



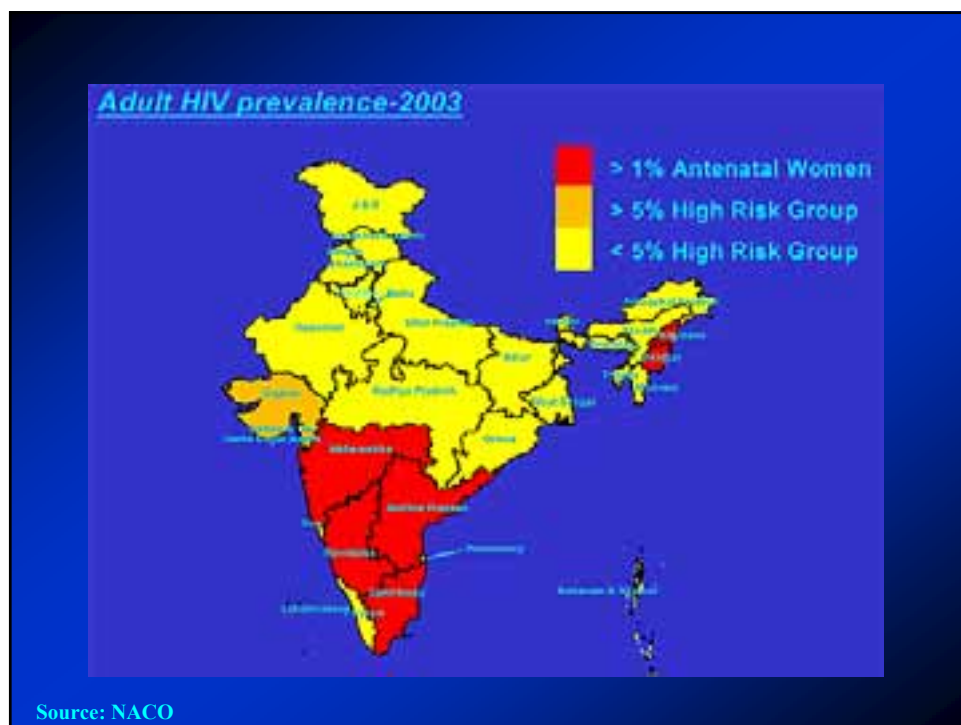
Rationale, Needs, Challenges, Uptake and Impact of Female Condom



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Research & Education



Distribution of infected population according to rural - urban

Residence	Male (Million)	Female (Million)	Infected Population (Million)	Per cent
Urban	1.329	0.798	2.127	41.43
Rural	1.803	1.204	3.007	58.57
Total	3.132	2.002	5.134	100

