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CONSTELLA GROUP

CONSTELLA FUTURES

Preparing for Microbicide Access

INDIA COUNTRY PROFILE

Submitted to: The International Partnership for Microbicides (IPM)

Submitted by: Constella Futures, Ltd.

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PREFACE

With funding from the European Community, the International Partnership for Microbicides (IPM) commissioned a series of country profiles that compile information on demography, HIV and health systems in countries hosting or planning to host microbicide trials. These profiles are intended to provide basic overviews that can inform the development of more detailed policy research agendas and support future planning for the introduction of microbicides. They do not set out detailed microbicide introduction strategies or address product specific challenges.

Constella Futures was commissioned to prepare profiles for India, Nigeria, Rwanda and Tanzania. Studies were also conducted separately in South Africa and Zambia. The country profiles are available at www.ipm-microbicides.org.

The recommendations made in the reports are those of the authors and do not necessarily reflect IPM's views, positions or plans.

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REPORTS IN THIS SERIES

Prepared by Constella Futures:
- India Country Profile
- Nigeria Country Profile
- Rwanda Country Profile
- Tanzania Country Profile
- Preparing for Microbicides Access: A Synthesis Report

Prepared by Jo Heslop (data are comparable to Constella Futures reports):
- South Africa Country Profile
- Zambia Country Profile

Prepared by Health and Development Africa:
- A Country Preparedness Assessment of Microbicide Access and Use in South Africa

Prepared by JHPIEGO/ Zambia:

- Microbicide Country Preparedness Assessment – Zambia: Prospective Introduction of a Microbicide to Prevent or Reduce HIV Transmission

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ACRONYMS

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal clinic
ANM	Auxiliary nurse and midwife
ART	Antiretroviral therapy
ARV	Antiretroviral(s)
ASHA	Accredited social health activist
AYUSH	Ayurveda, Unadi, Siddha, and homeopathy
BSS	Behavioural Surveillance Survey
CIA	Central Intelligence Agency
CIDA	Canadian International Development Agency
CHC	Community health centre
CDSCO	Central Drug Standard Control Organisation
CSW	Commercial sex worker
CBO	Community-based organisation
DBT	Department of BioTechnology
DCGI	Drugs Controller General of India
DFID	Department for International Development (UK)
DHS	Demographic and health survey
DSACS	Delhi State AIDS Control Society
DSPRUD	Delhi Society for the Promotion of Rational Use of Drugs
EC	European Commission
ESI	Employees State Insurance
FBO	Faith-based organisation
FC	Female condom
FSW	Female sex worker
GCM	Global Campaign for Microbicides
GDP	Gross domestic product
GFATM	The Global Fund to fight AIDS, Tuberculosis and Malaria
GOI	Government of India
GFCCM	The Global Fund Country Coordinating Mechanism
HIV/AIDS	Human immunodeficiency virus/ Acquired immune deficiency syndrome
HLFPPT	Hindustani Latex Family Planning Promotion Trust
HRG	High-risk group
ICMR	Indian Council of Medical Research
IDU	Injecting drug user
IEC	Information, education, communication
IPM	International Partnership for Microbicides
IUD	Intrauterine device
KSAPS	Karnataka State AIDS Prevention Society
LHV	Lady health visitor
MAP	Multisectoral AIDS Programme
MOHFW	Ministry of Health and Family Welfare
MOU	Memorandum of understanding
MPW	Multi-purpose worker
MPW (M)	Male multi-purpose worker
MSM	Men who have sex with men
MWRA	Married women of reproductive age
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NARI	National AIDS Research Institute
NCT	National Capital Territory
NFHS	National Family Health Survey
NGO	Non-governmental organisation

NIDI	Netherlands Interdisciplinary Demographic Institute
NIHFW	National Institute of Health and Family Welfare
NIRRH	National Institute for Research in Reproductive Health
NRHM	National Rural Health Mission
OI	Opportunistic infection
OVC	Orphans and vulnerable children
PEPFAR	The President's Emergency Plan for AIDS Relief
PHC	Primary health centre
PLWHA	Person living with HIV/AIDS
PPTCT	Prevention of parent-to-child transmission
PMTCT	Prevention of mother-to-child transmission of HIV
PRB	Population Reference Bureau
PSU	Public sector undertaking
RCH	Reproductive and child health
SACS	State AIDS Control Society
SEAM	Strategies for Enhancing Access to Medicines Programme
SMO	Social marketing organisations
SRH	Sexual and reproductive health
STD	Sexually transmitted disease(s)
STI	Sexually transmitted infection(s)
SWAp	Sector-wide approach(es)
TBA	Traditional birth attendant
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on AIDS
UNDP	United Nations Development Fund
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
UT	Union territory
VCT	Voluntary counselling testing
VCTC / VCCT	Voluntary counselling and testing centre / Voluntary counselling and confidential testing
WHO	World Health Organization

EXECUTIVE SUMMARY

This report for India is one of a series of country profiles commissioned by the International Partnership for Microbicides (IPM) to build a background on which to begin to examine microbicide access at the country level. The objectives of the project are to look at country settings and begin to identify the implications for a future microbicide in developing countries. The team built the profiles as desk-based research using standard data sources. In-country consultants assisted the researchers by interviewing stakeholders and filling important gaps unavailable in the grey literature. This profile looks in more detail at two states: Karnataka in the south and Delhi in the north.

Demographic situation. India's total fertility rate is 2.9. Although India's fertility is lower than many developing countries, India is expected soon to become the most populous country in the world, overtaking China by 2050. The ideal family size is 2.7 and the unmet need for family planning is 16 percent (women who say they don't want any more children but are not using contraception). More than 50 percent of women use contraception and the vast majority use modern methods. India is 29 percent urban and the average Indian lives to 63 years of age. There are 933 females for every 1,000 males, indicating some (illegal) sex selection before birth is taking place.

HIV trends. India's HIV epidemic is heterogeneous; it seems to be following a type 4 pattern, where the epidemic shifts from the most vulnerable populations such as female sex workers (FSWs), injecting drug users (IDUs) and men who have sex with men (MSM) to bridge populations (clients of sex workers, people with sexually transmitted diseases (STIs) and partners of drug users) and then to the general population. The epidemic is centred in urban populations but is increasingly spreading to rural areas, thus becoming more generalised. There is significant variation in prevalence and transmission patterns between the states in India, with the highest prevalence in some southern states (predominantly through sexual transmission) and some states in the northeast (predominantly through injecting drug use).

Health system and expenditure. India has one of the world's most privatised health care systems. The government health sector makes up 21 percent of all health expenditures and provides curative and preventive health services from primary to tertiary level throughout the country. In theory, this service is free to the consumer, although the patient often has to pay for medicines. Its quality varies from state to state, and often, only people who can't afford to go to the private sector will go to government hospitals and clinics. A fee-levying private sector (79 percent of health expenditures) plays a dominant role in the provision of individual curative care through ambulatory services. Per capita expenditure on health is US$30. Only 42 percent of Indian children are fully vaccinated.

Regulatory capacity. Nationwide market approval for new drugs is granted by the central drug authority, the Drug Controller General of India (DCGI). The DCGI is the key group in the Central Drug Standard Control Organisation (CDSCO) and the DCGI works under the Ministry of Health and Family Welfare (MOHFW). An Indian manufacturing company can negotiate the complicated registration process. A local sponsor, while technically not required, is almost indispensable.

Manufacturing. India is a major supplier of generic drugs worldwide and is almost completely self-sufficient in drug production. Although at a nascent stage, India's research capabilities are also growing. Recently, the country's ability to supply certain generic ARV drugs to developing countries was called into question when the Indian Parliament enacted laws to make the country compliant with international patent protection laws.

Crown Agents has advised that teaming with Indian companies is the best option. Many Indian companies have drugs registered in multiple countries and are already on the WHO/UN pre-qualified list. These companies could then do all the legwork on registering, licensing and distribution within India and could also facilitate fast-track licensure.

Procurement. India has a strong cadre of highly experienced technical procurement experts and the market is heavily biased towards Indian manufacturers. Donors almost universally source their drugs within India, so there is little need for importation requirements (although they do exist). Some specialty items are brought in by large drug companies, if required.

HIV programming. The National AIDS Control Organisation (NACO) was launched in 1987. The National AIDS Control Programme (NACP) Phase I was set up in 1992 (1992-1999). NACP II (1999-2006) focused on a decentralised and comprehensive programme with targeted interventions for high risk groups (HRGs); preventive interventions for the general community; and capacity-building through institutional strengthening, decentralisation and effective partnerships with civil society organisations.

NACP III (2006-2011), the third phase, is under preparation and may be signed in 2007. It plans to include prevention programmes for high-risk populations and will provide a package of integrated voluntary counselling and testing (VCT), prevention of mother-to-child transmission (PMTCT), treatment of STIs and care and treatment of opportunistic infections at primary level. It will focus on the gaps of the two previous programmes.

This profile also includes an institutional mapping section of organisations working in HIV/AIDS and sexual and reproductive health (see Annex).

IMPLICATIONS FOR A FUTURE MICROBICIDE

Two Indian consultants interviewed a range of key stakeholders, asking them what might influence or have an impact on future microbicide introduction. The following gives a summary of their views.

DELIVERY CONSIDERATIONS

Private sector delivery channels are essential. India has one of the most privatised health systems in the world and ensuring optimal coverage will require the participation of the private sector in addition to the public sector. Care must be taken, however, to ensure that quality standards are maintained.

Reproductive health delivery channels may be important. HIV stigma is very high in India and married women in monogamous relationships are unlikely to attend VCT or STD clinics. This poses an important marketing challenge for microbicides. Reproductive health programmes and family planning clinics should be considered as an avenue to reach women. Also, for rural women in high-risk regions who are increasingly becoming infected, family planning clinics might be their only interaction with the health system.

However, the limitations to outreach through family planning programmes should also be kept in mind. For one, India's epidemic is concentrated, and the general population is considered to be at risk only in certain states (six states have prevalence over one percent, four are in southern India and two are in the northeast, where injecting drug use playing an important role in transmission). Furthermore, a large proportion of Indian women undergo sterilisation by the age of 25 and may stop visiting family planning clinics thereafter. Therefore, microbicide introduction through reproductive health programmes would have to be targeted geographically and separate programs may be needed to reach older women.

Social marketing is well established in India. A number of social marketing organisations distribute a variety of health products, including sexual and reproductive health (SRH) and HIV services, in rural, semi-rural and urban slum areas, and microbicides could be integrated into their product portfolios. The Government of India (GOI) subsidises socially marketed condoms and contraceptives and might consider a similar approach to microbicides.

Prescription versus over-the-counter (OTC). It is a widespread practice in India for pharmacists to provide prescription drugs regardless of proper prescriptions. However, registering microbicides as OTC, if possible, will facilitate distribution in public clinics and NGO-operated programmes where prescriptions are more likely to be required.

Partner with relevant NGOs and programmes. India has a vibrant civil society with several NGOs that are active in HIV/AIDS and SRH. Many international organisations partner with local groups. For example, the Bill & Melinda Gates Foundation is working with 151 NGOs on a a programme focused on HIV prevention. It may be possible to integrate microbicides into this network.

WOMEN

Understand price sensitivity and willingness to pay. For comparison, intrauterine devices (IUDs) sell for approximately Rs.50 (US$1) in the private sector. One social marketer speculated that women may be willing to spend Rs.20-25 (US$0.50)/ month on microbicides.

Vaginal products are a new concept. Women are not used to vaginal products in India, but the limited data from microbicide studies conducted suggest that they may be acceptable.

Early sterilisation negates positioning of microbicides as contraceptives. Early sterilisation practised by many Indian women (as young as 25) makes negotiating condom (or a future microbicide) use difficult as the risk of pregnancy is no longer applicable. In addition, many women who choose early sterilisation have not previously practised any other method of family planning. This means they will not have visited a family planning clinic or had any practice negotiating health-seeking behaviour with their husbands. This warrants further research.

Envision positioning microbicides as a hygiene product. Sex is a taboo topic in India and stigma around HIV is a major issue. If microbicides are not explicit about HIV, then women may find negotiating use easier.

Train, counsel and keep the concept simple. Based on past microbicide studies in the country, the concept of microbicides was found difficult to understand, particularly the notion of partial efficacy and using them as the last option if condoms cannot be negotiated. A principal investigator indicated that it takes up to two hours to explain the concept of microbicides to study participants. Adding to the complexity of the task is the fact that vaginal products are not common in India. This is particularly relevant because experience has shown that the willingness to use a product is very much linked to the first-use experience.

Female condom experience. One of the major lessons from the recent female condom introduction in India is to beware of too much focus on high-risk populations. If microbicides are only used by high-risk populations, it will be difficult to then try to market them to women in primary partnerships as they will carry the **stigma of being associated with high-risk groups.**

Male approval is likely to be necessary, although the best ways to gain male consent will require further study. In general, women's socio-economic status in India tends to be very low, making the negotiation of safer sex challenging.

Take into account the potential of increased gender violence. Gender violence is widespread in India. Its implications for microbicide use must be researched further as women may need to get their male partner's approval before using a product. This has caused difficulties with the use of the female condom. A recent study by YRG Centre for AIDS (PATH, 2005) found that a request from woman for her partner to use a female condom was seen as a reason to 'hit the woman' by her partner.

Further research is required on the complicated issues of AIDS stigma, male power, early sterilisation and the implications of these on the introduction of a future microbicide.

REGULATORY ISSUES AND MANUFACTURING

Manufacture in India; partner with an Indian manufacturer. India has several world-class pharmaceutical manufacturers that could be potential production partners. A survey and evaluation of potential Indian manufacturing and distribution partners is warranted. Having someone who knows the regulatory system will save considerable time, as getting approvals can be a complex and lengthy process.

ADVOCACY

The **Global Campaign for Microbicides** has been working with Indian partners since 2001. This has involved participation in many conferences and workshops to raise awareness and advocate for more prevention options for Indian women. This work included a national stakeholders meeting in 2003 which yielded several recommendations to form a multisectoral working group. **PATH India** is also active in microbicide advocacy and has convened a national microbicides steering group.

Partner with the Microbicides 2008 conference. The 2008 Microbicides meeting will be held in Delhi in February 2008 and is an excellent opportunity to increase awareness within government, amongst Indian scientists, healthcare providers and with user groups.

Women as microbicides champions. There are various prominent women in the medical, scientific, policy and NGO fields as well as high-profile personalities from the film and business communities who could make strong microbicide advocates.

Conduct a large-scale advocacy programme to reach women's and gender groups. Women have very low standing in India. They lack empowerment and have poor HIV awareness. They may be reached through women's groups and self-help groups. There is more research required on the nuanced treatment of a microbicide introduction and the attitude of women's groups. For example, there is some history of mistrust among women in India regarding the introduction of new reproductive health technologies, following concerns raised over the approval of injectable contraceptives in the mid-1980s and early 1990s.

STAKEHOLDERS

Build a relationship with NACO. There is strong donor support for HIV prevention in India and it is aligned with the GOI. NACO support for microbicides will be essential. NACO and the GOI are the decision-makers who can introduce microbicides into existing programmes as well as to subsidise them via social marketing. However, considerable decision-making is also decentralised to the state level (and a number of donors, such as DFID, work directly with states).

Understand variances between states. The political environment and the prevalence of HIV/AIDS vary from state to state, and some will be more favourable to microbicides than others. **The state AIDS control societies (SACS)** are important to engage at the state level. Given the enormous size of India, introduction in targeted states will be necessary, with roll-out nationally requiring considerable time.

Build a relationship with the Indian Council of Medical Research (ICMR) and empower an ICMR champion**.** ICMR's role is key and ICMR representatives are sensitised to microbicides and interested in partnering with various international organisations. The M2008 conference provides an opportunity to strengthen these links.

Develop cross-party advocacy at national, state and, if possible, district levels. There is a high turnover in government leaders at every level, since governments are often coalition-based, and it is important not to be dependant upon one person or one group.

Use accredited social health activists (ASHAs) as microbicides advocates in rural areas. ASHAs will be involved with multiple SRH issues and activities in communities. Also engage auxiliary nurses, midwives and community workers.

Understand village self-government committees (panchayati raj) needs. These are predominantly male committees (although a quota for women ensures some female participation). Their agendas may be far removed from health but it might be possible to use this channel to introduce microbicides, particularly in high-risk regions.

Gain early support from doctors. Doctors are highly respected and consumers trust their recommendations, often not seeking independent information. Because of this, doctors must be educated about microbicides early on, as any scepticism they exhibit about microbicides could be detrimental. Medical associations could play an important role. The Federation of Obstetric and Gynaecological Societies of India (FOGSI) is one place to start. This is important also at lower levels, with auxiliary nurses and midwives.

