedural requirements — such as efforts to obtain a voluntary licence and prior hearing — for issuing a compulsory licence for drugs for HIV/AIDS, malaria and tuberculosis. However, to invoke this provision the government must notify HIV/AIDS as a national emergency. Such a notification is yet to be made.

Government use

The amended Patents Act provides for three types of government use. First, a patent is granted in India on condition that the government may import the medicines for the distribution of drugs in public sector hospitals or at any other hospital. Second, the government or authorised persons may use the patent against a royalty payment. Third, the central government may acquire a patent after paying compensation. The government can exercise these powers at any time.

However, the Act permits the patent holder to file legal challenges to the government's decision to use or acquire the invention. This means the patentee can delay such use and the government will have to prove its need before the court. Using the TRIPS flexibility the government should have opted for administrative review. It also fails to use the flexibility of barring courts from issuing an injunction in the case of government use. These provisions must be amended if they are to be implemented effectively.

Second-line drugs: The real barriers to access

As stated earlier, there is an urgent need to provide second-line treatment through the free ARV treatment programme. It is clear from the above discussion that it is not the patent but the cost of drugs that prevents the introduction of free second-line treatment. Press reports have indicated that while the government spends Rs 7,500 PPY for first-line ART drugs, it will have to spend Rs 1 lakh PPY for second-line drugs. Patent protection is not responsible for this high price, at least for the moment.

At present, Indian companies manufacture all the drugs that are on the international market for first-line and second-line treatment. Does that mean that people are able to get these drugs in the market at affordable prices? No. The prices charged by generic pharmaceutical companies in India itself are putting these drugs out of the reach of many people. The prices charged in India are higher than that charged by the companies, in certain cases, on the international market.

Indian companies produce generic versions of all types of protease inhibitors (PIs) used for second-line treatment including the heat-stable RTV-boosted Lopinavir (LPV/r). Unlike first-line drugs, the prices of second-line generic drugs are high. Currently, the second-line regimen (TDF+ABC+LPV/r) would cost approximately Rs 100,000 or more PPY in India. The same regimen is available in 66 developing countries for Rs 47,951 as a result of measures taken by the Clinton Foundation.

One of the standard explanations for the high drug prices is that there is no competition among generic manufacturers. But there are between six and 10 Indian manufacturers of AIDS drugs and the drugs are not under patent in India, though patent applications are pending on many of them.

In any case, patents have not acted as a barrier in the production of ARV drugs in India. Indian generic companies either opposed patent applications or obtained royalty-free voluntary licences such as for the production of Atazanavir and Tenofovir. As a result, they are made by more than one manufacturer; for instance, there are at least four manufacturers of TDF and six manufacturers of LPV/r in India.

This shows that competition in the market has failed to bring down prices and warrants government intervention to do so. One should keep in mind the fact that approximately 80% of people in India seek healthcare from the private sector. In the absence of such government intervention, one has to depend only on the public sector to access ARV treatment. This results in great delays in reaching out to people who need immediate treatment in light of various constraints currently faced by the public sector including infrastructure and human resources.

Many companies blame the tax regime in India for higher prices. It is a fact that taxes in the form of excise duty, VAT/sales tax and octroi contribute approximately 20-25% of the price of a drug. But there is no credible explanation for the other 75% of the difference in drug prices. While the government has a duty to re-examine the tax regime for these life-saving drugs, companies cannot blame high prices entirely on the tax regime.

Conclusion

The new patent regime continues to threaten access to new-generation first-line treatment as well as second-line treatment. While there are various legal safeguards to ensure the availability of essential life-saving drugs, their implementation depends on a proactive government and active public interest groups. Equally serious, Indian pharmaceutical companies must explain why their generic drugs are many times more expensive in India than in other developing countries.

Indians with AIDS have the right to affordable treatment with both first-line and second-line drugs. This requires the cooperation of government, industry and the health movement.

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Prevention of HIV transmission: Do we know what works and what doesn't?

We know that HIV prevalence has stabilised or dropped in some parts of the country and amongst certain groups of the population. We know, for instance, that prevalence in the general population in Tamil Nadu has dropped from 1% to 0.5%. But do we know why? An analysis of prevention efforts in India, the successes and failures, throws up more questions than answers

MARIETTE CORREA

IT IS CLEAR that the prevalence of HIV has stabilised in some parts of the country and populations. In Karnataka and Maharashtra, for instance, prevalence at antenatal clinics (ANCs) has remained 1.25% between 2003 and 2005, and in the same period remained nil in Bihar and Assam. National data on HIV prevalence among female sex workers (FSWs) shows a decrease from 10.3% to 8.44% from 2003 to 2005. There have been significant drops in HIV prevalence among FSWs in Maharashtra, for instance, with prevalence of 54.29% in 2003 dropping to 23.62% in 2005. In Andhra Pradesh, figures for FSWs have dropped from 20.00% in 2003 to 12.97% in 2005. There is also a decrease nationally amongst injecting drug users (IDUs) from 13.3% to 10.16% between 2003 and 2005. But simultaneously, prevalence has increased in some parts. In Nagaland, rates of STDs have gone up from 0.98% to 3.50% between the years 2003 and 2005.

We attribute these successes or failures to assumptions about the forces that contributed to HIV spread in the first place and the factors that contributed to its reduction.

Our baseline data for the general population regarding HIV prevalence is weak. This is true not only for the estimates of those infected but for the sources of transmission too. However, data from ANC clinic attendees, which has been discredited as a source on which national estimates are based, may not be useful for estimate projections but could be used to get some sense of trends in local populations. More importantly, what we do have is data from sentinel surveillance sources which give us information about specific population groups. These annual surveys form the basis on which comparisons can be made regarding HIV prevalence in specific populations.

However, we are still uncertain about the relative contribution of factors driving the HIV epidemic in the country. Conventional wisdom and national statistics on the proportion of factors contributing to the spread of HIV are based on data generated through AIDS case surveillance which has completely faulty methodologies. Given this, when there are noticeable declines or increases in HIV prevalence in various parts of the country, it becomes difficult to attribute these changes to specific factors.

Further, it is impossible to gauge the success of individual programmes, since any drop in HIV prevalence is the result of an interplay of factors. However, one can broadly credit some efforts when there are significant drops in prevalence in certain areas. It is clear through ANC surveillance over several years that HIV prevalence has dropped in Tamil Nadu (from over 1.00% in 2000 to 0.5% in 2005). This success is officially attributed to various factors including the expansion of groups covered under prevention and care and support; establishment of consortiums to bring different stakeholders together; setting up of antiretroviral treatment centres and integrated counselling and testing centres. Further, the intersectoral approach and the strategy of moving well beyond the government machinery have contributed to the decreasing prevalence. Consortiums or working groups which have served to bring all agencies together on the same platform have helped to reduce duplication of tasks and facilitate sharing of information. However, it is not clear which factors played a predominant role or whether there were additional factors responsible for declining prevalence.

Again, in Tamil Nadu, despite the drop in prevalence in the general population there are noticeable increases in HIV prevalence among MSM populations (from 2.40% in 2002 to 6.40% in 2005). The reasons for this increase become unclear in a scenario where there are so many factors helping to reduce HIV prevalence overall.

The credit for successes (drop in HIV prevalence) is assumed by the AIDS sector, ignoring other influences. For instance, organisations working to reduce trafficking of women into prostitution are contributing a great deal to the reduction of HIV among sex workers. However, it is only the condom-distributing organisations, working under the AIDS umbrella, that are credited with success, if any, when HIV prevalence in a sex worker community reduces.

Conversely, failures to reduce prevalence are attributed to various socio-economic vulnerabilities that are beyond the control of AIDS programmes.

With specific population groups (like FSW, MSM, IDU) we may be more aware of the factors contributing to the spread of the epidemic and can plan our efforts accordingly. Still, prevention efforts seem to be donor-driven and straitjacketed. There is a focus on one route of transmission — for example, sex among sex workers, forgetting that sex workers also have to access healthcare and are exposed to

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unsafe invasive procedures. In fact, in the overall prevention scenario the inadequate attention given to safety in healthcare is serious cause for concern.

Sentinel surveys show a drop in HIV prevalence among some sex worker populations, and it is likely that the credit goes to interventions in the area. However, it is unclear why some interventions work and others do not when the package of services may be similar. Why are there significant drops in HIV prevalence among some sex worker sites and not in others? In some places, like the Sonagachi project in Kolkata, maintaining the HIV prevalence below 5% over the years despite a state average of 6.80% in 2005 has been attributed to an effective community development approach to HIV/STI prevention. However, the fluctuating sentinel surveillance data across the country for sex worker sites makes the role of HIV prevention interventions difficult to assess.

Successes are also attributed to what was assumed to be the route of HIV transmission; other factors contributing to HIV spread and consequently to a reduction in the rate of increase in HIV prevalence are ignored. To give a more or less universal example in the national context, most success stories are attributed to safer sex programmes. The fact is that much of HIV has been spreading iatrogenically and increasing the safety of healthcare in some areas could have contributed significantly to reduction in HIV spread.

In fact, the risks of unsafe invasive procedures (in healthcare, and in tattooing) to which sex workers are exposed have been documented. When there are improvements in healthcare for sex workers, this is not even considered a factor contributing to decline in HIV rates. Sentinel surveillance shows a drop in prevalence in Maharashtra from 54.29% of sex workers infected in 2003 to 23.62% in 2005 at the sentinel sites. It becomes impossible to say how much of these reductions have been due to safer healthcare practices. For instance, a private practitioner in Sangli reported that he was forced to shift from glass to disposable syringes and needles as the sex workers (a large part of his clientele) insisted that he make the shift. They were concerned about their own safety as well as that of other patients.

Attributing the drop in HIV prevalence among specific groups or states solely to the AIDS programme ensures of course that resources keep pouring in. In fact, one of the reasons for the outcry (voiced by many) over the new NFHS-3 estimates of infections in the country is concern that funds for HIV will be reduced. When the inflated figures were in existence, they were hardly ever questioned despite the fact that the basis for these estimates was inherently biased. The

national figures were based largely on prevalence of HIV among ANC attendees, and these figures were extended to the overall population. UNAIDS figures have been discredited in many countries, especially following the more rigorous and objective demographic and health surveys (see Global Reports of AIDS epidemics 2005 and 2006).

Preventing HIV spread: Analysing strategies

Prevention of HIV infection depends on a number of factors — knowledge of how the virus spreads, power equations between sexual partners, the status of women and disadvantaged groups in society, the actions of healthcare professionals and institutions, and so on.

Where are prevention efforts in India focused? What are the hurdles in implementing them? Can we gauge their success?

Preventing heterosexual transmission

Two main strategies are adopted to prevent heterosexual transmission: the ABC approach (Abstain or Be faithful to one partner; if not, use a Condom), and treating sexually transmitted infections.

But the ABC approach ignores the realities of women's position in patriarchal societies, the limited negotiation spaces that women have to insist that their partners use condoms.

Further, efforts to prevent heterosexual transmission have been sporadic and only a part of larger HIV prevention programmes. Prevention programmes are expected to focus on 'high-risk' groups — that is where the money is. So if you are not a sex worker, injecting drug user, man having sex with men, or closely associated with these groups, you are likely to be left out of prevention programmes. As there are no specific programmes that focus on prevention of HIV transmission in marital or long-term relationships, the success of these efforts becomes difficult to gauge.

The second strategy of prevention amongst heterosexuals, which is treating STDs, does reduce the risk of contracting HIV through unprotected sex (provided the treatment itself is safe). However, the direct association between HIV transmission and STD prevalence becomes difficult to establish. In fact, NFHS-3 findings show that the reported prevalence of STIs is much higher in states with the lowest HIV prevalence: "The reported prevalence of STIs or STI symptoms varies substantially across states, ranging from a low of 2% among women in Goa to a high of 25% among women in Assam, closely followed by Madhya Pradesh (23%). In addition to Assam and Madhya Pradesh, states with a prevalence of 15% or higher among women are Bihar, Tripura, Rajasthan, and Uttar Pradesh. States, in addition to Goa, with prevalence below 5% are Karnataka, Andhra Pradesh, Nagaland, Meghalaya, Tamil Nadu, Himachal Pradesh, and Maharashtra. Prevalence among men is highest in West Bengal (11%), followed by Tripura (10%) and Orissa (9%). States with prevalence among men of less than 2% are Karnataka, Mizoram, Tamil Nadu, Haryana, Andhra Pradesh, and Nagaland."

States with the highest levels of HIV prevalence have very low reported prevalence of STIs. Also, STD prevalence rates around the world do not correspond to HIV prevalence patterns. In 2002, Bangladesh combined a low HIV prevalence (0.1%) with an STD prevalence of 60% (1) while in the same year a study in Zimbabwe showed a prevalence of 2%, 1% and 2% respectively for gonorrhoea, chlamydia and syphilis, with an HIV prevalence rate of 26% (2).

Further, several studies have shown greater association between STD treatment and HIV than between STDs and HIV (3). One survey showed that HIV prevalence for those with STDs and taking injections was almost double the HIV prevalence for those with STDs and not taking injections (4). It has also been convincingly argued that associations between HIV and sexual variables could be confounded by medical exposures to treat STDs (5) and that expanded STD treatment without attention to injection safety could, ironically, increase rather than decrease HIV incidence (6).

