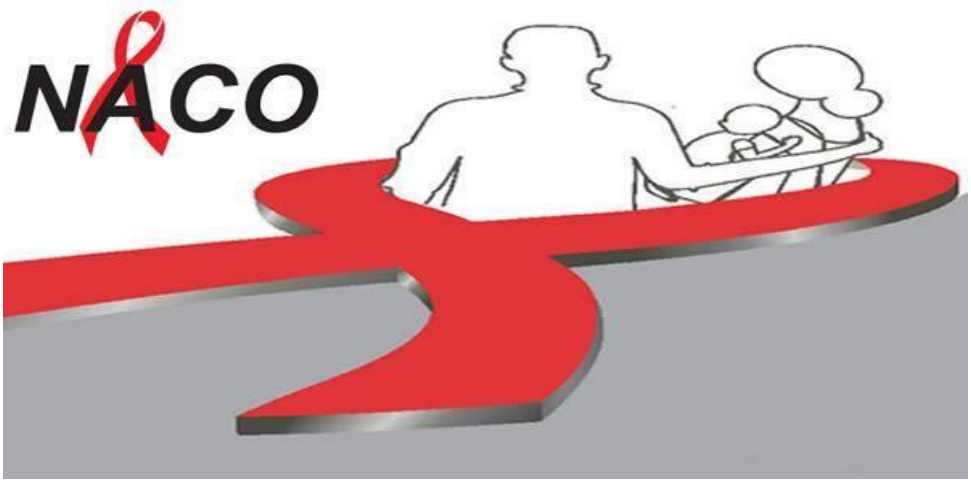

Health Technology Assessment for Strengthening Prong 2 Interventions of PPTCT Program at Public Health Facilities through Provision of Linked HIV and Family Planning Services

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“HEALTH TECHNOLOGY ASSESSMENT FOR STRENGTHENING PRONG 2 INTERVENTIONS OF PPTCT PROGRAM AT PUBLIC HEALTH FACILITIES THROUGH PROVISION OF LINKED HIV AND FAMILY PLANNING SERVICES”

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ANC	Ante-Natal Care
ART	Anti-Retroviral Treatment
ARV	Anti-Retroviral drugs
AXIS	Appraisal of cross-sectional studies
BCC	Behavioral Change Communication
CASP	Critical Appraisal Skills Program
DHR	Department of Health Research
FP	Family Planning
EQ-5D-5L	EuroQol-5 Dimensions-5 Levels
EQ-VAS	EuroQol Visual Analog Scale
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRQoL	Health Related Quality of Life
HRG	High Risk Groups
HTA	Health Technology Assessment
HTAIn	Health Technology Assessment in India
ICER	Incremental Cost Effectiveness Ratio
ICUR	Incremental Cost-Utility Ratio
IEC	Information Education and Counselling
INR	Indian Rupees
IPD	In-Patient Department
IDU	Injectable Drug Users
IQR	Inter-Quartile Range
IUD	Intra-Uterine Device
LARC	Long Acting Reversible Contraception
MS	Microsoft
MSACS	Maharashtra State AIDS Control Society

MSM	Men have Sex with Men
NFHS	National Family Health Survey
Non-RCT	Non- Randomized Control Trial
OC pills	Oral Contraceptive pills
OB-GYN	Obstetrics and Gynaecology
OOPE	Out of Pocket Expenditure
OPD	Out-Patient Department
OSWA	One Way Sensitivity Analysis
OT	Operation Theatre
PLHIV	People Living with HIV
PPTCT	Prevention of Parent to Child Transmission
PRISMA	Preferred Reporting items for Systematic Reviews and Meta-Analysis
PSA	Probabilistic Sensitivity Analysis
QALYS	Quality Adjusted Life Years
RCT	Randomized Control Trail
ROBINS 1	Risk of Bias in Non- Randomized Studies
SD	Standard Deviation
SOC	Standard of Care
TFR	Total Fertility Rate
TI	Targeted Intervention
TS	Transition Probabilities
VAS	Visual Analog Scale
UN	United Nations
WHO	World Health Organization
WLHIV	Women Living with HIV

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EXECUTIVE SUMMARY

One of the main goals outlined in India's National Strategic Plan is the eradication of mother-to-child HIV and syphilis transmission. The four pronged PPTCT focused on i) preventing HIV, ii) Preventing unintended pregnancies among women living with HIV (WLHIV), iii) Preventing mother to child transmission (MTCT), and iv) Provide care, support and treatment to WLHIV, her children and family in women in child bearing age.

India have primarily been focused at the third prong of the PPTCT after adopting the WHO strategy for its PPTCT programme. The plan was to lower the mother-to-child transmission rate to less than 5% by introduction HAART therapy for pregnant WLHIV patients with the Option B+ medication regimen.

We have addressed the policy question of whether strengthening Prong 2 interventions of the PPTCT program through the provision of linked HIV-FP services to prevent unintended pregnancies among WLHIV in public health care settings is cost-effective in this report. Health technology assessment has been the chosen approach to explore this question. A step-wise methodology has been followed to conduct this HTA. The study evaluated the effect of various facility-based interventions to integrate HIV care and family planning services among WLHIV. The integral elements of an HTA: Primary data methods, integrative methods (decision analytical modelling), economic and equity analysis were carried out.

The effectiveness of health facility-based interventions in reducing unmet family planning needs, increasing uptake of modern contraception and dual methods among PLHIV in the reproductive age group, and decreasing the incidence of unintended pregnancy among WLHIV was assessed through a systematic review and meta-analysis. The pooled odds ratio for uptake of dual contraception was found as 1.42 [1.03, 1.95] ($p<0.05$; $I2=90\%$), and that of unmet family planning needs was 0.75 [0.59, 0.94] ($p=0.01$, $I2=83\%$).

Health system costing from the provider perspective were taken from different study sites. The unit cost for providing ART services was INR 1729.4 per visit per year. The annual health system package costs, including the program and follow-up cost for various family planning services, ranged from INR 433.2 for condom users to INR 9254.6 for the permanent method with condom

use. The same for pregnancy-related services were INR 595.7 for antenatal services, INR 3936.2 for vaginal delivery, INR 15739.6 for C-section delivery, and INR 6918.3 for abortion.

Primary data was also collected to estimate health utility scores of WLHIV in the reproductive age group, particularly in -the context of contraceptive use, during pregnancy and the postpartum period. The mean utility and VAS scores were 0.976 (±0.519) and 82.21 (±15.77). Subgroup analyses revealed significantly higher utility scores [0.986 (±0.029)] among contraceptive users as compared to non-users 0[6258/6+-0.976 (±0.028)]. WLHIV who had undergone sterilization had the highest utility score among contraceptive users. Currently pregnant WLHIV had least utility score [0.959 (±0.088)]. Unfortunately we did not get adequate numbers to interview dual contraceptive users and hence the expected difference in utility scores among dual method users and only condom users was not evident.

Primary data was collected to estimate the OOPE among WLHIV to avail of ART, family planning, and pregnancy-related services. The median OOPE for ART services was INR 1000 (500-1800) and for family planning services was INR 2200 (1050-6000). The OOPE was highestfor C-section delivery among all the pregnancy-related conditions at INR 6860 (3170-10740). Thehealth system costing study aimed to determine the health system cost of providing ART care, family planning services, and management of pregnancies among WLHIV.