Informal medical practitioners provide an important portion of health care. Hence, they are a key point of entry to the health system for many. Consider them in any strategy.

Test communication materials with different **partners at all levels.** This is key to ensuring that the materials are appropriate to the local diversity and sensitivities.

1 INTRODUCTION

This report for India is one of a series of country profiles commissioned by the International Partnership for Microbicides (IPM) to build a background to begin to examine microbicide access at country level. This country profile for India is meant to be a resource for the microbicide community as access to microbicides becomes a reality over the next few years. IPM commissioned Constella Futures in April 2006 to carry out the project, which is funded by the European Commission. The primary aim of the project is 'to accelerate access to microbicides for women in less-developed countries as soon as possible after clinical trials have demonstrated their effectiveness in preventing HIV infection'. Broadly, the objectives of the project are to look at country settings and begin to identify implications for a future microbicide in developing countries.

The profile includes summary demographic and health information as well as an overview of the health system, and the procurement, regulatory, and manufacturing situations. Finally, the profile includes institutional mapping, outlining the key players in HIV/AIDS and sexual and reproductive health (SRH). Implications for a future microbicide in India conclude the report.

As India is such a large country, IPM asked the team to examine two states of India in further depth. This was partly to learn more detail about those areas of the country and partly to discover information about the quantity and quality of state-level data. Delhi was chosen to represent the north and the state of Karnataka was chosen for the south. In many cases, the state-level data was very difficult to find.

2 METHODOLOGY

The microbicides access country profiles are meant to be background documents for future microbicide research and modelling. IPM provided the outline for the country profile series and this outline is reflected in the table of contents for the report. The team built the profiles using standard data sources from the UN system, the Population Reference Bureau, the Demographic and Health Surveys, and the Global Fund, among others. These data were chosen to allow comparability across countries. Additional studies and in-country data were included, if available. In-country consultants assisted the researchers by interviewing stakeholders and filling important gaps unavailable in the grey literature.

Finally, two meetings were held by Constella Futures, one in London including international experts, and one in Nairobi bringing together in-country consultants (with the exception of the consultants for India). Both sets of experts provided additional information, giving their opinions on the best ways to accelerate microbicides access, as well as identifying obstacles.

3 SUMMARY DEMOGRAPHIC INFORMATION

3.1 BASIC DEMOGRAPHIC AND SOCIO-ECONOMIC CONTEXT

TABLE 3.1 DEMOGRAPHIC DATA

	India (comparable data to other countries)	India[1] (comparable data to states)	Delhi	Karnataka
Total population *(PRB, 2006/GOI 2006).*	1,121m	1,028m	13.85m	52.85m
Population density per square mile *(PRB, 2006/GOI 2006).*	884	842	21,190	715
Percentage of population living in urban areas *(PRB, 2006/GOI 2006).*	29%	28%	93%	34%
GDP per capita *(WHO, 2005).*	US$484	-	-	-
Human Development Index *(WHO, 2005).*	0.602 (127th/177)	-	-	-
Percentage of population on under $2 a day *(PRB, 2006).*	80%	-	-	-

[1] As sources for state data are different from national data (where internationally comparable sources have been used), they are not directly comparable. For this reason, Indian national data from both sources (i.e. international and national) have been included. Sources are included in the tables next to each indicator (international data source for the first column and national data sources for the final three columns).

India is the seventh-largest country in the world in area, and the second largest in Asia, after China. It borders Pakistan, China, Nepal, Bhutan, Bangladesh and Burma to the north and is flanked by the Indian Ocean on the south. With over one billion people, it is the second most populous country in the world after China. It has a high population density of 884 people per square mile but fewer than one in three people live in urban areas. These figures mask substantial regional variations. India has a GDP per capita of US$484. It has a rapidly developing economy and is an increasingly important global economic player. However, this masks extremely uneven distribution of wealth and development as eight in 10 Indians live on less than US$2 a day and India has is ranked 127th on the Human Development Index (with a score of 0.602). The services sector is expanding rapidly, constituting over half of the country's GDP. India's economy includes a multitude of modern industries as well as agriculture (which accounts for 60 percent of the labour force, despite contributing a small percentage of GDP).

India became independent from British rule and separated from Pakistan (which at that time included Bangladesh) in 1947. India has been relatively peaceful since independence, although there are ongoing border disputes with China and with Pakistan over Kashmir. India is the largest democracy in the world, with the largest voting population among democratic countries. It operates under a federal system, with 28 autonomous states and seven union territories. All states and the union territories of Delhi and Pondicherry have their own elected governments. States and union territories are further divided into 602 districts.

Hindi is the national language and primary tongue of 30 percent of Indians. English enjoys associate status but is the most important language for national, political and commercial communication. Fourteen other official languages are widely spoken. The population is 81 percent Hindu, 13 percent Muslim, two percent Christian, two percent Sikh and two percent are other religions.[2]

The metropolis of **Delhi** is a National Capital Territory (NCT) in the north of India. It has a population of 13.85 million and is one of the largest cities in the world. (Delhi is projected to surpass New York and Mexico City by 2015.) Its population density of 24,190 per square mile is 30 times that of India as a whole, and 93 percent of its population lives in urban areas. The metropolis or city of Delhi is not strictly defined as the same as the National Capital Territory of Delhi, but for most purposes they are treated as the same (although the metropolis of Delhi stretches further than the territory boundaries). The NCT of Delhi contains nine districts, including New Delhi, the capital of India. Delhi is an important commercial centre in Asia and services such as IT and telecommunications have expanded rapidly in recent years. Forty percent of people live in slums; this has contributed to challenges including water pollution,

[2] CIA, 2006.

traffic congestion, water and power shortages, and is indicative of a highly uneven distribution of wealth.[3] Delhi is considered to be a low-prevalence state for HIV/AIDS.

Karnataka is a large state in the south of India. It has a population of almost 53 million and, although the overall density is lower than that of India as a whole, it has a higher proportion of inhabitants living in urban areas than the national average (see Table 4.1). Karnataka's capital is Bangalore, a city of over six million people. Karnataka is split into 27 districts that are grouped into four divisions for administrative purposes. Major industries are coffee, ragi (finger millet) and gold. Agriculture dominates the labour force but Karnataka is also highly industrialised and Bangalore is a major information technology hub of India. Karnataka is considered to be an HIV/AIDS high-risk state.

3.2 HEALTH AND FERTILITY

TABLE 3.2 HEALTH AND FERTILITY DATA

	India (comparable data to other countries)	India[1] (comparable data to states)	Delhi	Karnataka
Crude Birth Rate (per thousand) *(PRB, 2006/GOI 2006).*	24	25	17	22
Crude Death Rate (per thousand) *(PRB, 2006/GOI 2006).*	8	8	5	7
Projected population increase 2006-2050 *(PRB, 2005)* /Population Growth 1991-2001 *(GOI, 2006).*	45%	22%	47%	18%
Life expectancy at birth (years) *(PRB, 2006).*	63	-	-	-
Life expectancy at birth (male) (years) *(PRB, 2006/GOI 2006).*	62	62	-	62
Life expectancy at birth (female) (years) *(PRB, 2006/GOI 2006).*	63	64	-	65
Sex ratio (women per 1000 men) *(GOI 2006).*		933	821	965
Total Fertility Rate *(PRB, 2006/NFHS-2, 1999).*	2.9	2.9	2.4	2.1
Ideal family size – women *(NFHS-2,*	2.7	2.7	2.4	2.2

[3] DSACS, 2005.

	India (comparable data to other countries)	India[1] (comparable data to states)	Delhi	Karnataka
1999).				
Percentage of married/in union women of reproductive age (MWRA) using contraception *(PRB, 2006/NFHS-2, 1999).*	53%	48%	64%	58%
Percentage of MWRA using modern contraception *(PRB, 2006/NFHS-2, 1999).*	46%	43%	56%	57%
Unmet need for family planning *(PSP-One, 2005/NFHS-2, 1999).*	16%	16%	13%	12%
Age at first marriage (women) *(DHS, 2006).*	17.1	-	-	-
Age at first sex (women) *(BSS, 2001).*	18	18	19	18
Age at first birth (years) *(NFHS-2, 1999).*	19.2	19.2	21.3	18.5

Life expectancy in India is 63 years and the fertility rate is 2.9. Although its growth rate is lower than in many developing countries, India's population is expected to rise by 45 percent by 2050, thus making it the most populous country in the world, ahead of China. This is because of the large population base, a significant proportion of which is of child-bearing age. The ideal number of children is 2.7 and the unmet need for family planning is 16 percent (women saying they don't want any more children but not using contraception). More than half of women use contraception and the vast majority use modern methods.

Delhi has better health outcomes and lower fertility than the national average. Birth, death and fertility rates are lower and contraceptive use is higher, while the ideal number of children and unmet need for family planning is lower in Delhi than in the whole of India. Delhi's population is, however, rising at double the national rate and this is largely due to the rural-urban migration (see Table 4.2).

Karnataka is also characterised by slightly better health outcomes and lower fertility than India as a whole. Birth rates, death rates and life expectancy are similar to India's national average (see Table 4.2).

3.3 GENDER

TABLE 3.3 GENDER DATA

	India (comparable data to other countries)	India[1] (comparable data to states)	Delhi	Karnataka
Percentage of women aged 15-24 who are literate (can write a simple sentence) *(PRB, 2005)* / Literate women aged 15-49 *(BSS, 2001).*	65%	65%	75%	60%
Literate women as a percentage of literate men *(PRB, 2005/ BSS, 2001).*	81%	77%	86%	76%
Percentage of women aged 15+ who are economically active *(PRB, 2005)* / Proportion of main workers to total population - women *(GOI 2006).*	41%	15%	8%	21%
Percentage of men aged 15+ who are economically active *(PRB, 2005)* / Proportion of main workers to total population - men *(GOI 2006).*	86%	45%	50%	52%
Percentage of women with access to newspaper, TV and radio *(PRB, 2005)* / Percentage of women with exposure to newspaper, TV or radio in the last month *(BSS, 2001).*	12%	93%	97%	96%

Literacy levels for girls are average for the south-central Asia region but lower than the international average, both in terms of proportion of literate women and female literacy as a proportion of male literacy. There are large disparities between the economic productivity of men and women, similar to those for the region but larger than international disparities. Only one in 10 women has full access to the media. India's sex ratio of 933 females to every 1,000 males (see Table 4.2) illustrates the growing tendency to use sex selection during pregnancy (which is illegal). This is followed by abortion in the case of female offspring. Another factor is that male infants receive better care, which increases their relative survival rates. The favouring of sons is associated with high gender inequality and women's low status.

In **Delhi,** the female literacy rate is higher than the national average but there is greater disparity in terms of economic activity than in India as a whole. Unsurprisingly, media access

is extremely high. Delhi has a more extreme sex ratio of 821 females to every 1,000 males. Women's status in India is, in general, lower in the north.

Karnataka has lower levels of literacy but the male-female ratio is similar to India's average. However, women are more economically active (as are men) than the country average. Karnataka also has a less extreme sex ratio of 965 females to every 1,000 males.

4 Summary HIV Levels and Trends

Table 4 HIV data

	India (comparable data to other countries)	India[1] (comparable data to states)	Delhi	Karnataka
HIV prevalence *(UNAIDS, 2006/NACO 2006).*	0.9%	-	0.25%	1.25%
# people living with HIV (adults and children)	5,700,000	-	-	-
# children (0-14) living with HIV	120,000	-	-	-
# adults (15-49) living with HIV	5,600,000	-	-	-
# adult women living with HIV (percent of the adult population living with HIV)	1,600,000 (29%)	-	-	-
# of orphans due to AIDS	-	-	-	-

Source: UNAIDS, 2006, unless otherwise stated)

Although national prevalence is lower than in many other countries, it translates into one of the biggest HIV/AIDS burdens worldwide, with 5.7 million people living with HIV/AIDS, according to UNAIDS. The NACO estimate is slightly lower, at 5.2 million. Of these, 120,000 are estimated to be children and 1.6 million are women (29 percent of the adult population with HIV). Sexual transmission (86 percent) continues to be the main route in most parts of the country. Major vulnerable groups include injecting drug users (IDU) (10 percent prevalence), female sex workers (FSW) (8 percent), men who have sex with men (MSM) (9 percent) and migrants and other mobile groups such as truck drivers who travel the major north-south highways.[4] India's HIV epidemic is heterogeneous; it seems to be following a type 4 pattern, whereby the epidemic shifts from the most vulnerable populations (such as

[4] NACO, 2006.

FSW, IDUs and MSMs) to bridge populations (such as clients of sex workers, people with STIs, and partners of drug users) and then on to the general population.

Little is known about MSM. A study in a Chennai slum found that 6 percent of men have had sexual intercourse with another man and almost 7 percent of MSM were found to be HIV-positive (more than half of them were married[5]). There is no data available on the number of children orphaned by AIDS. Blood transfusion also carries a risk of HIV transmission with 2.7 percent being infected this way.[6] A significant proportion of new infections are occurring in women who are married and have been infected by husbands who have visited sex workers. This information would strengthen the case for the importance of a microbicide that women can control.

There have been many challenges in measuring the epidemiology of the disease in the country. HIV prevalence is mostly measured through routine sentinel HIV surveillance from antenatal (ANC) and STD clinics (393 ANC and 179 STD clinics in 2005[7]), with the number of sentinel sites having expanded rapidly in recent years. However, a recent population-based survey in southern India indicated that this method may be overestimating the extent of the epidemic.[8] There is limited data for northern India.

Based on recent surveys, the epidemic is centred in urban populations but is increasingly spreading to the rural population. There is significant variation in prevalence and transmission patterns between states in India, with the highest prevalence in some southern states (predominantly through sexual transmission) and some states in the northeast (predominantly through injecting drug use). In Nagaland, HIV prevalence reached 14 percent amongst drug injectors between 2000 and 2003.[9] The GOI has categorised states into high, medium and low prevalence.

High prevalence – six states Four in southern India: Andhra Pradesh, Tamil Nadu, Maharashtra, Karnataka and two in northeastern India: Manipur and Nagaland	Generalized epidemic with > 1.0% HIV prevalence in general population, based on ANC prevalence
Moderate prevalence – three states Gujarat, Goa and Pondicherry	Concentrated epidemic with > 5% prevalence in high risk groups (HRG)

[5] Go VF et al, 2004: Journal of AIDS, 35(3):314-319
[6] DSACS, 2005.
[7] NACO, 2006
[8] Dandona et al, 2006
[9] NACO, 2004

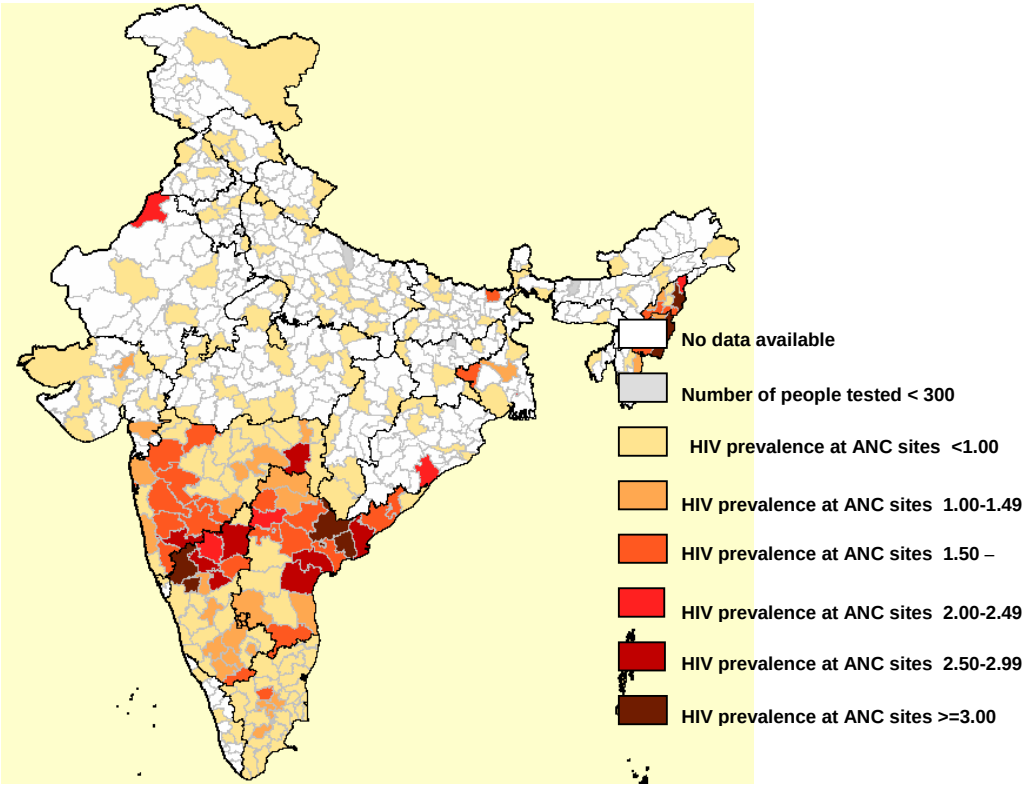
Low prevalence – remaining states	

Levels of HIV infection prevalence appear to have stabilised in some states such as Tamil Nadu, Andhra Pradesh, Karnataka and Maharashtra (group I below); however, overall, HIV prevalence has continued to rise. Chandrasekaran, et. al have categorised Indian states into four groups[10]:

Group I: Maharashtra, Karnataka, Andhra Pradesh, Tamil Nadu	Population of 292m, 3.5m HIV infection, primarily via heterosexual transmission, comprehensive mapping
Group II: Manipur, Nagaland, Mizoram	5.5m inhabitants, 50-75% of districts report over 1% antenatal prevalence, transmission primarily via IDU, reasonable to extensive mapping
Group III: Delhi, Goa, Gujarat, Kerala, West Bengal	187m inhabitants, no district shows over 1% prevalence 40-50% of districts covered, primarily heterosexual transmission, reasonable mapping
Group IV: Rest of India	Population of 576m, ANC surveillance sites in about 25% of the districts, no district showed over 1% antenatal prevalence, transmission most likely via primarily heterosexual, limited mapping

[10] Chandrasekaran et al, 2006.