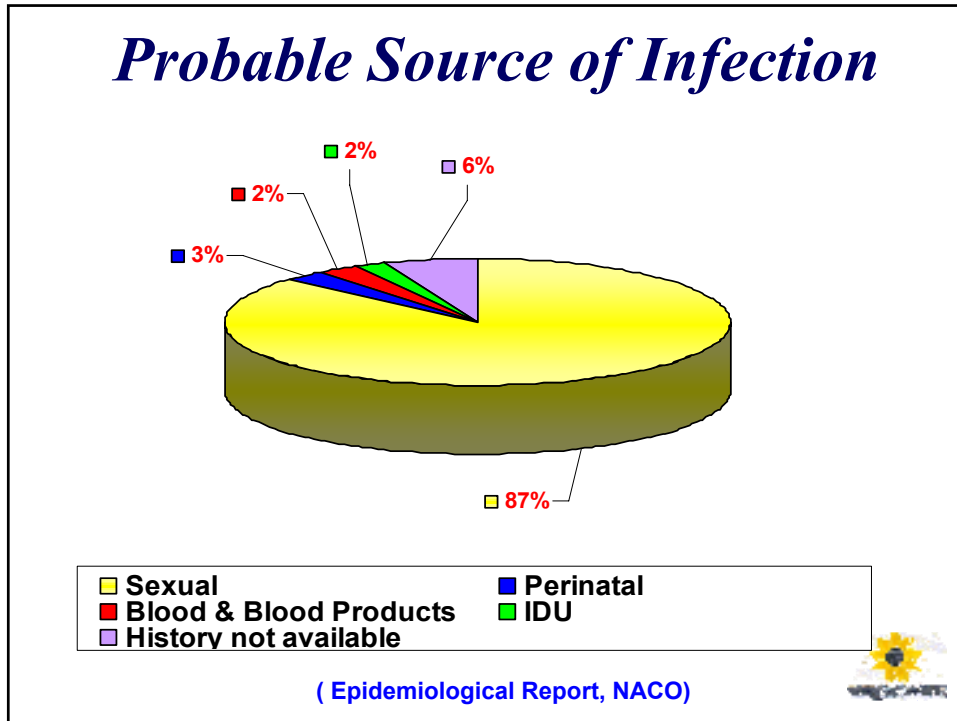
Source: NACO

Marriage, monogamy and HIV: a profile of HIV-infected women in South India


International Journal of STD & AIDS 2000; 17: 250-253 – A SHORT REPORT
S.Newmann MD, P Sarin MD, N Kumarasamy MBBS, M Rogers MD,
P Madhivanan MBBS, T Flanigan MD, S Cu-Uvin MD,
S McGarvey Ph.D., MPH, K Mayer MD and S Solomon MBBS, MD

- Mean age - 29 years
- 81% were housewives
- 95% were married
- 89% were infected thro' heterosexual route
- 88% reported history of monogamy





Challenges

- Cultural Issues
 - Acceptability (Men/Women)
 - Cost
 - Disposal of used condoms
 - Substance Abuse
 - Domestic Violence
- 

In your experience, what is the likelihood that a man will become violent towards his wife or intimate partner as a result of the following things?

(Only Female Respondents, n=1969 {99.4%} have experienced)

Q.No.	Question	Likely %	Possible %	Unlikely/ No %
1	Disagreement about money	93.4	5.4	1.2
2	Argument over actual or suspected male affairs	88.1	11.7	0.2
3	Man's criticism of woman's cooking, cleaning or performance of other household work	60.4	35.9	3.7
4	Woman's desire for greater freedom	50.5	44.1	5.4
5	Man Is drunk	95.7	4.0	0.3
6	Woman's refusal of SEX	78.5	18.8	2.7
7	Woman initiated condom use	55.7	10.7	9.2
8	Dowry as an issue	75.8	22.3	1.2
9	Barren woman as issue	80.1	19.1	0.5

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%



Sexual Behavior over time among the men in the last one month

Engaged in vaginal sex with non primary partner [n (% Yes)]	131 (52)	61 (29)	38 (18)	< 0.0001	< 0.0001	0.001
Number of vaginal sex episodes [Mean (SE)] ⁴	4.02 (0.49)	3.00 (0.41)	2.89 (0.47)	0.1313	0.0753	0.9332
Used a condom during vaginal sex [n (% Yes)] ⁵	49 (37)	28 (46)	14 (37)	0.2082	0.9067	0.3835

Sexual Behavior over time among the women in the last one month

Engaged in vaginal sex with non primary partner [n (% Yes)]	122 (49)	80 (35)	74 (31)	< 0.0001	< 0.0001	0.0927
Number of vaginal sex episodes [Mean (SE)] ⁴	9.42 (1.1)	7.86 (1.51)	7.97 (0.93)	0.2003	0.1990	0.9837
Used a condom during vaginal sex [n (% Yes)] ⁵	92 (75)	68 (85)	62 (84)	0.0418	0.1810	0.7334
Percentage of time condom was used [Mean (SE)] ⁴	91.3 (1.99)	94.6 (1.91)	97.6 (1.37)	0.1699	0.0166	0.2329

Cultural Issues

- Marriage
- Bride inheritance
- Fertility pressures
- Son preference
- Forced abstinence
- Breast feeding