Following recent studies in Africa which reported that male circumcision can reduce HIV infection, there has been much interest in and support for this method as a preventive technique. However, these studies have conflicting findings: they show that while in some age-groups circumcision reduced HIV infections, in other age-groups it was associated with an increased risk of HIV infection. Further, circumcision under unsterile conditions may actually be responsible for HIV infection. Nor are all the studies conclusive. One study that attributes lower HIV prevalence in Muslim men than Hindu men in Kolkata to circumcision shows no significant difference in STD prevalence (7). Therefore, while HIV

Prevention efforts seem to be donor-driven and straitjacketed. There is a focus on one route of transmission — for example, sex among sex workers, forgetting that sex workers also have to access healthcare and are exposed to unsafe invasive procedures

prevalence was significantly higher among Hindu men, the prevalence of syphilis and gonorrhoea were not significantly different between the two religious groups. Further, the prevalence of syphilis and gonorrhoea among HIV-positive and HIV-negative men were not significantly different.

Preventing HIV from sex among MSM

In concentrated epidemics, where there is high HIV prevalence among specific populations, the risks of transmission within those populations are better identified than in generalised epidemics. Prevention efforts are also therefore more focused. The decreases in prevalence among, for example, MSM in the US and Australia could be attributed to the combined efforts of the MSM community, care and support services, and to some extent, national policy.

The situation in India is different. First, while the AIDS programme strives to reduce HIV transmission among MSM, this work is thwarted by the fact that the activity for which this population is targeted is illegal. Despite efforts made by organisations to repeal Section 377 of the IPC, which criminalises "unnatural" private consensual sex between adults, this law is still untouched. Section 377 affects HIV prevention efforts and criminalising predominantly homosexual acts in effect provides moral and legal sanction for continued social discrimination against sexual minorities. It is clear that India's laws on homosexuality threaten human rights and encourage the spread of HIV.

Further, while the NACO guidelines have been in place to address this population, many State AIDS Control Societies (SACS) are reluctant to follow these guidelines. Also, due to their marginalised status, not many MSM groups have either been formed or come forward for support across the country. With poor mapping in place to estimate the size of the population and the lack of adequate sentinel sites, it is difficult to assess whether there have been actual changes in prevalence over the years.

If one looks at the sentinel data from the years 2003 to 2005, Maharashtra shows a decrease in HIV prevalence rates among MSM (16.80% in 2002, 18.80% in 2003, 11.20% in 2004 and 10.40% in 2005) and Tamil Nadu shows an increase (2.40% in 2002, 4.20% in 2003, 6.80% in 2004 and 6.20% in 2005). But there are wide fluctuations in the sentinel survey data. For example, Delhi shows HIV positivity among MSM of 27.42%, 6.67% and 21.60% in the years 2003, 2004 and 2005 respectively, and Goa's surveillance data for MSM shows HIV prevalence of 9.09%, 1.68% and 4.90% for the years 2003, 2004 and 2005 respectively. These fluctuations are cause for concern and raise questions about the methodology adopted. Informal reports from NGOs (that are expected to 'provide' the MSM population for testing during these surveys) show that some have been pressurised to meet the target requirements for fear of their projects being discontinued, and have therefore included any (read heterosexual) men in their sample.

Preventing mother to child HIV transmission

Most mother to child HIV transmission can be prevented. In

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2001, NACO and the health department began testing pregnant women and offering medical interventions to protect children from HIV infection through perinatal transmission. Antiretroviral drugs reduce HIV transmission to 10% (down from 33% otherwise). This rate can be further lowered with better combinations of antiretroviral drugs, which are available through the private sector, along with caesarean delivery and avoidance of breastfeeding.

The PPTCT programme in India includes single-dose Nevirapine to the mother and later to the baby.

However, successes in the West on the prevention of perinatal transmission have in fact relied more on combination therapies than on Nevirapine. In the United States and Europe, where today fewer than 2% of babies born to HIV-positive pregnant women have the virus, it was mainly due to routine use of Zidovudine during pregnancy.

Even in Botswana, which has successfully reduced the rate of HIV transmission from mother to child to less than 4%, the regimen has been dual drug treatment — four weeks of AZT, and then a single dose of Nevirapine at birth to mother and child. The success in Botswana is also attributed to political support and policy decisions, like opt-out testing (the testing of all pregnant women for HIV unless they refuse); providing HIV test results in 20 minutes to expectant mothers; and giving dual drug treatment for HIV-positive women. The success of Botswana is particularly creditable considering 34% of its pregnant women are HIV-positive.

However, the global scenario on prevention of perinatal transmission remains bleak. According to the Global AIDS Report 2006, a mere 9% of pregnant women in low- and middle-income countries were offered services to prevent transmission to their newborns in 2005, as compared to

7.6% in 2003. In 2005, the percentage of HIV-positive pregnant women who received prophylactic antiretrovirals was 9.2. Since these are global figures and considering that most HIV-positive women in developed countries receive ARV to prevent their babies from getting HIV infection, it is evident that developing countries fall far short of adequate coverage.

Preventing HIV from injecting drug use

Given the limited success of de-addiction programmes, prevention programmes relating to injecting drug use educate injecting drug users on sterile injecting equipment — avoiding sharing needles, syringes, water, or drug preparation equipment; using syringes obtained from a reliable source; sterilising previously used equipment in boiling water or disinfecting it with bleach before reuse. Injection drug users and their sex partners are also advised to take precautions, such as using condoms consistently and correctly, to reduce the risks of sexual transmission of HIV.

NGOs supported by SACS or international agencies have comprehensive harm-reduction programmes which include community outreach, abscess management, safe injecting, needle syringe exchange programmes, and oral substitutes. Buprenorphine and methadone are commonly used opioid substitutes given under medical supervision to injecting drug users. The former is being increasingly used among NGOs working with IDU in different parts of the country. Opioid substitution therapy is also part of the next phase of the National AIDS Control Programme (NACP-III). For those who can and are willing to give up drugs altogether, detoxification, rehabilitation and other therapies are available in many parts of the country.

While some NGOs have been partially successful in reducing harm to IDU, it is again unclear how much the success of individual organisations has accounted for changes in HIV prevalence in various states. Sentinel surveys show an increased HIV prevalence amongst injecting drug users in Delhi (7.23, 14.40, 17.60 and 22.80 for the years 2002, 2003, 2004 and 2005 respectively) over the last few years, whereas there have been drops in Maharashtra (39.42, 24.90, 29.20 and 12.80 for the years 2002, 2003, 2004 and 2005 respectively), Manipur (39.01 in 2002, 21.00 in 2004) and Nagaland (9.56 in 2002, 3.22 in 2004), till 2004, with slight increases again in 2005 (24.10 and 4.51 in 2005 in Manipur and Nagaland respectively). Much of the success can be attributed to various NGO programmes as there have been practically no government interventions (apart from some support by SACS and from the Ministry of Social Justice and Empowerment) for programmes for IDU. This is despite the fact that IDU continues to be a criminalised activity, with constant police harassment impeding the efforts of organisations working to prevent HIV among this population.

Preventing HIV from other blood exposures

Unsafe invasive procedures in healthcare contribute significantly to the spread of HIV. But this is accorded low priority, making it difficult to contain this route of transmission. Much effort has been made over the years (especially through the AIDS programme) to train doctors and nurses on standard biosafety precautions; but healthcare workers and facilities often do not have the necessary equipment.

Some changes have been made over the years to improve injection safety, including shifting from glass to disposable syringes and needles and the promotion of auto-disable (AD) syringes. The government has introduced AD syringes in all centrally-sponsored immunisation programmes.

Because of the risks that healthcare providers face in administering care, the government has a programme where health providers are given medication after a possible risky exposure to HIV (post-exposure prophylaxis) to prevent them from getting infected. This is available to all doctors and nurses working in government health facilities. Unfortunately, not many access this facility even after accidental injuries as the procedures are often cumbersome. The medications are not always available, requisitions need to be made to the authorities, and confidentiality of the healthcare worker is not always protected. In the more remote areas, medical staff are not even aware that these facilities exist, nor are there enough doctors trained to administer the regimen across the country.

Irrespective of the resources that flow into HIV prevention and how much this may detract from other public health priorities, we will be a long way from fighting the epidemic in India without clear evidence-based research on the proportionate contribution of various factors driving the epidemic.

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Falling through the cracks

Parent to child transmission of HIV in India infects 56,700 children every year. The third phase of the National AIDS Control Programme aims to reach 7.5 million women and give prophylactic treatment to 75,600 infected mother-baby pairs. The task is ambitious: in 2005, just 2.9 million women were reached

MAYA INDIRA GANESH

PREVENTION OF PARENT TO CHILD TRANSMISSION (PPTCT) of HIV/AIDS is a complex task. Like other efforts against the epidemic, much hinges on how effectively scientific progress and research can be transmitted through the under-resourced public health systems of most parts of the HIV-affected world. An anecdote from Africa shows how this can sometimes be successful (1).

In 2000, the pharmaceutical company Boehringer Ingelheim made large-scale donations of Nevirapine — a single-use drug for mother and baby which enables the prevention of transmission of HIV — to select countries in the developing world. However, the company found that countries were not accepting their donation. At the behest of the corporation, the international non-profit organisation PATH found that the resistance was a logistical issue. A woman giving birth at home needs to administer a teaspoon of Nevirapine syrup to her newborn, but many mothers have to travel miles for a chance to meet a health worker before they deliver, a last chance to actually collect the medication that could be lifesaving. Even if she were to collect the medication, how would she transport it home, keep it clean and remember how and when to administer it to her baby? Ingenious health workers in Kenya found a way to use materials at hand to fill an oral dispenser with the dosage, seal it, wrap it in aluminium foil and pack it in an old carton from another medication. PATH eventually stepped in to create safe, hygienic and clearly marked packaging for a single-use oral dispenser. The Nevirapine pouch reduces the risk of the syringe being accidentally squeezed, has clear instructions reminding the mother to give her baby the medicine, and a place for health workers to write down the medicine's expiry date to prevent the medicine being handed off to another woman.

However, such stuff of great public relations is less common than could be wished for.

Programme requirements

Preventing parent to child transmission of HIV requires the safe and ethical testing of a pregnant woman to find out whether or not she is HIV-positive. Her husband needs to have been tested as well. She needs to return to the health centre to collect her test results and, if she is positive, she needs to be fully informed of what to expect and how she can minimise the risk of transmission. If she opts to have her delivery at a different health centre (if not at home), or possibly at her mother's house which may be far away from where she's received antenatal care, she has to be confident of sharing her HIV status and ensuring that she and her baby both receive Nevirapine. She has to contend with the pressure of family and her own conditioning about how to feed her infant (replacement feeding poses the least threat of infection as against breastfeeding or mixed feeding). And so on. Therefore, ensuring that an HIV-positive woman minimises the risk of transmission of infection to her baby is fraught with the possibility of women falling out of the system, worsened by the limited access that women have to services anyway.

Parent to child transmission of HIV in India amounts to less than 4% of HIV infections but that still translates to 56,700 children infected every year (2, 3). This figure implies burdens and responsibilities for entire families — from the spiralling cost of healthcare to dealing with social issues such as stigma and discrimination from the very beginning of the child's life.

The PPTCT programme in India is part of a four-pronged strategy (4) that recognises vulnerabilities to HIV through the lifecycle. From prevention education for adolescents to the minimisation of the risk of HIV transmission in pregnant women, to the continuing care and support of affected and infected mothers and babies, the strategy aims to be an overarching focus on the entire lifecycle of risk and vulnerability. According to the national PPTCT guidelines, government hospitals should be able to provide HIV-positive pregnant women with Nevirapine as antiretroviral (ARV) prophylaxis, and at the onset of labour. The newborn infant is also provided a single dose of Nevirapine within 72 hours of delivery.

Counselling, consent and communication

However, the issue in India eventually is one of how the public healthcare system reaches out to women and children at risk. As of December 2005, there were 488 PPTCT centres in the country, 90% of which were in high-prevalence states. NACO reports that 2.9 million women have been reached through its programmes by 2005, whereas the target for the year was 6.9 million (5). Under NACP-III (National AIDS Control Programme 2007-2012) NACO aims to reach 7.5 million women and provide ART (antiretroviral therapy) prophylaxis to 75,600 infected mother-baby pairs (6). The

PPTCT programme, funded by the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF), is another initiative that supports nine organisations in Andhra Pradesh, Maharashtra, Karnataka and Tamil Nadu in diverse private sector, faith-based and NGO-supported healthcare settings (7). EGPAF's support is focused, yet is the only other significant player in PPTCT service delivery.

Within these large national public health efforts, the details matter. The PPTCT programme mandates that women are to be counselled on HIV and informed enough to give consent. How this is handled is difficult to say, and not many assessments of this aspect of PPTCT services are readily available.

What is becoming the norm is 'opt out' testing, in which all women are informed either verbally or through information leaflets that they will be tested for HIV unless they specifically state that they don't want it. The rationale behind opt out testing is that it normalises HIV testing and tries to ensure that as many women as possible are tested. The problem with this approach of 'sweeping' a whole population is that, in the regimented routine of antenatal care settings, women may not realise that they can refuse a test, particularly if they are young, poor and not well-educated.

An assessment of innovations in PPTCT service delivery in four Mumbai hospitals conducted for UNICEF and the Mumbai District AIDS Control Society by this writer found counsellors and doctors saying that providing counselling was one of the most challenging aspects of PPTCT in a busy hospital setting.

Beyond addressing the fear, stigma and misunderstandings associated with HIV, counsellors found it difficult to address the more sensitive issues of sexuality, gender, addressing both male and female partners and their needs (8). Moreover, counsellors consistently raised the issue of the pressure to fill in endless registers and records, a common administrative burden that seems to mark the fight against HIV; sometimes women get herded through the tests and counselling when, in fact, that is precisely where they require time and attention. There appears to be a sincere effort to ensure that women don't miss out, but this could result in hurried counselling.