Lastly, to access the cost-effectiveness of strengthening the PPTCT program through the provision of linked HIV-FP services to prevent unintended pregnancies among WLHIV in public health care settings. We designed and constructed a decision analytical Markov model. We tried to replicate a real life scenario through the transition probabilities, discontinuation rates, failure rates, and switching probability of various contraceptive methods. The sources for these parameters were MSACS program data for 2019-20 and NFHS-4 (2015-16).

We ran the model to estimate the Incremental Cost-Effectiveness Ratio (ICER). The results of the modeling exercise are summarized below:

- ICER (We preferred to use ICER/clinical events such as pregnancies and child birth averted rather than per QALY gained as EQ5D measures are not expected to grossly vary due to single contraceptive use vs dual method users and as mentioned above we did not get adequate data to justify the difference)

    - Unintended pregnancies averted, live births averted, abortions averted, and maternal deaths averted
    - Infant HIV infections averted
    - Sensitivity analysis
- A cohort of 782107 WLHIV (National AIDS Control Organization (NACO), India *HIV estimates, 2020)* in the reproductive age group using the model and a time horizon of 31 years were followed up. At an incremental cost of INR 11,435, an unintended pregnancy is averted by providing linked HIV-FP services that focuses on promoting dual methods of contraception. ICER value of INR 11,435 per unintended pregnancy averted is below the WTP threshold of one time Indian GDP per capita value. Similarly, at an incremental cost of INR 46647, INR 19553, and INR 95192 livebirths, abortions, and deaths are averted by providing linked HIV-FP services that focuses on promoting dual methods of contraception. And, ICER values of these livebirths, abortions, and deaths averted are below the WTP threshold of 1 time Indian GDP per capita value. Hence, intervention is cost-effective.
- About 72604 unintended pregnancies, 17425 unintended livebirths, 41610 induced abortions, and 8722 maternal deaths (among a cohort of 15-year old for 34 years i.e. until age of menopause) could be averted by considering HIV and FP linkage.
- Assuming 2% PPTCT transmission rate with mother on HAART , about 2752 infants diagnosed with HIV could be averted by considering HIV and FP linkage.
- However in programmatic settings, this transmission rate reported is 5%. At this level of transmission 6880 infant diagnosed with HIV positive status could be averted.
- Of the 1000 simulations, pregnancies averted showed 100% cost-effective, 71.7% showed that livebirths averted is cost-effective, with 95.7% are cost-effective for abortions averted falling in upper right quadrant and only 57.1% of deaths averted is cost-effective.

Limitations:

Our model measures a few benefits of the intervention (unintended pregnancies averted, abortions averted, live births averted, deaths averted, etc). There are more benefits of the intervention in terms of health of the women, financial implications of bringing up a child due to unintended pregnancy and the implications on the HIV status of the infant and future outcomes. But measuring all the benefits would have increased the complexity of the analysis.

Conclusions:

- The intervention to integrate HIV care and FP services was determined to be cost-effective and cost-saving.
- The intervention would reduce unintended pregnancies, live births, abortions, and maternal deaths and infant with HIV infections.

Recommendations

- Access to all contraceptives is a matter of right of PLHIV to be able to use effective methods, plan, when and how many children to born. This will reduce burden on the pregnant women as well as health system to manage HIV +ve pregnancies and their outcomes.
- The existing PPTCT program could be strengthened to promote dual methods among PLHIV women by holistic counseling and providing linked ART services to OBGYN department to address sexual and reproductive health needs
- Improve knowledge among service providers during training and correct any misconceptions regarding use of various contraceptives among PLHIV
- Inform and motivate the stakeholders regarding the efficiency and effectiveness of this simple intervention that could help achieve SDG targets of 0% new infections.

CHAPTER 1: INTRODUCTION

With no cure, HIV remains a major global public health concern with 37.7 million individuals living with the condition and 1.5 million people getting newly infected in the year 2020 [1, 2]. Significantly, an estimated 1.3 million pregnant women were living with HIV thus exposed to the risk of maternal-to-child transmission [2]. A four-prong PPTCT strategy was recommended by the WHO to prevent the parent-to-child transmission of HIV infection [3]. The first prong deals with the prevention of the infection; the second focuses on the prevention of unintended pregnancies among WLHIV; providing specific interventions to inhibit the transmission of the disease from the pregnant mother to her infant is prong 3; care, support, and treatment for infected mothers and children is prong 4 [3].

India has shown a decline in the prevalence of adult HIV from 2001 to 2020 (0.54% to 0.22%) reflecting the excellent dedicated National AIDS Control vertical program of the government [4–6]. Maharashtra has the highest number of People Living with HIV (PLHIV), and the number of cases was 3.94 lakhs i.e. 3940 PLHIV per million in Maharashtra (2021) [7]. The mother-to-child transmission rate has fallen to <2% due to the HAART Option B plus [8]. However, studies from India report a high unmet need for family planning among WLHIV, highlighting the low priority of the PPTCT program on the prevention of unintended pregnancies [9].

The Sustainable Development Goals targets to end epidemics like AIDS by 2030 [10]. For achieving this, strengthening all prongs of PPTCT including preventing unintended pregnancies is vital. The integration of HIV care services into family planning services and vice versa could improve the uptake of sexual and reproductive health services among People Living with HIV (PLHIV). It could also assist in reducing the stigma related to the condition. Therefore, this could improve both the quality of life and service coverage among this vulnerable population [11].

The bidirectional linkage between HIV and family planning services considering the low prevalence of HIV in the general population may not be a cost-effective measure considering the extensive need for resources for catering to the entire population. Instead, linkage of the HIV service delivery institutions to family planning services is a more feasible option.

Studies conducted in the African region have demonstrated the clinical [12–14] and cost-effectiveness [15, 16] of prong 2 interventions compared to Prong 3. Although evidence of its

clinical effectiveness exists in the Indian setting [9] there is no study on its cost-effectiveness. Considering that the country has completed its fourth phase of the National Aids Control Program and via its National Strategic Plan for the year 2017-24 aims to achieve targets of HIV elimination by the year 2030, and the 90-90-90 target by 2020 remains unachieved. This study will help policymakers and implementers by improving the evidence basis for decision-making on the approach to be set for achieving the set targets. This study will assess the cost-effectiveness of linking HIV to family planning services that will add to the limited global evidence for the cost-effectiveness of linked HIV and sexual and reproductive health services for people living with HIV.

CHAPTER 2: OBJECTIVES

2.1 Research Question

What is the cost effectiveness of strengthening Prong 2 interventions of PPTCT program through provision of linked HIV-FP services to prevent unintended pregnancies among WLHIV in public health care settings?

2.2 Aims and Objectives of the study

Aim:

To assess the cost effectiveness of strengthening Prong 2 interventions of PPTCT program through provision of linked HIV-FP services to prevent unintended pregnancies among HIV infected women

Objectives:

Primary Objectives:

- To collate evidence on effectiveness of providing integrated HIV and FP services to improve the uptake of contraception and in reducing unmet FP needs and unintended pregnancies among WLHIV
- To estimate the cost-effectiveness of providing linkage of HIV to FP services in reducing unintended pregnancies among WLHIV.

Secondary Objectives:

- To estimate Health Related Quality of Life (HRQoL) and health utility scores for WLHIV in India.
- To estimate the Out of Pocket Expenditure (OOPE) by the beneficiary for availing the HIV-FP services & pregnancy related services
- To estimate the health system cost of providing linkage of HIV-FP services along with management of pregnancy outcomes in the current Indian setting

The need for this HTA evaluation has been proposed by the Family Welfare Division of Maharashtra State Government to address unmet needs of contraception of vulnerable population (WLHIV).

