Challenges in the Management of HIV Disease in India

Suniti Solomon, MD

Director

YRG Center For AIDS Research & Education

Challenges

1. What is the true burden of HIV disease in India and how is it distributed?
2. Who are the emerging risk groups?
3. What are the various challenges that we face in prevention?
4. What are the major challenges we face in the treatment of HIV in India?

HIV in India

UNAIDS | NACO National AIDS Control Organisation | World Health Organization

Press release

2.5 million people in India living with HIV, according to new estimates

Improved data from more sources gives better understanding of AIDS epidemic in India

New Delhi, 06 July 2007 – The new 2006 estimates released today by the National AIDS Control Organization (NACO), supported by UNAIDS and WHO, indicate that national adult HIV prevalence in India is approximately 0.36%, which corresponds to an estimated 2 million to 3.1 million people living with HIV in the country. These estimates are more accurate than those of previous years, as they are based on an expanded surveillance system and a revised and enhanced methodology.

As part of its continuing effort to know its epidemic better, the Indian Government has greatly expanded and improved its surveillance system in recent years and increased the population groups covered. In 2006, the government created 400 new sentinel surveillance sites and facilitated National Family Health Survey-3, which is a population based survey.

Launching the third phase of the National Programme, Dr. Anbumani Ramadoss, Union Minister for Health and Family Welfare said, "Revision of estimates based on more data and improved methodology marks a significant improvement in systems and capabilities to monitor the spread of HIV, a sign of the progress we have made in understanding the epidemic better. This is welcome progress. Unfortunately, the new figures still point towards a serious epidemic with the potential to trigger off if the prevention efforts identified in the NACP III are not scaled up rapidly and implemented in the desired manner. We must remember that India has nearly 30 lakh[1] people living with HIV. These are people facing stigma, discrimination and irrational prejudice everyday of their lives and need all our support and understanding." The Minister called upon his colleagues in the medical profession and civil society organizations to fight stigma and discrimination.

Resulting from a more robust and enhanced methodology, the revised estimates will be used to improve planning for prevention, care and treatment efforts. "While it is good news that the total number of HIV infections is lower than previously thought, we cannot be complacent. The steady and slow spread of the HIV infection is a worrying factor. The better understanding of India's epidemic has certainly enabled us to have more focused HIV prevention and treatment strategies and more effective deployment of resources," said Mr. Naresh Dayal, Secretary Health and Chair of the National AIDS Control Board.