Many women may have missed or avoided every opportunity to be tested and then arrive for delivery at centres where PPTCT facilities are available. Despite the potential benefits of reduced transmission risks, rapid testing during labour raises ethical dilemmas about pre-test counselling and the ability of women to give consent at such a time. Moreover, women in labour need to be aware that rapid tests also result in false positives and they need to be reassured that ART will be stopped if confirmatory tests are negative. All this requires a skilled and sensitive labour room within an efficient healthcare setting.

A continuum of care and support

After an HIV-positive mother delivers her baby, she should ideally have a network of care and support services to ensure that she maintains her health and that of her baby. Reproductive and sexual healthcare options, general health resources, counselling and emotional support systems,

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An HIV-positive child at the CCDT Centre. Parent to child transmission accounts for 4% of HIV infections in India

nutritional advice, are just a few of the things an HIV-positive mother needs. These can be provided through a network of referrals to public and private healthcare settings, CBOs and NGOs. A recent study by Horizons conducted in three locations across the country found that this was limited (9) although bigger towns and cities have access to a range of services. Interestingly, this study found that women in Imphal, Manipur, had better access to a range of well-networked healthcare settings because the prevalence of HIV has, over time, implied the need for services. The population has also had to deal with HIV in their midst for a lot longer. The assessment of Mumbai hospitals found that health centres that developed ties with NGOs were generally better at outreach and in follow-up care and support to HIV-affected families (8).

Are fathers really part of the programme?

Male partners are traditionally not welcomed in an antenatal care setting. While individual centres may make efforts to reverse this, the woman is more likely not to get the care she needs if her male partner does not understand the risks and vulnerabilities associated with being HIV-positive. For example, while PPTCT policies mandate the routine testing of women, their male partners are often not tested. This could result in situations like the following: a newly-married pregnant woman's HIV-positive husband is not tested, and her test results emerge negative (as she is in the window period, or has had enough sex to get pregnant but not enough to contract HIV) when in fact she and her child (and future children) face a significant risk. While the change of acronym from the earlier PMTCT (prevention of mother to child transmission) to PPTCT was intended to call attention to the role and responsibility of men in the transmission of HIV to their children, the recent NACO policy guidelines and strategic targets do not specifically mention, apart from the testing of husbands, how men as fathers and caregivers are to be incorporated into antenatal care of the mother-to-be.

What about drug resistance?

A significant technical issue in PPTCT is the drug resistance that mothers develop to Nevirapine. This prevents them from being able to take the drug should they become pregnant again. Recent research from the Harvard AIDS Institute in Botswana indicates that delayed dosage of the drug could address the problem, as drug resistance decreases over time (10). However, studies of this nature in India are not conclusive; it is unclear what the effects of single-dose Nevirapine are on mothers and babies. UNICEF and NACO are now planning to conduct a nationwide study of existing drug regimens and will propose shifts in treatment protocols if they do indeed find that single-dose Nevirapine significantly affects HIV-positive mothers and babies (4). NGOs supported by EGPAF follow a combination of drugs, providing a tail of Zidovudine and Lamivodine to address the issue of resistance *(Dr Sanjeevani Kulkarni, PRAYAS, personal communication).* However, this is not a national protocol endorsed by NACO and is not followed across its PPTCT facilities.

With drug protocols being patchy, it is as yet unclear what the fallout will be. However with Nevirapine being relatively cheaper than the more complex combination drug therapies, and easy to administer, in a country like ours it may be the only chance for some women to protect their babies. There have also been concerns about drug toxicity in long-term use of Nevirapine resulting in skin infections and life-threatening liver toxicity; underweight women face a particular risk from Nevirapine-related liver toxicity, which is not uncommon in India. Diagnosing and managing such adverse effects is not easy and requires constant medical attention and monitoring, not something that the average HIV-positive mother in India has access to (11).

PPTCT is about many things — both the capacity of public healthcare as well as of the people who staff and run them. It is about the social and cultural issues and attitudes surrounding pregnancy and childbirth and how they are integrated into the delivery of information and treatment. It is about balancing an efficient service delivery mechanism against an empathetic engagement with women and babies at risk. For programmes to be effective there are many variables to be controlled; systems being as they are, things fall through the cracks, and unfortunately so do far too many women and children.

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Do we need a separate law on HIV/AIDS?

Stigma and discrimination lead to the most significant human rights violations for persons living with HIV/AIDS and are the greatest barriers to preventing further infection and providing care, support and treatment. But India has no existing legislation which would cover discrimination on the grounds of HIV. And the framework of public health legislation is too limited to adequately cover HIV issues

KAJAL BHARADWAJ

INDIA'S FIRST HIV LITIGATION arose when HIV-positive activist Dominic D'Souza was incarcerated in the late-1980s. D'Souza, a resident of Goa, was found to be HIV-positive when he donated blood at a Goa hospital. The test was performed without his knowledge or consent, and the results were revealed, not to him, but to the local police. D'Souza was subsequently arrested and confined in an unused TB sanatorium pursuant to the Goa, Daman and Diu Public Health Act, 1985, an amendment to which, in 1986, authorised the State to mandatorily test any person for HIV and isolate them if they tested HIV-positive. Dominic's mother, Lucy D'Souza, filed a writ petition before the Goa bench of the Bombay High Court arguing that the provision in question violated her son's fundamental rights.

In its decision, the high court recognised the serious consequences of the State's policy to isolate, but held that the interest of public health supersedes an individual's rights, and while isolation may not be 'ideal', it was 'practical'. (Although the Act in question still remains in the statute books, following the judgment the government decided to stop implementing it; more recently, it was reportedly amended.)

Dominic's case highlighted several aspects of law related to the HIV epidemic, beyond the application (or mis-application) of public health laws. Dominic was tested for HIV without his consent, his confidentiality was breached, and eventually when he was released he had lost his job.

Since that first case, violations of the rights of people living with or affected by HIV have increasingly come to light, many legal cases have been fought and won or lost, and many judgments have been pronounced by the courts. The HIV epidemic has thrown up a myriad legal issues and the responses of the judiciary have been mixed.

The framework of public health legislation is too limited and cannot be transposed to adequately cover HIV issues. Given this fact, and in the absence of any law or statute that specifically addresses the issues that are raised in the context of HIV in India, both appellants and the judiciary have had to make their complaints, decisions and rulings by extrapolation from a variety of sources of law.

- *Constitutional law:* Where the law is based on principles contained in the Indian Constitution.
- *Common law:* Laws that are established by precedent or case law, or, in other words, by judgments previously made in similar cases.
- *Statutory law:* The written or codified laws of a country that are made by its legislature.
- *Personal law:* Laws that are a part of an individual's religious code.

Before discussing some of the key legal issues and cases in the HIV context, it is useful to understand the difference between law, human rights, ethics and policy. As stated above, law may come from various sources but is ultimately enforceable in a court of law. Human rights are the basic rights and freedoms that all human beings enjoy. These are enshrined in various international covenants and conventions to which India is a signatory. Human rights are also reflected in the fundamental rights chapter of the Indian Constitution, and the Supreme Court has held that provisions of an international convention or covenant, which elucidate and effectuate the fundamental rights guaranteed by the Indian Constitution, can be relied on by courts as facets of those fundamental rights and are hence enforceable as such.

Ethics refer to a set of principles and guidelines by which certain professions are guided. Often ethics are considered in the application of law — for instance in determining whether a doctor has been negligent in his or her care of a patient, the courts will consider medical ethics guidelines. In India, medical ethics are also represented in law such as the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002.

Policies and administrative orders of the government are statements of government intent and action; these are however not enforceable in a court of law. For instance, India's National AIDS Prevention and Control Policy (NAPCP) states in part that "…when human rights are protected, fewer people become infected and those living with HIV/AIDS and their families can better cope with HIV/AIDS. Government recognises that without the protection of human rights of people who are vulnerable and afflicted with HIV/AIDS, the response to the HIV/AIDS epidemic will remain incomplete". While the NAPCP supports an approach that ensures the protection of rights as a key element in successfully dealing with HIV/AIDS, its directives are unenforceable. So while the NAPCP states that there should

be no discrimination based on HIV status, a person living with HIV who loses his/her job cannot approach a court of law on the basis of this policy.

Legal issues that arise in the HIV context

Discrimination

Stigma and discrimination triggered by HIV and AIDS lead to the most significant human rights violations for persons living with HIV/AIDS (PLHAs) and are the greatest barriers to preventing further infection, providing adequate care, support and treatment and alleviating the impact of the epidemic. PLHAs today face segregation in schools and hospitals under cruel and degrading conditions, denial or loss of employment, denial of shelter in the matrimonial home, arbitrary testing, violence and even murder.

A landmark anti-discrimination case in the Bombay High Court that affirmed the rights of PLHAs in the workplace was MX vs ZY [AIR 1997 Bom 406] where MX, a casual labourer, was tested for HIV by his employer, ZY, a public sector corporation, prior to being regularised in a permanent position. MX tested positive for HIV, and though otherwise fit, was rejected from regularisation, and his contract terminated. The court ruled that:

- A government/public sector employer cannot deny employment or terminate the services of an HIV-positive employee solely because of his/her HIV-positive status, and any act of discrimination towards an employee on the basis of HIV-positive status is a violation of fundamental rights.

- An HIV-positive employee's services can only be terminated if a substantial risk of transmission is posed to co-employees or if she/he is unfit or unable to perform the essential functions of the job. Determining whether a person is unfit or incapable of performing the job depends on an individual inquiry (beyond a mere diagnostic test) into each specific case.

While the Constitution makes it clear that the public sector cannot discriminate on the basis of HIV, discrimination in and by the private sector is more difficult to address. While most countries have anti-discrimination legislation to cover discrimination in the private sector, this is not the case in India.

Consent

The principle of consent is based on the fundamental principle of the autonomy of an individual, and is recognised within the framework of the right to life and personal liberty in Article 21 of the Indian Constitution. Not obtaining informed and voluntary consent could result in a criminal charge of assault or battery or a civil claim for damages or trespass to a person.

In India, mandatory HIV testing policies were, as in the case of other countries, mooted at the beginning of the epidemic. The NAPCP recognises the counter-productive nature of mandatory testing and notes that the State "feels that there is no public health rationale for mandatory testing of a person for HIV/AIDS". In 1995, the National HIV Testing Policy was formulated to lay down protocols for testing to monitor the trend of HIV infection, to test blood or organs or tissues for ensuring safety to the recipient, to identify individuals with HIV infection for diagnosis and voluntary testing purposes and for research. Mandatory screening for HIV is recommended only for blood transfusion safety and for screening donors of semen, organs, or tissue to prevent transmission to the recipient of the biological products. In these circumstances, the tests cannot be linked to the identity of the individual.

However, the Indian private sector remains virtually uncontrolled while adopting discriminatory practices such as mandatory testing for employment and access to services, particularly healthcare. Mandatory testing is also being conducted by the armed forces.

Confidentiality

Although India does not have a specific law on confidentiality, the courts have construed Article 21 of the Constitution — the fundamental right to life and liberty — to include the right to privacy, from which is derived the right to confidentiality. This implies that every person has the right to a sphere of activity and personal information that is exclusive to them and that they have the right to disclose as they please. In legal terms, confidentiality exists within the parameters of a special relationship (doctor-patient, attorney-client, for instance) that is dependent on factors such as mutual trust, or to impart services.

The maintenance of confidentiality of an individual's health status is one of the cornerstones of a rights-based legal and public health response to HIV/AIDS. People avoid a healthcare system that violates their confidentiality and leads to their stigmatisation, which ultimately drives the epidemic underground, making attempts to control it ineffective. However, the principle of confidentiality is not absolute. Two divergent interests are balanced in legal approaches to this issue — the public interest of maintaining the confidentiality of an individual vis-a-vis the public interest in disclosure of the information.

In the Supreme Court case of Mr X vs Hospital Z [(1998) 8 SCC 296], the Supreme Court chose to pass a judgment that:

- An HIV-positive patient who may transmit the disease to his or her prospective spouse is not entitled to the maintenance of confidentiality, since the life of the spouse has to be saved. Therefore, a hospital can disclose a patient's HIV status to his/her prospective spouse (partner), and in fact, since acts that are likely to spread communicable diseases are a crime under the Indian Penal Code, the failure of the hospital to inform the spouse of the disease would make them participant criminals. The court also ruled that since being infected with a venereal disease (read HIV/AIDS) is grounds for divorce under Indian matrimonial law, a person suffering from such a disease has

no right to get married until he/she is cured.

In its judgment on the appeal, while the Supreme Court rescinded its earlier observations regarding marriage, and restored the right to marry for PLHAs, it upheld its previous decision about partner notification maintaining that this disclosure was permissible.

Access to treatment

Article 21 of the Indian Constitution recognises every individual's right to life and liberty, which the Supreme Court has held includes the right to health. It has also held that the maintenance and improvement of public health must rank high amongst the State's obligations, as these are indispensable to the very existence of the community. Additionally, the courts have ruled that providing adequate medical facilities for people is an essential part of the government's obligation. Article 47 of the Indian Constitution which is a Directive Principle of State Policy also directs the State to regard the improvement of public health as amongst its primary duties. Therefore, the Indian government has a duty to protect and preserve the health of its citizens, which in the context of HIV/AIDS addresses the crucial issue of providing universal access to treatment.