CHAPTER 3: METHODOLOGY

The present study is a Markov model-based analysis for estimating the cost-effectiveness of strengthening WHO Prong 2 intervention through linkage of HIV-FP services among WLHIV in public health care systems in India. The model follows a hypothetical cohort of WLHIV in the reproductive age group (15-49 years). The outcomes measured for cost-effectiveness in terms of ICER, for unintended pregnancies, livebirths, abortions, and death averted and the number of infant HIV infections averted. A disaggregated societal perspective was used for the model.

Ethics approval was taken from the Institutional Ethics Committee Board. Participant's informed consent was obtained for primary data collection.

3.1 Conceptualization of the Model

A Markov-transition state model was conceptualized and populated through literature review and expert consultation, within the context of the tertiary public health settings in India. The model aimed at determining the cost-effectiveness of linking HIV (ART)-FP services for WLHIV (15-49 years) in the current public tertiary health setting. Health states pertaining to use of various contraceptive methods and pregnancy related events were considered in the model (Figure 3.1). These health states were:

1. Not using any method of contraception
2. Using only condom
3. Using reversible contraception methods along with condom (dual method)
4. Using reversible contraception methods without condom
5. Using irreversible contraception methods along with condom (dual method)
6. Using irreversible contraception methods without condom
7. Pregnancy
8. Death

The pregnancy could be intended or unintended. Both intended and unintended pregnancies would result in either live births (vaginal or C-section), or abortion. After birth, the infant would receive ARV prophylaxis and will be tested for HIV at 6 months. Post the testing, the new born could be diagnosed with HIV or not.

3.1.a Model characteristics:

Population: The model cohort included WLHIV (15-49 years) who may be in a concordant or a discordant relationship. These participants were expected to have various contraception use patterns depending on their fertility desires and choices. Therefore, the Markov model began with a cohort of WLHIV in the reproductive age group who transitioned through varied contraception use, pregnancy, and pregnancy outcomes. As listed above these states include non-users of contraception, only condom users, using reversible methods with/ without condom use, and using irreversible methods with/ without condom use. The cohort would move through the cycle length and result in either pregnancy or would continue in a state of no pregnancy. The pregnancies would result in live births (vaginal or C-section), still births, or abortions. Death is an absorptive state (due to all-cause mortality and HIV-specific mortality).

Intervention: The strengthening of linkage of HIV (ART) and family planning services at public health facilities with interventions such as i) training of the healthcare providers (both ART & FP to promote dual methods), assessment of the unmet need for contraception among PLHIV, comprehensive counseling, and providing linked HIV (ART) & FP services, to improve the promotion of dual method use, iii) monitoring and supervision.

Comparator: Current standard of care consists predominantly of condom promotion for HIV infection control without much emphasis on other methods of contraception and limited referral for linked FP services in absence of effective linkage.

Outcome: The outcome of the pregnancy would result in unintended pregnancies, live births (vaginal or C-section), abortions averted and deaths averted. Death is an absorptive state in the model (due to all-cause mortality and HIV-specific mortality). In addition, eventually, the delivery would result in HIV-positive live birth or HIV-negative live birth. The model will be run twice separately for linked and non-linked services to estimate the possible outcomes.

Cycle length and time horizon: The cycle length considered was one year (9 months with pregnancy & 3 months post-partum period) and the time horizon was 31 years.

Discount factor: Discounting rate of 3% (2-5%) was applied to costs and outcomes of the model, as per the HTAIn reference case.

3.1.b Model Assumptions:

1) The hypothetical cohort of WLHIV was either using a modern contraceptive (assuming majority of women are using modern method) or was considered as a non-user of any family planning methods (even if she was using a traditional/ less effective method).
2) Discontinuation of the particular contraceptive method, desire to become pregnant, or failure of family planning methods were the reasons for exit/ switching between the various family planning-related health states
3) Death is an absorptive state and can happen when the woman is in any health state
4) Due to the unavailability of better data on contraception use patterns after intervention among non-users and only condom-users, we have assumed a 10% decrement in both these health states after intervention while 22% increment for all other relevant health states based on study reported the same [9].
5) Both state centers and OBGYN departments are in district and tertiary facilities. About 46 ART exist in tertiary hospitals and medical college of Maharashtra as reported by MDACS. Cost of incentives for training and ICE . Cost of beneficiaries was derived from Government of Maharashtra & applied to cohort size. Hence, cost of interventionincluded was used for training and IEC @ Rs.5000 each center.
6) Different transition and switching probabilities were assigned for each age group. For example, less than 20-year-old WLHIV would have a lesser chance of using permanent method.

2.1.d Quality check of the Markov model:

The model was checked and validated by experts, other than the investigators for the concept, data flow, and analysis.

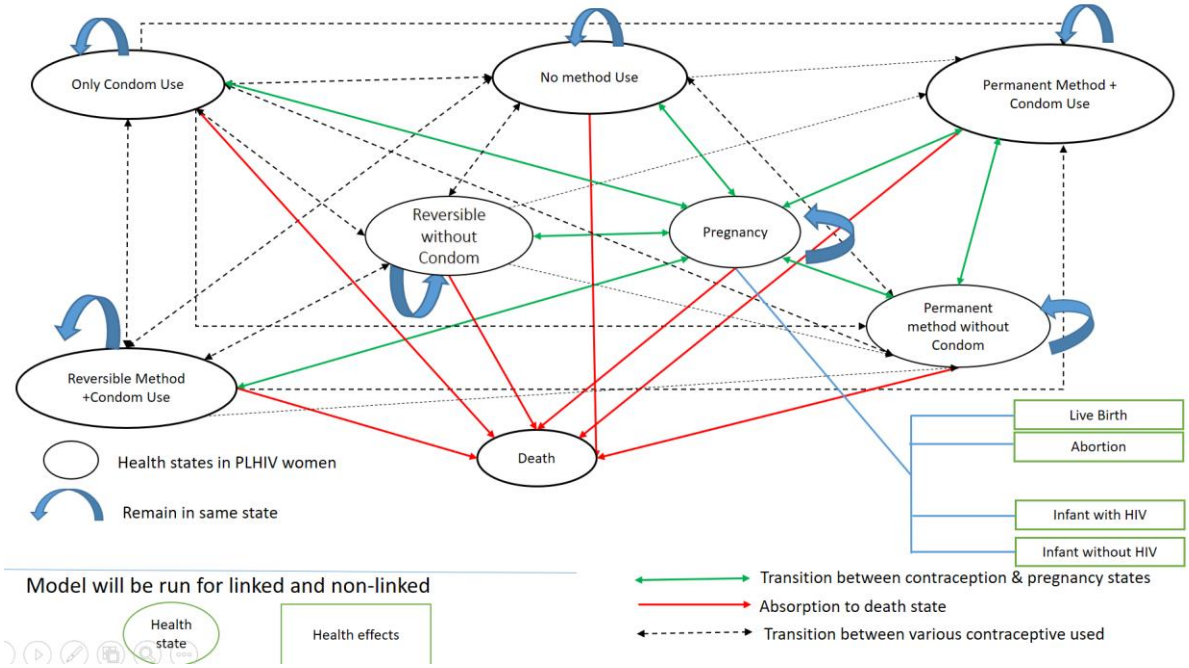


Figure 3.1: Markov model for WLHIV in the reproductive age group using different methods of contraception and possible outcomes