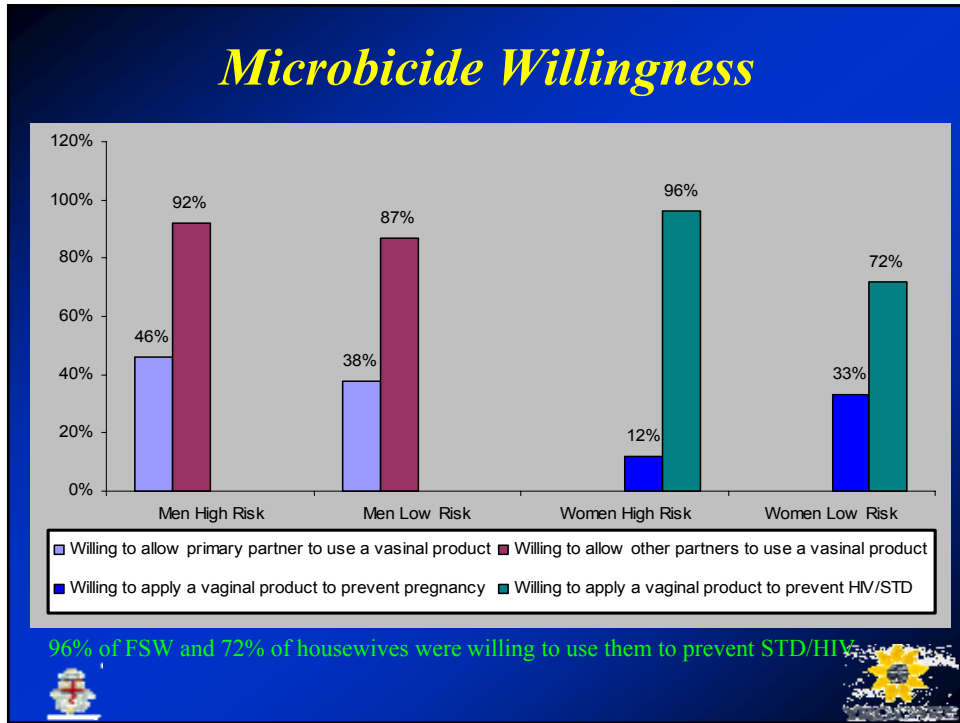


Barren women are not welcome at a Valaikappu Ceremony

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

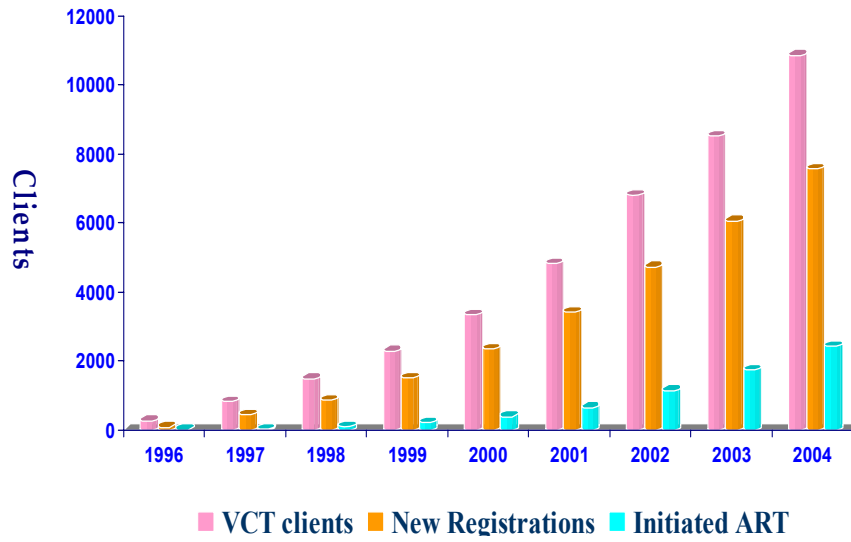




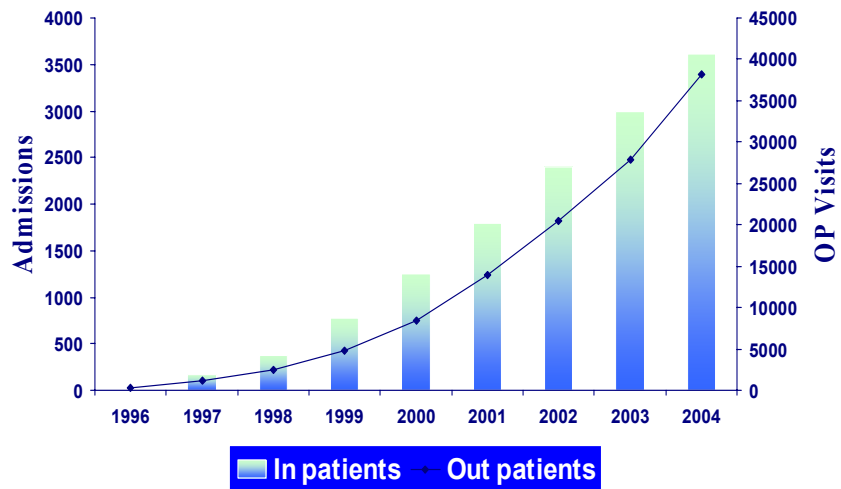
YRGCARE Data (Upto Aug'05)

Total # of Couples	-	2408
Concordant	-	1154
Discordant	-	1254
Male (Positive)	-	1132
Female (Positive)	-	122

Cumulative patient flow at YRG CARE

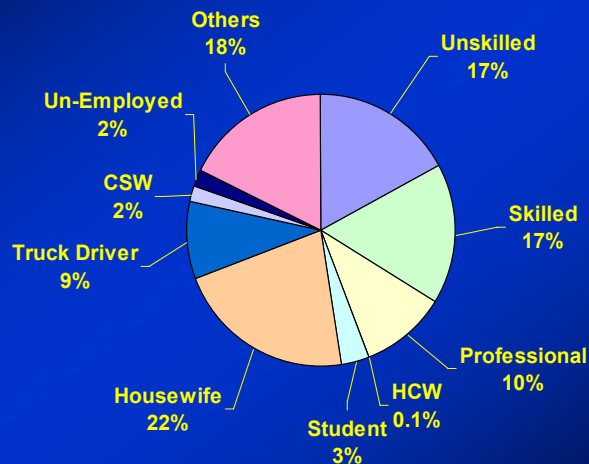


Cumulative patient flow at YRG CARE



Voluntary Counseling and Testing

Occupation of HIV+ Clients



HIV among Sex Workers in India

- **1.1 % of women in adult population could be FSW, hence 2.9 million FSW in India (estimated).**
- **Prevalence of HIV among FSW – 6.2% hence total HIV Positive Sex Workers about 1.8 lakhs**

Preliminary findings of Wine-shop Patrons and Women Sex Workers (Baseline)

Sexually Transmitted Infection	Male	% on Attended Till Date	Female	% on Attended Till Date	Total	% on Attended Till Date	
		2852		619		3471	
Trichomonas			182	29.40%	182	29.40%	
Syphilis	RPR	109	3.82%	125	20.19%	234	6.74%
	TPPA	98	3.44%	122	19.71%	220	6.34%
HIV	71	2.49%	35	5.65%	106	3.05%	
HSV2	643	22.55%	411	66.40%	1054	30.37%	
CT	15	0.53%	28	4.52%	43	1.24%	
NG	5	0.18%	5	0.81%	10	0.29%	
HBV	171	6.00%	16	2.58%	187	5.39%	
HCV	222	7.78%	47	7.59%	269	7.75%	



APAC Study

CSW : Prevalence 9.2% (27/295)
 Incidence rate of 2.04 per 100
 persons per year
 (based on Detuned assay (BED-EIA)).