Criminalising injecting drug use

Criminalising drug users pushes them underground and exposes them to exploitation, harassment, abuse and arrest by the law enforcement machinery. 'Harm reduction' is the umbrella term used to explain interventions that aim to reduce the negative health consequences of a specific behaviour (for example, drug use) rather than eradicate the behaviour. The two most widely practised models of harm reduction in the context of drug use are needle syringe exchange programmes, or NSEPs (where clean needles are provided in exchange for used ones in order to reduce the risk of transmission of HIV and other bloodborne diseases) and drug substitution programmes (where drug users are weaned off illegal opiates by being put on a regimen of buprenorphine in a supervised and regulated setting). Both these interventions are controversial because they are seen as abetting the criminal offence of drug use — giving a drug user a clean needle, which is drug apparatus, assists him in the crime of injecting drugs. Studies show that these programmes are successful in controlling the spread of HIV without increasing drug use while also bringing down crime. Such programmes do exist in some parts of India, but despite the law, and are constantly in fear of being caught, harassed and even shut down. The absence of laws protecting such crucial interventions leaves them open to the caprice of law enforcement personnel in preventing or permitting them.

Criminalisation of sex work

The HIV epidemic has led to increased attention on sexual behaviour, particularly the behaviour of populations that have multiple sex partners. In this context, sex workers have come to be seen as a 'high-risk group', being susceptible to sexually transmissible infections and HIV. Concerns about the spread of HIV from high-risk groups into the bridge (clients) and general population (regular sexual partners of clients, including wives) led to the introduction of HIV prevention interventions among sex workers.

The Immoral Trafficking Prevention Act, 1986 (ITPA), the main statute dealing with sex work in India, does not criminalise prostitution or prostitutes *per se*, but mostly punishes acts by third parties facilitating prostitution, such as brothel-keeping, living off the earnings of sex workers, and procuring. There are exceptions however, and practising prostitution in the vicinity of public places and soliciting are two activities for which sex workers are penalised. The criminalisation of soliciting sex greatly diminishes the sex worker's ability to negotiate the terms of service, including income and condom use, and pushes sex workers underground or into ghettoised locations where they are difficult to reach and more vulnerable to abuse. Peer-based interventions have been hampered as women carrying condoms are apprehended by the local police on charges of 'promoting prostitution'. Ironically, the same sex workers who are engaged by one arm of the government to distribute condoms and carry out HIV prevention efforts among sex workers are criminalised by another arm for doing just that.

In 2003, Sahyog Mahila Mandal, a sex workers collective in Gujarat, challenged the provisions of ITPA on grounds that they violated the fundamental rights guaranteed under Articles 14 (equality before law), 19 (right to freedom of speech) and 21 (right to life and personal liberty — and thereby livelihood). The court's judgment in Sahyog Mahila Mandal & Another vs State of Gujarat & Ors [Special Civil Application No 15195 of 2003 with Special Civil Application No 4594 of 2003] was as follows:

- The court rejected the sex workers' contention that sex work ought to be recognised as a legitimate means of livelihood and that they should be permitted to carry on their work outside the notified area.

- The court further held that the restriction of personal liberty imposed by Section 7, ie the deprivation of liberty to carry on prostitution in public places, is in the interest of the general public and is in keeping with procedures established by law as well as the Convention for Suppression of Trafficking in Persons and of the Exploitation of Prostitution of Others to which India is a signatory.

- The court also said that ITPA was aimed at combating trafficking, and that rescuing and rehabilitating trafficked women was a part of its objective. Therefore, the special powers given to the police (search without a warrant) did not violate any fundamental rights.

The need for a law on HIV

HIV has revealed the inadequacies of both existing laws as well as of the health infrastructure in India in an unprecedented way. It has highlighted most particularly the

While the Constitution makes it clear that the public sector cannot discriminate on the basis of HIV, discrimination in and by the private sector is more difficult to address. While most countries have anti-discrimination legislation to cover discrimination in the private sector, this is not the case in India

tensions and conflicts between health, human rights, State power and wealth. In the healthcare setting, lack of adequate resources pits the rights of PLHA (to treatment) against the rights of doctors and healthcare workers (to universal precautions), making everybody vulnerable and exacerbating discrimination. Existing laws and policies reveal deeply-rooted biases and inherent contradictions which make it difficult for PLHAs and vulnerable people to access services. Prime examples are the criminalisation of sexual activity between men, soliciting for sex work, or injecting drug use, resulting, as discussed earlier, in the isolation of these communities and the negation of their rights.

Different countries have adopted different legal strategies to address HIV. In some countries, HIV has been included in existing anti-discrimination and health legislations to address the issues discussed above. Accordingly, discrimination on the basis of HIV is prohibited in the US under various laws. In some of these countries HIV-specific legislation may be found in the context of HIV testing or confidentiality. Some countries have enacted omnibus HIV legislations.

India has no existing anti-discrimination legislation which would cover discrimination on the grounds of HIV status. Nor is there sufficient existing health legislation in India to address all the issues discussed above. Specifically, a law on HIV is required for the following reasons:

- *The vagaries of common law:* Most legal issues that arise in the context of HIV/AIDS are governed by common law — where law is defined by principles set down in prior case law by judges. This allows for the personal predilections of judges to impact cases of HIV and AIDS, an approach that lends itself to inconsistency and to rulings that are sometimes in opposition to the existing, well-thought-out policy of the government.

- *Addressing discrimination:* The guarantee of equality in the Indian Constitution is available only against State entities and there is no restriction on discriminatory practices in the private sector, be it in healthcare, employment, or education. Most countries have enacted anti-discrimination laws applicable to the private sector to ensure a universally applicable legal system.

- *Insufficiency of policies:* As we have seen earlier, though the NAPCP mandates a rights-based approach, it does not have the status of law and is neither binding nor enforceable in court.

- *Law reform:* There are various interventions amongst marginalised populations in India that effectively check the spread of HIV, notably condom promotion and needle syringe exchange programmes. Existing legislation could nullify these initiatives and the interventions have to be legally protected to ensure that they continue providing services and information that empower persons to protect themselves and others from HIV/AIDS.

- *Fulfilling international obligations and commitments:* In 2001, the United Nations General Assembly adopted the Declaration of Commitment on HIV/AIDS. India as a signatory to this declaration is committed to general obligations such as the prohibition of discrimination, and also specific obligations such as ensuring that by 2005 at least 90% of young persons aged 15 to 24 have access to information, education, and services necessary to reduce their vulnerability to HIV. The Indian government is obligated therefore to enact legislation that will fulfil these and other obligations such as the International Covenant on Economic, Social and Cultural Rights, and the Convention on the Elimination of all forms of Discrimination Against Women.

For all these reasons we need a specific statute to address HIV/AIDS — its prevention, its treatment, and the manner in which we respond to the people most affected by it. A nationally applicable rights-based statute would serve several purposes: it would provide holistic coverage, consistency, clarity and predictability in order for courts to effectively pass judgment in HIV/AIDS cases; it would provide certainty for people to seek remedy from a strong, reliable legal system; and it would enshrine ethical, equitable and just practices that become harbingers of change in the many, many other contexts and spheres in which people are continuously disempowered. It will ultimately reflect the ideals and principles for a more inclusive and humane society.

The HIV/AIDS Bill 2007

A unique joint initiative of the government and civil society has led to the preparation of a comprehensive HIV/AIDS Bill that will soon be introduced in Parliament. The HIV/AIDS Bill 2007 is the culmination of a rigorous three-year research, drafting and consultative process that has involved

stakeholders from across the country and from every region. Regional-level consultations organised in coordination with the National AIDS Control Organisation (NACO) and State AIDS Control Societies (SACS) and their representatives, along with NGOs, were held in the north, south, east, west and northeast of the country. Groups and communities with specific perspectives on the epidemic like PLHAs, sex workers, men who have sex with men, injecting drug users, healthcare providers, workers, women, children and legal experts have discussed and debated the Bill at length. Ultimately, it is these discussions, debates and consultations that have shaped the Bill. Drafted by the Lawyers Collective HIV/AIDS Unit (LCHAU), the Bill embodies principles of human rights and seeks to establish a humane and egalitarian legal regime to support India's prevention, treatment, care and support efforts vis-a-vis the epidemic.

Highlights of the Bill

Prohibition of discrimination: The HIV/AIDS Bill specifically prohibits discrimination related to HIV/AIDS in both the public and private spheres. Under the Bill, no person may be discriminated against in employment, education, healthcare, travel, insurance, residence and property, etc, based on their HIV-related (be they infected or affected) status. It covers all acts and omissions that are discriminatory on the basis of HIV status, whether it is actual or perceived and whether the person discriminated against is HIV-positive, a relative, a friend, or is associated with HIV, as in the case of groups considered in the public imagination to be 'vectors' of the epidemic, such as sex workers, injecting drug users, truckers or migrants. (Collectively, in the Bill, these persons are referred to as 'protected persons'.) Further, since discrimination in healthcare settings is attributed largely to the lack of healthcare workers' right to a safe working environment, the Bill imposes an obligation on healthcare institutions to provide universal precautions and training to all healthcare workers. The Bill also addresses hate and discriminatory speech, making it punishable.

Informed consent for testing, treatment and research: The Bill requires specific, free and informed consent for HIV-related testing, treatment and research. HIV testing must be accompanied by pre- and post-test counselling. HIV treatment may commence only after an explanation of the risks, benefits and alternatives available, while HIV research may take place only after the research subject is informed of the aims, methods, sources of funding, possible conflicts of interest, institutional affiliations of the researcher, potential benefits and risks, possible discomfort, and the right to withdraw consent. The Bill statutorises existing standards of informed consent and exceptions to it while also increasing access to healthcare services for children and young persons. The Bill also requires special attention to be given to women and young persons and specific counselling regulations that would create an atmosphere conducive to individual decision-making. Consent for HIV testing under the Bill is not required when it is ordered by the courts, required for testing blood, organs, semen, etc, or for surveillance.

Disclosure of information: The Bill guarantees the confidentiality of HIV-related information (including the HIV status of a person) and outlines the exceptions under which disclosure can be made — 'partner notification' and the 'duty to prevent transmission'. The Bill specifies the exact protocol for, and circumstances in which, a healthcare provider can notify the partner of an HIV-positive person about their status. It recognises the particular vulnerability of women to violence in such situations and specifies that partner notification should not take place if there is an apprehension of violence. The Bill imposes a duty on all HIV-positive persons to prevent transmission through various measures like using safer sex practices or informing their partners. Here too the duty does not exist in the presence of violence.

Right to access treatment: The Bill provides for universal and free access to comprehensive HIV-related treatment, prevention, care and support. This includes services, information, voluntary testing and counselling services in every sub-district, medicines for opportunistic infections, post-exposure prophylaxis, antiretroviral therapy, nutritional supplements, prevention of mother to child transmission, diagnostics, etc. Many of these services are already part of the national HIV/AIDS programme, including the ARV roll-out plan of the Indian government. Under the Bill, access to treatment must be provided in a sustained, accessible and acceptable manner. The Bill also requires the National

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HIV/AIDS Authority to notify protocols for HIV-related treatment and testing.

Risk reduction: Strategies for risk reduction are actions that minimise a person's risk of exposure to HIV/AIDS and include programmes that promote safer sex, provide clean needles to drug users, or provide information to children. Typically, they are provided to communities and persons often subject to criminal sanction under various laws, like sex workers, injecting drug users, etc. The Bill specifically protects risk-reduction strategies from civil and criminal liability and law enforcement harassment. This does not mean, for instance, that injecting drug use is legalised; it simply means that providing clean needles to protect a person from HIV cannot be stopped on grounds that this promotes drug use.

Information, education and communication (IEC): Information is the key to any successful prevention programme. The Bill treats the government IEC programme as an essential component in the fight against HIV/AIDS. Communication messages should be positive and evidence-based, and should speak not just about prevention but also about care, support and rights. The Bill recognises the right of all persons to information and education relating to health and the protection of health from the State, and focuses particular attention on women and young persons and on the need to create IEC specific to their needs. The Bill obligates the State to institute IEC programmes that are evidence-based, age-appropriate, gender-sensitive, non-stigmatising, and non-discriminatory.

Implementation and grievance redressal: The HIV/AIDS Bill creates innovative grievance redressal and implementation mechanisms. The Bill provides for health ombudsmen to be appointed in every district to provide easy and quick access to health services for all persons should they be discriminated against or denied treatment. It also provides for internal complaints mechanisms in institutions. Grievance redressal provisions also include special procedures in courts like suppression of identity, speedy trial, etc. The emphasis is on quick trials and creative redressal. Thus, a case related to discrimination could see a court awarding damages and directing the person who discriminated to undergo sensitisation and training and community service. In terms of implementation, the Bill establishes HIV/AIDS authorities that will take over from NACO and SACS with an independent and accountable structure and expanded policy and programme base.

Special provisions: The Bill specifically recognises certain rights for women, children and persons in the care and custody of the State who, due to social, economic, legal and other factors, find themselves more vulnerable to HIV and are disproportionately affected by the epidemic. Prisoners and detainees are provided with specific access to risk-reduction strategies, counselling and healthcare services. The Bill attempts to recognise and address some underlying causes of the vulnerability of women to HIV and suggests the registration of marriage, provision of maintenance and the right of residence for HIV-positive women. The right of pregnant HIV-positive women to proper counselling and treatment options is specifically recognised. The Bill also recognises the link between sexual violence and HIV and provides for counselling and treatment of sexual assault survivors and directs the setting up of sexual assault crisis centres. Special provisions addressed at children and young persons include the right against discrimination in education and to access healthcare services and information in their own right. This is particularly important for street children and those living on their own. It also provides for protection of inheritance and property rights and recognises community-based alternatives to institutionalisation for vulnerable and affected children; provisions that were a direct result of feedback from the consultation with children's groups.

The HIV/AIDS Bill 2007 envisages a detailed and carefully planned strategy to address the HIV epidemic through an extensive prevention, care, treatment and support programme that entails widely disseminated and easily accessible IEC, an accountable and accessible government response, access to healthcare services and treatment, and the protection and promotion of the rights of persons living with or affected by HIV. One of the key visions of the Bill is to establish a government initiative on HIV/AIDS that is completely accountable and that is implemented at every stage with consultations.