3.2 Model Parameters:

To generate the required input parameters for the model, four sub-studies were carried out:

1. Systematic review to collate evidence on the effectiveness of integrating HIV and FP services to improve uptake of contraception and reduce unmet FP needs and unintended pregnancies among WLHIV
2. Primary cross-sectional study to estimate the HRQoL using EQ-5D-5L tool among WLHIV
3. Primary cross-sectional study to estimate the OOPE for availing ART, FP, and pregnancy-related services among WLHIV
4. Bottom-up micro-costing study to estimate the health system cost for providing the ART, FP, and pregnancy-related services to WLHIV

3.2.1 Systematic review and Meta-analysis on effectiveness of health facility-based interventions in improving uptake of contraception and preventing unintended pregnancies among people living with HIV

Methods:

We searched for published studies in three electronic databases. The databases were PubMed, Cochrane Library, and Web of science. We looked for grey literature to identify the unpublished conference abstracts, dissertations, and thesis on the subject. The search terms used were [family planning] or [contraception] or [contraceptive] or [birth control] or [birth spacing] or [reproductive counseling] or [dual contraception] or [unmet need] or [unintended pregnancy] AND [HIV] or [AIDS] AND [integrate] or [integration] or [linked] or [linkage]'. We limited the search to studies published between 1st January, 2010 and 15th November, 2022. We also checked references of suitable articles to identify more studies.

We included articles in the English language that measured one or more of the desired outcomes and considered only those studies that had a comparison group for the review. We did not restrict the search to any geographic location.

The population of interest was PLHIV in the reproductive age group. Care was taken to avoid studies with titles and abstracts mentioning that the study population was exclusively high-risk groups like sex workers and men who have sex with men (MSM), etc because these individuals may have very different sexual practices and their contraceptive use cannot be generalized to the common public. Patients who suffered from WHO stage IV of HIV infection were also excluded [17] as some contraceptives are contraindicated for them [18]. We included comparison studies among PLHIV in their reproductive age group that evaluated various methods to integrate HIV and family planning services at the health facility level and measured any one or more of the desired outcomes.

The outcomes of interest were the uptake of modern contraception and dual methods along with the incidence of unintended pregnancies and unmet family planning needs among the population. Two reviewers assessed the titles and abstracts based on inclusion and exclusion criteria. We documented the rejected articles with the reason for exclusion. If the reviewers had uncertainty regarding the inclusion/ exclusion of any study, a third reviewer was involved in decision making.

We exported the search result to MS Excel and removed duplicates. Those studies selected for full-body review were recorded with title, author details, year, geographic location, study design, sample size, methodology, results, and limitations of the study.

We assessed the quality of the studies with appropriate risk of bias tools. We used the Cochrane risk of bias tool for randomized control trials [19]; Risk of Bias in Non- Randomized Studies (ROBINS-1) for non-randomized trials [20]; Evidence Project Risk of bias tool for pre-post-intervention studies [21]; Critical Appraisal Skills Program (CASP) for cohort studies [22] and Appraisal of cross-sectional studies using AXIS tool for cross-sectional studies [23]

Analysis:

The studies were assessed and summarized as text and tables. The narrative results focused on elaborating the various components of the intervention and the desired outcomes reported by the studies. Uptake of dual contraception and prevalence of unmet FP needs were measured uniformly by the included studies and thus considered ideal for inclusion in the meta-analysis [24]. We considered the incidence of unintended pregnancies as a proxy indicator for unmet FP needs for meta-analysis. The desired outcome was noted and entered in RevMan 5.4.1 software as dichotomous results. The pooled Odds Ratio (OR) in the random effect model summarized the outcomes. The I^2 values identified heterogeneity, and p values measured significance. Funnel and forest plots identified publication bias and dispersion of effect sizes among the individual studies, respectively. We also conducted a sub-group meta-analysis based on the study design for both the outcomes.

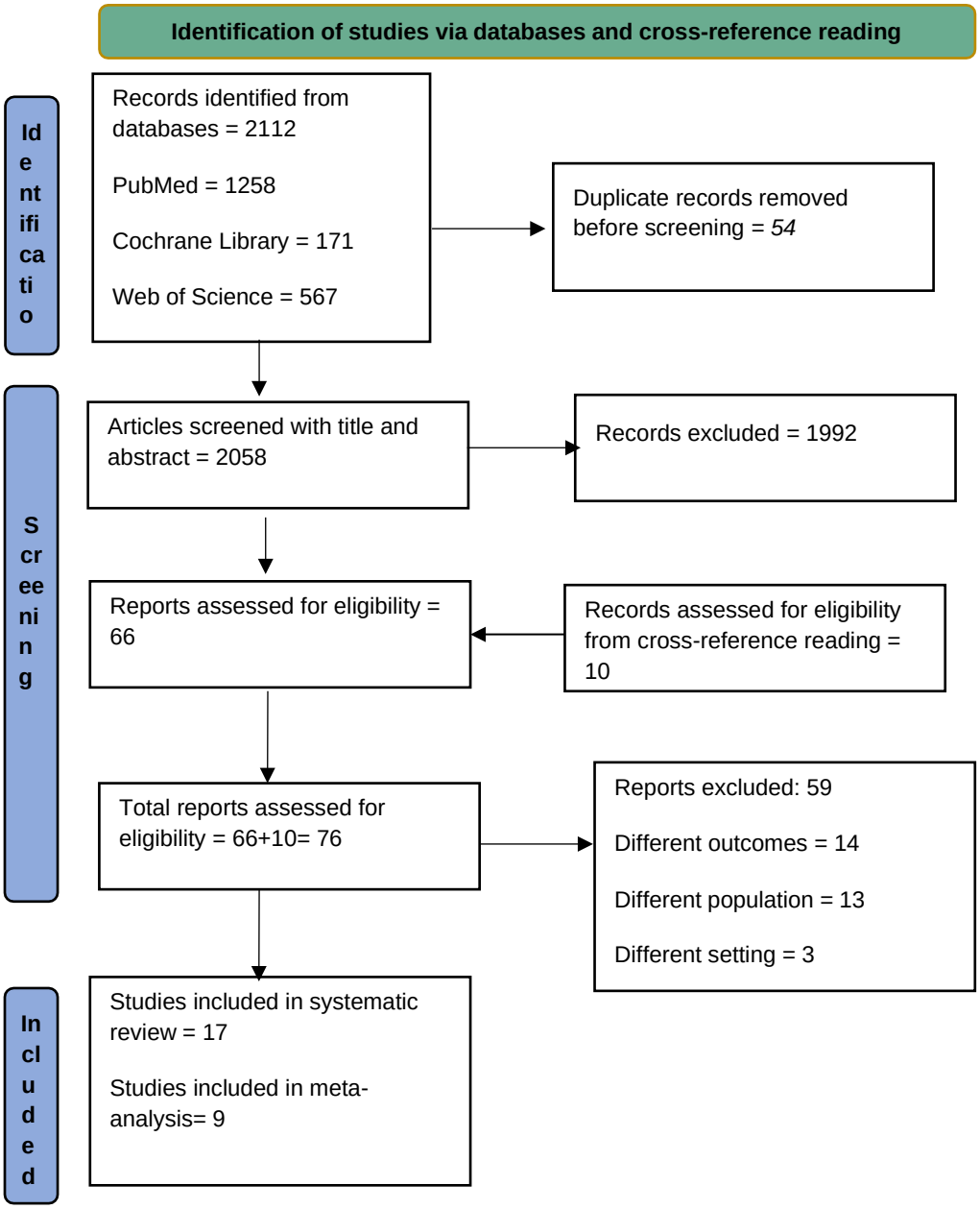


Figure 3.2: PRISMA flowchart for identification, screening and inclusion of the studies for the systematic review and meta-analysis