ULAR | TIMES TOPICS

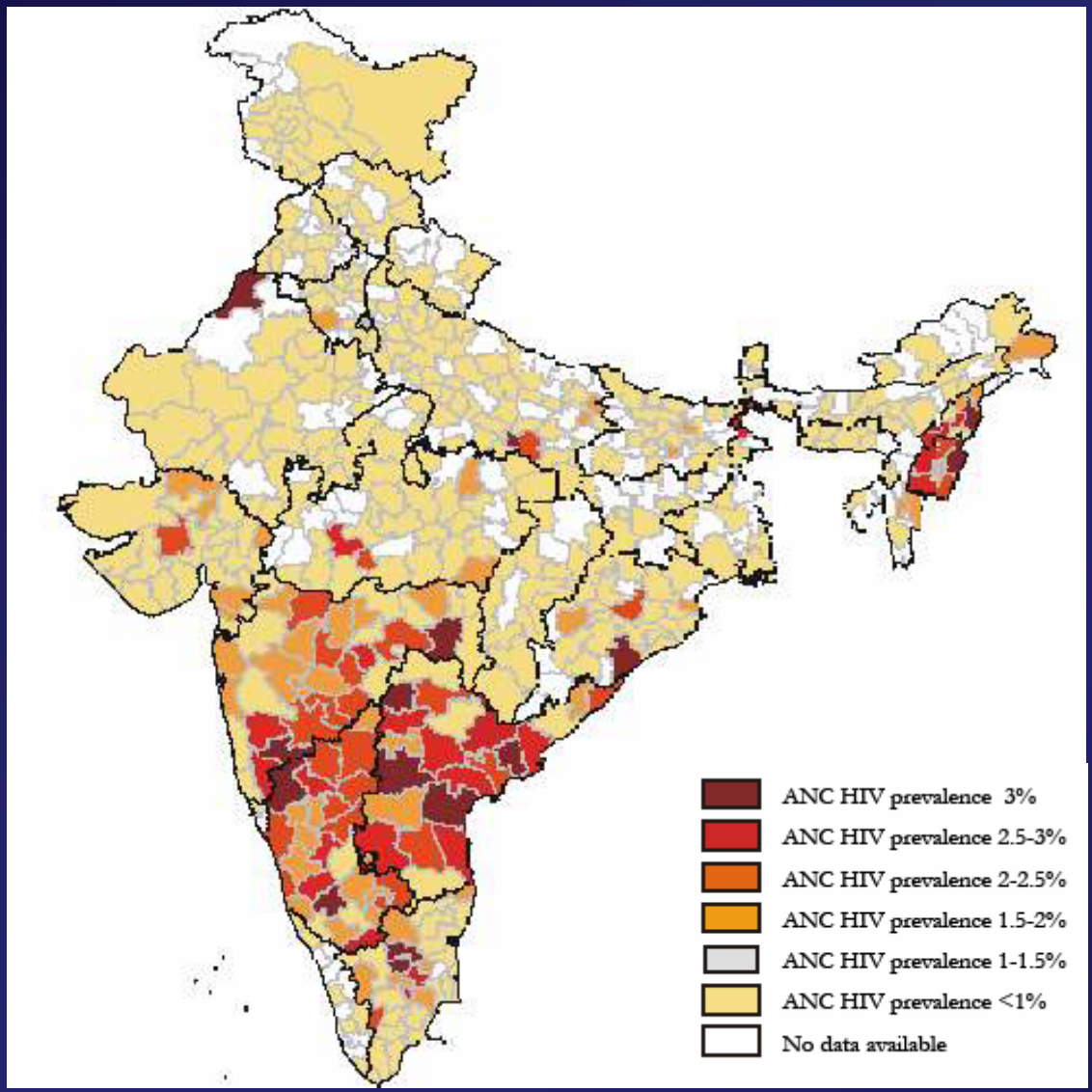
Asia Pacific

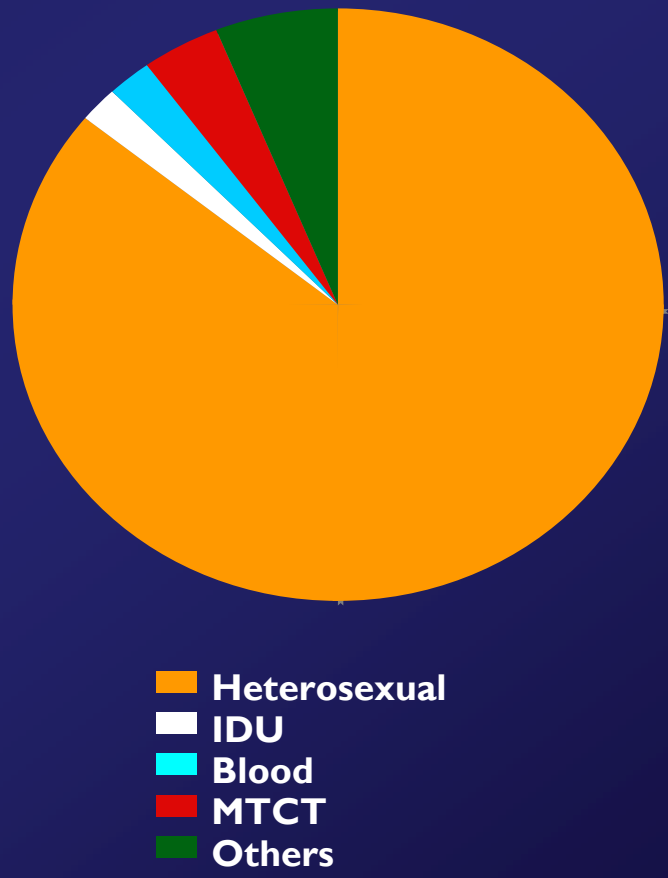
Many Fewer With

Prashanth Vishwanathan/Bloomberg News

AIDS awareness. A new but still probably has millions fewer victims of

Distribution of HIV



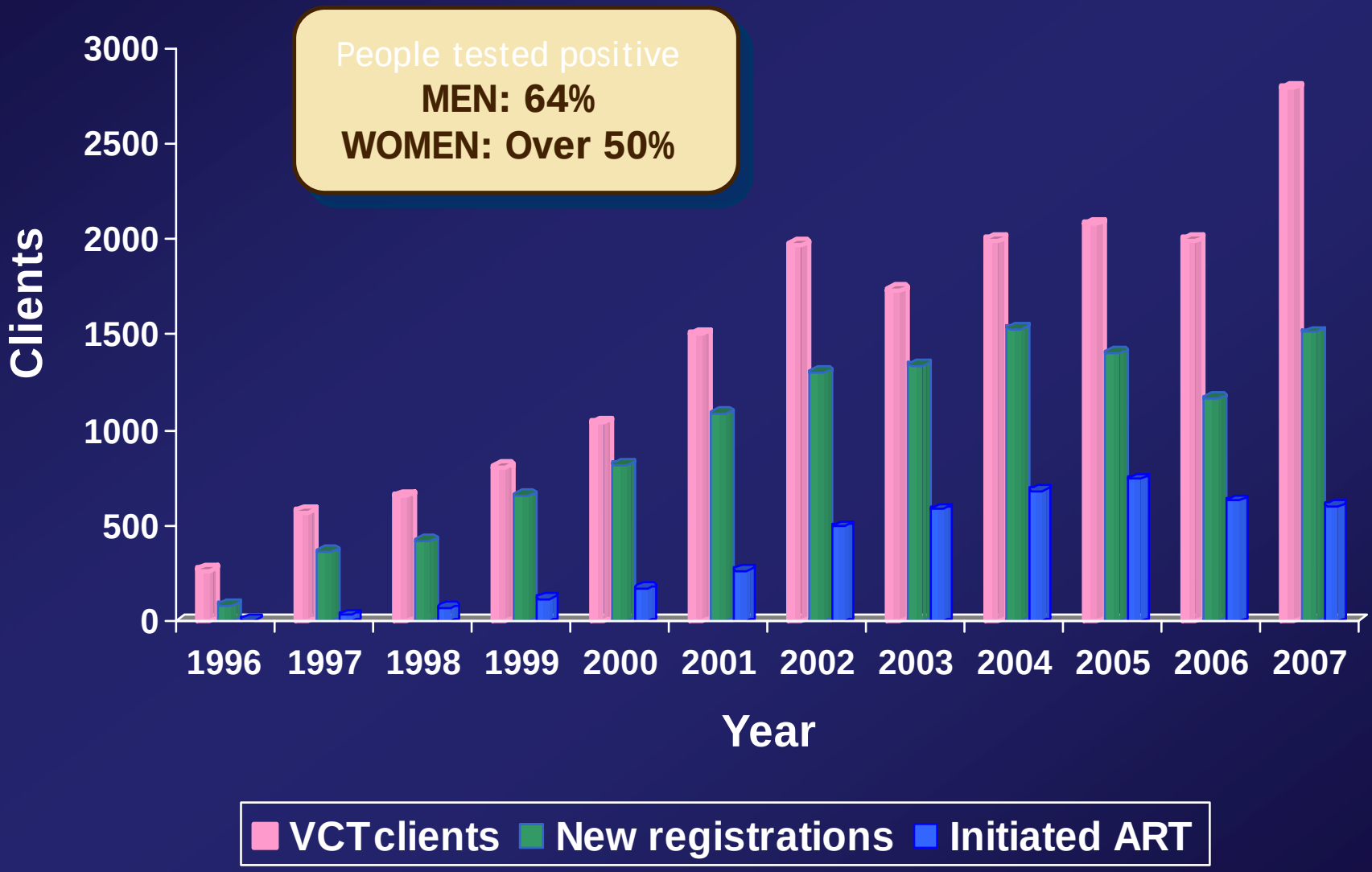


Source: NACO, India

People think that AIDS is someone else's Problem, and it could NEVER happen to them!!!!

90% of HIV Positive Persons are unaware of their Status!!!

Trend of Voluntary Counseling and Testing at YRG CARE



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Evolution of Risk-Groups

Important note: Information in this article was accurate in 2006. The state of the art may have changed since the publication date.

THE WALL STREET JOURNAL

In India, Call Centers Warn Young Workers About HIV Risk

Wall Street Journal - August 9, 2006

Peter Wonacott and Marilyn Chase

As loud music throbs in the air, Rohit Nag and his friends recline on steps just off the dance floor at the nightclub Elevate in N New Delhi. The 22-year-old Mr. Nag sports a thumb ring and four tattoos. His female companion, who works at the same call stud in her nose and another piercing her chin.

Young and free-spending, Mr. Nag and other workers at India's call centers are relishing social freedoms that their parents coul learning that a new lifestyle brings new risks and the need for precautions, especially amid the looming threat of HIV/AIDS. "E use a condom during sex," he says. "And when we get tattoos, we insist on disposable needles."

As India grapples with a growing AIDS problem, activists and industry executives have identified the country's 1.3 million cal as a surprising new risk group, alongside truckers, migrant workers and prostitutes. Predominantly young, single and mobile, c from the traditionally strict family life and partying hard when they are not working diligently.

As a result, some companies in India are establishing in-house programs to educate their workers about the disease.

"If you look at the way the pandemic in India is progressing, [call-center workers] are at risk because they are young and sexua spokeswoman for Standard Chartered Bank PLC. The London-based bank, which has nearly one-fourth of its 43,000 employe roughly 6,000 call-center workers in Chennai for classroom-based AIDS education. Soon, HIV prevention messages will pop u as part of an online refresher course.

A study in February of 2006 found that 11% of 1,100 workers at iEnergizer Inc., a call center and outsourcing business in Noi five sexual partners. By contrast, 7% of 1,300 adults across the country said they had had more than five sexual partners, a se

In one free cellphone game in India, cricketers take a swing against AIDS.

The data speak to a dramatic lifestyle change in a society where parents often arrange marriages for their children and rarely sp surveys, the only such ones conducted to date, were done by SSL International PLC, maker of Durex condoms. The call-center Global Business Coalition on HIV/AIDS, a nonprofit New York-based advocacy group, with iEnergizer's cooperation.

organisation called Jagruthi.

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From The Times

October 20, 2007

Call centre romeos are 'a major HIV risk'

Jeremy Page in Delhi

It was not the pay that made Prashant Singh join a call centre in the Delhi satellite town of Noida. It was certainly not the working hours – 6pm to 3am – or the abuse from American callers. "I did it for the girls," he told *The Times* as he surveyed the crowd at a popular Delhi nightclub. "When I was living at home, it was hard to date girls. Now it's easy – I've had three girlfriends in the last year."

Like many of India's 1.3 million call-centre workers, Mr Singh finds that living away from home and earning decent money gives him more freedom than ever before, not least when it comes to sex. The 23-year-old shares a flat with two male friends and spends much of his spare time drinking, dancing – and sleeping – with female colleagues. But with greater sexual freedom there is

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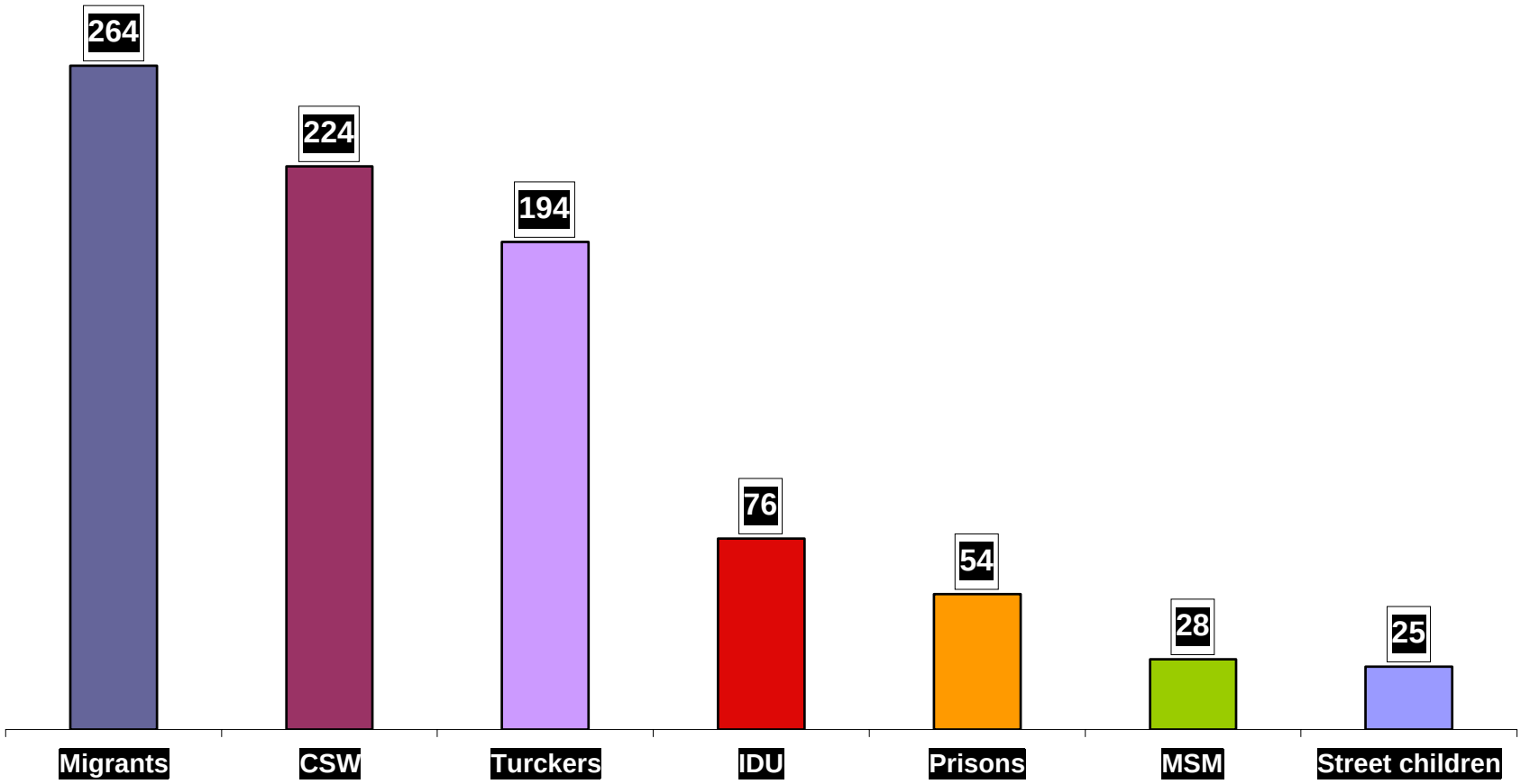
- Food allergies and intolerance? The doctor replies

Targeted Interventions



Source NACO

HIV Incidence among cohorts at YRGCARE

Risk Reduction Counseling Is Associated With Decreased HIV Transmission-Associated Behaviors in High-Risk Indian Heterosexuals

Sunil S. Solomon, MBBS, MPH, Suniti Solomon, MD,* Benoit R. Masse, PhD,† A.K. Srikrishnan, BA,* Geetha Beauchamp, MS,† Easter Thamburaj, MSW,* Menaka Gulvady, MA,* S. Anand, BSc, ADCA,* and Kenneth H. Mayer, MD‡§*

Objective: To estimate the incidence of HIV and study the impact of risk-reduction counseling (RRC) in a cohort of people with high-risk behavior for HIV transmission in Chennai, India.