General Women Population: Prevalence 0.3%
 Incidence rate of 0.3 /100
 persons per year

Uptake

- **Regular and Timely counselling on potential problems**
- **Partners perception and acceptance**
- **Training**
- **Advocacy**
- **Sensitise Police on PITA**



Response & Perspectives from the field – Study of Female Condom, our Experience

Comparative Research study of the Reality® Female Condom and Modified Reddy Female Condom (version 4)

Objective:

Acceptability & Functional performance of version 4 of Reddy Female Condom, compared to Reality Condom

Safety was evaluated by any Adverse experiences associated with the device used

Study Details

- Reality female condom- made of polyurathane, Female Health Company, UK
- Reddy female condom - made of latex, Medtech Co., Chennai, India
- Sample size – 60, literate couples, in monogamous relationship, using any other contraceptive method
- Study sites – National AIDS Research Institute (NARI) , Pune and YRG Centre for AIDS Research and Education, Chennai



Study Design

Study design – The design of the study was a prospective cross over design with simple randomisation of the sequence of the study condoms. Volunteers were requested to use atleast one condoms per week

Reality
A1,A2,A3
B1,B2,B3

Reddy
B1,B2,B3
A1,A2,A3

Demographic characteristics

Characteristic	Total	Male		Female	
		N	%	N	%
Age in Years					
18 to 30	50	15	25	35	58.3
31 to 40	57	35	58.3	22	36.7
> 41	13	10	16.7	3	5
Total	120	60	100	60	100
Mean (s.d.)		36.08(6.98)		30.32(6.03)	
Median		35		30	
Range		22-59		20-48	
Education					
Up to 10th Std	84	41	68.3	43	71.7
> 10th Std	36	19	31.7	17	28.3
Total	120	60	100	60	100

Marital status & personal history

Characteristic	Total	%
Relationship with current partner		
Married	59	98.30%
Living together	1	1.70%
Separated/ not living together	0	0%
Total	60	
Current method of contraception		
Birth Control pills	6	3.34%
Menopause (no periods for 1 year)	1	0.60%
Tubes tied	44	24.45%
IUD	8	4.45%
Partner has a vasectomy	3	2%
Total	62	
1 couple with IUD and vasectomy both and the other with birth control pills and vasectomy		

Study condom usage details

Characteristics	Reddy	Reality
Condom was successfully inserted	100 %	100 %
Male Partner inserted the condom	21.1 %	26.7 %
Both Partners inserted the condom	4.4 %	6.7 %
Had Trouble in inserting the penis into the condom	-	6.7 %
Had Sex while wearing the study condom	100 %	100 %

No. of condoms	Reddy version 4			Reality		
	N	%	95% CI	N	%	95%CI
Opened	180	100%		180	100%	
Broken while opening	0	0		0	0	
Broken after opening, before insertion	0	0		0	0	
Broken during insertion	0	0		0	0	
Broken after insertion, before intercourse	0	0		0	0	
Used during vaginal intercourse	180	100%		180	100%	
Broken during intercourse	0	0		0	0	
Broken during removal	0	0		0	0	
Clinical Breakage	0	0		0	0	
Nonclinical breakage	0	0		0	0	
Total breakage	0	0		0	0	

Acceptability of Female condoms by gender and condom type

Data items with response ranked as most (score=1) to least favorable (score=7)	Median Scores			
	Females (n=60)		Males (n=60)	
	Reddy	Reality	Reddy	Reality
01. Ease of inserting condom	1	2	2	2
02. Comfort during insertion of condom	2	2	2	2
03. Feel of lubricant on condom during insertion	2	2	2	2
04. General appearance of condom after insertion	2	3	2	2.5
05. General fit of condom	2	2	2	2
06. Feel of condom material	2	2	2	2
07. Smell of condom	3	3	3	3
08. Comfort during use	2	2	2	2
09. Sensitivity/Stimulation during use	2	3	2	2
10. Noise during use	1	1	1	1
11. Feel of lubricant on condom use	2	2	2	2
12. Ease of removing condom	1	2	1	1