Table 3.1: Study design, quality and components of intervention of studies included in the systematic review

	Study short tile, year and country	**Components of intervention**	**Design**	**Risk/ quality***
1	Mantell et al. 2017, South Africa	Counselling and referral of clients Training of providers	Randomized Control Trial	Low risk of bias
2	Joshi et al. 2016, India	Counselling, IEC activities and referral of clients Training on providers		Low risk of bias
3	Grossman et al. 2013, Kenya	Counselling of clients Training of providers Availability of FP services within HIV clinic		Low risk of bias
4	Cohen et al. 2017, Kenya			Low risk of bias
5	Atukunda et al. 2019 Uganda	Counseling , Family planning voucher postpartum SMS reminders to utilize the voucher within 3 months postpartum		Low risk of bias
6	Sarnquist et al. 2014, Zimbabwe	Counselling, IEC activities among clients	Non-Randomized Control Trial	Low risk of bias
7	McCarraher et al. 2011, Nigeria	Provider training Facility assessment and monitoring Community mobilization		Low risk of bias
8	Baumgartner et al. 2014, Tanzania	Counselling, referral and follow up of clients Training of providers	Pre-post Interventional Studies	Good
9	Hoke et al. 2014 South Africa	Referral and IEC activities for clients Training of providers		Good
10	Weilding et al. 2016, UK	Training of providers Availability of FP services within HIV clinic		Fair
11	Tweya et al. 2017, Malawi	Electronic Medical Record (EMR) system to prompt providers		Good
12	Hawkins et al. 2021, Botswana	Training of providers		Fair
13	Medley et al. 2022, Zambia	Training on providers Availability of FP services within HIV clinic		Fair
14	Kosegi et al. 2011, Kenya	Availability of FP services within HIV clinic	Cohort Study	Good

15	Wanyenze et al. 2015, Uganda	Counselling Availability of FP services within HIV clinic	Cross-sectional Comparative Study	Fair
16	Phiri et al. 2016, Malawi	Counselling and referral of clients		Poor
17	Chen et al. 2020, Kenya	Availability of FP services within HIV clinic		Fair

Note:

* Method of scoring the studies: The Evidence project tool, CASP and AXIS checklists did not have a method to score the studies. A score of >4 suggested that the study is of good quality; 3 was fair and <3 as poor quality, while using the Evidence project tool. For CASP, among the 11 questions if the study gave ≤2 "no/ can't tell" it indicated good quality; 3-5 "no/ can't tell" meant fair quality and ≥6 indicated poor quality. For AXIS, among the 20 questions, <3 negative answers meant good quality; 4-8 indicated fair quality and >9 was of poor quality.** Randomized control trial *** Non-randomized control trial

Summary findings of systematic review:

Seventeen studies were included for the systematic review. Four randomized control trials (RCT) and one 2-year follow-up analysis of an RCT [25-29] , two Non-RCTs [30-31] , six pre-post intervention studies [32-37] one cohort study[38], and three cross-sectional comparison studies [39-41].

Among the studies, uptake of modern contraception was assessed by 16 studies [28] [30-44] and dual methods by seven [25-28] [32] [37] [41]. Four studies evaluated prevalence of unmet FP needs [35] [36] [39] [41]. Unintended pregnancies were reported by only four [26] [31] [34] [41]. Table 1 presents the study designs, quality assessment, and components of interventions.

Among the 16 studies that assessed the uptake of modern contraception, the major components of interventions implemented in these studies were counseling, referral, IEC activities for clients, and training of service providers. Among various modern contraception, Intra-Uterine Device (IUD) use and implant use followed by sterilization, injectable, oral pills, and condom showed commendable increase in use. Utilization of modern contraception improved in 14 studies. Four studies [34-36] [39] reported the improvement in uptake of modern contraception, in general, to be significant. A Zambian study [40] reported significant uptake of injectable along with significant reduction in use of oral pills. A study from Kenya [41] reported significant improvement in uptake of Long-Acting Reversible Contraception (LARC) methods in specific,

along with modern methods in general. One study [38] reported significant improvement in uptake of modern contraception only when a condom was included as a method and a reduction otherwise. A two-year later analysis of an RCT [28] showed a significant reduction.

Seven studies assessed dual methods. These studies implemented client counseling, referral, and IEC activities with the training of service providers and availability of FP commodities from the facility. The uptake improved in six studies [25-27] [32] [37] [41], with significance reported by two [26] [37]. A two-year later analysis of an RCT [28] reported a significant reduction in uptake of dual methods in both the control and intervention groups.

Four studies analyzed unmet FP needs. All studies implemented client counseling and provider training as a part of their intervention and reported a reduction in unmet FP needs among the intervention group, of which one study reported statistical significance. Four studies reported the incidence of unintended pregnancies. Three studies reported reduction in the incidence of unintended pregnancies among the intervention groups.

Meta-analysis:

Uptake of dual methods:

This outcome was measured by seven studies, four RCT's, and three comparative studies. While considering all studies , the pooled OR in random effect model (REM) with 95% confidence interval (CI) (Figure 3) for uptake of dual contraception was 1.69 [1.14, 2.50] (p= 0.008; I^2=90%). The same outcome was analyzed after grouping the studies into subgroups, based on their study designs. When only considering the RCTs, the pooled OR was 1.22 [0.86, 1.73] (p= 0.26; I^2= 86%), and for the comparative studies it was 2.63 [1.72, 4.01] (p<0.001; I^2= 34%).

Unmet need for family planning:

To measure unintended pregnancies, we considered it as a proxy indicator for unmet FP needs, as these two indicators reflected each other [42]. Four of the included studies directly measured unmet FP needs and three others measured unintended pregnancies. The pooled OR in REM (Figure 4) with 95% CI was estimated to be 0.57 [0.47, 0.67] (p<0.0001; I^2= 0%). Here again sub-group

analysis was conducted based on the study design. The pooled OR for the comparative studies was found to be 0.56 [0.47, 0.67] ($p<0.0001$; $I^2= 0\%$).

To summarize the findings, this systematic review and meta-analysis found that integrating HIV and FP services would improve uptake of dual contraception and reduce the occurrence of unmet FP needs among WLHIV when compared with a non-integrated setting.