Design: Prospective cohort follow-up of 500 HIV-negative people (250 men and 250 women) at increased risk for HIV acquisition in Chennai, India for a maximum of 1 year was conducted. They received RRC at 0, 6, and 12 months. Generalized estimating equation methodology was used to determine the statistical significance of differences reported in behavior between baseline, 6 months, and 12 months.

Results: The overall HIV incidence in this cohort was 0.44 per 100 person-years (95% confidence interval: 0.05 1.60). In the course of the study, both male and female participants reported statistically significant decreases in the number of different sexual partners, the number of new partners, and the proportion of sexual encounters with nonprimary partners. Participants who had more than 3 different partners at baseline and/or exchanged money for sex in the 6 months before enrollment demonstrated the greatest reductions in the number of different sexual partners.

Conclusions: Individualized sexual RRC seems to be a useful intervention to reduce risk-taking behavior among at-risk heterosexuals in India.

Key Words: risk-reduction counseling, high-risk individuals, counseling, HIV, India

(*J Acquir Immune Defic Syndr* 2006;42:478 483)

HIV infection was first detected in India in 1986 among sex workers in Tamil Nadu.[1] Since then, the number of people living with HIV and AIDS (PLWHA) in India has been steadily increasing,[2] and it is estimated that more than 5.1 million Indians were infected with HIV at the end of 2004.[3] It has also been established that heterosexual contact is the predominant mode of transmission of HIV in India, accounting for 85.7% of all infections.[2] The National AIDS Control Organization, India also estimated that 87.7% of all HIV infections in India occur in the most sexually active age group, 15 44 years.[2] A study by Mehendale et al in Pune, India reported an HIV-1 prevalence of 21.2% among people attending sexually transmitted disease (STD) clinics.[4]

Despite the numerous therapeutic innovations that have followed the discovery of HIV as the cause of AIDS,[5] behavioral interventions to promote condom use are still among the most effective means of limiting the sexual spread of this infection.[6] It is therefore essential to provide some form of risk-reduction counseling (RRC) or education to such individuals, especially those manifesting high-risk behavior. RRC has been reported to be effective in reducing risk of acquisition of HIV/sexually transmitted infections (STIs) both in India[7,8] and in industrialized countries.[9] RRC has been shown to reduce the risk of acquiring HIV and other STIs, which have been shown to act as cofactors for HIV transmission.[10,11]

As part of a study of risk factors of HIV seroconversion among high-risk individuals, our group evaluated the efficacy

Acceptability of Microbicides Study

Use of Condom during Vaginal Sex

Description	Men Low Risk	%	Women Low Risk	%	Men High Risk	%	Women High Risk	%
No	432	73.59%	381	89.44%	484	69.74%	42	11.26%
Rarely	79	13.46%	13	3.05%	77	11.10%	9	2.41%
Sometimes	22	3.75%	2	0.47%	59	8.50%	13	3.49%
Always	29	4.94%	13	3.05%	63	9.08%	299	80.16%

Challenges

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YRGCARE

Social Stigma

CHENNAI, THURSDAY, FEBRUARY 17, 2005

HIV-positive woman 'killed'

AHMEDABAD, FEB. 16. An HIV-positive woman has allegedly been killed by her relatives at Dharasana village in Gujarat's Valsad district, police said today.

She was found dead in her hut on the outskirts of the village on Monday. — UNI

NATIONAL

• ' Tamil-Brahmi script

Last Updated: Tuesday, 12 December 2006, 13:39 GMT

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Indian school throws out HIV boy

A four-year-old boy has been thrown out of nursery school in India because he has been found to be HIV-positive.

These children in Kerala fought for two years to get back to school

-run school in
southern city of
the child home
other children

BBC NEWS WATCH One-Minute World News

News Front Page

Last Updated: Monday, 3 July 2006, 12:38 GMT 13:38 UK

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'HIV stigma' drives India suicide

A 15-year-old Indian boy whose parents had HIV was driven to suicide by the stigma associated with the virus, police say.

Despite efforts to raise awareness, stigma about HIV persists

Santosh Baniya died of burn injuries after setting himself on fire in the western city of Ahmedabad last week.

Both his parents were diagnosed with HIV two years ago. They are among more than five million people infected with the virus in India.

Before he died the boy had expressed fears about surviving his parents.

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Medical Stigma

Remembering

Ashok Pillai

(1968-2002)

INDIAN EXPRESS
JUNE 3, 2007

Diagnosis of HIV infection

- Over 1000 labs in Chennai alone with no quality checks

	TOTAL
1. Do you co your lab?	1138
2. Do you pr counseling?	100%
3. Approxima this take? • < 10 minut • 11-25 minu	

Hospital sued for wrong HIV report

BY T S SEKARAN

Chennai, Feb 21: A leading private hospital in Adyar was sued for allegedly wrongly certifying a cook as having tested positive for HIV.

The cook, R Mohanan (46), of Thiruvalluvar Nagar in Tiruvanmiyur had been provisionally selected by a Japanese firm in Algeria. His selection was subject to a medical test. He was sent to Malar Hospitals in Adyar, which, after tests on February 23 last year, said in its report that Mohanan had tested positive for HIV.

The hospital also declared as its final impression that he was not fit for the job. This resulted in the immediate cancellation of the provisional selection and job offer.

There was also immediate and disastrous effect of the report on his family. He and his wife Parimala started suspecting each other's fidelity, leading to constant and endless quarrels.

Later, Mohanan and his wife got tested at the Voluntary Health Services Hospital which, in the first week of March last year, declared both of them HIV negative.

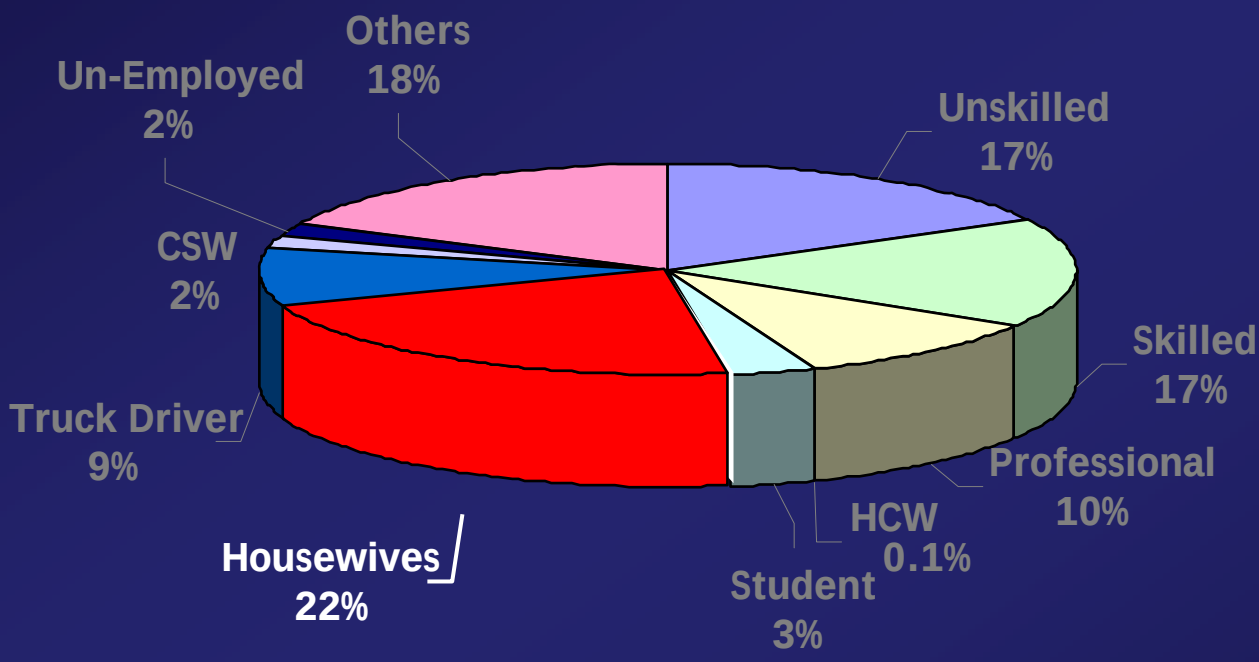
Mohanan and his wife moved court and lodged a complaint against the hospital with the TN Consumer Disputes Redressal Commission, seeking Rs 15 lakh for the loss of job and another Rs 15 lakh towards compensation for the turmoil and mental agony. The commission has sent a notice.

The hospital refused to comment when approached by *Express*.