FIGURE 5 HIV PREVALENCE



Source: Chandrasekaran et al, 2006.

Delhi is a low-prevalence state, based on data from antenatal clinics. However, with more than five percent seropositivity in high-risk groups, it is considered highly vulnerable. Sexual contact is the predominant transmission route (65 percent) and infections are spreading from high-risk to lower-risk populations. Five percent of transmissions occur in blood transfusions/blood products, which is twice the national average.[11] Prevalence increased in antenatal (lower risk) and STD (higher risk) clinic attendees between 2002 and 2004 in Delhi.[12]

Karnataka is considered a high-risk state, with a prevalence of over one percent in pregnant women in rural areas, indicating a generalised epidemic. Prevalence among STI and gynaecology clinic attendees was 13 percent. Prevalence is higher among women who are urban, illiterate and married to truck drivers.[13] Prevalence decreased in ANC attendees (a

[11] NACO 2006
[12] NACO, 2005.
[13] NIDI, 2004.

lower-risk group) and increased in STI clinic attendees (a higher-risk group) between 2002 and 2004.[14]

Districts with the highest prevalence tend to be located in and around Bangalore in the southern part of the state, or in northern Karnataka's "devadasi belt," where religiously sanctioned prostitution is practised. Many women from this part of the country are supplied to the sex trade in big cities like Mumbai. HIV prevalence among FSWs was 18 percent in 2005.[15] Twenty-six percent of sex workers were found to be HIV-positive in Mysore, with just 14 percent of the women consistently using condoms with their clients, and 91 percent never using them with their regular partners.[16] Other high-risk groups are MSM (11 percent prevalence) and IDUs (three percent).

5 Health System Profile

5.1 Description

The health sector in India is characterised by:

- **A government sector** (21 percent of health expenditures) that provides publicly financed and managed curative and preventive health services from primary to tertiary level throughout the country. In theory, these are free to the consumer, although the patient often has to cover the cost of medicine. Quality varies from state to state, and often, only people who cannot afford to go to the private sector will go to government hospitals and clinics. The GOI is launching the National Rural Health Mission (NRHM), whose "goal is to improve the ability of and access to quality healthcare by people, especially for those in rural areas, the poor, women and children."[17] The NRHM has a special focus on 18 states with the weakest public health indicators and one of its stated goals is to integrate family planning and health services as well as sexual and reproductive health (SRH) and HIV services (vertical systems to date). These are connected at the policy level and disconnected at the implementation level. Some of the key challenges at every level of the public system are the lack of officers, high staff turnover, poor oversight, no incentive to perform, a lack of privacy and a judgmental attitude of staff.

- **A fee-levying private sector** (79 percent of health expenditures) that plays a dominant role in the provision of individual curative care through ambulatory services. India has one of the world'' most privatized health care systems. According to data from the National Sample Survey'' 55th consumer expenditure survey, more than two thirds of outpatients' expenses go towards the purchase of drugs. Nationwide health care utilisation rates show that private health services are directed mainly at providing primary health care and are

[14] NACO, 2005.
[15] Avert, 2006.
[16] Reza-Paul SR et al, 2005.
[17] MOHFW, 200x.

financed from private resources, placing a disproportionate burden on the poor.[18] The private system includes for-profit institutions, not-for-profit NGOs, missionary hospitals, private pharmacies and unqualified providers. It is largely unregulated, often resulting in variable quality of testing, care and drugs, and a lack of integration with public health issues.[19] Untrained, unregistered practitioners are widely used. Subsidised social franchised clinics may offer a good alternative to the public sector.

GOVERNMENT HEALTH MANAGEMENT STRUCTURES

Health administration is governed by the Ministry of Health and Family Welfare (MOHFW), encompassing:

- Department of Health
- Department of Family Welfare
- Department of AYUSH (Ayurveda, Unadi, Siddha and Homeopathy)

The central administration provides coordination and direction to a network of state health ministries for implementation. The provision of health care by the public sector is a responsibility shared by state, central and local governments, although it is effectively a state responsibility in terms of service delivery.

The process has been initiated to decentralize authority to enable responsive decision making. Besides this, the *panchayati raj* bodies (system of self-governance at village level) are also being revitalized. Training facilities for health management are being augmented with the National Institute of Health and Family Welfare (NIHFW) playing a pivotal role. A consortium of institutions dealing with health management has also been formed. As a further step towards managerial process development, the NIHFW is making efforts to strengthen institutions all over the country, including State Institutes of Health and Family Welfare.[20]

Responsibilities are as follows:

District government (zilla panchayat)

The 603 districts are responsible for the implementation of health programmes. The district health and family welfare officer is the administrative head of the Health Department at district level and is responsible for the implementation of all programmes and the management of primary health centres (PHCs), community healthy centres (CHCs) and taluk hospitals. Below the district level there is an elaborate administrative structure to manage health services at different levels.

[18] WHOSEA, 2006.
[19] World Bank, 2005.
[20] Ibid.

State government

The 26 states and two of the seven union territories (UTs) have elected governments, including Karnataka and Delhi. Each has a state ministry of health and a directorate of health and family welfare. They are responsible for the delivery of health services and areas on the "state list," including public health, sanitation, hospitals and dispensaries.

Central government

The central government is responsible for policy-making, guiding, assisting, evaluating and coordinating the work of state health ministries as well as linking them with funding agencies. Central and state governments are jointly responsible for programmes under the "concurrent list," including population, family planning, medical education and drugs and poisons and responsible for union territories without a legislature. The central government is also responsible for programmes falling under the "union list," which include national programmes of major diseases such as HIV/AIDS, TB and cancer. Efforts are being made to embed HIV/AIDS programmes throughout the health structure.[21]

GOVERNMENT HEALTH SERVICE DELIVERY STRUCTURES

There is a complex health service delivery structure in India. Up to the district level, each centre has a supervisory relationship with the one below and a referral relationship with the one above.

Sub-centres. A female auxiliary nurse and midwife (ANM) and male multipurpose worker (MPW (M)) are stationed at the sub-centres. There are about six sub-centres under the jurisdiction of the PHCs. Sub-centres serve a population of about 5,000 people. The NRHM aims to train 250,000 women volunteers as accredited social health activists (ASHAs) in the states with the weakest rural health systems. These community-link health promoters' remunerations are performance-based. They will be involved with SRH services and could be a relevant resource for microbicides counselling.

Primary health centres. Normally, these are staffed by a medical officer and 14 paramedical and support staff, with four to six beds for patients. A lady health visitor (LHV) is also posted here and supervises the work of the ANMs. PHCs serve a population of about 30,000 people.

Community health centres (CHC). Normally provided with four medical specialists (surgeon, physician, gynaecologist and paediatrician) and other support staff and about 30 beds with X-ray, labour and laboratory facilities, CHCs serve a population of about 120,000 people. CHCs provide curative, preventative, promotive, rehabilitative, health information processing, training and medical legal services.

[21] NIDI, 2004

District hospitals. These serves as the major curative centres for the districts, including the urban and rural areas. Hospitals have between 100-150 beds and provide in- and out-patient care in most general specialities.

Specialist hospitals. There are various specialist and teaching hospitals, major general hospitals and general hospitals for certain groups, such as those run by the railways and defence services in the urban areas.

Source: NIDI, 2004.

URBAN AREAS		RURAL AREAS	
Tertiary medical colleges & Hospitals	117	District & taluk hospitals	4,400
ESI[22] & PSU hospitals	1,200	Community health centres	2,400
Urban health posts	15,000	Primary health centres	23,000
		Sub-centres	132,000

Source: India Brand Equity Foundation

5.2 Annual Expenditure

Table 5.2 Health Expenditure Data

Total annual expenditure on health	US$33.6 billion
Per capita expenditure on health	US$30
Percentage of government budget spent on healthcare	4.4%
Total expenditure on health as a percentage of GDP	6%

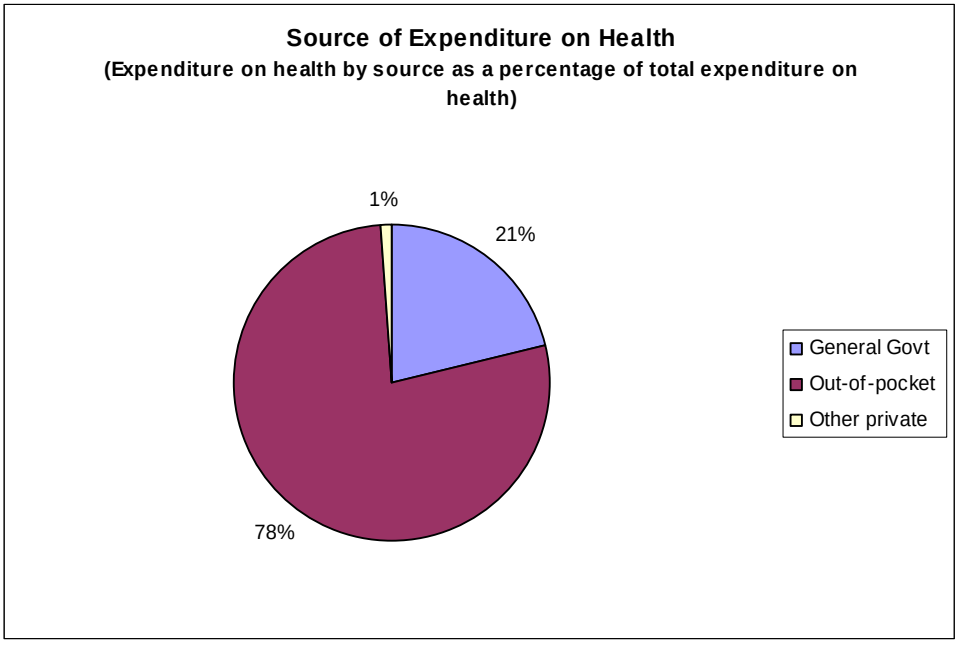
Source: WHO, 2005.

Health spending in 2002 was $30 per capita. However, over three-quarters of this is borne by the patients and government health expenditure was only 4.4 percent of its budget in 2002 (see Table 6.2). The reliance on out-of-pocket expenditure is one of the highest in the world.

Under the constitutional structure in India, the majority of public health concerns are the responsibility of the states. As a result, the principal contribution for funding public health services is from states' resources, with supplementary input (about 15 percent) from central resources. [23]

[22] The Employee State Insurance (ESI) Corporation Hospitals are developed by the government insurance scheme of the same name.
[23] World Bank, 2001.

FIGURE 5.4.1



Source: PSP-One, 2005.

5.3 PROPORTION OF DONOR FUNDING

TABLE 5.3 ESTIMATED HEALTH FUNDING SOURCES IN 2003

Funding source	Amount in US$	Percentage
External (donors)	0.5 billion	1.6
Domestic	33.1 billion	98.4
TOTAL	33.6 billion	**100**

Source: WHO, 2006.

Donor funding to the health sector is extremely low, at 1.6 percent of expenditures, and funding stayed relatively steady (in proportion to overall budget) between 1999 and 2003. There is little reliable information of funding sources at state level.

5.4 PUBLIC/NOT-FOR-PROFIT/PRIVATE MIX

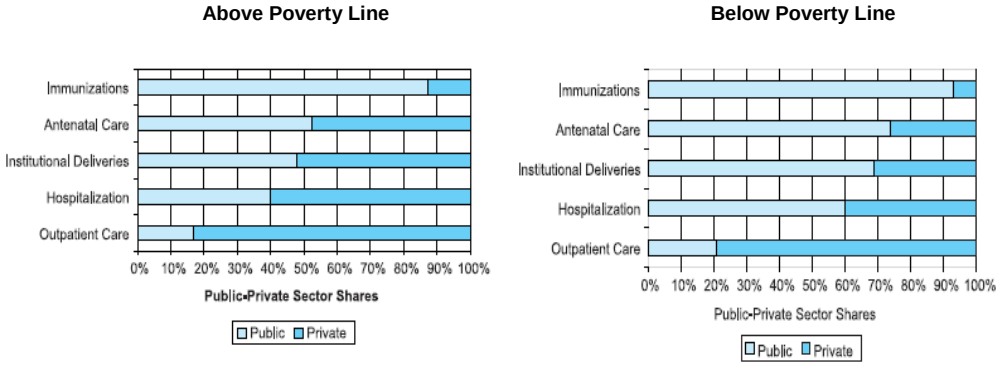
The private sector plays a key role in the delivery of health services, particularly in primary health care, but also in hospital services, and accounts for most curative services in the country. Private hospitals (called 'nursing homes') are generally small (10-30 beds), concentrated in urban areas and have been growing in number rapidly, from 750 in 1974 to 5,650 in 1990. The private sector finances itself through payment at point of delivery, with poorer Indians using the public sector more than wealthier Indians (see Figure 5.4.2.1).

- Only 10 percent of Indians have some form of insurance, and most of this is inadequate.
- Hospitalised Indians spent more than half (58 percent) of their total annual expenditures on health care.
- More than 40 percent of those hospitalised borrow money or sell assets to cover expenses.[24]

There are a few community-insurance schemes like Yashaswini in Karnataka. This programme covers 2.5 million farmers for up to Rs.100,000 in medical expenses for a price of Rs.75/year (Rs.60 being paid out-of-pocket by the farmers and Rs.15 by the government). The GOI also offers a nationwide universal health insurance scheme called Jan Arogya, for 1Rp./day with Rs.100 contributed by the government. However, the success of these programmes is limited.

FIGURE 5.4.2.1 (Source: World Bank, 2001)

Public- and private-sector shares in service delivery, according to wealth, 1995-96

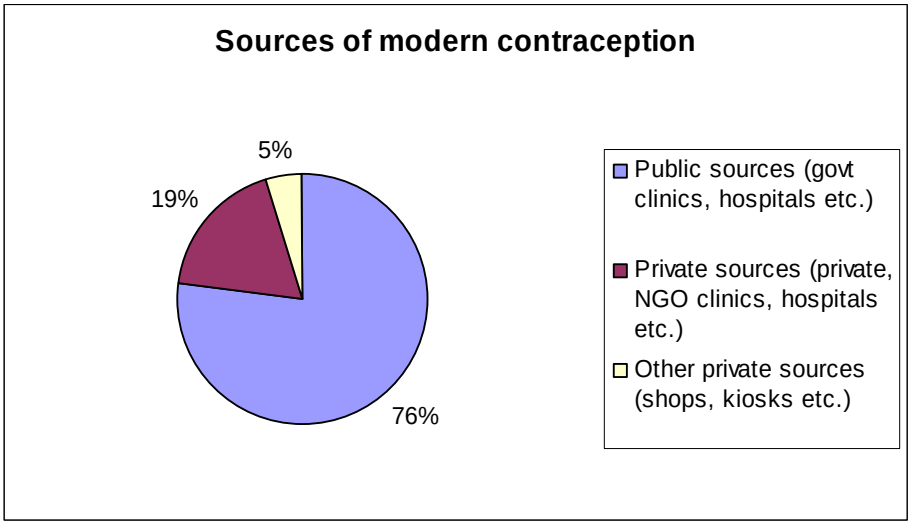


Public/private mix for family planning

The family planning market, however, is dominated by the public sector, with three-quarters of women getting contraception from public sources (see Figure 5.4.2). This is a very different picture from other personal expenditure on medicines. The government puts a reasonably high priority on its family planning programme.