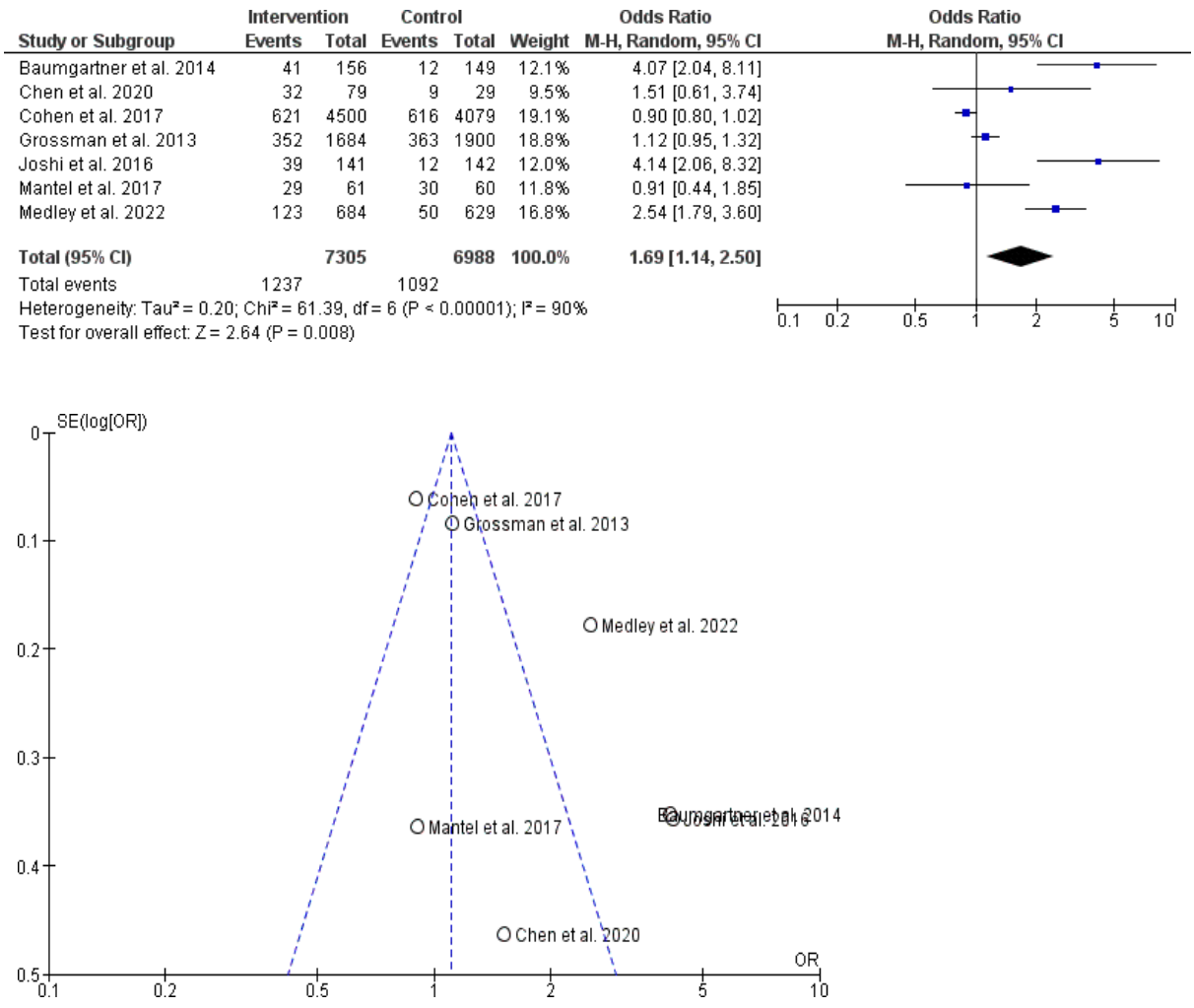


Figure 3.3: Forest plot and funnel plot summarizing the number of events, total number of participants and pooled odds ratio for the uptake of dual methods among people living with HIV and publication bias.

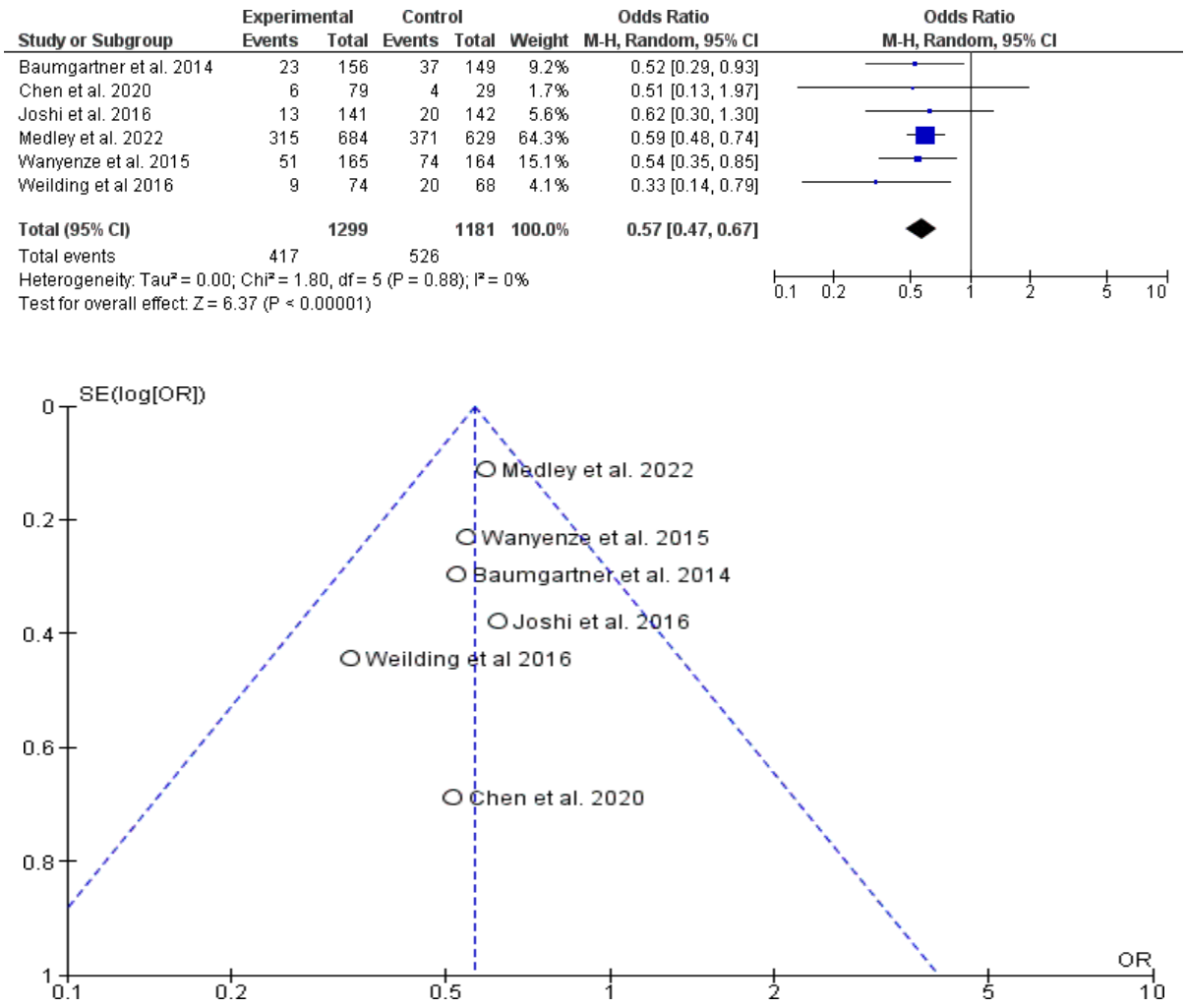


Figure 3.4: Forest plot and funnel plot summarizing the number of events, total number of participants and pooled odds ratio for the occurrence of unmet needs of family planning among people living with HIV and publication bias.