» Test for HIV: A primer, P3

YRGCARE

Voluntary Counseling and Testing
Occupation of HIV+ Clients



Over 20,000 walk-in clients

(Referral from other clinicians forms over 60%)

Cultural Issues

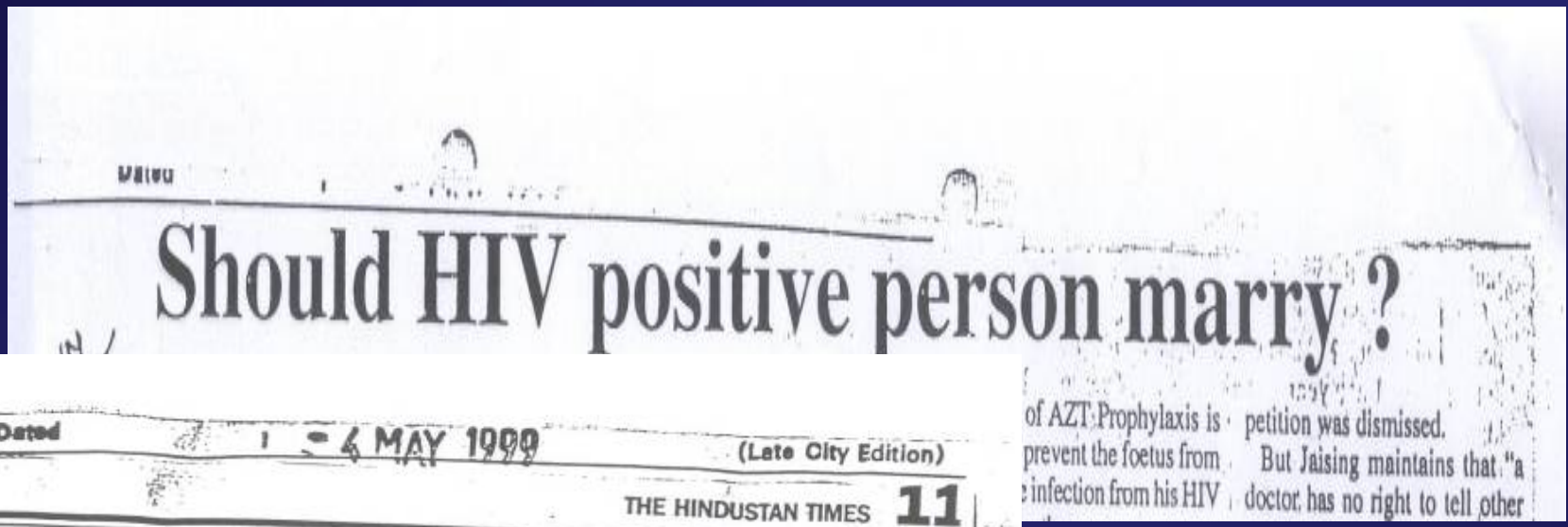
1) Marriage Counseling
2) Fertility Pressures
3) Reducing the risk of mother to child transmission by **98%**
4) Counseling on Domestic Violence to reduce incidence of HIV
5) Couple and Family counseling

YRGCARE Matrimonial Service

Murthy & Bavana

- Murthy, an engineer
- Was pressurised to get married by parents
- Turned to the support services of YRGCARE
- His C.V. along with photo circulated to network NGO in Maharashtra
- Murthy flew to Mumbai & their love blossomed
- Married two months later
- Today proud parents of AKASH, HIV Negative

Legal Issues & Policy



Should HIV positive person marry ?

of AZT Prophylaxis is prevent the foetus from infection from his HIV

petition was dismissed.

But Jaising maintains that "a doctor has no right to tell other

Dated 1 - 6 MAY 1999 (Late City Edition)

THE HINDUSTAN TIMES 11

Order on AIDS patients' marriage sparks row

New Delhi, May 3

THE SUPREME Court's recent order suggesting that it was an AIDS afflicted person's duty not to

can spell doom for the society. There is no cure for it as yet. The basic principle of law is that whatever is good for people in general is law. It is

order but public good."

The Supreme Court ruling point out that the marriage of an AID patient would be an offence unde

(City Edition)

ETHICS

Should AIDS patients be allowed to marry?

THE Supreme court's recent order suggesting that it was an AIDS

Code, which relate respectively to negligent act and malignant acts likely to spread a disease dangerous to life. A

with it social security and companionship.

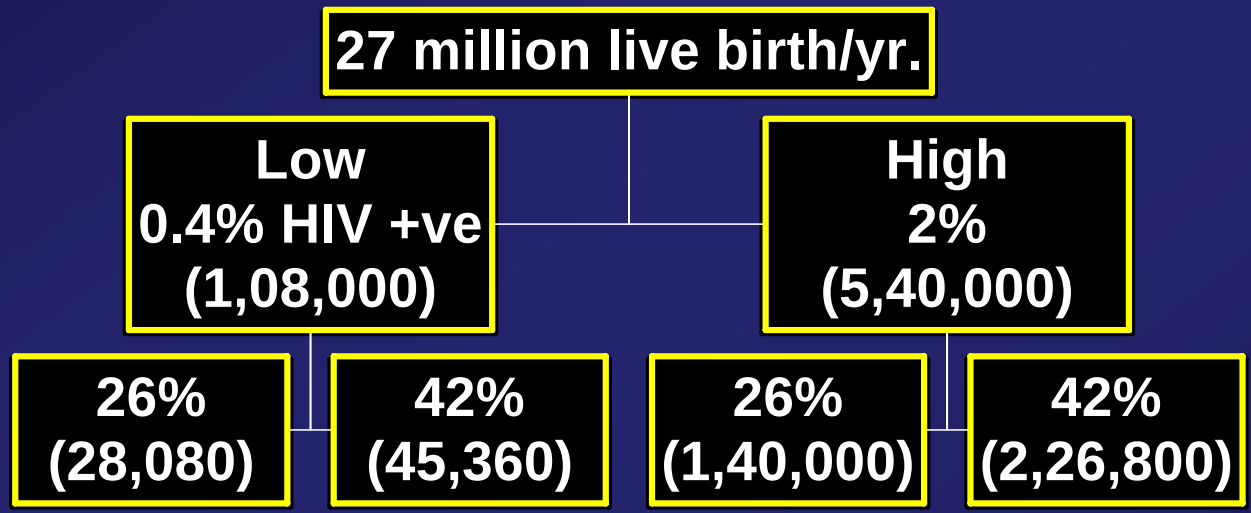
Such marriages have taken place in the United States

Barren women are not welcome at a Valaikappu Ceremony

Baby at any cost

- Revathi was married to her uncle, her mother's brother
- She was aware that he was HIV+ but agreed as it was the custom.
- Two years later she had pressure from the family for a baby
- Revathi travelled 400 miles to Chennai
- Had an AI which only the couple were aware
- And today they are proud parents of Aarthi

Children with HIV in India
Estimate for one year



NEVARAPINE @ Labour ➔ 1 Tablet & Syrup for the baby at 72 hours

Cost Rs.20/- per pt. Rs10.8 m ($ 0.216 m)

Policy has to be Revisited
- HIVNET012 (Single dose NVP)

- Kampala, Uganda
- Nevirapine 200mg single dose PO 2 hrs before delivery to mother
- Nevirapine syp 2mg/kg body weight within 72 hrs to the infant

- Nevirapine lowered the risk of HIV-1 transmission during the first 14-16 weeks of life by nearly 50% in a breastfeeding population.

ARV resistance after MTCT prophylaxis

- Characterization of Nevirapine resistance mutations in women with HIV-1, 6-8 weeks after Single dose Nevirapine (HIVNET012)
- Study confirms a higher rate of NVP resistance in women and further defines the pattern of NVPR mutations that emerge 6-8 weeks after single dose NVP prophylaxis.
- Differences by subtype C > D > A
- Resistance in the child – as high as 87% when only sd-NVP was given to the child and mother

Breastfeeding

- Culturally acceptable but increases risk of HIV
- Breast milk vs formula feeding for prevention of HIV transmission (Mashi Study)
- Alternate strategies
  - SWEN: Uganda, India, Kenya
  - PEPI Study (Resistance data not available)
- Cost-effectiveness – a factor to consider!

Circumcision

- Religion
- Cost-Effectiveness

"In the riots if the perpetrators or the Police are not
entify victims with their religion they forcefully
pants of the victims to check whether they are
ised or not. Once they find that the victim is
d he is targeted without further analysing which
community he belongs to.

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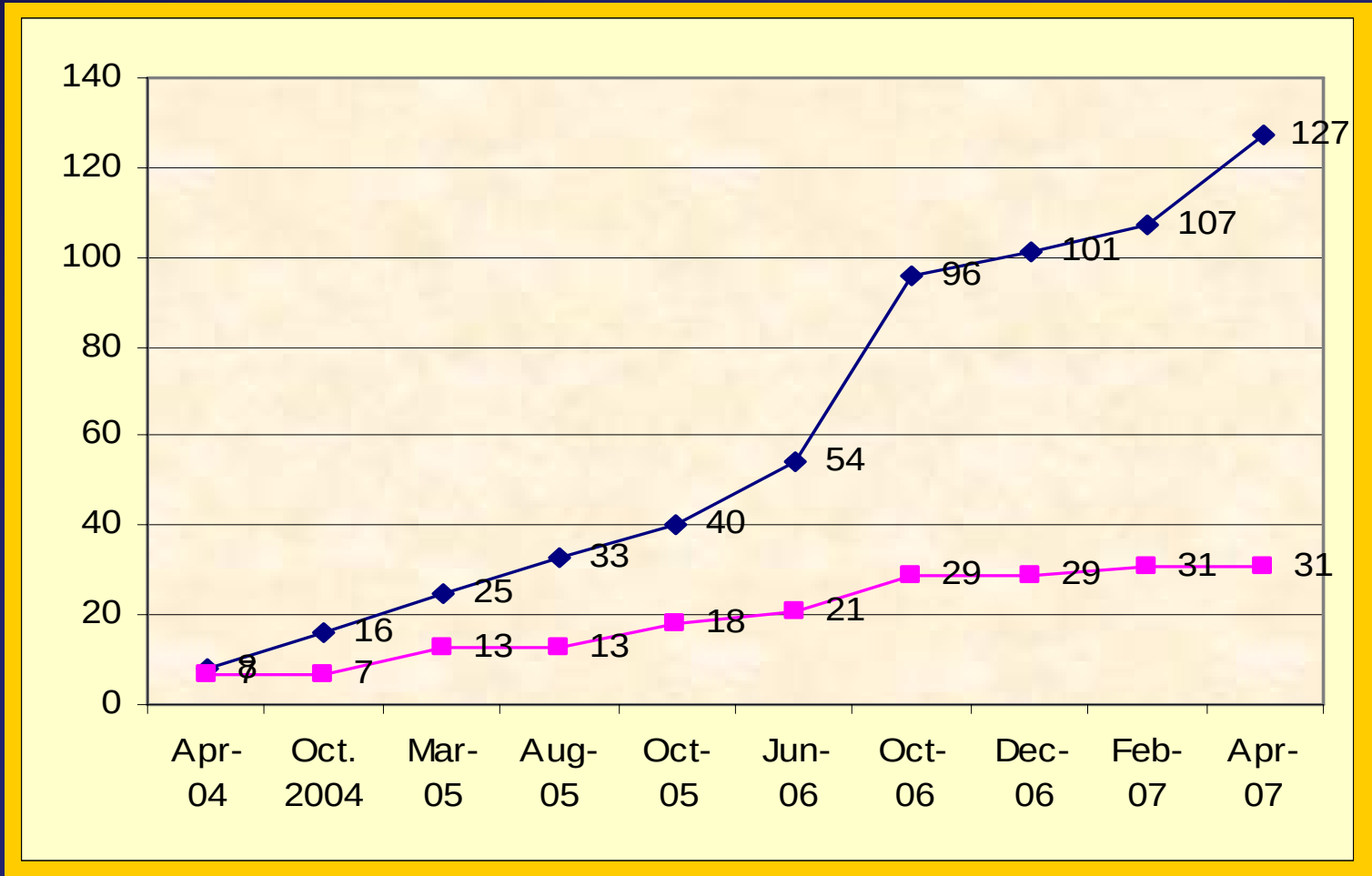
National ART Program