It is worth reiterating that in the HIV context, only by protecting the rights of those most vulnerable can we hope to tackle the epidemic and thereby protect all. By providing for a right against discrimination, to informed consent, to confidentiality, and to access to treatment, we encourage people to come forward for testing with the understanding that there will be no adverse consequences to their HIV-positive status and if there are, the law will offer protection. By recognising the rights of women, we empower them to demand information and safer sexual practices from their partners. By premising the IEC programme on the right to information, we empower all persons to demand IEC in their languages, regions and to suit their specific needs. By protecting needle exchange, condom promotion and sexual health information programmes, we help those most marginalised in society by morality and law to protect themselves and others from HIV. By recognising the right of all citizens to question their government we make government bodies accountable, consultative and democratic, creating a strategy to tackle the HIV epidemic where every person is a stakeholder, every voice is included, and no one is left behind. We help the epidemic emerge from underground so that HIV/AIDS is no longer a synonym for fear, neglect, discrimination and violence but for empowerment, compassion, united action and triumph.

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Is premarital HIV testing feasible — or desirable?

Three states are considering legislation on compulsory HIV testing before registration of marriage. Such a law might end up increasing the social ostracisation of the HIV-positive, adversely affecting women, the very group the law sets out to protect

MANJIMA BHATTACHARJYA

IF YOU'RE GETTING MARRIED in Andhra Pradesh, Goa or Karnataka some time soon, don't be surprised if you're asked for your HIV test results at the registrar's office. These three states have proposed that HIV tests be made mandatory for couples before registration of marriage, opening up a Pandora's box of controversies around the limits of individual privacy, women's rights and how far the State can go in dictating or monitoring personal choices such as marriage.

Andhra Pradesh Chief Minister YS Rajasekhara Reddy defended the logic of initiating this legislation by stating at a public function: "It may be infringing (the) human rights of victims to go for compulsory testing. But the rights of the partner and rights of future generations must be defended. The human rights of innocent young women married off to HIV-positive men who hide their status should be given higher priority."

Such "compulsory testing" is contrary to National AIDS Control Organisation (NACO) policy which encourages voluntary testing as the most suitable public health policy for HIV.

A matter of public health

Public health expert Dr Ritu Priya from the Centre of Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi, says: "There are two aspects to this debate from the public health perspective. One, is it feasible? Are our public health systems up to it? Is it implementable at all? And second, does it have real value in terms of prevention? This is the real question mark, because such measures have not worked in the past."

Dr Jasmine Gogia, Director, HIV programme, of the international non-governmental organisation Project Concern International that runs programmes in communities in five states with the goal of improving the quality of life of people living with HIV/AIDS, asks: "Where are the infrastructure and resources for this? Test kits are not enough, there are not enough counsellors, a whole chain of service delivery systems needs to be put in place to implement such a law. We are not ready to cater to those who voluntarily want to test — in fact, tests are not easily accessible in many places; imagine what will happen if we have to cater to compulsory testing for the million marriages that happen in one state."

Dr Gogia feels that the proposed legislation itself is based on a flawed understanding of the behavioural aspects of HIV/AIDS. She says: "If legislation was an answer and could prevent the spread of the disease, we could have controlled it early on in the epidemic. Legislation has not brought about behavioural change in anything, let alone HIV/AIDS."

Ground realities

Meena Seshu, Director of SANGRAM, an HIV/AIDS prevention, treatment, and support organisation working with socially marginalised populations in Maharashtra, says: "Forget the human rights aspect of it. At a practical level, it doesn't work. This is what we keep arguing with women on the ground. Premarital testing is okay, but what happens post-marriage? The assumption is that after marriage people have only one sexual partner, which is not the truth. On the ground it sounds like a good idea. Young women first believe this is the best thing to do. Slowly, when you start bringing out these points, they realise that this is not so. That you can't control people by this method and you can't predict their behaviour. What is important is to

"There are two aspects to this debate from the public health perspective. One, is it feasible? Are our public health systems up to it? Is it implementable at all? And second, does it have real value in terms of prevention? This is the real question mark, because such measures have not worked in the past"

educate people about safe sex, and empower women and encourage them to prevent themselves from getting infected."

Asha Ramaiah, National Women's Coordinator of the 15,000 member-strong Indian Network of Positive People (INP+), seconds this: "What we need is counselling and information centres. Counselling can be made compulsory and information given to the couple. If they opt for testing, then it is fine. But instead of increasing awareness, the government is scrapping most sexual health and HIV programmes in schools, saying that it is vulgarity and will lead to young people indulging in these immoral activities."

P Kousalya, Director of the Chennai-based Positive Women's Network, admits that "women are hearing and saying 'good', but actually it is not good". Coming from Kousalya, this is worth listening to. Kousalya was 19 when she was infected by her newly-wed husband, who knew he was HIV-positive when he married her. Despite having been cheated by him and his family — her husband's father was also aware of this — Kousalya feels that even if such a law had already been in place, it would not have helped the situation. "I didn't have the capacity to ask," she says. "I did not even know anything about it."

Inherent flaws

The Lawyers Collective HIV/AIDS Unit, which drafted the HIV/AIDS Bill to be tabled in Parliament this year, sent letters to the chief ministers of the three states proposing mandatory premarital testing. The organisation opposes such legislation and has initiated a series of public debates on the proposal. It has also pointed out that technically such a proposal is based on a misunderstanding of HIV and AIDS. The 'window period' between the time HIV is contracted and the time it begins to show up in a test is around three months, and any test conducted within this period will show negative results even if the person tested is HIV-positive.

Other flaws are that such laws can easily be bypassed — whether by marrying in other states which do not have such legislation, or by generating false certificates in the black market or by simply not registering marriage with the State at all, which is a common practice across the country. There is also the possibility of results known as 'false positives' and 'false negatives' which run the risk of stigmatising for life persons with invalid results.

It is this aspect of HIV — the stigma and social ostracisation — that makes flirting with this law akin to playing with fire, and magnifies the possible negative impact on women, the very group the law sets out to protect. Like various other legislations that aim to 'protect' women (such as the law that proposed women should not be working night shift, ostensibly for their own safety), this too is a double-edged sword.

"Here, more people obey culture than law," says Asha Ramaiah. "If a girl is found positive through compulsory testing, the stigma is very high, much higher than if a man is found positive. We don't know how her family will react, or the community. If she has sisters, they will not get married, the whole family is stigmatised. There is not enough education or awareness about HIV for people to support anyone testing positive."

Activists are also not confident that the call for legislation will be sympathetic to individuals who test positive, providing them confidentiality and encouraging them to begin treatment immediately. The legislation appears to be more focused on the uninfected potential spouse who has to be 'saved'. The outcome of this would be the identification and isolation of persons testing positive, adding to the AIDS stigma and paranoia.

Also of concern and reminiscent of debates around eugenics is what the government will do with the information of those tested. In the wrong hands, this information could be grossly misused. States trying to engineer their populations and cleanse HIV through coercive measures are latent possibilities. Where does this sort of testing end? Kousalya asks: "Then why only HIV? Tests should be there for everything, all diseases, the ability to reproduce and so on. So many women are targeted as being infertile if they cannot bear children, when it is the man who is in fact to blame."

Seshu's biggest concern, however, is that "a law like this lulls women into a false sense of security, which actually harms them in the long run. People stop practising safe behaviour."

A real dilemma

While most AIDS health workers are toeing the NACO line, women's groups admit that there is a dilemma. It is a gendered phenomenon, and there are certainly examples of men hiding their HIV status and marrying women so that there will be someone to cook, clean and care for them — work that is considered 'women's work'.

A report from the Planning Commission in preparation for the Eleventh Plan notes that there is a growing feminisation of the HIV/AIDS epidemic. NACO estimates that one in three persons living with HIV in India is a woman, and that nearly 60% of HIV-positive widows are less than 30 years of age and live with their natal families as 91% of them receive no financial support from their marital homes.

Moreover, both AIDS activists and women's groups accede that young women in the arranged marriage set-up, especially in rural areas, are hardly empowered or informed enough to ensure the use of condoms in their newly-married lives. So wouldn't the law help women make this demand of their prospective spouses?

But Kousalya points out the impracticality of such a clause in the law: "Even though it may be the law, how many can actually demand this from their would-be husbands? We have lots of laws — against dowry, child marriage, under-18 marriage — but how many people are using the law? In an

arranged marriage the family decides everything, not young people, and definitely not the young woman." Instead, Kousalya suggests that the pattern be changed. "First, make marriage registration compulsory. Then counselling must be undertaken, after which testing should be done if both parties agree."

Seeking alternatives

Dr Ritu Priya feels there are other ways to address the central problem. She says: "From the woman's angle one can't say no to (the law) so easily because there *is* a problem. But to address that, one can take up an individual case and interpret it as a criminal act. It is possible under present criminal law to prosecute men who marry and infect their partners knowingly without informing them. If a few cases like that are dealt with by law, it may be a deterrent." This does not take away from the fact that a woman, or any prospective spouse, has the right to ask her partner for an HIV test. Sandhya Gokhale of the Forum Against Oppression of Women (FAOW), a feminist group in Mumbai, feels that although a law is unwarranted and gives too many powers to the State, some measures should be taken to enable women to exercise their right to know the HIV status of a prospective spouse. She says: "It is true that women are particularly vulnerable and there are cases of such cheating. The question is, how do women take control of the situation."

FAOW's alternative suggestion is that a disclosure agreement be part of the marriage registration form and rules itself. A question along the lines of: 'Have you revealed your HIV status to your prospective spouse?' must be compulsorily answered in the form. "The marriage registrar does not need to know, but the person should have communicated his/her HIV status with the to-be spouse. Nobody needs to lose their privacy vis-a-vis other members of society or the State, but husband and wife must tell each other." Elaborates Gokhale: "We all know that none of this is foolproof, and rules can be circumvented in various ways. But the idea is to make women aware through this question that it is something they should think about and demand from their spouse."

Women's vulnerabilities

Clearly, one cannot discount the issues that the proposed legislation brings up. Women's vulnerabilities must be kept in mind when reviewing alternatives for such legislation, and long-term measures sought rather than knee-jerk, quick-fix solutions which only provide a false sense of security to both individuals and the State.

Many will remember the 1985 Oscar-winning film *Out Of Africa* in which actor Meryl Streep plays out the true story of Danish baroness Karen Blixen who contracts syphilis from her philandering husband at the end of her first year of marriage. Even though, after World War II, a syphilis outbreak led to compulsory premarital blood testing in many countries and safeguards existed on paper, as women like Karen Blixen realised, there were no guarantees in real life.

Provider-initiated HIV testing

Does shifting from client-initiated to provider-initiated testing for HIV make sense in India?

AJITHKUMAR K

RECENTLY, THE WORLD HEALTH ORGANISATION (WHO) and UNAIDS released a document, *Guidelines on Provider-Initiated HIV Testing and Counselling in Health Facilities.* This document has provoked strong reactions on the feasibility and acceptability of shifting from client-initiated to provider-initiated testing.

When stigma and discrimination against HIV were the norm and no treatment was available, the knowledge that a person was HIV-positive meant ostracism, denial of healthcare, education and job opportunities, and even death. For this reason it has been internationally accepted that people should be tested for HIV only with their informed consent. They must be made aware of the consequences of the test. The request for the test should come from them, not from the provider.

However, this principle has not been practised uniformly. Client-initiated testing has not been the norm in many communities. Many healthcare professionals subject their clients to all the tests and procedures that they consider necessary, without their consent. One reason is that they fear the disease being transmitted from patient to provider, apparently unaware that standard infection control procedures prevent such infection. It is also a fact that healthcare institutions do not make provision for uniform infection control precautions against all infections. Nor are providers assured post-exposure prophylaxis following needlestick injuries. The problem is compounded by the shortage of voluntary counselling and testing facilities, inadequate training and sensitisation of healthcare workers and the inertia of the system to adapt to emerging challenges.

Client-initiated testing strategies too are not completely free of problems. Surveys in 12 high-burden countries in sub-Saharan Africa showed that a median of only 12% of men and 10% of women in the general population had been tested for HIV and received the results. This indicates that client-initiated testing programmes have failed in detecting the vast majority of infected individuals, effectively denying them prevention and treatment services.

Global commitment and resources to combat the HIV pandemic have increased markedly in recent years. Thanks to the efforts of various international agencies, there has been a rapid scale-up of care and support mechanisms in the developing world in the last few years. With the advent of

effective treatment which can suppress the virus effectively and give the infected person a prolonged and quality life, AIDS has become a chronic manageable disease, especially in affluent countries. It is therefore argued that we need to detect as many individuals as possible and early in the infection in order to treat them effectively.

What is provider-initiated testing?

This shift makes the healthcare provider responsible for initiating testing. The new guidelines suggest different approaches for scaling up and detecting HIV testing according to the local context:

- Regardless of the type of epidemic in that community, the healthcare provider should recommend HIV testing to patients who show features suggestive of HIV infection, children of HIV-infected mothers, children with suboptimal growth, and men seeking circumcision.
- In a generalised epidemic (if resources are available), healthcare providers should suggest HIV testing to all clients who seek care, regardless of whether the patient shows signs and symptoms of underlying HIV infection, and regardless of the patient's reason for approaching the health facility.
- In concentrated and low-level epidemics, healthcare providers should recommend testing for all clients with signs and symptoms suggestive of underlying HIV infection, including tuberculosis, and to children known to have been exposed perinatally to HIV.
- Such recommendations should be made with proper and detailed pre- and post-test counselling, with special components for special groups like adolescents and children. The test may be repeated every 6-12 months in high-risk groups.