Level of confidence in study condom compared to male condom by gender and condom type

Characteristics	Females (n=60)				Males (n=60)			
	Reddy		Reality		Reddy		Reality	
	N	%	N	%	N	%	N	%
<i>Confidence in the study condom to protect from diseases and pregnancy compared to male condoms used before</i>								
01. More confident	30	50	33	55	27	45	33	55
02. Somewhat more confident	11	18	9	15	10	17	11	18
03. About the same amount of confidence	6	10	9	15	11	18	6	10
04. Somewhat less confident	2	3	1	2	0	0	1	2
05. Less confident	1	2	0	0	2	3	1	2
06. Never used male condom before study	10	17	8	13	10	17	8	13
Total	60	100	60	100	60	100	60	100
Willing to buy study condom in the future	51	85	53	88	53	88	50	83
Would recommend the study condom to others	51	85	55	92	55	92	51	85
<i>For both females and males, none of the comparisons between the two condoms were statistically significant</i>								

Condom Functionality						
Condom functionality	Reddy version 4			Reality		
	N-180	%	95% CI	N-180	%	95% CI
Trouble with insertion of the penis into the female condom(? incorrect penetration)	4	2.22%	0.58-5.64	9	5.00%	2.29-9.31
Outer ring/ frame displacement	66	36.67%	29.61-44.17	71	39.44%	32.24-46.99
Pullout	19	10.56%	6.46-16.01	14	7.78%	4.30-12.73
Complete slippage	5	2.78%	0.88-6.41	1	0.56%	0.0002-3.14
Partial slippage	14	7.78%	4.30-12.73	10	5.56%	2.67-10.01
Total slippage	19	10.56%	6.46-16.01	11	6.11%	3.07-10.70
Complete turning inside out (during intercourse)	0	0.00%		1	0.56%	0.0002-3.14
Complete turning inside out (during withdrawal)	0	0.00%		1	0.56%	0.0002-3.14
Partial turning inside out (during intercourse)	12	6.67%	3.47-11.38	5	2.78%	0.88-6.41
Partial turning inside out (during withdrawal)	9	5.00%	2.29-9.31	11	6.11%	3.07-10.70
Total clinical failure (clinical breakage, condom completely/ partially turned inside out during intercourse/withdrawal, complete slippage during intercourse, outer frame displacement, incorrect penetration during intercourse/withdrawal)	96	53.33%	45.75-60.79	99	55%	47.41-62.41
Total failure (Tot. Clinical failure + pullout)	115	63.89%	56.39-70.90	113	62.78%	55.26-69.86

Possible reasons of failure-

1. Participating females had never seen a female condom
2. Insertion requires some skills
3. Insertion is easier with repeated applications-previous reports
4. Participants were not literate enough to properly complete the questionnaire after each condom use

Adverse events reported:

One participant reported burning of micturation for 1-10 minutes after using the Reality condom.

Reddy condom when compared to Reality (Female participants comments)

- Easier to use
- Manufacturer's instructions were easy to understand
- More comfortable
- Feel of lubricant better than Reality
- General appearance after insertion good
- General fit, feel of the material better
- Smell – better
- Better sensitivity/ stimulation during use
- Less noisy
- Easy to remove
- Less confident as compared to Reality for protecting against pregnancy and STDs

There was no statistically significant difference.

Challenges

A Woman's initiations is seen as in-subordination/sign of her infidelity – triggers violence

Men's comments are similar – will hit a woman if she suggests a condom use

Third party intervention is often unsuccessful

Conclusion

Female and male participants reactions centered on satisfaction – same feeling and pleasure

General feeling that condom kept moving and was intrusive during sexual act

Privacy in use of disposal of condom were raised

Co-operation from the male partners provided better ability to discuss condom use

Participation of men in such studies must go beyond mere informed consent