[24] World Bank, 2001.

FIGURE 5.4.2



Source: PRB, 2002.

The private sector is also prominent in **Karnataka.** At the primary healthcare level, the private sector is heavily used, despite the vast public healthcare system network. The private sector is also quite significant at secondary and tertiary levels within the state. In 1992, the private sector provided 40,900 beds (56 percent) of the 72,740 beds in Karnataka. Eighty-three percent of private hospitals are owned by individuals. The remaining are owned by charities, religious missions, societies, limited companies and partnerships. Unqualified health practitioners constitute an important category of healthcare providers, including the performing of abortions and treatment of STIs, although no exact estimates are available. traditional birth attendants (TBAs) provide an important function in maternal healthcare in rural India, particularly where modern treatment facilities are not available. The National Health Policy (2002) recognises their role and has made provision for training through the panchayat raj system.[25]

Little information is available on **Delhi**, but the situation appears similar to that of Karnataka with private hospitals, untrained practitioners, and TBAs.[26]

5.5 KEY HEALTH INTERVENTIONS

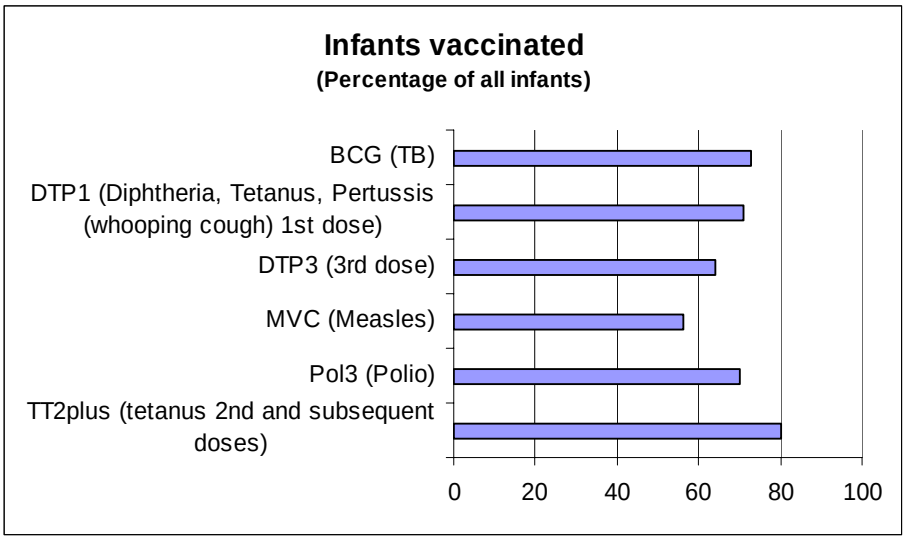
5.5.1 KEY VACCINES

In India, as a whole, only 42 percent of children are fully vaccinated. **Delhi** and **Karnataka** have better coverage, with rates of 70 percent and 60 percent, respectively.[27]

[25] NIDI, 2004.
[26] World Bank paper: India Private Health Services for the Poor, Ismail Radwan, May 2005.

As part of the National Health Policy, the National Immunisation Programme is being implemented on a priority basis and follows the Expanded Programme on Immunisation. Immunisation coverage is moderate - between 56 and 80 percent for the different vaccinations (see Figure 5.5.1).

FIGURE 5.5.1



Source: UNICEF, 2006. TT is administered to pregnant women.

5.5.2 CONTRACEPTIVE COVERAGE

Overall, contraceptive prevalence is 47.8 percent, with the vast majority using modern methods (see Table 5.5.2). Female sterilisation strongly dominates the contraceptive method mix, with over one-third of women overall and 80 percent of modern contraceptive users practising this method. (Male vasectomies are rare.) Women have children early in marriage and then stop: Eighty-two percent of sterilised women had not practised any other family planning method previously. This will make the negotiation of a microbicide more difficult. Women, on average, are sterilised at the age of 25 and after bearing three children.[28] These early sterilisations will have an impact on women's ability to negotiate condom use with their husbands, as there is no 'excuse' for using condoms other than for the prevention of STDs, implying that the man (or the woman) has been unfaithful. That will also have an impact on microbicide acceptability if positioned as a contraceptive.

[27] NFHS-2, 1999.
[28] NFHS-2, 1999.

TABLE 5.5.2 CONTRACEPTIVE METHOD MIX

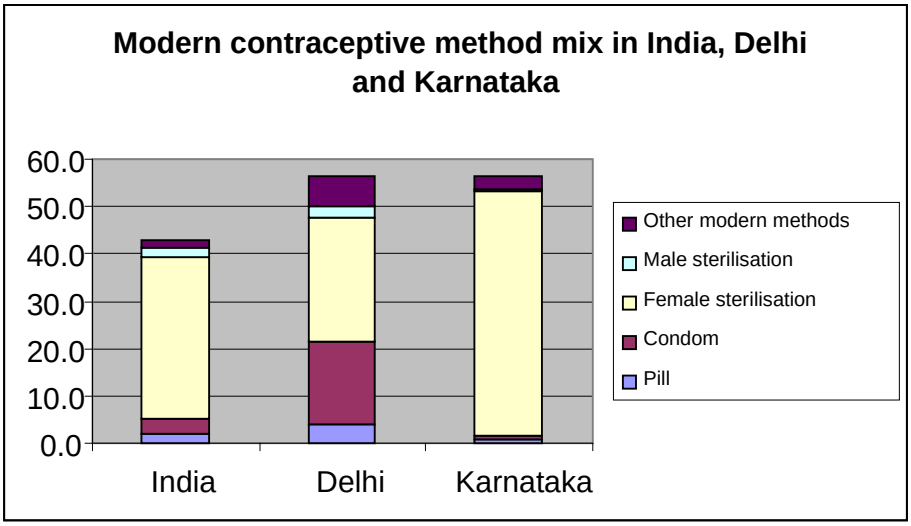
(Selected methods, married/in union women of reproductive age, 15-49)

Modern methods	Pill	2.1%
	Condom	3.1%
	Female sterilisation	34.2%
	Male sterilisation	1.9%
	Other modern methods	1.5%
	Total	**42.8%**
Traditional methods	**Total**	**5.0%**
No method	**Total**	**52.2%**

Source: PRB, 2002.

Contraceptive use in **Karnataka** and **Delhi** is higher than in India as a whole, with 56 percent using modern methods in each state (see Figure 5.5.2). The method mix varies significantly between the two states, however. In Karnataka, female sterilisation heavily dominates the method mix; in Delhi the mix is much more balanced, with the use of condoms much higher. It is not clear whether increased availability of services in Delhi accounts for this more balanced method mix or whether there are other factors.

FIGURE 5.5.2



Source: NFHS-2, 1999.

5.5.3 ESSENTIAL MEDICINES

India has the largest number of people, an estimated 649 million, without regular access to essential medicines, which is ironic given the size of India's pharmaceutical industry.[29] This is because of poor availability of drugs in the public health sector and poor affordability in the private system. There has been a progressive decline in the number of drugs under price control, and deregulation of drug prices has contributed to increasing costs of healthcare and pushing millions into debt. In 2003, a group of experts drafted the National List of Essential Medicines (354 in all), which could take care of most of the healthcare need of Indians. The Minister of Chemicals in July 2006 circulated a draft policy to the cabinet, which plans to regulate the prices of the 354 essential medicines in the National List.[30] The National List of Essential Medicines is available at http://cdsco.nic.in/nedl.pdf.

A recent assessment on accessibility of essential medicines in the state of Rajasthan found that the private sector has over 20,000 manufacturers producing more than 70,000 drug formulations, which are shipped through more than 12,000 distributors and retailers in Rajasthan. The National Drugs Policy has been responsible for the prolific growth of the private sector, albeit with significant concerns for quality, irrational drug use, and inappropriate sales and marketing activities. (Please note that Rajasthan has poorer wealth and health indicators than India as whole and this data cannot necessarily represent the situation in India). See box for further information.

[29] WHO's World Medicines Situation Report of 2004
[30] The Hindu, 17/10/06

Accessibility of Essential Medicines in Rajasthan

Geographic accessibility: Despite Rajasthan's vast infrastructure of public and private health facilities, residents in rural areas need to travel long distances, often spending a day or more to access a health facility.

Availability of medicines and information: In general, drugs are widely available, but essential generic drugs are neither widely available in pharmacies nor frequently prescribed—physicians and pharmacists promote the use of branded drugs. In addition, unbiased information on drugs is not available to health care professionals and consumers.

Affordability: Although drugs are generally less expensive in India than in most other countries, between 30 and 40 percent of the state's population is unable to afford drugs. The problem of affordability is exacerbated by wastage through irrational prescribing and dispensing. Groups that cannot afford drugs include a segment of the rural population such as farmers, slum residents, and individuals with chronic diseases, such as cancer, asthma, and diabetes.

Acceptability/satisfaction: There is low acceptability of generic drugs dispensed in the public sector—in general, patients consider generic drugs in the public sector to be of inferior quality and only use free or low-cost public-sector drugs if they cannot afford drugs in the private sector.

Quality of products and services: Assay results indicate that about 10 percent of samples collected by the MSH team have quality problems; however, as reported in the media, between 20 and 30 percent of the population believes that Indian drugs are of poor quality, spurious, or counterfeit. Few health care practitioners provide adequate information regarding drug use. The interaction between the dispenser (often not a pharmacist) and the consumer is limited to an exchange of goods for cash. There is little or no counselling regarding intake of drugs, their side effects, contraindications, and interactions. Few of the drugs are appropriately labelled, whether dispensed in a blister pack or in a small folded piece of paper.

Source: SEAM, 2003.

6 Regulatory Capacity

Nationwide market approval for new drugs is granted by the central drug authority, the Drug General Controller of India (DCGI), headed by Dr. M. Venkateswarulu since September 2006. The DCGI is the key official in the Central Drug Standard Control Organisation (CDSCO) and information on drug regulatory requirements can be found on the CDSCO website (www.cdsco.nic.in) (A chart at the end of this section shows the split between central

government and state government for the CDSCO). Regulations pertaining to requirements for import, manufacture and market approval for new drugs are governed by the Schedule Y, as per the Drugs and Cosmetics Act.[31] Although statutory power lies with the DCGI, the Indian Council of Medical Research (ICMR[32]) provides technical input and recommendations to the DCGI.

There is no control on prices charged for drugs, except for essential medicines, which are based upon the WHO list of essential medicines. Price control is under the authority of the Ministry of Petroleum and Chemicals and price control may be expanded from 74 to the entire list of 354 essential medicines. The authorisation to manufacture a drug is granted by the state, whereas market approval is nationwide.

Specific guidelines for microbicides are under development. ICMR has a network of institutions to conduct clinical trials, and an expert group on R&D of microbicides (Centre for Policy Research, Delhi; formerly of ICMR). It is important to involve and partner with ICMR early on so ICMR has some ownership of the project.

Quality assurance for the manufacture and sale of drugs is weak, although there are various national and state policies regulating these activities. The weak link is implementation and enforcement. States do not have sufficient human and financial resources to monitor the trade in pharmaceuticals.[33] According to a World Bank study (Govindaraj, 2000), 'quality assurance and control regulations [in India] are not properly enforced and need to be strengthened.' However, the requirements for medical products are much more stringent than for consumer products. The procedures for licensing a new drug in India are extremely complicated and negotiating these without an Indian pharmaceutical partner is not recommended (Crown Agents).

An Indian manufacturing partner is better placed to get through the complicated registration process. Therefore, a local sponsor, while technically not required, is almost indispensable. With assistance from an Indian company, timelines could be fast-tracked to within six to nine months (Crown Agents).

In India, there are three agencies involved either in consultancy or management of drugs and provide services extending from operational research to procurement, storage and distribution.

[31] http://cdsco.nic.in/html/GCP1.html
[32] Additional information on ICMR in Appendix A
[33] SEAM, 2003.

I. Tamil Nadu Medical Services Corporation Limited, an independent government agency. Address:417, II Floor, Pantheon Road, Egmore, Chennai - 600 008. Tel.: 91-44-28191890, 28190259, Fax: 91-44-28190636
E-mail: enquiry@tnmsc.com/ tnmsc@tn.nic.in www.tnhealth.org/ www.tnmsc.com

II. Delhi Society for Promotion Rational Use of Drugs, a NGO:
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Dr. Anand Prakash
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Tel.: 2396 7511

Drugs Control Administration

Functions undertaken by central government	Functions undertaken by state governments
Statutory functions	**Statutory functions**
Laying down standards of drugs, cosmetics, diagnostics and devices.	Licensing of drug manufacturing and sales establishments.
Laying down regulatory measures, amendments to acts and rules.	Licensing of drug testing laboratories.
To regulate market authorization of new drugs.	Approval of drug formulations for manufacture.
To regulate clinical research in India.	Monitoring of quality of drugs & cosmetics manufactured by respective state units and those marketed in the state.
To approve licences to manufacture certain categories of drugs as central licence approving authority i.e. for blood banks, large-volume parenterals and vaccines & sera.	Investigation and prosecution in respect of contravention of legal provisions.
To regulate the standards of imported drugs.	Administrative actions.
Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).	Pre- and post- licensing inspection.
Testing of drugs by central drugs labs.	Recall of sub-standard drugs.
Publication of Indian Pharmacopoeia.	
Other functions	
Coordinating the activities of the state drugs control organisations to achieve uniform administration of the Act, and policy guidance.	
Guidance on technical matters.	
Participation in the WHO GMP certification scheme.	
Monitoring adverse drug reactions (ADR).	
Conducting training programmes for regulatory officials & govt. analysts.	
Distribution of quotas of narcotic drugs for use in medicinal formulations.	

• Screening of drug formulations available in Indian market.	
• Evaluation/screening of applications for granting No Objection certificates for export of unapproved/banned drugs.	

When areas of responsibility fall into both central and state areas, the central body takes precedence. For further reference, visit: http://www.cdsco.nic.in/html/importdrugs.htm

7 Local Manufacturing Capacity[34]

At US$10 billion, India's pharmaceutical industry ranks fourth worldwide in volume of production and 13th in value. Twenty-two percent of the world's generic drugs and a significant proportion of the vaccines made for the developing world come from here. India is also one of the major suppliers of ARVs globally (84 percent of the ARVs used by Médecins sans Frontières in more than 30 countries are manufactured in India).

There are 300 companies of large and moderate size and approximately 5,000 smaller companies. As of 1999, the Indian pharmaceutical industry supplied 70 percent of the bulk drugs and 80 percent of the formulations consumed domestically, making India one of the few countries in the world achieving self-sufficiency in drugs. One-third of the production, or about US$3.5 billion, is exported, and export growth averages 25 percent per annum. India has the largest number of units approved by the Food and Drug Administration (FDA) outside the United States, numbering 65. One-half of the exports are to the US alone. Large exports also go to China, Brazil, Nigeria and Mexico.

Many pharmaceutical multinationals use India as a research base as it is cheaper than American or European sites. India's domestic industry is also increasingly focusing on R&D. In 2004, the 10 largest domestic firms spent over $170 million on R&D. This figure is expected to exceed $200 million by 2006. Ranbaxy Laboratories, for instance, expects to spend 10 percent of its revenue on R&D in the future. Such increases in R&D expenditure are beginning to produce results. For all Indian companies, drugs in Phase I and II of the R&D pipeline have more than tripled, going from five in 2003 to 16 in 2005.[35]

Until 2005, India only allowed patents on processes and set a seven-year expiration on patents. This was one of the reasons the Indian generic pharmaceutical market flourished and become a leading global player. In 1994, the Trade Related Aspects for Intellectual Property Rights (TRIPS) agreement was established with the World Trade Organization. It set the

[34] Crown Agents
[35] Grace, 2005

minimum standards for intellectual property protection that all WTO signatories had to implement. In 2005, India implemented the Patent Amendment Act in order to make its domestic legislation TRIPS-compliant. As India is a crucial worldwide manufacturer of ARVs, this could have implications for AIDS treatment.

Rather than taking on the impossible task of summarising Indian manufacturing capacity in a few paragraphs, Crown Agents has advised that teaming with some specific suggested firms would be by far the best option. Crown Agents would suggest Cipla, Ranbaxy or Hetero as potential firms for partnering, provided that they have the expertise required for specific microbicides products. They each have drugs registered in many countries worldwide and are already on the WHO/UN pre-qualified list. These companies could then do all the legwork on registering, licensing and distribution with India and could also fast-track. If any of these large firms are uninterested in working on microbicides, they may be able to provide suggestions as to the best smaller firms. This is important as there are many firms and some are not reputable.