Data collection:

3.2.1 Data related to proportion/probabilities were collected from following sources:

- MSACS data on PLHIV for the year 2019-20, with a focus on the proportion of various contraceptive method users, the incidence of pregnancies, and deaths were obtained
- Proportion of WLHIV who is currently pregnant with intended and unintended pregnancies
- Proportion of WLHIV with live births (vaginal and C-section deliveries), stillbirths, and abortions with differentiation on intended and unintended pregnancy outcomes
- WLHIV pregnant women on ART during the antenatal period and proportion of infants tested in 6 months, started on ARV prophylaxis, and confirmed as positive case, since birth.

3.2.2 Primary cross-sectional study on assessment of health related quality of life using EQ-5D-5L tool with Indian tariffs among reproductive age group WLHIV

Methods:

Study setting:

The data was collected from these women availing services at ART centers situated within two tertiary and one secondary level public hospital in Mumbai and suburbs with a high HIV prevalence in Maharashtra state.

Data collection:

A hospital-based cross-sectional study was conducted to ascertain HRQoL utility weights in the Indian context among WLHIV. WLHIV registered with the Anti-Retroviral treatment facilities at selected three public health facilities were enrolled over a period of six months (N=195) after fulfilling the inclusion criteria and obtaining written informed consent. Concordant or discordant WLHIV in the reproductive age group of 18-45 years, married, currently sexually active, or pregnant in the last one year were eligible to participate in the study. We excluded women who had attained menopause, were involved in commercial sexual activities, or were in WHO stage IV of the infection [43].

For calculating sample size, we explored literature evidence on the utility score of any contraceptive user. Based on the study conducted in China [44] as 0.77 (±0.1), the anticipated difference in the utility score from the known population as 2%, Type-I error as 0.05, and 80% power of the study, a sample size of 199 was estimated to be appropriate.

We used a five-dimensional Euro-QoL questionnaire (EQ-5D-5L) to measure the quality of life. Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression were the five dimensions, with each dimension having five-level response options: no problems, slight problems, moderate problems, severe problems, and extreme problems [45]. The participant received a descriptive profile by combining the values. We estimated a single index value for health status and documented the self-rated health of the participant using a vertical analog scale. The terminal points of the scale are marked with 0 (worst health the participant can imagine) and 100 (best health the participant can imagine). Additionally, we collected details on the participant's socio-demography (age, education, occupation, etc.), the income of the family, clinical conditions (stage of HIV infection and $CD4^+$ cell count), and health services availed from the facility (services related to contraception, antenatal care, postnatal care). The Institutional Ethics committee approved the study. We obtained the translated versions of the tool in local languages (Hindi and Marathi) from Euro-QoL for administering it to the local population. A team of trained staff from our institution administered the certified tool to the eligible WLHIV after obtaining their written informed consent. They collected data through face-to-face interviews. The team obtained clinical characteristics of WLHIV from the medical records post-interview. All the data was checked on a day-to-day basis and entered into the SPSS Version 20.

We used the Indian value set to calculate the utility scores from the patient health dimensions obtained from EQ-5D-5L [46]. To obtain the utility score of a health state, the Indian tariffs corresponding to and lesser than the dimension level were added and then subtracted from one [46].

Data analysis:

The health states of the individuals were exported into STATA Version 17 and the utility scores were generated for each participant. To describe the WLHIV we used the descriptive statistics of frequencies and percentages. In the study, we used the mean with standard deviation, median with inter-quartile range, and minimum-maximum values to describe EQ-5D and EQ-VAS and non-parametric tests for comparing the utility values between various categories of socio-demographic and clinical variables. The non-parametric tests used were Mann–Whitney U test and Kruskal–Wallis test with a significance at <0.05. The previous quality of life studies conducted in Southeast

Asia had used the Thai Tariff scores to calculate utility scores. For assessing the bias between Indian and Thai Tariff scores, the mean difference (mean bias) was compared. Since the assessment showed zero mean difference as 0.007±0.021 with the limits of the agreement being -0.03416 and 0.04816 according to the Bland-Altman plot, we used the Indian tariffs for calculating the utility scores. We performed the Bland-Altman analysis to assess the relationship between utility values and VAS scores.

Table 3.2 Distribution of Health states in EQ-5D-5L among WLHIV

Health State	Frequency	Percentage
11111	130	66.7
11121	28	14.4
11112	12	6.2
11211	4	2.1
11122	3	1.5
21121	3	1.5
21221	3	1.5
12222	2	1
11132	1	0.5
11212	1	0.5
12111	1	0.5
12221	1	0.5
21111	1	0.5
21132	1	0.5
21211	1	0.5
22221	1	0.5
22222	1	0.5
33332	1	0.5

Table 3.3 Utility Scores as per method use and health states

Not using any method of contraception	40(20.5)	0.976 (0.02)	0.021	81.63 (17.14)	0.010
Using any method of contraception	52 (26.7)	0.986 (0.02)		85.85 (15.22)	
Currently pregnant	42 (21.5)	0.959 (0.08)	-	78.02 (17.16)	-
Post-partum period					
Vaginal	33 (16.9)	0.980 (0.04)	0.831	82.48 (11.87)	0.918
C section	23 (11.8)	0.976 (0.04)		82.09 (17.02)	
Abortion	5 (2.6)	0.979 (0.02)		83.00 (12.04)	

3.2.3 Primary cross-sectional study to estimate the OOPE for availing ART, FP and pregnancy-related services among WLHIV

Methods:

Study setting:

We conducted a hospital-based cross-sectional study to estimate the OOPE among WLHIV. We collected the data from women availing services at ART centers situated within two tertiary and one secondary level public hospital in Mumbai and suburbs with a high prevalence of HIV, in the state of Maharashtra.

Data collection:

Recruitment of WLHIV**:**

According to the inclusion criteria, for over six months we enrolled 195 WLHIV that were registered with the ART center in these three public health facilities. We interviewed these WLHIVs after obtaining written informed consent. As per the eligibility to participate in the study: Concordant or discordant WLHIV in the reproductive age group of 18-49 years, married, currently sexually active, or pregnant in the last one year were recruited. We excluded women who had attained menopause, were involved in commercial sexual activities or were in WHO stage IV of the infection.

Face-to-face interviews were conducted by trained research assistants proficient in the local language using a predesigned questionnaire that focused on socio-demographic information, family consumption data, and clinical information. Direct medical expenditure included registration fees, medications, diagnostic tests, and other medical services. Non-medical expenditure included transport, food, lodging/boarding, any informal payments, and other overhead charges. We adapted this questionnaire from a multi-centric study funded by DHR, the Government of India. In the questionnaire, a larger range of questions was asked to the participant to determine the extensive variety of expenses in obtaining ART therapies over the previous five month's ART center visit. The total number of ART center visits in one year was recorded to proportion the expense for a year.

WHO suggests a threshold level of 40% of household income as an individual's 'capacity to pay [47]. Although the WHO suggests using the capacity to pay method, the UN suggests considering 'total income' as a baseline for calculating catastrophic expenditures. Based on this technique, the

threshold levels for catastrophic spending varied between 5% and 40%. Following the National Health Policy document and WHO recommendations, we chose 40% of capacity to pay as the threshold value [48]. We did, however, compute the catastrophic spending based on other ranges. Clinical factors such as the treatment duration, the WHO staging, and recent CD4+ cell counts were recorded. We recorded various socio-demographic variables such as residence, age, education, occupation, insurance, monthly income, and the number of households to understand the pattern of OOPE as per existing literature [49] [50] [51].Socio-economic status was measured by a modified Kuppuswamy scale classification [52].