The WHO guidelines state that the proposed changes are due to the success of patient-initiated testing in various countries in making use of this opportunity for systematic testing and care. This guideline also discusses the details of testing strategies, techniques and programmatic details and plans to scale up testing.

What does this change mean?

Many apprehensions have been raised about this shift in strategy:

We are able to provide standard testing to a limited number of people and are still expanding and standardising our voluntary counselling and testing centres. Do we have the facilities to test each of the millions of patients who attend healthcare facilities?

Do our resources allow us to test millions of people when the majority of these tests are going to be negative? Is it right to spend resources to test all inpatients when there are no basic facilities especially where the prevalence of the disease is not very high, as it is in sub-Saharan Africa.

The new guidelines are proposed in the context of a healthcare system in which universal testing (without consent) rather than universal precautions, is the norm. People who test positive, especially in private hospitals, face discrimination. We are yet to introduce comprehensive legislation on HIV and the mechanisms to implement existing guidelines effectively. The proposal for provider-initiated testing is already misinterpreted by many as a mandate for mandatory testing even though it clearly does not recommend mandatory testing.

It is estimated that the majority of the estimated 2.5 million people with HIV in India are unaware of their infection. We still need to make drugs available for all those who have tested positive and need treatment. If we increase the number of testing facilities without increasing access to treatment and mainstreaming care, what are we going to do for newly detected HIV-positive people? Should we not scale up care and support facilities before this shift in strategy?

In our overcrowded healthcare facilities, doctors get barely a few minutes per patient, too little even for basic care. Can we expect them to provide pre- and post-test counselling even if we train them?

There is an unequal power equation between caregivers and the ill. Patients' rights are not respected in the same way as they are in the West. How do we ensure that those who opt out of testing are not discriminated against, especially where HIV care facilities are not available?

If provider-initiated testing is started without adequate preparation and sensitisation of care providers it can inhibit groups with high-risk behaviour from approaching care facilities.

The HIV epidemic is an opportunity for us to recognise many things that we did not acknowledge before. This includes the right of patients to be part of decision-making regarding their own health, to fight for their own wellbeing, to be involved in policy decisions about their own health. This epidemic is unlikely to have a vaccine in the near future. HIV has actually brought patients' rights to the fore. We are learning how to balance the community's interest and individuals' rights in the fight against this modern-day scourge. If we shift to provider-initiated testing without preparation, we may lose the opportunity to go forward and generalise the lessons we have learnt from HIV.

Of course, we must experiment in scaling up HIV testing, treatment and care. But we should be careful in each step forward. We do need to scale up testing and treatment facilities. We need to detect as many individuals as possible. It is imperative to have a national discussion on this issue and fine-tune the guidelines as suggested by the WHO and UNAIDS document itself before we start advocating them for the entire country.

Dr Ajithkumar K is a dermatologist with a special interest in HIV/AIDS-related problems, particularly mainstreaming care and support

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Vaccine development: Still a shot in the dark

There are more than 20 trials of HIV vaccine candidates across the world. But the most promising one has failed. We are far from achieving the goal of an HIV vaccine, says Dr Shahid Jameel of the International Centre for Genetic Engineering and Biotechnology

SANDHYA SRINIVASAN

Shahid Jameel is Group Leader of the Virology Group at the International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi, India. He has served in this position since 1988.

Dr Jameel's research focuses on viral biology and virus-host interaction. He uses the hepatitis E virus (HEV), human immunodeficiency virus (HIV) and the SARS virus as models to study how viral proteins modulate signalling and cell fate in the host. His interests also lie in understanding human immune responses to HEV and HIV, vaccine design and high throughput platforms for virus detection.

He received his BSc (1977) and MSc (1979) in chemistry from Aligarh Muslim University and the Indian Institute of Technology, Kanpur, respectively and his PhD (1984) in biochemistry from Washington State University. He carried out his postdoctoral work in molecular virology at the University of Colorado Medical School and has been a Visiting Fellow at the National Institute for Infectious Diseases, Tokyo, and Emory Vaccine Center, Atlanta. Dr Jameel has received the Rockefeller Foundation Biotechnology Career Development Award (1990), the Shanti Swarup Bhatnagar Award in Medical Sciences (2000) and the Wellcome Trust International Senior Research Fellowship (2001).

What are the issues in vaccine development, and what are the challenges?

To my mind there are two big challenges — two big scientific challenges, because a vaccine is not just about the science of developing it but also the process of its manufacture.

The central scientific issue is that the virus mutates rapidly. So, do you make vaccines for specific regions and strains or those that are broadly applicable? This has plagued people since the very beginning.

To give you a sense of how much variation there is in HIV, consider the variation in influenza, for which a new vaccine needs to be developed every year to cover the flu outbreak for that year. The genetic variation in influenza is only 5-10% of what you see in HIV. So HIV genetic variation is huge. And what makes it further complicated, unlike viruses like influenza that cause an outbreak and go away, is that HIV causes a very persistent infection. It remains with the host, continually evolving with the host, so that change is constantly happening. The first scientific challenge is how to address this variation.

So far, since all the money in basic biology as well as in vaccine research is coming from western sources, they are obviously focusing on HIV strains that are dominant in the western world. Now if you look at the major group of HIV viruses, they can be divided into 10-11 sub-types. Sub-type C accounts for about 50% of global HIV infection whereas most of the effort in vaccine development research is in the sub-type B virus which is the dominant virus in the western world: the US and Western Europe. Africa is a melting pot of all kinds of strains. In India, 80% of infection is due to sub-type C. So far, a majority of the vaccine candidates that have advanced in the pipeline are basically sub-type B. How they will perform against sub-type C or other isolates, no one really knows.

Traditional scientific thinking would say that since there is quite a bit of variation between these two groups of viruses, a sub-type B vaccine is most likely not going to work against sub-type C infection. But the point that most people are after is: At least let us set a proof of concept — what will work and what will not work — and once we have discovered what works, it can be engineered for sub-type C or other sub-types.

The two vaccine candidates being tested in India, at the National AIDS Research Institute, Pune, and the Tuberculosis Research Centre, Chennai, are both against sub-type C viruses.

What is the other scientific challenge to vaccine development?

The other critical issue is: What are the correlates of immune protection? We really do not have a very clear idea.

What do you mean by "correlates of immune protection"?

What will protect? Is it antibodies alone, or do you only need to destroy virus-producing cells, or is it a combination of both? We do not have markers to predict whether, if an HIV vaccine candidate works in an animal model (monkeys),

it will also work in humans.

When a pathogen infects our system, the host comes up with two kinds of immune responses. The first is based on the production of antibodies. Antibodies will neutralise viruses that are extracellular, that are present outside cells, because antibodies cannot enter cells. Once the HIV virus infects a cell, the virus' genetic material integrates with the cellular genetic material and the cell becomes a factory for producing more viruses. So in addition to having antibodies to neutralise the virus, one must also have a mechanism to destroy cells that are already infected with HIV.

HIV is characterised by a drop in our CD4 cells, the very cells of the immune system that are critical for developing an effective immune response. CD4 cells are also those cells that are infected by HIV. Traditionally, one would think that once viruses infect cells, these cells die. But in HIV infection, the cells that are infected by the virus are actually preserved. It is the uninfected cells that are killed, by things that the virus produces. In an HIV-infected person only about one in 10,000 blood cells is actually infected by the virus. The numbers of cells that die during a viral infection are far greater. This is something that we call the 'bystander effect'. That is the whole strategy of this virus, that it preserves infected cells and kills uninfected cells.

So how do we identify infected cells? And how do we selectively kill infected cells? That is a critical issue. The host immune system has ways of dealing with this problem, but the virus seems to be one step ahead and it has already evolved mechanisms to evade all those steps.

Many of the vaccine candidates being developed perform very well in animal models. The closest animal model we have is the monkey model. But the monkey immune system does not respond in exactly the same way as our immune system does.

So those are the two core scientific challenges: how to address the genetic variation and continuous mutation in the virus, and what sorts of vaccines should be made to raise the right immune responses.

What are the vaccines being developed?

People are testing two types of vaccine candidates. One type is designed to raise antibody responses. Typically these are protein-based vaccines where you produce a recombinant protein that mimics what the immune system sees in the virus, and raises an antibody response. When a virus infection happens, the immune system sees certain viral surfaces. A vaccine candidate tries to mimic those viral surfaces with recombinant viral proteins.

The other type of vaccine candidate uses a virus vector. This strategy raises specific killer cells in the host that will target virus-infected cells. The adenovirus vectors, MVA, all these viral vectored vaccines raise a response in the host to destroy infected cells. Maybe a successful HIV vaccine has to be a mixture of both, but what sort, how much of each…

People are also trying a prime boost strategy: you prime the immune system by directly injecting naked DNA that can express one or more HIV proteins, and you boost with either one or more recombinant proteins or with a virus vector vaccine to get different responses. Modified Vaccinia Ankara (MVA) is usually used in this prime boost strategy: prime with DNA and boost with MVA. In this case, both naked DNA and MVA carry the same HIV genes.

In India, the Pune vaccine candidate uses an adeno-associated virus (AAV) as a vector. That vaccine candidate, produced by Targeted Genetics, a US-based company, is the one that IAVI tested first in India. IAVI was also testing the AAV vaccine candidate in Germany and Belgium. So far, the results have indicated "a modest immune response".

The other vaccine candidate they are currently trying at the Tuberculosis Research Centre, Chennai, was originally made by Shekhar Chakravarty at the National Institute of Cholera and Enteric Diseases, Kolkata. Shekhar made the original construct and then collaborated with Therion (a biotechnology company) which had prior experience in MVA technology. There were lots of ups and downs trying to stabilise this construct, and finally the stabilised multi-gene MVA was tried on people in Chennai.

The first large HIV vaccine trial that took place, the Vaxgen trial, essentially used the surface protein of HIV, produced in a recombinant manner. It raised really nice antibodies. The problem was that those antibodies never protected. The vaccine was first tried in animals that had been infected with HIV, and it worked. Their mistake was that during animal testing they used lab-adapted strains of the virus to test the vaccine. These strains were neutralised very nicely, but the field isolates were not neutralised. When the Phase 3 trial happened, there was no difference in effect between placebo and vaccine.

But I still wouldn't call it a failed trial. From the Vaxgen trial we did learn how to do HIV vaccine trials. We developed the in-vitro assays needed to see whether the antibodies are actually neutralising the virus. We arrived at the numbers required to get statistically significant answers.

What are the steps in HIV vaccine trials?

Vaccine trials in a human population are generally conducted in three phases. The first phase is a safety trial. You make sure the product is safe to administer to humans. Sometimes people also want to see whether the vaccine raises certain kinds of immune responses. So while normally Phase 1 is for safety, it can also include immunogenicity. Phase 1 is done on very small numbers, 30 individuals would be taken for a Phase 1. If a vaccine is proven safe, then it goes into Phase 2 which is really addressing the issue of immunogenicity and dosage — how much and how frequently. So typically a Phase 2 is divided into different arms, where you test different dosages and combinations to work out what would be the best amount to use and the best schedule.

Once you have done that and come up with an optimal schedule and an optimal dose, you go to the large Phase 3 trial which is an efficacy trial. A Phase 3 trial essentially tells you whether this vaccine will work in the field or not. Now, in animals you can actually inject the virus and see whether the vaccine works. In humans you can't do that. So in humans you have to depend on natural infection. Typically, Phase 3 trials are done in populations where the natural rate of infection is high. Phase 3 trials for an HIV vaccine will be done on sex workers, in men having sex with men. I don't think they have done any trials in haemophiliacs. There are plans to do them on injecting drug users. You have a group that gets the vaccine and a control group that gets a placebo. And at the end of the trial, which typically lasts anywhere from three to five years depending on the numbers you want — typically you are looking at large numbers, huge expenses, many ethical issues — you come up with an answer to the question: did the vaccine population get fewer infections than the control population?

Vaxgen went all the way to Phase 3; they failed in Phase 3.

There is also this new concept of Phase 2b, between 2 and 3, which does limited efficacy testing with fewer numbers. After Phase 2 gives you information on dose and scheduling, you increase numbers and test efficacy in a smaller population to give you a quick answer.

You may have read recently that Merck has stopped trials of its HIV vaccine. The Merck vaccine was farthest in the pipeline right now in the human population. Then in late-August 2007 it announced that it had stopped its Phase 2b trial because the vaccine was not working. The Merck vaccine was based on an adenovirus, the common cold virus, modified to carry HIV genes. The idea was that if you infected people with this modified virus it would also raise an immune response against HIV. That vaccine had done very well in animal trials and it looked safe in human trials, so that was far into the pipeline. Merck had recruited 3,000 volunteers, and midway, when they looked at the two populations, they found 24 infections out of 1,500 in the vaccine arm, and there were 21 out of 1,500 in the placebo arm, so there was no statistical difference. Their vaccine was not protecting. So they did the right thing and stopped the trial then and there.

Right now the situation is that your best vaccine candidate has failed.

How long ago did research start in vaccines?

HIV vaccine research started immediately after HIV was discovered as the virus that causes AIDS, around 1984. They developed the blood test very quickly. Remember that the mid-1980s was when a very successful hepatitis B vaccine was made and licensed. They used a very simple trick: they expressed a recombinant protein that makes up the surface of hepatitis B, produced this protein in yeast, purified it, put it into people, and they were protected. SmithKline Beecham and Merck did it simultaneously. That was the mid-1980s, when HIV was discovered. It also had a surface protein on it and they said, well that is simple.

If you go back and read some of the interviews of the time, the US secretary of health announced that a new virus had been identified for what they called the 'gay disease' at the time. She said, now that the virus has been identified we are going to get a vaccine in the next two years. We are talking 1984. That euphoria was based on the hepatitis B vaccine where a simple trick had worked and people thought an HIV vaccine too would be a piece of cake. That was not to be.