All-India Small-Scale Pharmaceutical Manufacturers Association (Delhi)
Tel.: 91 11 2919140, 2918567

India Drug Manufacturers Association (Mumbai)
Tel.: 91 22 4974308, 4944624

Organisation of Pharmaceutical Producers of India (Mumbai)
Tel.: 91 22 2045509, 2044518

8 PROCUREMENT SYSTEMS [36]

India has a strong independent cadre of highly experienced procurement experts and the market is heavily biased towards Indian manufacturers. As all essential medicines are available within India, donors almost universally source their drugs within India, so there is little need for imports (although they do exist). Some specialty items are brought in by the large drug companies, if required. As previously mentioned, many ARVs are manufactured in India for worldwide export, so there would never be a reason to import ARVs into India.

8.1 PUBLIC PROCUREMENT

Public procurement is managed through a series of official tenders which appear on a Ministry of Health and Family Welfare website (www.mohfw.nic.in/tenders.html). It is usual practice to purchase the tender documents. The tenders are evaluated by a Tenders Board on the basis of price and compliance with the conditions of the tender. A two-envelope process for

[36] Crown Agents

procurement is the favoured method. Bidders must submit their bids in separate envelopes so the financial and technical bids are kept separate. A standard points system is then used to evaluate the technical bids, and companies not reaching the basic technical requirements are not considered. The financial bids are then assessed for value-for-money and the cheapest bids are not always the ones chosen. Inspection of any drugs entering India is required on arrival, with many delays slowing the system down.

8.2 Donor Procurement

Donor procurement is carried out in a variety of ways but is most often channelled through the MOH. Some donors contribute through the United Nations system or use a basket approach whereby many donors can contribute. For large donor projects, a locally staffed Project Management Unit is set up to manage the procurement. In some rare instances, a foreign firm is used (but they are usually in a consortium with Indian firms). Depending on the value of the goods, the tenders will be issued locally or internationally, evaluated and placed. This is typical of the way that World Bank tenders are managed (in addition to some Bank procurement guidelines) with many technical requirements built in. The World Bank is working to make tendering more transparent in India by introducing an e-tendering process. DFID might use a mix of these approaches, giving some funding directly through the government or through the UN or through one of their preferred private procurement agents.

In fact, DFID recently announced a programme from 2006-2011 supporting the Indian Reproductive and Child Health Programme (RCH II). As part of this, DFID will be putting in place new measures to clean up procurement 'irregularities' in the first programme phase. This will include setting new quality standards for products as well as strengthening tendering procedures and increasing the transparency of the purchase of both drugs and equipment. It is hoped that these new rules will reduce 'collusion' between suppliers and ensure more competition. (Currently, contracts over $200,000 are being handled by international procurement agents. This will stay the case until the Indian government has set the new systems in place.)

8.3 Not-for-profit/Mission

Not-for-profit or mission organisations tend to purchase locally and these purchases are usually quite small in scale. As supply arrangements in India are reasonably well organised, these smaller organisations can afford to purchase when required. Even consolidated procurement by a group of these organisations would tend to purchase locally.

8.4 Private Sector

Private-sector health providers would try to purchase Indian products, which is possible most of the time. Larger equipment such as MRIs or CTs might be tendered but would use the

Indian system to reach the offshore companies. All large drug companies have their own local agents with whom they work.

Prior to 1994, **Delhi's** procurement practices were characterised by constant supply shortages of essential medicines, erratic prescribing of expensive branded products, many poor quality drugs and unhappy consumers. Each hospital used to obtain its drugs independently.

In the late 1990s, the situation changed and WHO has since proclaimed the Delhi State Drug Policy to be an 'effective, transparent pooled procurement and distribution system…with good quality essential drugs procured at reasonable prices and…most available in the public sector,' WHO has also advocated the replication of this policy in other Indian states. The new Delhi drug policy aims at ensuring the availability of all essential drugs in city hospitals by procurement at competitive prices with safety and efficacy of the drugs ensured. Other states, including **Karnataka**, have begun to replicate the model.

An NGO called the Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD) worked closely with the government to develop this model and to implement various components of the policy. An essential drug list was compiled by a committee of multidisciplinary experts and contains 250 drugs for hospitals and 100 drugs for dispensaries. The list is revised every two years. A pooled procurement system has been estimated to save about 30 percent of the annual drugs bill for the Government of Delhi. The system in now in place in all state-run hospitals and 150 primary health centres in Delhi.

Dr. Ranjit Roy Choudhur, president of DSPRUD. is credited as the main architect of the system called the Delhi Model. DSPRUD has decided to compile the 'Delhi Model' into a book so that the model will be documented for other states to replicate. DSPRUD also has the participation of the universities and other government agencies.

What is good about the Delhi Model?

- Delhi has the majority of essential drugs available and most are generic.
- Pre-tender qualification criteria is set so only established manufacturers need apply.
- GMP inspections and random testing of products are conducted.
- There is a selective inspection of sources of supply with in-house test reports for each batch from approved laboratories.
- All activities are well documented.
- Treatment guidelines for each disease are provided to each institution ordering drugs.
- Credentials of manufacturers are thoroughly checked.

The Central Procurement Agency for Delhi, established by the Directorate of Health Services, carries out these regulations. **Karnataka** has begun to replicate the Delhi Model.

9 HIV PROGRAMMING

9.1 LEVEL OF POLITICAL COMMITMENT

There is strong political commitment, including on prevention. The following frameworks are in place:[37]

The National AIDS Control Organisation (NACO) was launched in 1987, under the chairmanship of the Union Ministry of Health and Family Welfare with representatives from various sectors.

NACO is headed by the Additional Secretary and Director General, who reports to the Health Secretary of the MOHFW. The decision-making power within NACO rests solely with the Additional Secretary and Director General, with funds flowing from NACO to the state level. States AIDS control societies (SACS) have been established to coordinate prevention programmes and work with the private (primarily NGO) sector. Their members represent various ministries in addition to Health. Each of the states has established a SACS (formerly state AIDS cells) and technical advisory committees. In some of the states, the SACS are supported by a state management agency or technical support unit to strengthen the initiatives. These additional units are generally funded by DFID. The National Council of AIDS, headed by the prime minister, provides oversight to the entire national programme.

Policies are defined at national level, with implementation at state level, with the goal of decentralising to state and district levels. HIV and reproductive and child health programmes are connected at the policy level but not at the implementation level and the goal is to coordinate NACP III and NRHM during implementation. A “link worker” will be the liaison between the SACS and Health and Family Welfare units. NGOs are selected at state levels through Technical Advisory Committees set up by the state AIDS control societies.

The National AIDS Control Programme (NACP) Phase I was set up in 1992 (1992-1999). Bilateral partners like USAID (Tamil Nadu), DFID (Andhra Pradesh, Gujarat, Kerala, Orissa and West Bengal) and CIDA (Karnataka and Rajasthan) implemented focused programmes and contributed to the state and national efforts.

NACP II (1999-2006) focused on a decentralised and comprehensive programme with 1) targeted interventions for high-risk groups and preventive interventions for the general

[37] WHO, 2005; NACO, 2005 & 2006, GFATM, 2004

community; and 2) capacity-strengthening through institutional strengthening, decentralisation and effective partnerships with civil society organisations:

- NGOs were involved in the implementation of 1,033 targeted interventions among HRGs, setting up 875 voluntary counselling and testing centres (VCTCs) and 679 STD clinics at the district level;
- The Prevention of Parent-to-Child transmission (PPTCT) Programme was expanded across the states;
- Nation-wide and state-level behaviour sentinel surveillance (BSS) surveys were conducted;
- The Computerised Management Information System and Project Financial Management System were introduced;
- Many organisations and networks were strengthened during this process and the support from bilateral, multilateral and other partner agencies increased substantially. Multiple grassroots NGOs have a major role in the fields of HIV and SRH; many are contracted by the GOI for targeted interventions.

HIV prevalence has started showing declining trends in Tamil Nadu, Andhra Pradesh, Karnataka, Maharashtra and Nagaland. However, government programmes have faced significant recruitment difficulties that have, along with inefficiencies and poor programme evaluation, impeded implementation in some areas.

NACP III (2006-2011), the third phase, is under preparation and comes into force in 2007. It plans to ultimately put prevention programmes for high-risk populations – sex workers and their clients, IDU and their partners and MSM – at the forefront and will provide a package of integrated VCT, PMTCT, treatment of STIs, and care and treatment of opportunistic infections at the primary level. It focuses on gaps under the two previous programmes, and on scaling-up and improving the quality of projects. Efforts to educate the general populations will be accomplished both through mass media and educational efforts, using existing structures such as RCH-II and NRHM. The process for developing NACP III has been acknowledged to be transparent and collaborative.

- Responsibilities will be decentralized, with SACS to delegate some direct execution tasks to districts, while continuing to implement in specific areas;
- Procurement will be handled either directly by the states that have the capacity, or nationally by NACO procurement agencies;
- Programme management will be overseen by the National AIDS Control Board, headed by the Secretary of Health.

In addition:

- The National AIDS Research Institute was established in 1992 to provide leadership in biomedical research on HIV/AIDS and complement and strengthen the NACP.[38]
- The National AIDS Prevention and Control Policy (2000), the National Population Policy (2000) and the National Health Policy (2002) all specifically address HIV/AIDS.
- A Parliamentarians AIDS Forum has been established and has enrolled 200 of the 542 MPs. It aims to reach out to elected representatives at state and panchayat (village) level for purposes of advocacy, social mobilisation, dissemination of accurate information and linking prevention, care and support interventions. It had eight state level counterparts by 2005, including in Delhi and Karnataka.
- An India HIV/AIDS bill has been drafted and included widespread consultation with civil society. It will be tabled for discussion in Parliament shortly.
- There is a youth parliament on HIV/AIDS.
- A National Council on AIDS was established in 2005 with the prime minister as chairman and senior ministries and civil society representatives as members; it constitutes the highest body overseeing the NACP. Its aims are to:
  - Mainstream HIV/AIDS into all ministries by considering it as a development challenge rather than merely a public health problem;
  - Lead the multisectoral national response with a special reference to youth and workforce; and
  - Review the intersectoral commitment.

"The National AIDS Control Programme must move out of the narrow confines of the Health Department and become an integral part of all government departments and programmes to create a national response which alone can help reverse the epidemic." Indian prime minister, World AIDS Day, December 2005.

There is a microbicide working group under ICMR leadership. In addition to its involvement in various microbicides activities, ICMR is also partnering with the Department of BioTechnology (DBT) to jointly develop three microbicide screening facilities in Delhi and Pune.

Delhi State AIDS Control Society (DSACS) became functional in 1998. It is headed by Dr. J. P. Kapoor - address: B.S. Ambedkar Hospital, 1st and 2nd Floor, Dharamsala Block, Rohini Sector-6, Delhi 10085; phone: (011) 2705660, 2705650, 27055725.

[38] Please refer to Appendix A for additional information on NARI

Karnataka State AIDS Prevention Society (KSAPS) was established in 1999, but a state AIDS cell had been in operation since 1992 and implementing Phase I of the NACP. Karnataka's Phase II programme has the following components:

- Targeted interventions with high-risk groups involving NGOs and condom promotion
- Strengthening STD clinics and information, education and communication (IEC) activities
- Establishment of VCT and PPTCT centres and blood safety
- Low-cost care and support and intersectoral collaboration
- School AIDS education programme.[39]

KSAPS is headed by Mrs. T. Mukthamba - address: No. 4/13-1, Crescent Road, High Grds Bangalore-560001; phone - 080-22201438; email - sacs_karnataka@nacoindia.org.

9.2 FUNDING FOR HIV/AIDS

International funding for HIV is increasing in India and donors have agreed to a strong country-led coordination of the HIV response at national and state levels. In addition to joint funding by donors, including the Global Fund, the scale-up of NACP will require important domestic resource mobilisation and most of the work is being done in collaboration with the GOI and NACO. NACP III cost is estimated to be US$2.5 billion.

In contrast to the general public health sector, NACP I and II have largely been funded by external assistance. The NACP, including the NACP Phase II and the related bilateral projects of USAID and DFID involves a total outlay of Rs.14,250 million (US$350 million). The World Bank NACP II accounts for Rs.11,550 million (approximately US$284 million), with 85 percent of this amount being provided as a low-interest World Bank loan and the rest being provided by the GOI.[40]

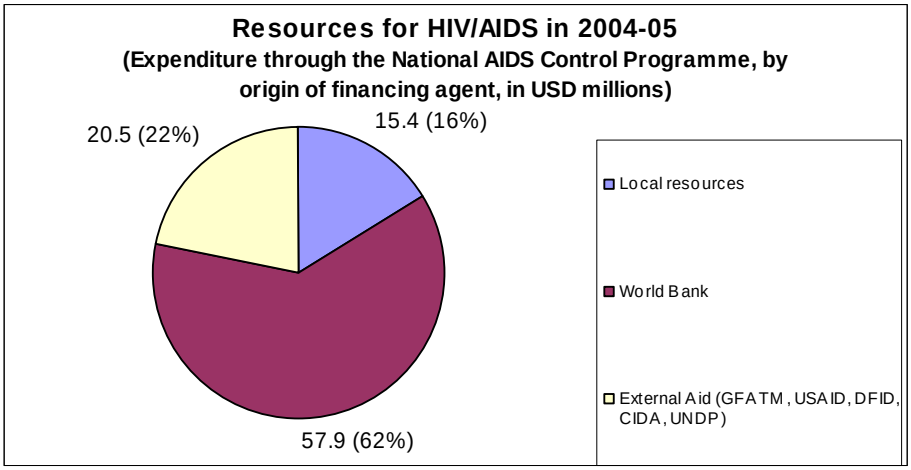
Total expenditure on the NACP in 2004-2005 was US$93.8 million, with the majority of funding from a World Bank loan and a much smaller proportion coming from external aid (see Figure 10.2). Bilateral donors such as USAID, CIDA and DFID have been involved since the early 1990s at the state level in a number of states. USAID has committed more than US$70 million since 1992, CIDA US$11 million and DFID close to US$200 million. NACP III cost may be as high as US$2.5 billion.

The number of major financers and the amount of funding available has increased significantly in the last year. Since 2004, the Gates Foundation has pledged US$258 million,

[39] NIDI, 2004.
[40] NACO

including US$23 million announced in October 2006, to help Indian health authorities train government health workers in HIV/AIDS prevention programmes, build capacity in public health infrastructure and fund groups that work with high-risk populations. The Global Fund has approved US$54 million for HIV/AIDS for projects in rounds two, three and four. DFID has also increased its financing and is considering the inclusion of additional states. Other more recent donors include DANIDA, SIDA, the Clinton Foundation and the European Union.[41]

FIGURE 10.2



Source: NACO, 2005.

However, this does not give the complete picture of HIV/AIDS funding in India. For one, it only includes funds budgeted under India's vertical HIV/AIDS programme. Other unquantifiable funding includes:

- Resources not channelled through NACO, for example technical support given to SACS or work independently with NGOs/CBOs.
- State governments' health budgets - additional funds are allocated for HIV/AIDS under state health budgets and some programmes, such as PPCTC and VCT, utilise infrastructure and personnel of the Health Department.
- State AIDS Control Societies – some SACS receive support directly from donors.
- Out-of-pocket spending – because private spending is over 80 percent, it is expected that the general public pays for a substantial part of the HIV/AIDS burden.[42]

Furthermore, the above breakdown of external funding does not take into account the fact that external funds are channelled through state governments as well as the central government – the majority of donors work with the GOI and support the NACP. There is no information available on state level funding on HIV/AIDS. It is known, however, that Karnataka

[41] UNAIDS
[42] NACO, 2005.