- Provide free access to ART for 100,000 PLHA by 2007
- 188,000 by 2010 in 6 high prevalence states and Delhi
- 300,000 by 2012 all over the country

National ART Roll-Out

- Nearly 76,000 patients are receiving free ART at these centers
- In addition, 35,000 patients receiving ART in private sector (based on pharma sales)
- Pediatric formulations have been made available

No of ART Centers as on April 2007 and States covered



Current Regimens

- Almost all ARVs available in India
- Combination of stavudine, lamivudine and nevirapine is the most common
  - Advantages:
    - Cheap: about 800 rupees (20 USD) per month
  - Disadvantages:
    - Cross-resistance
    - Toxicities (stavudine almost never prescribed anymore in the US)
    - Future treatment options limited
- Zidovudine and efavirenz are the only other agents available thru GOI ART rollout programs
- Jan 2008 – 2 Centers started 2nd Line Regimen

Low cost monitoring technologies

Test	Gold Standard	Low Cost I	Low Cost II	Low Cost III
Viral Load	Roche Amplicor **(US$ 90/-)**	Ultra Sensitive P24 Ag Perkin Elmer **(US$ 15)**	Cavidi Exavir (RTactivities) **(US$ 20/-)**	Real-Time PCR (ABBOTT) **(US$ 38/-)**
CD4	B.D. FACSCOUNT **(US$ 26/-)**	TLC **(< US$ 1/-)**	Coulter Cytosphere **(US$ 15/-)**	Guava Tech. Capillary Based Flowcyto **(US$ 2/-)**

CD4 + PVL = Rs.1000/- ! At YRGCARE soon….

GRADUATED COST RECOVERY MECHANISM FOR ARV

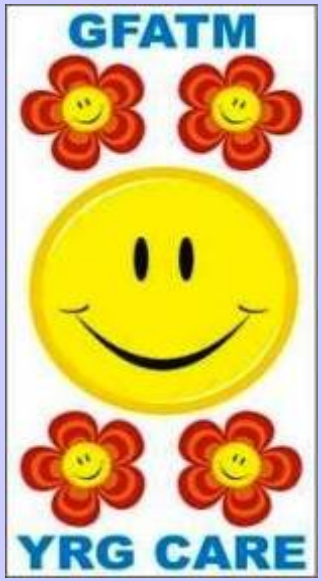
- High Income group patients (20%) – 100 %
  - Price of drugs matched with TNSACS pharmacy
- Middle income group patients (40%) – 75%
  - Price of drug lower than 75% of MRP
- Low socio-economic patients (20%) – 50%
  - Price of drug 50% of MRP
- Below Poverty Line (BPL) patients (20%) – 0 %

Indicators to Assess Ability to Pay

	Indicators	Weights
1.	Income	25%
2.	Occupation	15%
3.	Assets	10%
4.	Consumption	10%
5.	Medical Expenses	25%
6.	Dependents	15%

Tier I

0 %



Tier II

50%

Tier III

75%

Tier IV

100%

Status of Rollout (Jan 2008)

TIER	#	%	TARGET%
Tier 1 (free)	430	20	20
Tier 2 (50% support)	418	20	20
Tier 3 (25% support	839	40	40
Tier 4 (no support)	410	20	20
Total	2097	100	100

Immunological Response in the 4 Tiers of GCR Model

Tier	Baseline CD4	Gain in CD4 count in cells/µl at 6 months (n=1240)	Gain in CD4 count in cells/µl at 12 months (n=701)	Proportion with CD4 count greater than 350 cells/µl at 6 months (n[%])*	Proportion with CD4 count greater than 350 cells/µl at 12 months (n[%])
Tier 1 (free)	168 (94 – 343)	121 (39 -239)	191 (49 – 370)	130 (47.6)	104 (63.8)
Tier 2 (50%)	169 (91 – 308)	113 (12 – 215)	142 (50 – 316)	102 (44.7)	77 (62.1)
Tier 3 (75%)	190 (102 – 345)	115 (12 – 230)	172 (50 – 307)	234 (46.4)	166 (58.9)
Tier 4 (100%)	242 (144 – 458)	115 (16 – 232)	154 (36 – 305)	142 (59.9)	83 (62.9)

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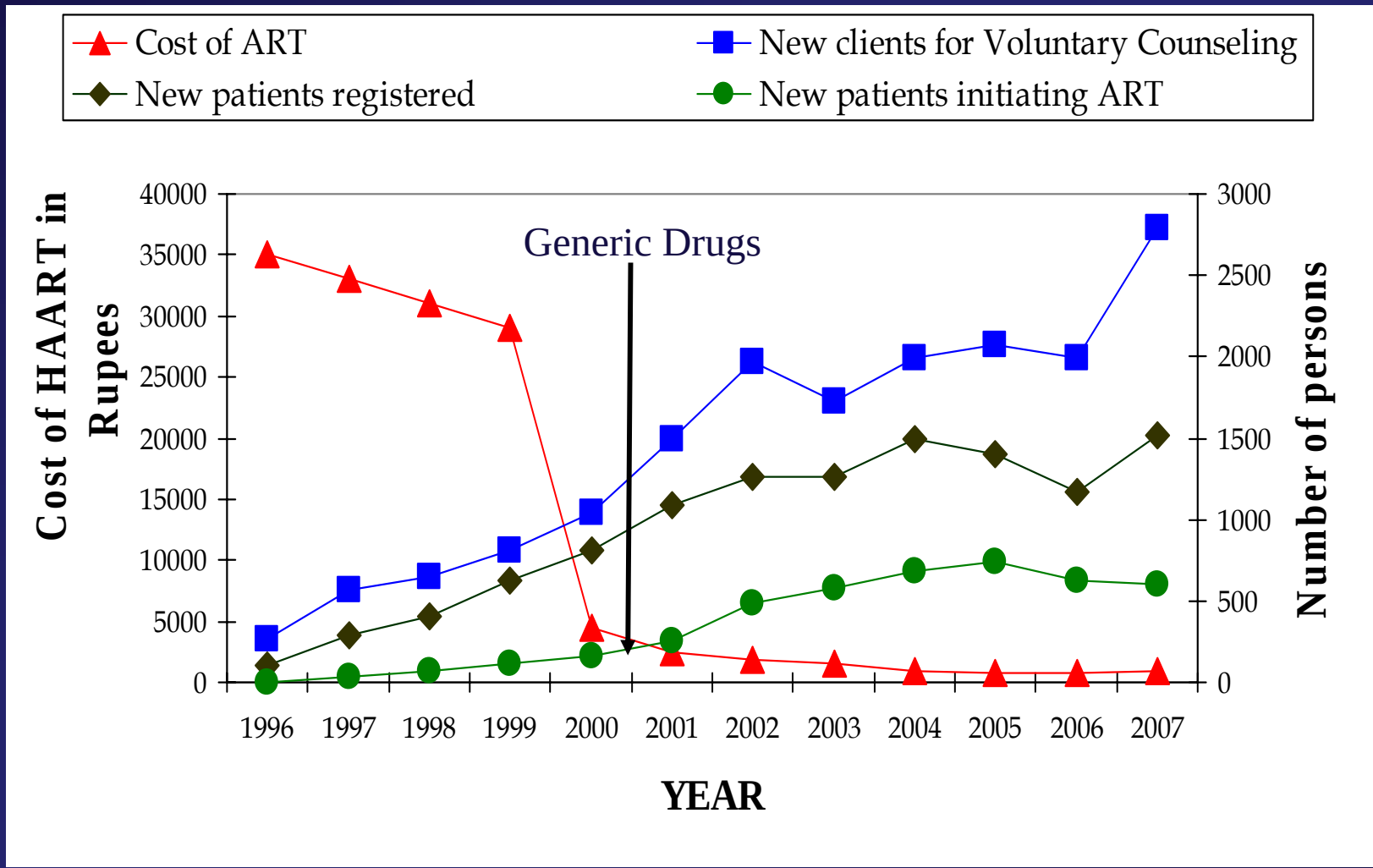
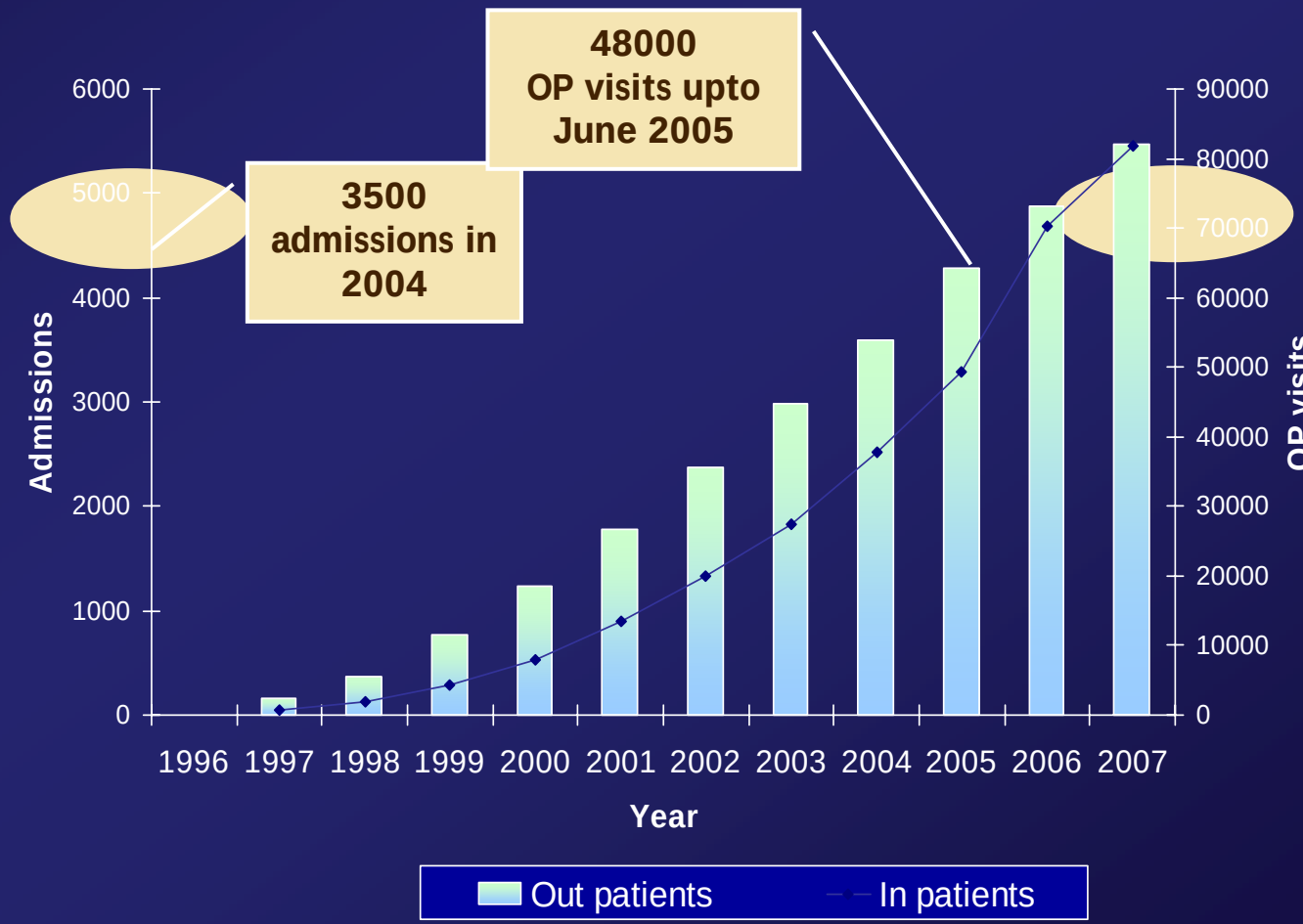
Trends in Antiretroviral Price, VCT Clients, Patients in Treatment and on HAART