In light of that if you want to know when we will have a vaccine, I don't think anyone will hazard a guess. Your best vaccine has just failed and there are many other candidates in the pipeline that work on principles that are similar to the failed Merck vaccine. So where does that place us?

Where is the vaccine effort today?

For at least 20 years we have been hearing that an AIDS vaccine will be developed in the next 10 years. The point is that some of the best candidates have failed. Even IAVI has gone back in its thinking. Earlier, it focused on vaccines to raise responses to kill infected cells. It is now shifting research to vaccine candidates that raise neutralising antibody responses.

Antibodies will only kill viruses that are outside cells. HIV spends most of its life inside the cell. So you also have to destroy the infected cell. The adenovirus vectors, MVA, all these vaccines raise a response in the host to kill infected cells. Soluble proteins tend to raise antibody responses. Maybe it has to be a mixture of both, but what sort, how much of each…

Where are we today? Even with the best vaccine we are now up to maybe a Phase 2 trial. There are maybe 20 vaccines in Phase 1 and 2 right now, using various vectors. The candidate farthest down the pipeline failed at Phase 2b. So I guess one important thing is to learn from why the Merck vaccine failed. They are still analysing the data. It will be a year or two before they get some kind of answer. People have various theories but nothing is proven. It's only a month-and-a-half. One theory is that the adenovirus backbone used to make the Merck vaccine is based on adenovirus serotype five, which is very common in humans, 70-80% of humans have already been exposed to it. So when you give a vaccine based on this backbone, the host will raise a quick response to neutralise the virus. So the search is on for an adenovirus with a very low seroprevalence so it won't be recognised. But Merck had divided the study population into two: those with low titres against serotype five, and those with high titres. The vaccine failed in the low titre group.

There are other products already in the pipeline and we have no option but to test them. All of these have worked on animals. Even the Merck vaccine worked fantastically in

animals but failed in humans. Working in animals is not (a sufficient) measure. We don't have a surrogate marker for vaccine efficacy. The nature of the beast is such that you don't know if it will work until you test it. So to say that because the Merck vaccine failed we should stop testing would be wrong. You have to test. It is a gamble, a shot in the dark.

There are also the manufacturing challenges. Let's say tomorrow we have a situation where a DNA prime vaccine with an MVA boost strategy works. I saw an estimate that if, in 2007, it is shown that DNA plus MVA works, then your total global requirement of DNA in 2017 (10 years after the vaccine is shown to work) would be 600 kg. To put things in perspective, as of today, the entire world has produced 1 kg of DNA of that quality, safely injectable in humans. To reach the capacity you need in 2017 you need to plan 15 years ahead of time, or you won't have plants, regulatory requirements to make that product. In terms of that planning we have already missed the bus.

And obviously we can't plan unless we know what works and what doesn't. Even if we get something that works, it will take another 15 years to manufacture it and bring it to the market.

Is it really possible at all? Why are we looking for a preventive vaccine rather than a therapeutic vaccine?

A lot of people are realising that research in preventive vaccines can be used to look at therapeutic vaccine potential. Yes, absolutely, therapeutic vaccines should be tried. They are easier than preventive vaccine trials. You are going to try it on people who are already infected with HIV and you don't have to wait as long to see whether they work.

But there are problems even in therapeutic trials. Ethically you cannot give just the vaccine; you also have to give antiretroviral therapy. So you have to compare ART vs ART plus the vaccine. And ART in its initial phases shows a dramatic reduction in virus titres, an improvement in quality of life, etc. So even a therapeutic vaccine trial must go on for a fairly long time to address the question of whether the vaccine is actually providing an added benefit.

Why not just concentrate on drugs?

Drugs have improved the quality of life for people living with AIDS. But they will always be expensive. Second, the virus will always mutate, and drugs will never clear the virus, only suppress it. The nature of the virus is such that it cannot be eliminated with drugs. So, drugs are a tool, but to control HIV, to prevent its spread in the population, we have to introduce a preventive or therapeutic vaccine. A therapeutic vaccine would ideally reduce the concentration of virus and virus-infected cells in the body fluids. Transmission is based on numbers: the higher your titres the more frequently you transmit. Nevirapine reduces the chances of perinatal transmission because it reduces the viral titres in the infected mother.

What are the collaborations you see today?

There are 20 vaccine candidates, most for sub-type B, some for sub-type C. Some are in Phase 2. There are no longer any in Phase 3. They are being developed by various academic groups and companies. Merck was the single large company into HIV vaccine development. I don't know if Merck will continue in it or not. Large pharma is generally not interested in the HIV vaccine, in vaccines in general.

Is HIV vaccine research a priority for India?

I don't see a single serious group in India trying to develop an HIV vaccine. The vaccine candidate tested in Pune was not developed here at all. With the MVA vaccine, the original constructs were developed here by Shekhar but the larger scientific community was never involved. So as of today if you ask me whether there is a serious effort to develop an HIV vaccine in the country I would say no.

Are you asking me is it a priority, or should it be a priority? Well, should it be a priority, I would say yes, why not, if you have the funds. Because you may never develop a vaccine but you will learn so much as you go along. I may be biased; I also work on HIV.

I have often heard the argument that more children die of malnutrition and diarrhoea than HIV. My answer is I'm not saying *don't* reform your public distribution system. Reform it. Children die of diarrhoea because we don't get them oral rehydration solution in time. But HIV will not go away with something like ORS.

Having said that, I don't see any serious effort in India towards an HIV vaccine. You are trying something but money is not going towards basic research. I don't fault government agencies. The fault lies with the biomedical scientific community not coming together to think about novel ways of doing things.

We have to look at the systems too. The department of biotechnology put about Rs 5 crore into the vaccine effort at the All India Institute of Medical Sciences over the last 10 years. Then the person in charge of the programme, Pradeep Seth, retired, and the whole effort died. We knew he was going to retire. Why didn't the funding agency ensure that succession was in place? A body of work had been put together. We have systems problems that we need to address as well.

What are the challenges in conducting clinical trials?

India recently completed its first clinical trial for an HIV candidate, a Phase 1 safety trial at the National AIDS Research Institute, Pune. A second Phase 1 trial is ongoing at the Tuberculosis Research Centre (TRC), Chennai. Sanjay Mehendale, Deputy Director of the National AIDS Research Institute (NARI), discusses the logistical and ethical issues involved in running a trial for an HIV vaccine

SANDHYA SRINIVASAN

Sanjay Mehendale is Deputy Director and Head of the division of epidemiology and biostatistics at the National AIDS Research Institute, Pune. He was involved in conducting India's first Phase 1 trial of an HIV vaccine candidate.

What are the challenges in conducting an HIV vaccine trial?

To do any clinical trial we need a strong foundation of four pillars: clinic facilities, a laboratory infrastructure with world-class laboratories, data management, and community linkages to identify populations and recruit participants. This is necessary for every study site.

Clinic facilities are where you interact with participants for information exchange, counselling sessions, physical exams, where the vaccine candidate can be injected. There are two kinds of laboratory facilities for trials. One is small and near the clinic, to collect samples for processing in order to establish the eligibility of participants — pathology, haematology — to confirm that they are healthy and able to participate. The other kind of laboratory facility is more sophisticated. For example, if we want to find out if a vaccine candidate produces an immune response we will have to do cytotoxic T lymphocyte assays which are markers of cell-mediated immunity. This needs sophisticated equipment that has to pass certification in, for example, proficiency in testing sera which are known positive, known negative, and so on.

Then you require data management. All world-class trials have sophisticated data management facilities to record data of ongoing trials, generate interim reports on study outcomes and, if necessary, track all past records for 10-15 years after completion of the trial depending on the requirements of good clinical practice guidelines.

Finally, you need the right population for the right study. For this, you have to look at what you want to achieve.

In Phase 1 trials we need healthy volunteers and you will not get them from the hospitals so you have to go to the community. For Phase 2 trials you can have both high- and low-risk populations.

In Phase 3 trials the route of administration is fixed, the dose is fixed, and you want to see if the vaccine works. For this you need people at risk of infection. So you need to go to high-risk populations. This is where we may not be successful in getting people from the community. It might be a good idea to work in clinics for STD treatment or other health problems. The presumption is that if they are high-risk they are more likely to come to clinics for treatment. Or you go to voluntary counselling and testing centres because people who come here perceive themselves to be high-risk. Or you might work with non-governmental organisations dealing with people with high-risk behaviour — injecting drug users, commercial sex workers, men who have sex with men — to look for people who are not clinically sick but at high risk.

The challenge is in developing multiple and large sites in different parts of the country where we can do such studies, to accrue the samples that we need.

What is the sample size?

For Phase 1 trials we need 30-50 participants but the number can go up to 100. Phase 2 trials generally have between 100 and 500. Phase 3 trials are large and the sample size is in the thousands — 3,000, 5,000, 14,000. An ongoing HIV vaccine trial in Thailand has enrolled something like 16,000 people.

The sample size is determined by what you want to achieve. In a Phase 3 trial you want to find out the ability of the vaccine to prevent infection. So if the incidence — the rate of new infections — is low, you may need a huge sample.

Understand the difference between prevalence and incidence. Prevalence is the percentage of existing infections at any given time. Incidence is the rate of new infections over a specified period. When prevalence in a population is low — for example in India today, we are looking at a prevalence in the general population of much lower than 1% — then the incidence in the general population will be very, very low. Then, doing a Phase 3 in the general population will be practically very difficult because you will need a huge sample size.

I will give you two scenarios in India. If you have to choose between female sex workers and pregnant women attending a hospital, which of the two groups will give you more HIV-infected women by screening the smallest number

of women? Naturally female sex workers, because they have high-risk behaviour and more are likely to be positive. If you screen 100 you will be able to pick up 30-40.

I want to clarify, the reason you need a huge (or particular) sample size in a Phase 3 vaccine trial is that you need to have a certain number of people exposed to risk and a minimum number of people who get infected in order to establish whether that vaccine is actually working or not. One group will end up with a higher number of positives, the other group will have a lower number of positives.

So you have to have that number for comparison. Essentially that's why studies are done in high-risk populations. You can capture a greater number of people and observe the difference in the number of people who get infected by HIV, thereby indicating the efficacy of the candidate vaccine.

As part of vaccine trial protocol, investigators like us are expected to do extensive counselling on trial participants to ensure that risk behaviour is minimised during their participation in the vaccine trial.

The question often asked of us is how do you measure efficacy (a vaccine's usefulness in preventing actual infections) if you are putting so much emphasis on counselling, etc, as the participants will then reduce their risk behaviour and there will be no HIV infections. How will you know that the vaccine has worked? This is where the issue of a comparison group, the placebo control in a classical vaccine trial, comes in.

What is expected in such a case is that the impact of additional interventions like counselling and condom promotion will be there in both groups. What will be different is the administration of the vaccine in the vaccine group. That's why the difference between the incidence among the vaccinated and the comparison group will be able to statistically indicate to what extent the difference is attributable to the vaccine. I hope I have made my point clear.

You have made your point clear but I still have a question. There will be an obligation to counsel in order to minimise risk. Despite the fact that in both these groups the risk will be minimised, you still have to arrive at a comparison and an understanding of how effective a vaccine is. Doesn't the researcher have a conflict of interest? There is an interest in actually getting results, and there is also an obligation for the researcher to get that person to behave in such a way that there will be no results.

Of course as a researcher I will be interested in results. That does not mean that I will always be interested in positive results. I do not go with a preconceived notion as a researcher. If I am a principal investigator in a particular Phase 1 trial I do not go with a presumption that it is a safe vaccine or that it is able to produce an immune response. If I am a principal investigator of a Phase 3 trial I don't go with the presumption that it is an efficacious vaccine. For that matter, for a conscientious researcher it is always better to accept the fact that this might be a problematic case. I have a greater obligation to my community, to my participants. Anything bad that happens to them is not acceptable to me. If anything happens to them I have to be able to categorically comment on whether it is vaccine-related or not. If it is vaccine-related, I have to be able to boldly say that it is not acceptable because safety concerns are there, or efficacy concerns are there.

At the same time that does not mean that all researchers are unethical.

I am not suggesting that researchers are behaving unethically. I want to put forward the proposition that there is a conflict if risk behaviour actually gives the best results.

I wouldn't say this is a conflict. As a scientist and researcher I know that there are scientific ways in which you can analyse the data. You have to ensure that all proper practices are followed, the appropriate information is conveyed to the participants, so that risk gets minimised through counselling or any other intervention that is indicated in the research protocol. Even if this happens, the study is powered in such a way that in spite of this effect you eventually get analysable results. The study should be designed appropriately and have an adequate sample size, then no conflict exists.

We were talking about developing study sites…

One issue in selecting sites is an adequate incidence of infection. One of the important research agendas of this institute is vaginal microbicides and we had previously tested two products in Phase 1 trials — pro 2000 and buffer gel. We opted out of a Phase 3 trial of a vaginal microbicide because we did not observe the desired incidence the study protocol required. Currently an international protocol, HPTN035, is looking at the efficacy of the same two products. It required that all sites included had an incidence — rate of new infections — of 3% per year. This is a large number. You start with a population of 100 negatives and you should be able to have at least three positives at the end of one year without any interventions being done, and so on and so forth. In the studies that we conducted we focused mostly on female partners of male STD clinic patients, and women coming to gynaecology clinics with symptoms of STDs. We were not able to document that high an incidence. So we decided to back out of this study.

The point I'm making is that getting sites with a high incidence of HIV is difficult. Sex worker sites can be one choice, but although sex workers will be the primary users they are not necessarily the only users of vaginal microbicides. We also talk of married monogamous women at risk of HIV infection from their husbands and they would need to use microbicides as well. Doing studies in high-risk populations like female sex workers has its own limitations.