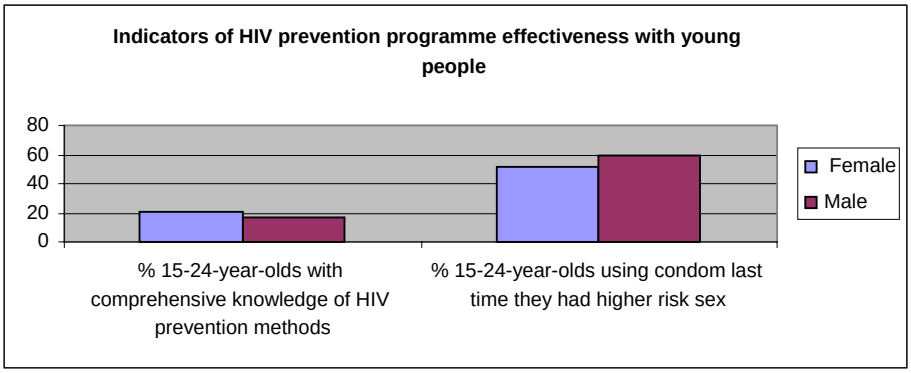
and Delhi have both made specific allocations to HIV/AIDS in their health budgets, in addition to SACS spending.[43]

9.3 Coverage of HIV/AIDS Interventions

Prevention coverage

Comprehensive knowledge of HIV prevention (being able to correctly identify condom use and limiting sex to one uninfected partner as major ways of preventing the sexual transmission of HIV, being able to correct two of the most common misconceptions about HIV and knowing that a healthy-looking person can transmit HIV) is fairly low, at 21 percent for young women and 17 percent for young men (see Figure 10.3.1). However, condom use with higher-risk sex seems to be much higher, indicating that safer-sex messages are getting through. Poverty is a huge barrier to HIV knowledge, reflecting the wealth inequalities and large number of marginalised and socially and economically excluded people in India (see Figure 10.3.2).

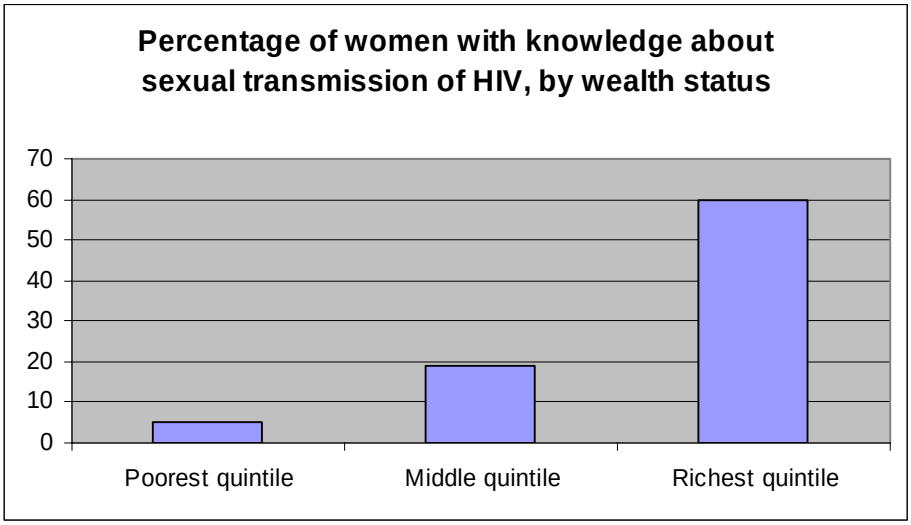
Figure 9.3.1



Source: WHO, 2005.

[43] Ibid.

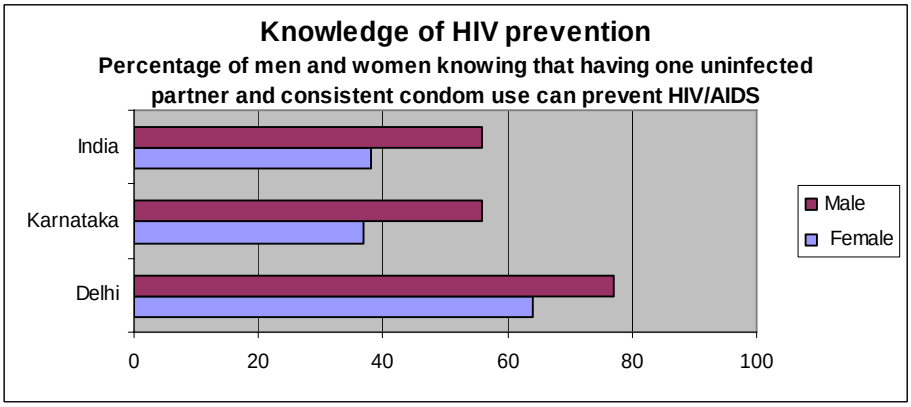
FIGURE 9.3.2



Source: PRB, 2004.

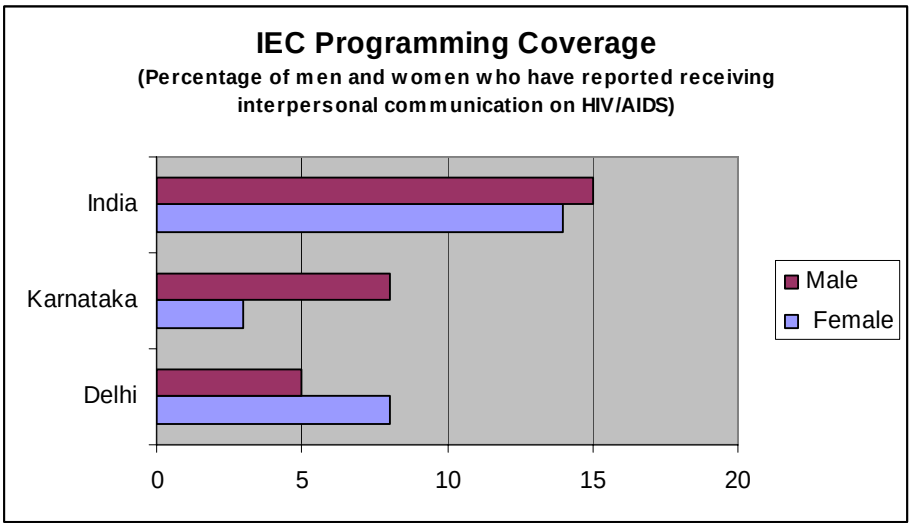
Knowledge of prevention is higher in **Delhi** and there is a smaller gender knowledge gap than India as a whole, suggesting higher prevention programming coverage, education and wealth status (see Figure 10.3.3). Knowledge of prevention in **Karnataka** is on par with the national average. However interpersonal communication on HIV is low in these two states (see Figure 10.3.4). This could reflect higher access to the media in these more urbanised states. It could also reflect more concentrated IEC programming with high-risk minority groups rather than the general population.

FIGURE 9.3.3



Source: BSS, 2001.

FIGURE 9.3.4



Source: BSS, 2001.

Care coverage

Care is difficult to measure, as most care takes place in the home. Often, this care is provided by NGOs/CBOs/FBOs, many of which keep poor records. The quality of care is also extremely difficult to measure.

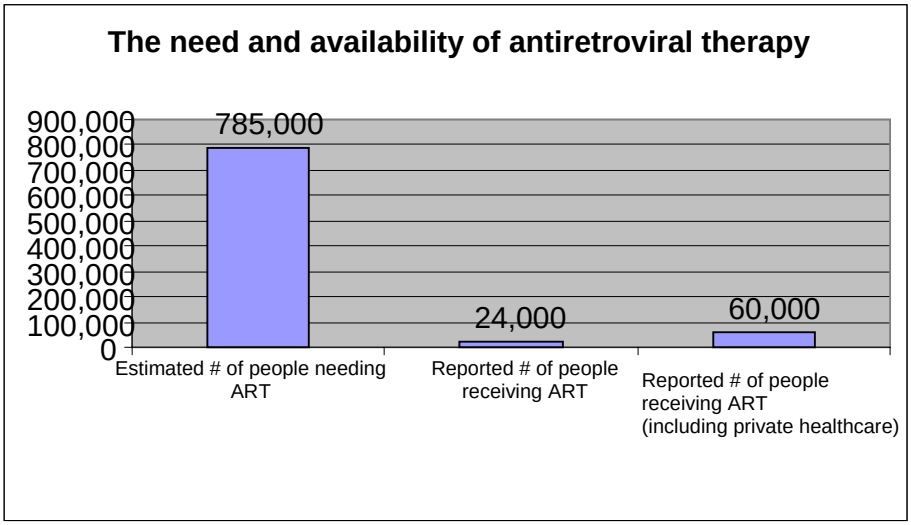
Treatment coverage

In November 2003 the government announced a commitment to provide free antiretroviral therapy to 100,000 people living with HIV/AIDS by 2007 , with implementation starting in April 2004. The main target subgroups of this programme are HIV-positive mothers who have participated in the PMTCT programmes, children under 15 and people with AIDS seeking treatment at the designated hospital.[44]

By the end of 2005, 24,000 people were receiving ART from 25 public facilities. With additional people receiving treatment through private (mostly fee-paying) sources, this takes the total receiving ART to 60,000 (see Figure 10.3.5). This only provides for eight percent of people in need, and only three percent receive government-funded treatment.

[44] WHO, 2005.

FIGURE 9.3.5



Source: WHO, 2005

Three of the 25 public ART centres are in **Delhi**.[45] In **Karnataka** there are four operational ART units in government hospitals, two in Bangalore, one in Mysore and one in Hubli.[46] There is an absence of state-level data on ART coverage.

9.4 SOCIAL MARKETING

The various components of social marketing include:

1. Distribution of contraceptives, condoms and other basic health products as oral re-hydration salts, iron-folic acid tablets, clean delivery kits, safe water systems, etc., via social marketing organisation (SMO) networks, health providers, chemists, retailers, NGOs, self-help groups, etc.;
2. Generic communication and information;
3. Provision of socially franchised health services.

Social marketing targets the underserved groups who have some ability to pay but can't afford to pay full commercial prices, especially in rural populations and urban slums. The socially marketed products complement the free products and services with the public sector; the products and education campaigns are heavily subsidised by the government and donors. Additional products, such as sanitary napkins, may complement the SMOs product range but are not subsidised. India started to socially market condoms in the 1960s via a private sector network; however the high costs and limited margins have been major barriers and the private

[45] DSACS, 2005.
[46] NIDI, 2004.

sector withdrew from that endeavour. In the 1980s, the GOI introduced an oral contraceptive pill and new brands of condoms along with education campaigns. SMOs then started to introduce their own brands along with the GOI's products. Communication campaigns funded by the government and other donors help promote the products for the purposes of family planning and increasingly for the purposes of STI and HIV prevention. Since 2001, USAID, DFID and the Gates Foundation have worked with SMOs to support communication with high-risk audiences in addition to community-based interventions supported by the GOI.[47]

To date, there are 15 social marketing programmes reported in India. Major brands include HLFPPT,[48] DKT International, PSI, Family Planning Association of India, Janani (DKT International affiliate), Management Sciences for Health. These SMOs generally have a specific and complementary geographic coverage.

Condom distribution

The Indian market is highly fragmented - there are over 200 brands sold and most of them are regional.

1.6 billion condoms were distributed in 2005

Free distribution	*Social marketing*	*Commercial sector*
900m units In PHC via the public system and NGOs	453 m units 3 GOI brands and SMO brands	248m units

Source HLFPPT

Generally, the GOI provides a subsidy per condom and donors fund the education programmes.

[47] PSI
[48] Please refer to Appendix 1 for additional information on HLFPPT

Some of the major socially marketed condoms in India include:

Organisation	Product	Details
Population Services International[49]	Deluxe Nirodh, Masti, Kamasutra – male condoms. Rishta – female condom.	Deluxe Nirodh, the government's brand launched 1988, is the leading brand, with 40% of the market share. Masti launched 1998, now sold in 22 states. Kamasutra, a premium condom brand launched 2000, sold in selected pockets of the country. Rishta launched 2005. PSI has since sold over one billion condoms
Family Health International (FHI)[50]		"aXess", a community-based social marketing (CBSM) project, has been piloted. Members of the target populations are trained and act as educators and distributors, earning commission on condoms sold.
DKT International[51]	Zaroor, XXX – male condoms	Zaroor – low-cost, mainstream. XXX – coloured, flavoured and studded condoms, marketed as international quality.

Social franchises

A number of social franchises are operating within the reproductive health field. They do not have a very significant impact today. However, they are increasing and may enlarge their service to primary health care. For instance, Janani has developed a network of private sector clinics in Bihar and Madhya Pradesh. Hindustan Latex Family Planning Promotion Trust (HLFPPT) is planning to expand its social franchises in paediatric and ob-gyn care and to open 25,000 beds in rural, semi-rural areas and urban slums.

Population Health Services operates a contraceptive social marketing programme in **Karnataka**. Some social marketing organisations are getting government subsidies for the distribution and promotion of condoms, oral contraceptives and IUDs in the state. HLFPPT benefits from a special grant for piloting innovative community-based social marketing and social franchising in four states, including Karnataka.[52]

[49] Ibid.
[50] UNAIDS, 2000.
[51] DKT, 2006.
[52] NIDI, 2004.

9.5 SCALE-UP PLANS

The government plans to provide free antiretroviral treatment to 100,000 Indians by 2007, 180,000 by 2010, and 200,000 by 2011. This is largely being funded by the Global Fund. However, that target has shifted from 2005 to 2007 and now 2008. In addition, there are a number of barriers, including a lack of enforcement of national ART programmes. NACP III is seen as an opportunity to implement the coordination principles of the "Three Ones." International funding for HIV is increasing in India and donors have agreed to a strong country-led coordination of the HIV response at national and state levels.

The Global Fund approved a grant of US$26.1 million over two years in Round 2, with a focus on PMTCT, implementing a comprehensive care package for mothers living with HIV/AIDS and their infants and partners and enhancing access to antiretroviral therapy through public-private partnerships.

India submitted a successful Round 3 proposal to the Global Fund to address HIV and TB co-infection, with a total five-year funding request of US$14.8 million and two-year approved grant funding of US$2.6 million.

India also submitted a successful Round 4 proposal to the Global Fund for US$140.8 million over five years. US$4.1 million has been granted to the Population Foundation of India for two years and another US$21.6 million to the Economic Affairs Division. Together, they focus on a large-scale, phased initiative on antiretroviral therapy access closely linked to expanded prevention and support and on increasing the engagement of the private sector and the civil society sector, including people living with HIV/AIDS. Component 1 (Population Foundation) supports strengthening the capacity of NGOs and networks of people living with HIV/AIDS in the six high-prevalence states (Maharashtra, Tamil Nadu, **Karnataka**, Andhra Pradesh, Nagaland and Manipur), including establishment of treatment and counselling centres and comprehensive care and support centres. Component 2 addresses scaling up antiretroviral therapy services in six high-prevalence states and **Delhi**, with a declared target of 51,000 people to receive antiretroviral therapy in the first two years through 120 centres, CD4 technology for 50 centres and training of health care workers. Over five years, the proposal's target is to have 137,000 people living with HIV/AIDS receiving antiretroviral therapy.[53] It plans to combine treatment scale-up with VCT, with a target of one million people being tested after five years, as well as IEC, condom social marketing and palliative care components. It also plans to carry out IEC programming in eight low-prevalence but highly vulnerable states.[54]

[53] WHO, 2005.
[54] GFATM, 2005.

9.6 Experience With Female Condoms

Two female condoms (FC) were approved for marketing in India in 1993: the FC of the Female Health Company (FHC) and a product from the Indian pharmaceutical company Dr. Reddy's.

FHC Reality FC

1993	Approval for marketing in India
1996	WHO approval
2002-04	Acceptability study in three states + one pilot, targeting CSW, MSM and HR couples Exclusive partnership between FHC and Hindustan Latex Limited; HLL to manufacture FC in India and distribute globally. Started social marketing of FC at Rs. 2/ unit
2006	Obtained NACO & MOHFW support to integrate FC into their programmes (in process 2004-06); 1m FC have been imported in India so far, procured by UNFPA
2006-07	Plans to socially market the FC to both HRG in six states and general population as a dual protection device in two states Programme integrated into NACP III and RCH-II 4. HLFPPT to distribute FC via NGOs & SACS @Rs.5/ unit – social marketing; 5. 2 programmes in West Bengal & Gujarat, free distribution
End 2007	Plan to introduce FC in the public sector in additional states; SACS to have funding in their budgets for FC Polyurethane FC, i.e. FC II, in development: CE Mark, under WHO review, approval in India planned in 2007; cost will be significantly less

Additional FC activities in India

Three studies are planned. (Additional information can be found at the websites provided.)