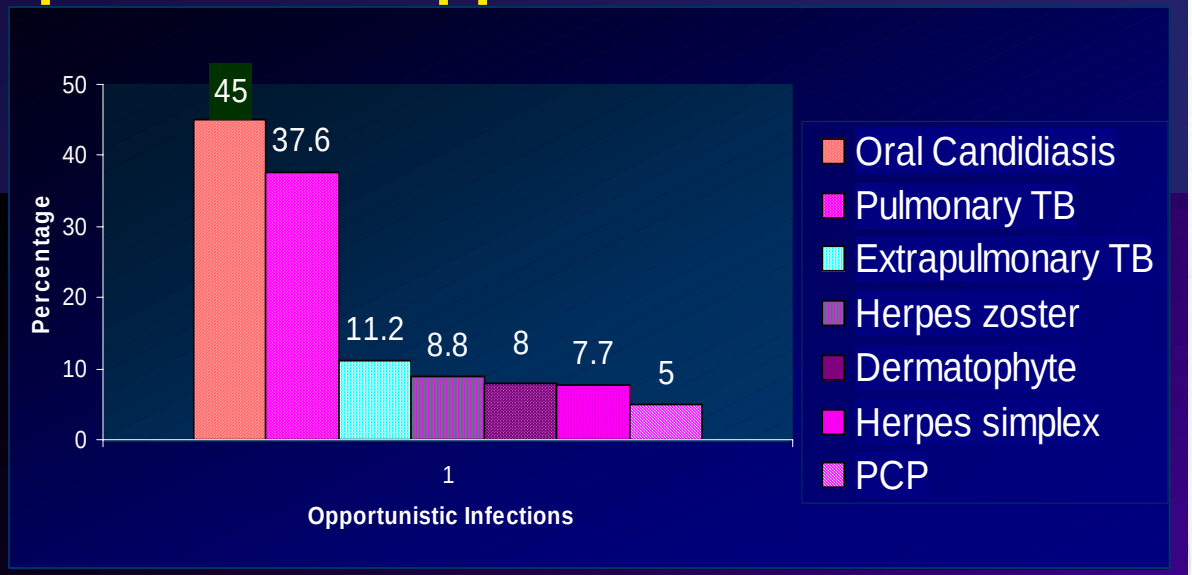


Cumulative patient flow at YRG CARE

- 1996 – 1 new patient a week
- 2005 – 10 new patients a day.
- Patient attend 85 per day
- 20 bed ward
- ICU facilities



Spectrum of Opportunistic Infections



International Journal of STD & AIDS 1995; 6: 447–449

SHORT PAPER

Spectrum of opportunistic infections among AIDS patients in Tamil Nadu, India

N Kumarasamy[1], Suniti Solomon[2], S A Jayaker Paul[1], Rosy Venilla[1] and R Edwin Amalraj[3]

[1]Government General Hospital, [2]YRG CARE, [3]Medical University, Madras, India

Summary: A retrospective case note review of 100 AIDS patients attending a large Indian centre was performed. Of these 100 patients, 94% gave a history of heterosexual HIV transmission, 68% were male. The majority of females were aged 21 to 30 years. The most common mode of presentation was tuberculosis (61%), both pulmonary (46%) and extrapulmonary (15%). Oral candidiasis extending on to the oesophagus was the second most predominant opportunistic infection.

This study also highlights the difficulty in detecting AIDS cases in India owing to difficulties in taking a sexual history and lack of laboratory facilities.

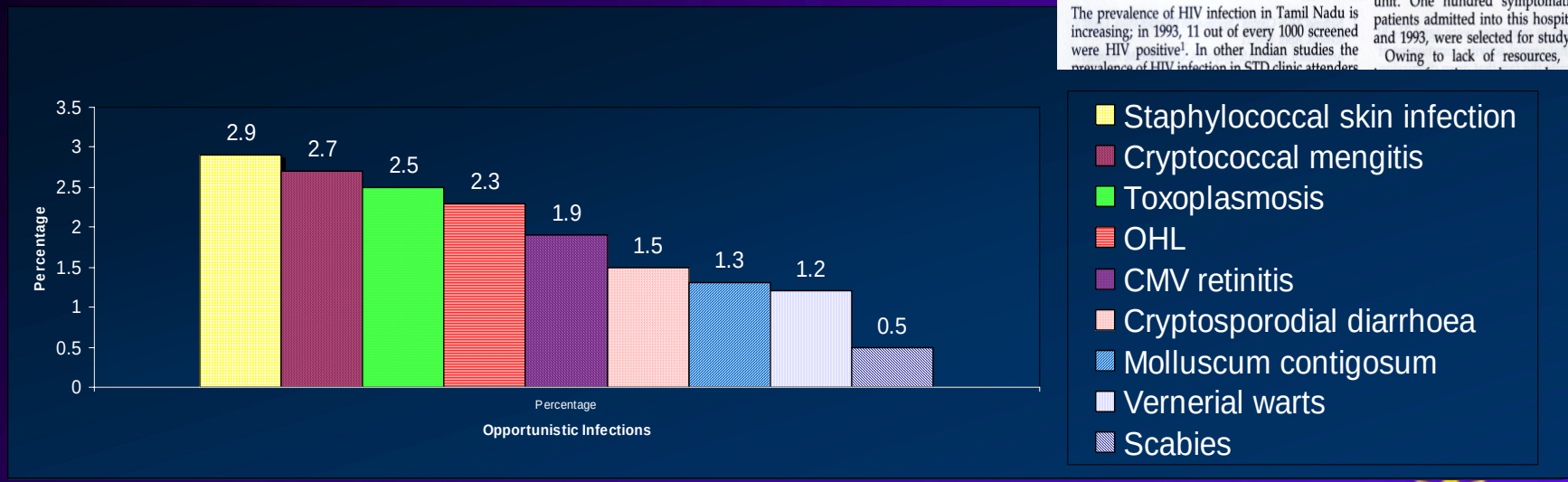
Keywords: AIDS, opportunistic infection, tuberculosis, HIV transmission, India

INTRODUCTION

The prevalence of HIV infection in Tamil Nadu is increasing; in 1993, 11 out of every 1000 screened were HIV positive[1]. In other Indian studies the