There are also problems in doing studies among sex workers. Because of their risk many of them are already infected. Second, they are labile populations, they keep moving around. For any clinical trial, that is another difficulty. Essentially for a Phase 3 trial, we need a population that we can keep track of with regular follow-up for three to five years. Female sex workers are also vulnerable as they are under someone's control. Finally, other concurrent infections make them vulnerable to getting infected and that makes evaluation of endpoints difficult. So doing studies on FSWs is difficult.

So how to find populations where the incidence of HIV is high but the people are not sex workers? That is a real challenge as far as India is concerned, I would say.

Are you looking at such populations?

In a Phase 3 trial of an HIV vaccine — or a microbicide — we have to look at high-risk populations including sex workers.

These are the issues related to study sites.

We also need researchers trained in this work. They should be educated in the capacities required to undertake this work, in the ethical issues, in the scientific methods, in good clinical practices, in that specific research protocol. In addition, there is other job-related training. For example, laboratory staff must be trained in that assay, data management staff must be taught the specific software, quality control, etc.

What is the difference between developing study sites and identifying groups for research?

Study sites are where you conduct the research, where you need to have the four components of a clinical trial: clinic facilities, a laboratory infrastructure with world-class laboratories, data management, and community linkages to identify populations and recruit participants. NARI is a study site for the Phase 1 HIV vaccine trial.

Identifying the population needs different considerations. In the NARI Phase 1 HIV vaccine trial we needed 14 visits in 12 months, so we didn't expand the recruitment outside Pune. You have to decide what group will be considered for recruitment, where and how they will be approached: in clinics, through NGOs, or in the general community.

Are you talking about identifying groups or recruiting participants?

I'm talking about both, there is an overlap. Identifying groups is the first step, where you get information on prevalence and incidence. That is relevant for Phase 3, but for Phase 1 we don't need this because we talk about healthy populations. Then the question is: where to go to find it? To social workers? Religious people? Women's groups? Healthcare professionals? Scientists? We have to think of all the possibilities for approaching a large number of people and giving them systematic information to eventually complete adequate recruitment.

There is no direct contact with individuals in recruitment?

Not necessarily. It is a combination of both. For a learned population you give them information on the website and they will approach us, but not for others. The crux is how to reach the right kind of people for your study and then how to recruit them.

The whole success of recruitment is in getting the right groups. For example, we went to a number of government organisations anticipating that as we were a government organisation, it would be easy to organise programmes and give information. But we didn't get a good response. Then we worked with anganwadi workers and got a good response. Then we went to individuals who had a primary level of motivation to participate…

I can't imagine what that motivation could be...

You may not imagine yourself in that position, but don't you agree that all the medicines we use have arrived after completion of clinical trials? Who participated in them? People like you and me, or else it would not have been possible.

We are new to clinical research, particularly Phase 1.

Most of the clinical trials in India are Phase 3, drugs that have been proved safe outside. We have few drug development trials. We did one of the first few Phase 1 trials in the country. It was challenging because it had the HIV tag. Perhaps if it had been a malaria or diabetes trial, people would have participated more easily.

One reason for people not to participate is that there is no direct benefit, and that is as it should be. Those people I know who have participated have done so for the money. Clinical trials should not provide direct benefits, and then why should people participate? Going back to HIV vaccine trials, those who participate in Phase 1 trials will have to see some benefit.

The single reason we identified, from among those whom we screened — which is around 80 to finally enrol 30 in the actual trial — was altruism: to do good for society. There was a variety of reasons, not necessarily that they had someone close who had HIV. They cared to participate for a social cause. There were a few who had someone in the family who was affected by HIV, who felt that this was an indirect way of helping them.

What is considered a benefit by one may not be seen as a benefit by others. For example, one of the comments made by an American when we talked about reimbursement of Rs 275 for women who participated in a vaginal microbicide trial was that this was an inducement. I tend to feel that he/she hadn't lived in India for a long time. He/she said this was too much for a villager and this is how US-funded research gets a bad name. He/she did not know that before we arrived at this amount we talked to women's organisations, to past trial participants and other advisory agencies to see what is and isn't an inducement.

In our vaccine trial, we decided on Rs 500 for travel and loss of wages since there were 10 visits in one year and any particular visit entailed a commitment of three-four hours a day. This amount was not insignificant but it was not enough to induce a person into the study.

Another way we tackled this issue is that we employed a three-level programme. First, in community-based programmes we talked to groups of 20-200 and gave them a brochure or motivating flyer with contact information. With anyone who came back to us we had a second-level meeting where we talked to groups of five to seven and gave them more information. Then we did a risk assessment to see their motivation, whether they had misconceptions such as that the vaccine would give them protection, etc. This was for the Phase 1 trial. The third level was one-to-one contact with a further assessment of risk and motivation. Then we asked them to consult their significant others and come back to us. When they came back, then we talked about reimbursement. This was to ensure that having passed through three stages they were interested, and now it was time for them to know also about reimbursement.

You have talked about various kinds of problems in getting participants: the need to identify high prevalence or rather high incidence. Then, how to recruit.

The number is always a challenge. For Phase 3 trials we need thousands and thousands of participants. This means finding institutes that are interested and have the required competency — trained researchers, clinic, laboratory, data management, community linkages for informing and recruiting adequate numbers of participants... And we need to find and prepare sufficient numbers of such sites with uniformity of procedures.

Do you need to try the vaccine on different populations besides female sex workers?

Of course. There are two or three ways in which HIV is transmitted: heterosexual, MSM, IDU, and mother to child. Which of these populations are ideal for preventive vaccines? You must do the study on all these groups because we need to know if the intervention will work in all of these settings.

The areas that you have described — competence, training, screening, counselling, identifying populations — are not really challenges but how to do things right. What are the challenges? Where do you think the problems will be?

I think these are big challenges because this is India. We are recruiting in a country where few have participated in clinical trials. We have to explain risk, etc. This is a challenge, I feel. There are so many technical terms. What approaches should we use when talking to the masses vs small groups, individuals? Should the mass media be involved? How do we ensure that informed consent is obtained? What procedure should we follow? Should it be textual, or audio, or both?

It is established that India has the technical competence. The challenge is to ensure that people understand what it means to participate.

What about the challenges of dealing with vulnerable populations?

I won't say the issue of vulnerability is different in India. For example, women all over the world are vulnerable but the vulnerability in Indian women is higher. Indian women have less access to healthcare, lower social status. They are given low priority in family decisions compared to women in developed countries.

Should we think about a timeline for an HIV vaccine?

As a scientist I would say we should have a specific timeline. Considering the pace at which this research is going on in different parts of the world there is a hope and there is not. You must have heard of the closure of the Phase 2 Merck trial. That is not proceeding to Phase 3.

The only trial in Phase 3 is in Thailand and the results will be out in 2008. The final follow-up is going on. It's a population-based Phase 3 envelop-based vaccine candidate. (Until it has cleared Phase 3 we describe it as a vaccine candidate. If it passes through a Phase 3 trial we will call it a vaccine.)

If the vaccine proves effective the issue is whether it will be applicable elsewhere where the sub-type is different. That's something that scientists have to work on. Even if it works we still don't know if it will work in other countries; we will still have to work on that.

What about the NARI vaccine trial?

The Phase 1 trial of the adeno associated virus (AAV) vaccine candidate tested at NARI had good safety but the immunogenecity was not as desirable.

Is it the same as the vaccine candidate tried in Belgium and Germany?

Yes.

Are the results out?

Yes. But it is not likely to proceed to Phase 2. But the MVA vaccine candidate in a Phase 1 trial at the Tuberculosis Research Centre (TRC) at Chennai — the results are not officially out but it seems to be a promising vaccine and might go for Phase 2 trials.

You say it is unlikely that the AAV vaccine tried in NARI will proceed to Phase 2, but there are trials of this in Africa.

Phase 2 trials are ongoing in Africa but a higher dose than we used is being used there… But still, the preliminary results are not encouraging, so it might not go further.

If TRC looks promising, what is the timeline?

I would say in the best case scenario we are talking about six years. The worst case is 10 years.

What is the timeline for a vaccine candidate?

Look at the hepatitis B vaccine. It took 16 years. The polio and measles vaccines took more than 40 years. But two-and-a-half years after SARS first appeared, we had a vaccine.

What if you have a vaccine candidate, presuming that it gives good results at each stage, what is the possible time from Phase 1 to Phase 3?

Eight to 10 years. Phase 1 will take two to two-and-a-half years. Phase 2 will take three to four years. Phase 3 will take five to six years. The minimum is 12 years if you're lucky…

When you talk about site preparation, what is the status?

As far as sites go, at NARI and TRC we have shown the ability to conduct AIDS vaccine trials by creating appropriate infrastructure and training personnel.

One more aspect, identifying high-risk groups… have you got that ready?

We started that in 1993 with an Indo-US collaboration, a study called PAVE (Preparation for AIDS Vaccine Evaluation). At the time the hope was that the vaccine would be ready in a year or two and the same cohort that was being prepared by us would be used in a vaccine study. But that was not to happen. So we have been doing long-term studies in high-risk populations that we could recruit.

Where are these populations?

In Kolkata, Pune, Chennai.

In Mumbai?

I don't think so.

In Sangli?

Sangli is a place with a known high-risk population but cohort studies are not being done there. A cohort study will be necessary to identify the incidence of HIV in that population and to maintain a population for a future trial. PATH along with the ICMR is working on site preparation of Phase 3 studies on vaginal microbicides. They could be used for vaccines as well. I don't know where…

Overall, there are sites and cohorts being followed. Preparatory exploratory studies are being undertaken to identify populations where trials can be undertaken in other parts of the country.

Tomorrow if you had to start a Phase 2 trial, for example if TRC's results come out and are good, are you ready?

Yes, at TRC, NARI, at Kolkata…

Can you talk about a therapeutic vaccine?

As a public health man, I am interested in prevention. A therapeutic vaccine would be a kind of immunomodulator that will possibly change the course of the disease, improve the quality of life, increase CD4, decrease viral loads, reduce opportunistic infections, lower death rates. Drugs are doing the same things. I don't know how this is different. Moreover, we don't know how frequently the vaccine will have to be given, the costs, dangerous reactions and side-effects, immune phenomena… moreover we will need to test them… the major difference is that they will be in HIV-positive individuals.

Can you talk about what it means if we have a vaccine that is not 100% successful?

Hardly any vaccine is 100% successful. I would be happy even with a 30-50% efficacy, because to start with such a vaccine with extensive coverage could significantly avert new infections. You would have to talk to people with a good math modelling background for a more elaborate understanding.

I want a rough picture...

A modelling has been done that if a vaginal microbicide came into the market with 30% efficacy and coverage was extensive — that is, if it reached 70% of the women needing it — we could bring HIV incidence down by 50%. That is a sizeable impact even with a low level of efficacy. Efficacy and coverage are two components of impact.

If there is a high incidence of a disease, a relatively ineffective vaccine will still be of value. But with a low incidence of disease, you need to have a high efficacy vaccine. As we now know that the prevalence of HIV is very low in India, the incidence is also expected to be low. That has a bearing on whether you will use the vaccine in India.

I think this is a good point. What you are trying to say is: to see a good impact on prevalence and incidence in India, where the rates are pretty low, we would have to have a vaccine with much greater efficacy. Unlike in Africa where a vaccine with lower efficacy would have a better effect.

This is an important consideration given that the prevalence and incidence were earlier believed to be higher. Now we really do have to have a vaccine of much greater efficacy.

Yes, possibly.

What do you think are the ethical challenges in all this?

We touched upon some of them. The major challenge is to ensure that people participate with full knowledge, to give information, to ensure that they understand, the success of the informed consent process, the spirit in which it is done.

Any trial is likely to fail if it does not ensure retention. Retention becomes an ethical challenge. If, in a trial, people have been enrolled but retention rates are poor, you have lost a lot of your participants, the results will not be good. What about those who participated? This is because the trial was started without ensuring that people would be retained. If science is defeated, ethics will be defeated.

What about care and treatment to vaccine trial participants?

As far as IAVI is concerned, they have a policy to give ARVs to all who become positive in the trial. Other institutes may not have this policy. However, as an institute we cannot differentiate between IAVI-sponsored trial participants and others. Suppose we have a Phase 3 trial, and we are not able to give the benefit of the vaccine to the population after the trial completion, it will be an ethical issue. So how do I link up with other programmes?

What is the current status?

We have been given an ARV centre by NACO so we can cover all our trial participants.

Post-trial access to the vaccine, if it is proved effective, is important. One issue is the ability to have an affordable vaccine. Before the trial is started the parties signing the agreement discuss this. The IAVI-ICMR-NARI memorandum of understanding addressed this. Two-three companies in India were inspected and an agreement was signed to transfer technology to them to manufacture the vaccine.

There have been discussions on the issue of negotiations between the different collaborating organisations in such research, where the local organisations may not be able to have equal negotiating power. Does this come up?

This is an issue of training. My job is to get the best deal for my participants. There are instances where the local site-level investigators do not have the skills or feel empowered, but we are changing, we are getting more experienced. That again is to some extent an issue of familiarity. Earlier we used to just accept clinical trials that came our way. We have more training in these areas, including good clinical practices. Also there is an awakening in the general population.

Do you think the ethics review at different levels is able to identify issues and to resolve them?

I think there is confidence in both levels. It is an evolving process. Maybe a raw person does not have the insight of an experienced person, but as you participate you get better or improve. We encourage our ethics committee members to participate in international programmes for training. If five years ago we did not have the confidence about a sound ethical review, we certainly have it now.

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