FC I vs. FC II: www.harmredux.org/HIVarticles/BeksinskaFemCondomRCTafr06.pdf

FC II vs. Reddy II (negative pressure)

http://www.path.org/files/gcfc2005/SUNITI_PATH_26Sep2005final.pdf

FC I vs. PATH women condom: www.path.org/files/EOL_22_2_may06.pdf

The following table includes the barriers encountered by female condoms and how they might be avoided for microbicides:

Barriers to FCs	***Recommendations for microbicides***
Multiple changes in leadership at MOHFW & NACO impeded access. Lacked policy to support FC	Communicate with a broad range of partners who can advocate within the GOI, getting NACO's support early on is key.
Government approval was long & difficult	A good Indian partner is key to facilitate government approval; Make the product in India and conduct trials in India.
Difficult to increase awareness and willingness to purchase with users; Successful in Sri Lanka with messaging around increase in men's pleasure	Identify specific women's groups, NGOs and health care providers to advocate and support; Spouses and friends influenced women more than doctors; Consent from male partner was necessary; Be prepared for a very long process.
Pricing: Rs.5 vs. male condoms free or < Rs.5	Evaluate ability and willingness to pay Free to Rs.5 for FC
Difficulty in enlarging market from CSW and MSM to general population	Model at small scale first to identify what works and what does not and always keep control of your market[55]
Stigma	Dual positioning is key in high-prevalence regions; communicate on pregnancy if not targeting sex workers
Inserting something into the vagina is a major barrier	Education will be key, very relevant for microbicides Extra lubrication was seen as a positive factor

Microbicides trials in India

Product	Phase	Site
PMPA (HPTN 059 n=200)	II	NARI, Pune - Ongoing
Cellulose sulphate (N=2574 I=?)	III	St. John's, Bangalore (og) - YRG CARE, Chennai
PRO2000 (n=?)	Safety	NARI, Pune - Complete
Praneem (n=100 x2)	I/II	NARI - Complete
Praneem (n=100)	II	NARI - Complete
Buffergel (n=38 I=?)	II	NARI -Complete

[55] An effort to expand the market from CSW to the general high-end population failed as the media made it impossible to dissociate the product from the image of the SW.

The cellulose sulphate clinical trial was just stopped in January 2007 as preliminary data were showing an increased risk of infection among women using the drug. While this is very disappointing for all microbicides research, the trial organisers felt strongly that it was best to halt the trial immediately.

10 Implications for a Future Microbicide

Two Indian consultants interviewed a range of key stakeholders, asking them what might have an impact or influence on future microbicide introduction. The following gives a summary of their views.

Delivery

Private sector delivery channels are essential. India has one of the most privatised health systems in the world and ensuring optimal coverage will require the participation of the private sector in addition to the public sector. Care must be taken, however, to ensure that quality standards are maintained.

Reproductive health delivery channels may be important. HIV stigma is very high in India and married women in monogamous relationships are unlikely to attend VCT or STD clinics. This poses an important marketing challenge for microbicides. Reproductive health programmes and family planning clinics should be considered as an avenue to reach women. Also, for rural women in high-risk regions who are increasingly becoming infected, family planning clinics might be their only interaction with the health system.

However, the limitations to outreach through family planning programmes should also be kept in mind. For one, India's epidemic is concentrated, and the general population is considered to be at risk only in certain states (6sixstates have prevalence over one per cent, four are in southern India and two in the northeast, where injecting drug use playing an important role in transmission). Furthermore, a large proportion of Indian women undergo sterilisation by the age of 25 and may stop visiting family planning clinics thereafter. Therefore, microbicide introduction through reproductive health programmes would have to be targeted geographically and separate programs may be needed to reach older women.

Social marketing is well established in India. A number of social marketing organisations distribute a variety of health products, including sexual and reproductive health (SRH) and HIV services, in rural, semi-rural and urban slum areas, and microbicides could be integrated into their product portfolios. The Government of India (GOI) subsidises socially marketed condoms and contraceptives and might consider a similar approach to microbicides.

Prescription vs. over-the-counter (OTC). It is a widespread practice in India for pharmacists to provide prescription drugs regardless of proper prescriptions. However, registering microbicides as OTC, if possible, will facilitate distribution in public clinics and NGO-operated programmes where prescriptions are more likely to be required.

Partner with relevant NGOs and programmes. India has a vibrant civil society with several NGOs active in HIV/AIDS and SRH. Many international organisations partner with local groups. For example, the Bill & Melinda Gates Foundation is working with 151 NGOs on an HIV prevention-focused programme. It may be possible to integrate microbicides into this network.

WOMEN

Understand price sensitivity and willingness to pay. For comparison, intrauterine devices (IUDs) sell for approximately Rs.50 (US$1) in the private sector. One social marketer speculated that women may be willing to spend Rs.20-25 (US$0.50)/ month on microbicides.

Vaginal products are a new concept. Women are not used to vaginal products in India but the limited data from microbicide studies conducted suggests that they may be acceptable.

Early sterilisation negates positioning of microbicides as contraceptives. Early sterilisation practised by many Indian women (as young as 25) makes negotiating condom (or a future microbicide) use difficult as the risk of pregnancy is no longer applicable. In addition, many women who choose early sterilisation have not previously practised any other method of family planning. This means they will not have visited a family planning clinic or had any practice negotiating health-seeking behaviour with their husbands. This warrants further research.

Envision positioning microbicides as a hygiene product. Sex is a taboo topic in India and stigma around HIV is a major issue. If microbicides are not explicit about HIV, then women may find negotiating use easier.

Train, counsel, and keep the concept simple. Based on past microbicide studies in the country, the concept of microbicides was found difficult to understand, particularly the notion of partial efficacy and using them as the last option if condoms cannot be negotiated. A principal investigator indicated that it takes up to two hours to explain the concept of microbicides to study participants. Adding to the complexity of the task is the fact that vaginal products are not common in India. This is particularly relevant because experience has shown that the willingness to use a product is very much linked to the first-use experience.

Female condom experience. One of the major lessons from the recent female condom introduction in India is to beware of too much focus on high-risk populations. If microbicides are only used by high-risk populations, it will be difficult to then try to market them to women in primary partnerships as they will carry the **stigma of being associated with high-risk groups.**

Male approval is likely to be necessary, although the best ways to gain male consent will require further study. In general, women's socio-economic status in India tends to very low, making the negotiation of safer sex challenging.

Take into account the potential of increased gender violence. Gender violence is widespread in India. Its implications for microbicide use must be researched further as women may need to get their male partner's approval before using a product. This has caused difficulties with the use of the female condom. A recent study by YRG Centre for AIDS (PATH, 2005) found that a request from a woman to use a female condom was seen by her partner as a reason to 'hit the woman'.

Further research is required on the complicated issues of AIDS stigma, male power, early sterilisation and the implications of these on the introduction of a future microbicide.

REGULATORY AND MANUFACTURING

Manufacture in India; partner with an Indian manufacturer. India has several world-class pharmaceutical manufacturers that could be potential production partners. A survey and evaluation of potential Indian manufacturing and distribution partners is warranted. Having someone who knows the regulatory system will save considerable time, as getting approvals can be a complex and lengthy process.

ADVOCACY

The **Global Campaign for Microbicides** has been working with Indian partners since 2001. This has involved participation in many conferences and workshops to raise awareness and advocate for more prevention options for Indian women. This work included a national stakeholders meeting in 2003, which yielded several recommendations to form a multisectoral working group. **PATH India** is also active on microbicide advocacy and has convened a national microbicides steering group.

Partner with the Microbicides 2008 conference. The 2008 Microbicides meeting will be held in Delhi in February 2008 and is an excellent opportunity to increase awareness within government, among Indian scientists, health care providers and with user groups.

Women as microbicides champions. There are various prominent women in the medical, scientific, policy and NGO fields as well as high-profile personalities from the film and business communities who could make strong microbicide advocates.

Conduct a large-scale advocacy programme to reach women's and gender groups. Women have a very low standing in India and lack empowerment and HIV awareness. They may be reached through women's groups and self-help groups. There is more research required on the nuanced treatment of a microbicide introduction and the attitude of women's groups. For example, there is some history of mistrust among women in India regarding the introduction of new reproductive health technologies, following concerns raised over the approval of injectable contraceptives in the mid-1980s and early 1990s.

STAKEHOLDERS

Build a relationship with NACO. There is strong donor support for HIV prevention in India and it is aligned with the GOI. NACO support for microbicides will be essential. NACO and the GOI are the decision-makers who can introduce microbicides into existing programmes as well as subsidise them via social marketing. However, considerable decision-making is also decentralised to the state level (and a number of donors, such as DFID, work directly with states).

Understand variances between states. The political environment and the prevalence of HIV/AIDS vary from state to state, and some will be more favourable to microbicides than others. **It is important to engage the state AIDS control societies (SACS)**. Given the enormous size of India, introduction in targeted states will be necessary, with national roll-out requiring considerable time.

Build a relationship with the Indian Council of Medical Research (ICMR) and empower an ICMR champion**.** ICMR's role is key and ICMR representatives are sensitised to microbicides and interested in partnering with various international organisations. The M2008 conference provides an opportunity to strengthen these links.

Develop cross-party advocacy at national, state and, if possible, district levels. Governments are often coalition-based and as a result there is a high turnover in government officials at every level. It is therefore important not to be dependant upon one person or one group.

Use accredited social health activists (ASHAs) as microbicides advocates in rural areas. ASHAs will be involved with multiple SRH issues and activities in communities. Also engage auxiliary nurses, midwives and community workers.

Understand village self-government committees (panchayati raj) needs. These are predominantly male committees (although a quota for women ensures some female participation). Their agendas may be far removed from health but it might be possible to use this channel to introduce microbicides, particularly in high-risk regions.

Gain early support from doctors. Doctors are highly respected and consumers trust their recommendations, often not seeking independent information. Because of this, doctors must be educated about microbicides early on, as any scepticism they exhibit about microbicides could be detrimental. Medical associations could play an important role. The Federation of Obstetrics and Gynaecologists of India is one place to start. This is important also at lower levels, with auxiliary nurses and midwives.

Informal medical practitioners provide an important portion of health care. Hence, they are a key point of entry to the health system for many. Consider them in any strategy.

Test communication materials with different **partners at all levels.** This is key to ensuring that the materials are appropriate to the local diversity and sensitivities.

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ANNEX I - SUMMARY INSTITUTIONAL MAPPING

HIV/AIDS AND SEXUAL REPRODUCTIVE HEALTH

This section includes summary information on main programmes and activities for key agencies working in HIV/AIDS and SRH in India.

More than 1,000 NGOs are involved in prevention, care and support programmes throughout India. This list is, of necessity, the tip of the iceberg.

ANNEX 1 – TABLE 1

KEY AGENCIES WORKING IN HIV/AIDS AND SEXUAL REPRODUCTIVE HEALTH IN INDIA

Organisation **Names and contacts**	**Responsibilities/activities**
Government Agencies	
NACO, Director-General Ms. Sujatha Rao http://www.nacoonline.org/index.htm	Under MOHFW, coordinates prevention, care and treatment activities relating to HIV/AIDS, particularly health service aspect, procurement etc. National M&E. Supported by state AIDS control societies.
ICMR[56] Director General Dr. N.K. Ganguly http://www.icmr.nic.in/	Under MOHFW, conducts research in clinical and bio-medical issues based on the health priorities of the country; funded by the GOI through the MOHFW.
NARI[57] Director Dr. R.S. Paranjape http://www.icmr.nic.in/pinstitute/nari.htm	One of the 21 ICMR institutions. Provides leadership in biomedical research on HIV/AIDS. Aims to complement the NACP. Multidisciplinary team of scientists.
National Institute for Research in Reproductive Health (NIRRH) Director Dr. C.P. Puri http://www.icmr.nic.in/pinstitute/irr.htm	An ICMR Institution involved with microbicides research and development.
MOHFW Minister for HFW Dr. Anbumani Ramadoss http://mohfw.nic.in/welcome.html	Encompasses departments of 1. Health, 2. Family Welfare and 3. AYUSH; as well as NACO and CDSCO. There are state ministries of HFW

[56] Please refer to Annex 2 for more information
[57] Please refer to Annex 2 for more information

Organisation Names and contacts	Responsibilities/activities
	Secretary of Health: Sh. Prasanna Hota.
Central Drugs Standard Control Organisation (CDSCO) http://cdsco.nic.in/index.html	Under the Directorate General of Health Services, MOHFW Dr. M. Venkateswarlu is the Drugs Controller General of India (DCGI) and grants approval for new drugs clinical trials and marketing.
Department of Family Welfare (within MOHFW)	Condom promotion through free and social marketing, STI treatment, family planning.
National Council on AIDS	Leads the multisectoral response on HIV/AIDS.
Ministry of Human Resource Development	Effect HIV mainstreaming in Department of Education and Woman and Child Development.
Department of Education	Manages the School AIDS Education Programme (SAEP), reaching 60,533 schools in 2004-5.
Department of Woman and Child Development	Integrating HIV into development and empowerment programmes for women, looking at cross-ministerial development of HIV/AIDS related gender policies.
Ministry of Social Justice and Empowerment	Integrating HIV/AIDS into drug detoxification programme. Integrating HIV into OVC and street children programmes is planned.
Ministry of Rural Development	Mainstreaming prevention into two national programmes including youth and self-help groups.
Department of Youth Affairs and Sports	Several youth HIV/AIDS prevention programmes in universities, volunteer schemes etc.
Ministry of Information and Broadcasting	Incorporates HIV/AIDS messages into several TV and radio programmes.
DONORS	
DFID[58] Dr. Billy Stewart – Senior Advisor (Health) Anne Philpott (from Sept. 07) http://www.dfidindia.org/about/broch.pdf	Strategically focused assistance to GOI for poverty eradication, and close partnership with four states of AP, MP, Orissa and West Bengal. In HIV, targeted interventions in Andhra Pradesh, Gujarat, Kerala and Orissa, sexual health project in West Bengal, intervention and capacity building in Uttar Pradesh and Bihar.
Bill and Melinda Gates	$200 million committed to prevent the spread of HIV in

[58] Please refer to Annex 2 for addition information on DFID and the Resource Centre for Sexual Health and HIV/AIDS (RCSHA)

Organisation Names and contacts	Responsibilities/activities
Foundation Director Avahan: Ashok Alexander	India, through its India AIDS initiative, Avahan, targeting CSWs, IDUs and mobile populations in the six high-prevalence states. Additional $23 million committed to enhance the capacity of the GOI's HIV prevention response.
USAID George Deikun, Mission Director, USAID India Robert Clay, Director, Office of Population, Health and Nutrition http://www.usaid.gov/in/	Involved with HIV prevention and care since early 1990s via various programs, i.e. Tamil Nadu AIDS prevention and control programme (IEC, STIs) (through Voluntary Health Services), prevention and care services in Maharashtra (through AVERT), prevention programmes in Delhi and Andra Pradesh
US-CDC	Focuses on strengthening ART centres, health systems, laboratory control, decentralisation of HIV services, training of healthcare providers in Tamil Nadu and Andhra Pradesh
William J. Clinton Foundation	Training private practitioners to manage HIV and OI, supporting NACO to train 15,000 doctors, strengthening treatment agenda with stakeholders, negotiating drug prices
CIDA	India-Canada Collaborative AIDS Project, targeting prevention, health systems strengthening, especially care and treatment, in Karnataka and Rajasthan
AusAID	Prevention and care projects for IDUs in four northeastern states
European Commission Frederika Meijer, Advisor Health sector/gender	Supports and funds programs in both SRH and HIV
GTZ Country director Dr. Rolf Suelzer http://www.gtz.de/en/weltweit/asien-pazifik/607.htm	
Ford Foundation 55 Lodi Estate New Delhi 110 003, India tel. 91-11-2461-9441 fax 91-11-2462-7147 ford-delhi@fordfound.org	Supports Global Campaign for Microbicides in India. Supports other HIV and SRH programmes.

Organisation Names and contacts	Responsibilities/activities
MacArthur Foundation Zone VA, 1st Floor, India Habitat Centre, Lodi Road, New Delhi 110 003 Tel: 011-24644006 Fax: 011-24644007 info@macfound.org.in	Supports maternal mortality and ASRH programmes at national level and in the states of Rajasthan, Maharashtra and Gujarat.
MULTILATERAL AGENCIES	
World Bank Country Director Michael F. Carter	Funding for HIV/AIDS response Dr. Sunita Singh: HIV programmes Dr. Ramana: Populations / SRH programmes
UNAIDS Dr. Denis Broun, Country Coordinator	Technical support to NACO, including establishment of an inter-ministerial task force on AIDS and the launch of antiretroviral therapy in public sector hospitals. UNAIDS is encouraging greater mainstreaming of AIDS in the operations of key ministries and supporting a participatory process to formulate national AIDS legislation.
UNDP	Supporting enabling environments and Greater Involvement for People Living with HIV/AIDS (GIPA)
UNICEF	$400 million programme from 2003 to 2007, support to GOI for PMTCT, technical support.
WHO Dr. Salim J. Habayeb - Representative, wrindia@whoindia.org	Supports the development of national plans concerning HIV, the “three ones” initiative, developing technical guidelines (e.g. health worker training), strengthening the state AIDS control societies, decentralising HIV services, M&E, drug procurement and supply
UNFPA Mr. François M. Farah – Representative, India@unfpa.org.in	

Organisation Names and contacts	Responsibilities/activities
NGOs	
YRG-Care[59] Dr. Suniti Solomon	Extensive experience in clinical trials and community-based research is internationally recognised. Involved in HIV vaccine and microbicides trials
Indian Network of NGOs Dr. Radium Bhattacharya http://www.innhivaids.org/	Registered national network of NGOs working on HIV/AIDS, exchanging ideas, strategies and approaches; access to grassroots NGOs.
Naz Foundation Dr. Anjali Gopalan http://www.nazindia.org/	Working on HIV/AIDS and SRH since 1994, on prevention and treatment, responding to issues around HIV/AIDS that have been ignored, denied or inadequately addressed.
Confederation of Indian Industries Shri Anand Mahendra – President, dilip.chenoy@ciionline.org	Support to develop workplace interventions and strengthen public-private partnerships.
Population Fund of India	NGO consortium that manages major sub-grants to community-level NGOs.
FHI Country Director Kathleen Kay http://www.fhi.org/en/HIVAIDS/country/India/index.htm	Work to avert major HIV/AIDS epidemic in India.
HIV Alliance India http://www.aidsalliance.org/sw7224.asp	Established in India in 1999; provides technical, programmatic and financial support to four lead partner organisations and 65 implementing NGOs in the states of Delhi, Andhra Pradesh and Tamil Nadu.
Saathi http://www.saathii.org/	Objectives: • To mobilise increased attention and political commitment on HIV/AIDS. • To bring people from multiple sectors together and foster collaborations. • To bridge knowledge gaps. • To strengthen and expand HIV/AIDS services in India.