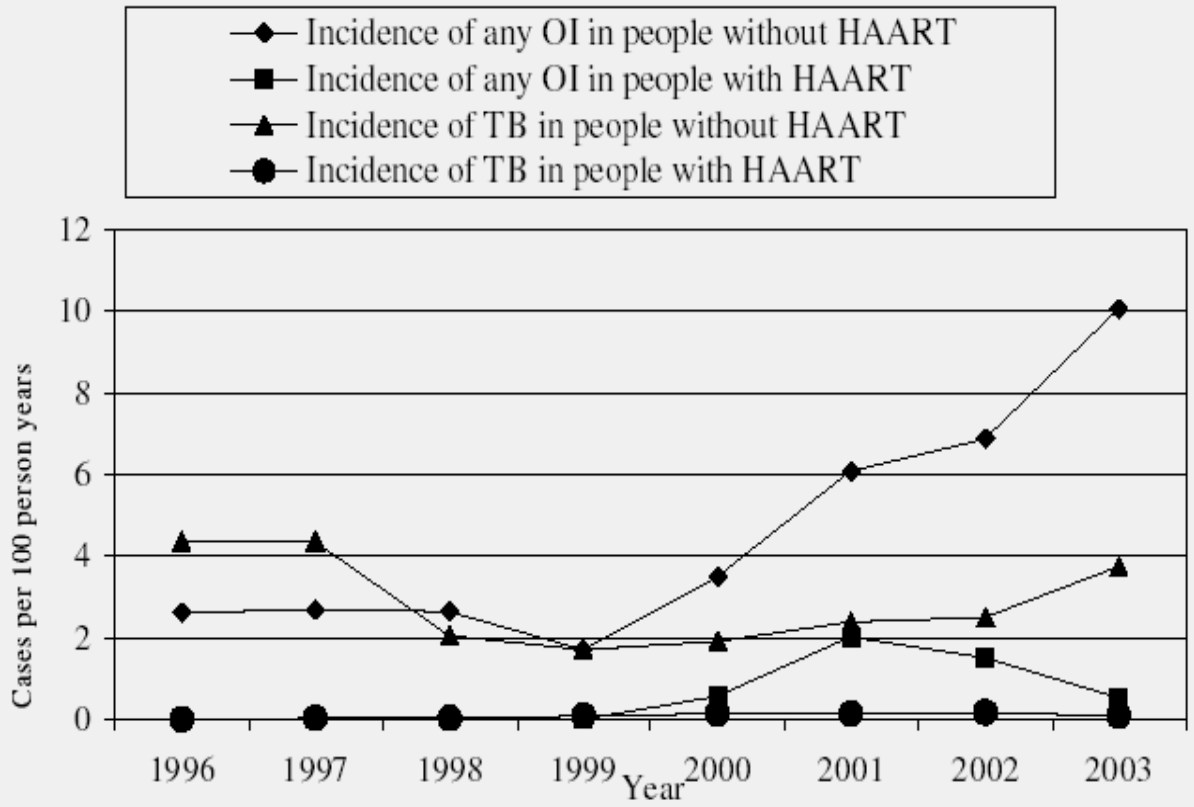
southern states of India and has a sepa unit. One hundred symptomatic HI patients admitted into this hospital bet and 1993, were selected for study.

Owing to lack of resources, the a



YRG CARE

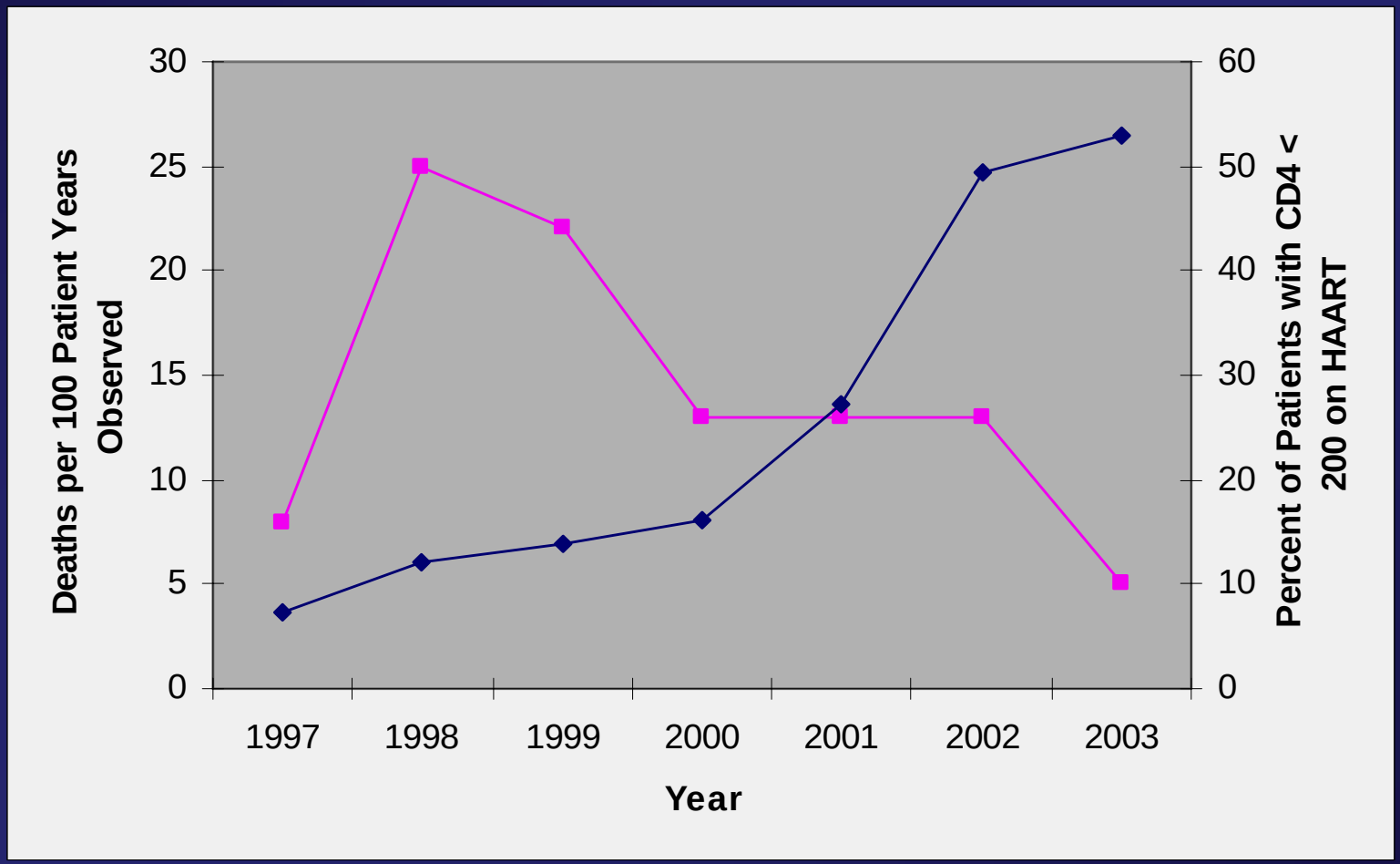
Figure 2 : Incidence of opportunistic infection in patients with and without HAART, 1996-2003



Kumarasamy et al. The Changing Natural history of HIV disease following generic HAART IN Southern India. Clinical Infectious Diseases 2005

Reduction in death rate following HAART

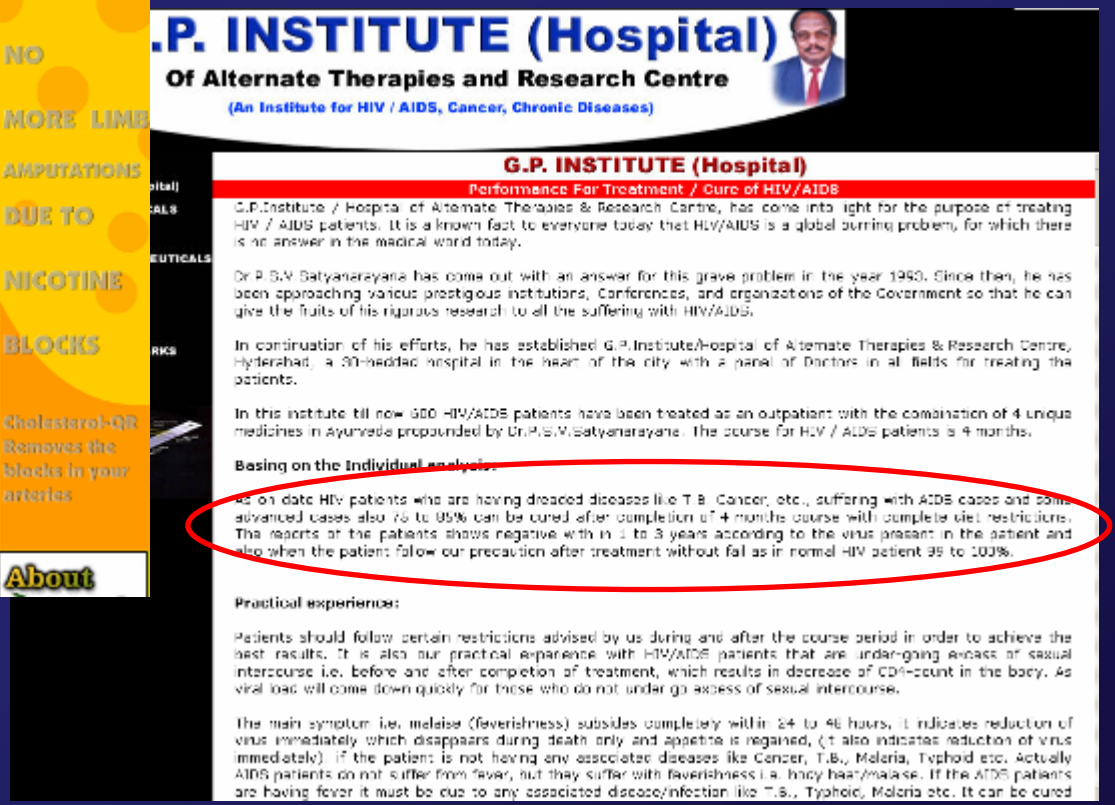
Kumarasamy, et al. IJMR 2005



Mismanagment

- Vitamins or HAART?
- Over the counter availability with pharmacists prescribing ART

Alternate Medical Systems and "Ducktors"



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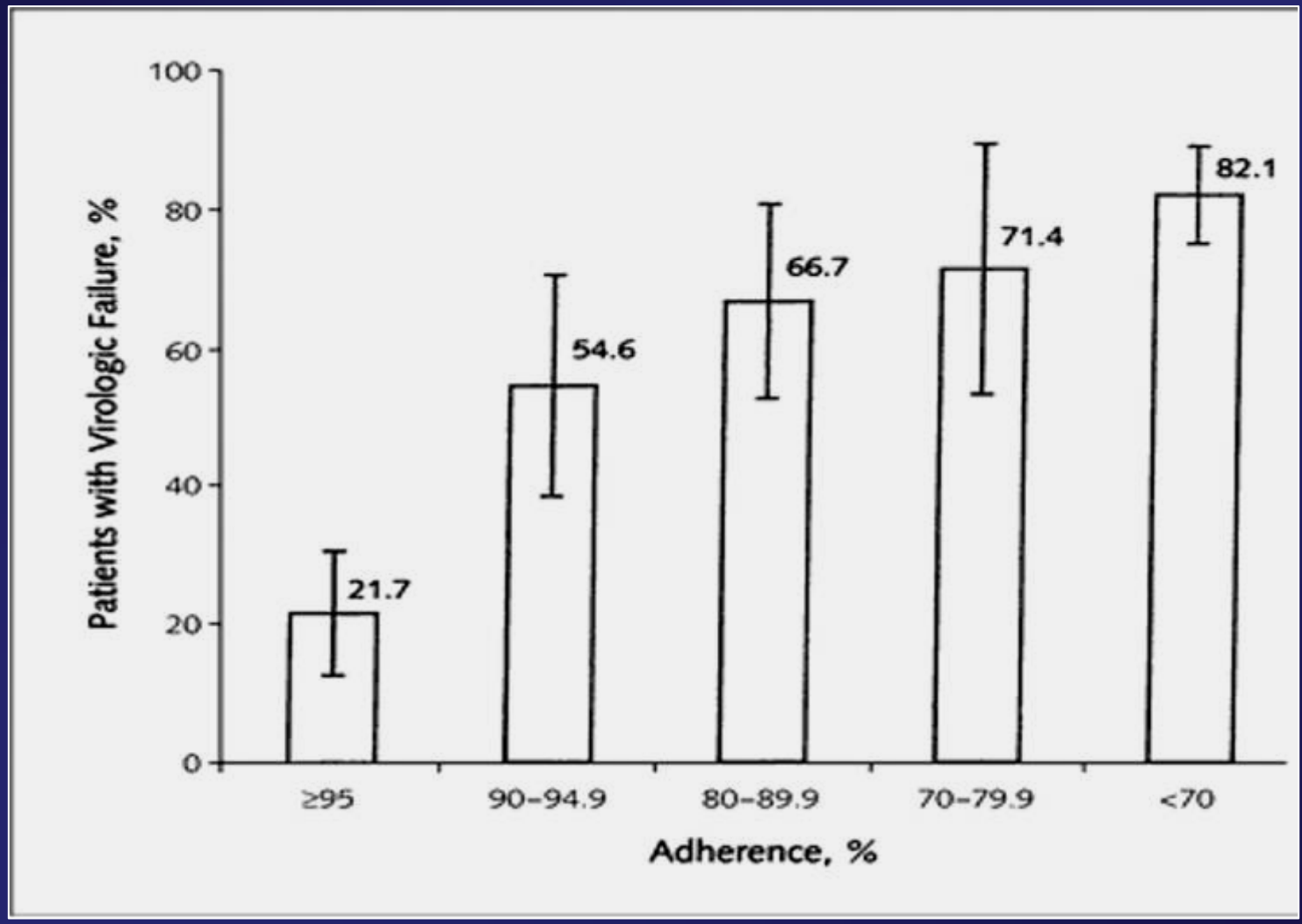
Challenges in HAART

- Adherence
  - At least 95% adherence is mandatory
  - “poor” adherence = “poor” treatment outcome
  - Out-of-pocket payment hinders optimal adherence
  - Stigma interferes with dosing at home/ workplace
  - Indian culture
    - Stop when feeling better
    - Low levels of education
    - Sharing of medications
    - OTC prescriptions
  - DOTS vs DAART
  - Emergence of drug resistant strains

Adherence to antiretroviral therapy and virologic failure



Paterson, D. L. et. al. Ann Intern Med 2000;133:21-30

HIV Drug Resistance among Treatment Naïve Populations

Sequence Note

HIV Type 1 Genotypic Variation in an Antiretroviral Treatment-Naive Population in Southern India

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ABSTRACT

Most studies of HIV-1 drug resistance have examined subtype B viruses; fewer data are available from developing countries, where non-B subtypes predominate. We determined the prevalence of mutations at protease and reverse transcriptase drug resistance positions in antiretroviral drug-naive individuals in southern India. The *pol* region of the genome was amplified from plasma HIV-1 RNA in 50 patients. All sequences clustered with IIIV-1 subtype C. All patients had at least one protease and/or RT mutation at a known subtype B drug resistance position. Twenty percent of patients had mutations at major protease inhibitor resistance positions and 100% had mutations at minor protease inhibitor resistance positions. Six percent and 14% of patients had mutations at nucleoside reverse transcriptase inhibitor and/or nonnucleoside reverse transcriptase inhibitor resistance positions, respectively. Larger scale studies need to be undertaken to better define the genotypic variation of circulating Indian subtype C viruses and their potential impact on drug susceptibility and clinical outcome in treated individuals.

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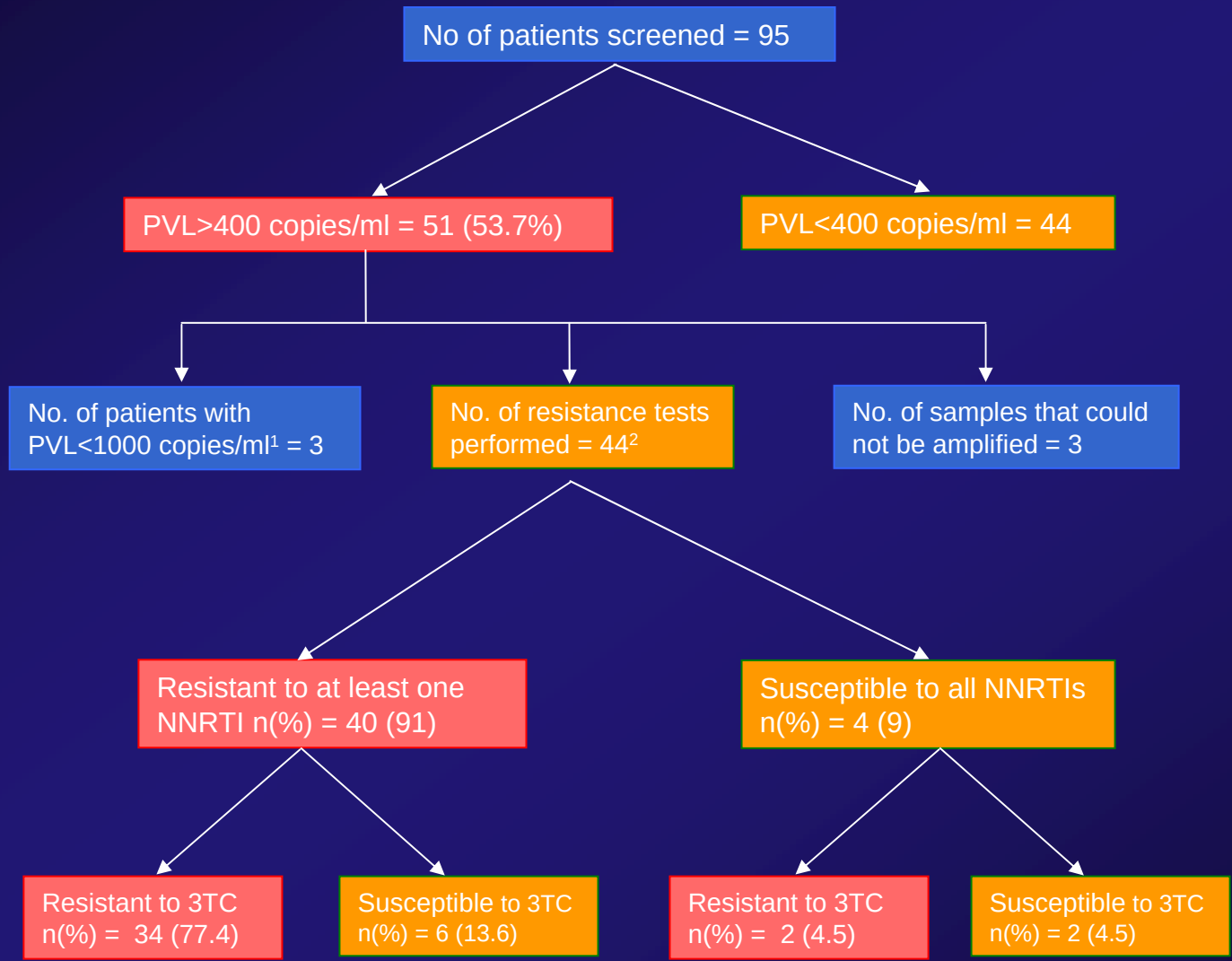
Treatment Failure and Resistance among 95 HIV-1 Infected Treatment Experienced Patients in Chennai, India



Solomon SS et al – In Press

Conclusion

- India still faces many challenges in the war against HIV
- Wars are won only one battle at a time
- India has made remarkable progress since 1986
  - Targeted Interventions
  - VCT in all districts
  - PMTCT
  - Free ART
  - Second-line in two centers


Namaste