[59] Please refer to Annex 2 for additional information on YRG-Care

Organisation Names and contacts	Responsibilities/activities
Indian Network for People Living with HIV/AIDS (INP+) Shri K. K. Abraham – President, inpplus@vsnl.com	Informs Policy, provides care and support to PLHA, ART referral, peer counselling, psychosocial support to family members, address issues of stigma and discrimination.
National Spiritual Assembly of Bahai (NSAB)	Implementing adolescent skill-building programme that includes HIV/AIDS in Delhi
Christian AIDS Network Alliance	Network of Christian organisations working on HIV prevention
Family Planning Association of India www.fpaindia.com	Disseminates information on population policies, educates people on RH, family planning and sexuality. Represented on all key policy-making bodies of the government. Through its recently formed National Network of NGOs, the FPAI provides aid to over 2,000 rural and urban NGOs. Technical and financial assistance is provided to 19 small NGOs to undertake family planning projects.
National Council of Churches in India	Apex organisation of Protestant and Orthodox church, HIV prevention. Its health arm Christian Medical Association in India (CMAI) has 350 institutional members that provide antenatal clinic services, detoxification centres, HBC and sexual health education in schools
PSI	Social marketing of condoms and other contraceptives, VCT services, IEC community activities
SAHARA – Centre for Residential Care and Rehabilitation Mr. Neville Selhore – Director, sahara@nde.vsnl.net.in	
Vivekananda Education Society Shri C. G. Chandra – Secretary, Chandra@cal.vsnl.net.in	

Source: GFATM, 2004; WHO, 2005; NACO, 2005.

ANNEX 1 – TABLE 2

KEY AGENCIES WORKING IN HIV AND SEXUAL AND REPRODUCTIVE HEALTH IN DELHI

	Organisation	Responsibilities/activities	Names and contacts
Government agencies	Delhi State AIDS Control Society	Implementation of the National AIDS Control Programme in the state	Sacs_delhi@nacoindia.org
Donors			
Multilateral agencies	World Bank	Funds India Population Project	
NGOs			

Source: DSACS, 2005.

ANNEX 1 – TABLE 3

KEY AGENCIES WORKING IN HIV AND SEXUAL AND REPRODUCTIVE HEALTH IN KARNATAKA

	Organisation	Responsibilities/activities
Government Agencies	Karnataka State AIDS Prevention Society (KSAPS)	Implementation of the National AIDS Control Programme in the state.
Donors	CIDA	Funds the ICHAP project (see below under NGOs).
	KfW (Germany)	Upgrading of 47 hospitals, developing infrastructure, referral systems.
Multilateral agencies	UNICEF	Maternal and child health care in four districts.
	World Bank	The key development partner in RH for the State since 1990s. Projects have increasing loan components and conditionality. Projects mostly implemented as stand-alone projects with little interaction at strategy level. India Population Project is a major one.
NGOs	India-Canada Collaborative HIV/AIDS Project (ICHAP)	CIDA-funded and government-partnered prevention and care demonstration projects in two districts, technical support to other NGOs.
	Karnataka Health Promotion Trust	Partnership between state government and University of Manitoba in Canada, conducts HIV prevention projects in 16 districts with

		NGO partners.
	Family Planning Association of India (FPAI)	IPPF affiliate. FPAI has 12 branches in the state that manage different types of service outlets, including RH/FP centres, urban family welfare centres, health centres, fertility clinics, male clinics and sex education, counselling and research centres.
	Bangalore Oniyavara Seva Coota (BOSCO)	Provides free medical support to PLHA from deprived sections of community in Bangalore.
	Community Health and Family Planning Centre (CHFPC)	FP and maternal health services provision and awareness in Haveri.
	Odanadi Seva Trust	HIV/AIDS awareness programmes and research activities in Mysore.

Source: NIDI, 2004.

KSAPS partners with 32 NGOs who work with high-risk groups in the state (migrant workers, truckers, CSWs, street children, PLWHA, transsexual and MSM) for targeted interventions.

Eight low-cost AIDS care and support centres are being run as a partnership between KSAPS and the following NGOs:

1. Freedom Foundation, Bangalore
2. Freedom Foundation, Udupi
3. Freedom Foundation, Bellary
4. Snehadaan, Bangalore
5. Snehasadan, Mangalore
6. ACCEPT, Bangalore
7. Samuha-Samraksha, Kustagi[60]
8. Moolika Samvrudhi Arogyabivrudhi Pratisthana, Shimoga

SEE ANNEX 2 FOR ADDITIONAL INFORMATION ON THE FOLLOWING ORGANISATIONS:

1. Indian Council of Medical Research (ICMR)
2. National AIDS Research Institute (NARI)
3. Hindustan Latex Family Planning Promotion Trust (HLFPPT)
4. Resource Centre for Sexual Health and HIV/AIDS (RCSHA)
5. YR Gaitonde Centre for AIDS research and education (YRG CARE)

[60] NIDI, 2004.

ANNEX 2: ADDITIONAL DETAIL ON A FEW KEY ORGANISATIONS

Indian Council of Medical Research (ICMR)

ICMR is the Government of India's apex body for biomedical research, under the Ministry of Health and Family Welfare. It conducts research in clinical and bio-medical issues based on the health priorities of the country, with a view to reduce the burden of the disease and promote the well being of the population.

ICMR has a **governing body**, presided by the union health minister, and is assisted in technical matters by the Scientific Advisory Board, which has scientific advisory groups, task forces, expert groups, steering committees to monitor different research activities.

There are 21 **permanent research centres** located in different parts of the country for conducting research activities. The Tuberculosis Research Centre and the National Institute of Epidemiology are located in Chennai; the National Institute of Malaria Research, the Institute of Pathology, the National Institute of Medical Statistics are in Delhi; the Food and Drug Toxicology Research Centre is in Hyderabad; the National Institute for Research in Reproductive Health, the Institute of Immunology and the Genetic Research Centre are in Mumbai; and the National Institute of Virology and National AIDS Research Institute are at Pune in Maharashtra.

In addition there are six medical research centres to address regional health problems and also build research capabilities in different geographic areas of the country. One of the regional centres is located in Belgaum, Karnataka.

National AIDS Research Institute (NARI) - NARI is an ICMR institute established in 1992 to provide leadership in biomedical research in HIV/AIDS in India in order to complement and strengthen NACO programme in India.

NARI conducts basic behavioural, social science and clinical research in HIV/AIDS. It has isolated strains of HIV-1 and HIV-2; is actively involved in AIDS vaccine research; incidence rates of HIV; TB and HIV; clinical trials for drug regimens appropriate for resource-limited settings etc. Another main prevention research area is that of vaginal microbicides. An Indian microbicide preparation, Praneem, has entered Phase I trial.

Some relevant key research activities are mentioned below:

1. Comparative Research Study of the FHC Female Condom and version 4 of the Reddy Female Condom

2. Epidemiology and Intervention Studies (National AIDS Research Institute Annual Report 2003-04)

Among the ongoing studies, enrolment in the HIV Incidence and Participant Retention Protocol [HPTN 034 Study] was continued and by March 2004, 365 HIV-negative women and 381 HIV-sero-discordant couples were enrolled in the study. Quarterly retention was 53-74 percent and 88-95 percent in women's cohort and sero-discordant cohorts respectively. Barriers to retention among high-risk women were identified and these included inability to inform the husband or family members, undue suspicion arising out of repeated clinic visits, lack of time due to household and family responsibilities, not remembering the dates and lack of community acceptance for couples frequently going together.

3. Two Phase I vaginal microbicides studies were initiated during this year. The primary objectives of the studies of PRO2000/5 Gel (P) and the Praneem polyherbal tablet were to assess safety on the vulvar and cervico-vaginal mucosa of sexually active HIV-uninfected women in Pune, India following twice-daily use for 14 consecutive days. The secondary objectives included assessment of acceptability in women and their male partners, adherence to a short-term regimen, effects on vaginal micro flora and feasibility of enrolling and retaining large number of women in a future Phase III vaginal microbicide trial. The study of PRO2000/5 Gel (P) was initiated on 25 July 2003. The study of Praneem polyherbal formulation (vaginal tablet) included a high-risk cohort of HIV-negative commercial sex workers (cohort B) in addition to HIV-negative low-risk women cohort (cohort A). The in-built Phase I component, involving women at low risk of HIV-infection, was expected to be completed by February 2004.

4. In a major initiative, in preparation for the Phase I HIV-1 C MVA vaccine trial [NARI-IAVI-NACO study] community work plan was developed.

HLFPPT – Hindustan Latex Family Planning Promotion Trust

HLFPPT is a trust set up by HLL (Hindustan Latex Limited) in 1992. HLL works at manufacturing and marketing a range of contraceptives and health care products, especially in remote villages, and makes available SRH services to vulnerable sections of society. It is one of the few organisations with a nationwide presence, an Indian company managing social marketing of contraceptives products in India.

Some of the programmes it is involved in are:

1. **Condom Access-Building Programme under AIDS Prevention and Control Project (APAC):** This is a USAID-funded project. The project looked into the condom distribution and logistics management in Tamil Nadu (one of the southern

states in India), increased the accessibility of contraceptives and broad=based the distribution channels by including the non-conventional outlets.

2. **Partnership for Sexual Health Project in Andhra Pradesh**: A tripartite contract between APSACS, DFIDI and HLFPPT for setting-up a state management agency for TI intervention project in the state of Andhra Pradesh. They provided technical support for these interventions.
3. **Chota Sansar Project in Uttar Pradesh**: Rural marketing of condoms in UP. Funded by the USAID-SIFPSA (State Innovations in Family Planning Services Agency)- Rs.42.2 million and duration from 1997-2000.
4. **Operations Research - Female Condom Acceptability Research India**: Conducted along with Female Condom Health Company (FHC), UK a three-month study in the three high-prevalence states (AP, Maharashtra and Kerala) among three sets of target groups (MSM, SW and married couples) through NGOs in these states and with support from SACS. The sexual behaviour and usage pattern was studied in the target audience. Encouraging response to FC from the target audience. One of the essential lessons learned: "It is necessary to integrate the FC into existing reproductive health programmes such as community-based distribution of contraceptives, STI clinics services, FP clinic services, HIV/AIDS/STI prevention programmes with vulnerable populations, adolescent and reproductive health programmes, social marketing, etc."
5. **Vanitha clinics – a social franchising model**: This is a network of HLFPPT-owned RCH clinics delivering affordable quality health services to lower- and lower-middle-class families with special focus on rural areas. Range of services offered through these clinics is: IUD insertion, FP counselling, dispensing of condoms, oral contraceptives pills, iron and folic acid tablets. Service points are: government hospitals (antenatal clinics, postnatal wards), slum areas (door–to-door counselling); factory workers, SHGs, etc.

Resource Centre for Sexual Health and HIV/AIDS (RCSHA)

RCSHA has been set up by the Department for International Development (DFID), as a resource centre to strengthen the national capacity to respond effectively to sexual health concerns, including HIV/AIDS prevention, care and treatment in India. The key role of RCSHA is to help NACO and AIDS control societies to deliver effective and informed sexual health programmes by providing the necessary technical assistance and capacities.

To achieve this, RCSHA works with and through a large number of organisations, institutions and individual consultants who become accessible resources for the state and national planning and implementation bodies.

RCSHA is funded by Department of International Development (DFID) India and managed by AC Nielsen ORG Centre for Social Research (a division of A C Nielsen ORG-MARG Pvt. Ltd.), Partners in Development Initiatives (PDI) and OPTIONS, UK.

The broad approaches of its functioning are:

1. To use the many ways that are needed to become a resource to strengthen the national response to the HIV/AIDS epidemic.
2. To act as a catalyst and facilitator to strengthen and build capacities within the country.
3. To create sustainable systems for capacity-building that can continue beyond the existence of the RCSHA.
4. To examine the particular nature of the epidemic in India and ensure that the response is epidemiologically and culturally appropriate, acceptable and timely.
5. To promote the use of evidence as a basis for decision-making.

RCSHA believes firmly in the values of participation, transparency and accountability. In addition, its systems and thinking promote flexibility. It has steadily built up a reputation of its own by supporting a wide range of national and state-level activities of its partners. Although not an exclusive list, these are broadly divided into:

1. Workshops and conferences
2. Research
3. Knowledge management
4. Guidelines, manuals and training programmes
5. Strategic planning
6. Partnership strengthening

Under the 'knowledge management' subsection, various research activities are carried out to build the evidence base for taking appropriate decisions and activities to support the National Programme on HIV/AIDS. They have commissioned research activities (2006) on female condoms too, through some NGOs – one of the NGO was Bhoruka Public Welfare Trust - a Calcutta-based NGO.

Y R Gaitonde Centre for AIDS Research and Education (YRG CARE):

Founded in 1993 by Dr. Suniti Solomon, this premier non-profit HIV referral centre is located in Chennai, Tamil Nadu. YRG CARE has extensive experience in clinical trials and community-based research. Internationally, it is recognised as a research institution for microbiological studies with a special emphasis on HIV.

6% cellulose sulfate	Phase III multicentric study in YRG CARE, Chennai and St. John's Medical College, Bangalore

I. YRG CARE is collaborating with TRC on the second Phase I AIDS vaccine clinical trial in Chennai, Tamil Nadu for community mobilisation and recruitment of volunteers.

II. YRG CARE collaborates with the Division of Infectious Diseases, Miriam Hospital, Brown University and studies the spectrum of HIV disease and the natural history of HIV disease in southern India through the Fogarty Program of Brown University.

Other ongoing projects with Brown University:

1. Usage of generic antiretroviral therapy in Indian setting
2. Reliability, validity and acceptability of assessment of adherence to antiretroviral treatment in Chennai
3. Fat redistribution syndrome following HAART
4. ARV resistance studies
5. A randomised controlled clinical trial of structured intermittent HAART therapy (SIT) vs. continuous HAART therapy in HIV-positive patients in southern India
6. HBV, HCV co-infection in persons attending HIV VCT services
7. Prevalence and incidence of STIs of HIV-negative men attending a government STD clinic. Hospital and sero-negative wives of HIV-infected male patients attending VHS-YRG CARE

III. YRG CARE collaborates with Sankara Nethralaya and studies the ophthalmic manifestations in persons with HIV disease.

IV. Through collaboration with Ragas Dental College, oral manifestations in persons with HIV are documented.

V. YRG CARE is one of the sites of HIV Prevention Trial Network (HPTN) of National Institutes of Health, USA (NIH). Under this network, YRG CARE is involved in the following studies:

a) HPTN033: Incidence of HIV among persons with high-risk behaviour
b) HPTN052: A randomised trial to evaluate the effectiveness of antiretroviral therapy plus HIV primary care versus HIV primary care alone to prevent the sexual transmission of HIV-1 in sero-discordant couples.-HPTN/NIH multi-site study (ongoing)

VI. YRG CARE is one of the sites of Adult AIDS Clinical Trial Group (AACTG) of National Institutes of Health, USA (NIH). Under this network YRG CARE is involved in the following study.- ACTG5175: A Phase III, randomized, open-label evaluation of the efficacy of three nucleoside reverse transcriptase inhibitor combinations for initial antiretroviral treatment of HIV-1-infected persons in resource-limited countries.