Data analysis:

Data analysis was done using SPSS version 22.0. Annual OOPE was calculated as mean± (SD) and also median [IQR] This data was tested for normal distribution. No normal distribution was found in the data and hence the median was used to describe the results. The categorical variables and proportions were represented by percentage (%). Association was assessed between OOPE and various socio-demographic and clinical variables. Catastrophic health expenditure was expressed as a binary variable with a threshold level of 40%.

Table 3.4: Out of pocket expenditure for WLHIV availing ART and family planning services from the ART centers (N=195)

		Value (in INR)	Lower Limit	Upper Limit	Source
Out of pocket expenditure (from primary study)	Non-user	1200	960	1440	Primary cross-sectional study
	Condom user	1490	1192	1788	
	Reversible method user	1650	1320	1980	
	Irreversible method user	2200	1760	2460	
	Pregnant	4160	3328	4992	

3.2.4 **Micro-costing study on health system cost for providing Anti-Retroviral Therapy (ART), family planning and pregnancy-related services to WLHIV in public health settings**

Methods:

Study setting:

We adopted a cross-sectional design combining the top-down and bottom-up micro-costing approach for the study. We selected three government hospitals with ART centers in Mumbai to obtain the economic costs from a health system perspective. We collected the health system costs for the financial year 2019-20 through observation, interaction, and review of the manual and digital records related to the centers. The five cost centers were the Anti-Retroviral Treatment (ART) center along with Out-Patient Department (OPD), In-patient wards, and Operation Theatre (OT) of the Obstetrics and Gynaecology (OB-GYN) Department of the hospital. Institutional Review Board approved the study. We obtained ethics committee permissions and written approvals from the study sites.

We adapted a health system costing questionnaire and a time allocation sheet from a multi-centric study funded by the Department of Health Research, Government of India using standard approach. The research team collected the capital and recurrent costs concerning ART, family planning, and pregnancy-related services. Capital cost refers to the expenditure on items that do not require replacement yearly. Regular short-term payments were the recurrent costs.

Description of the various sources of data collected from the various cost centers

Human resources data were collected from administrative department, observation of the facility, and interaction with staffs on time allocation. Drugs and consumables, stationary, and equipment were obtained from a) observation of the facility, b) stock registers and intents filed, and c) costs were taken from either the purchase list obtained from the hospitals or National Health System Costing Database. In case the prices were not obtained from the above two options an online platform called IndiaMart was accessed. Area occupied was measured using a digital laser distance meter by the research team. Electricity, water, telephone, and hospital area related data were taken from administrative department. At last, overheads (diet, laundry, blood bank) were obtained from records kept at the facility and data collected for a previous health system costing study.

3.2.4 Costs:

The average annual number of patients availing services from the three ART centers was 4986. The tertiary care hospitals had a higher patient load in the ART Centre. The average annual number of patients availing services from the OB-GYN OPD was 46627, IPD was 3670, and OT was 3784.

The unit cost for OPD services was similar for both the study sites [INR 198.6 (2.6 USD) and INR 198.7 (2.6 USD)] while the unit cost for the OT services showed maximum variation between the two hospitals by INR 1140.9 (14.9 USD) [INR 4824.8 (63.2 USD) and INR 3683.8 (48.3 USD)] as the patients availing the OT services was almost double in one hospital than the other. The unit cost of IPD services includes PNC ward, GYNAC ward, ANC ward, labor ward, PPS and POW ward in KEM hospital while NAIR hospital had only three wards namely PNC ward, GYNAC ward, ANC ward. The average unit costs of OPD, IPD, OT, and ART services of the OB-GYN Department and ART Center are presented in Table 3.1.

Table 3.5: The average unit costs of OPD, IPD and OT services of the OB-GYN Department and ART Center

	INR	**USD**
OPD	198 (163-233)	2.62 (2.1-3.1)
IPD	2735 (2653-2818)	36.0 (34.9-37.1)
OT	4417 (3720-1554)	58.2 (49-20.4)
ART	3942 (3230-4654)	52 (43-61)

The unit cost after adjusting for the utilization using weighted averages were INR 94 (1.2 USD) for OPD services, INR 1764.2 (23.2 USD) for IPD services, and INR 2982.02 (39.3 USD) for OT services. The unit cost for providing ART services, after adjusting for the utilization using weighted averages was INR 1614.3 (21.3 USD). The costs are presented here in Indian currency (INR), and converted to the currency of the United States of America (USD) at a conversion rate of one US 1$= 75.81 INR. [53]

Table 3.5 and 3.6 presents the total annual health system package cost for providing various family planning and pregnancy-related services to the WLHIV. Among the family planning methods users, the health system package cost for providing permanent method services to WLHIV was the highest, and that of condom-only users was the least. In pregnancy-related services, providingC-section deliveries was the most expensive, followed by abortion and vaginal deliveries.

Table 3.6: The annual health system package cost for providing family planning services to WLHIV (in INR and USD) in hospital for the year 2019-20

Family planning services	**Package health system costs**

	SOC		Linkage of HIV and family planning services	
	INR (95% CI)	**USD (95% CI)**	**INR (95% CI)**	**USD (95% CI)**
Condom only user	433.213 (346.57-519.86)	5.7145 (4.572-6.857)	433.224 (346.58-519.87)	5.7146 (4.572-6.858)
Short-acting reversible method with condom user	760.401 (608.32-912.48)	10.0304 (8.024-12.036)	760.412 (608.33-912.49)	10.0305 (8.024-12.037)
Short-acting reversible method without condom user	518.052 (414.44-621.66)	6.8336 (5.467-8.200)	518.063 (414.45-621.68)	6.8337 (5.467-8.200)
Permanent method with condom user	9254.596 (7403.68-11105.52)	122.0762 (97.661-146.491)	9254.607 (7403.69-11105.53)	122.0763 (97.661-146.492)
Permanent method without condom user	9009.897 (7207.92-10811.88)	118.8484 (95.079-142.618)	9009.909 (7207.93-10811.89)	118.8486 (95.079-142.618)

Table 3.7: The annual health system package cost for providing pregnancy-related services to WLHIV (in INR and USD) in hospital for the year 2019-20.

Pregnancy-related services	**Package health system costs**		**Linkage of HIV and family planning services**	
	INR (95% CI)	**USD (95% CI)**	**INR (95% CI)**	**USD (95% CI)**
Currently pregnant	595.662 (476.529-714.794)	7.857 (6.286-9.429)	595.673 (476.538-714.808)	7.857 (6.286-9.429)
Vaginal delivery	3936.242 (3148.994-4723.491)	51.9 (41.538-62.307)	3936.253 (3149.003-4723.504)	51.923 (41.538-62.307)
C-section delivery	15739.584 (12591.61-18887.50)	207.619 (166.095-249.143)	15739.595 (12591.68-18887.51)	207.619 (166.095-249.143)
Abortion	6918.264 (5534.612-8301.917)	91.258 (73.006-109.510)	6918.276 (5534.620-8301.931)	91.258 (73.006-109.510)

The cost of human resources contributed the most to the unit costs of the OB-GYN facility (68.7%), followed by drugs and consumables (21.7%). The drug costs contributed the most to the unit cost of ART Centre (77.2%), followed by the human resources (21.5%). The details on the distribution of the unit costs are presented in Figures 3.1 and 3.2.

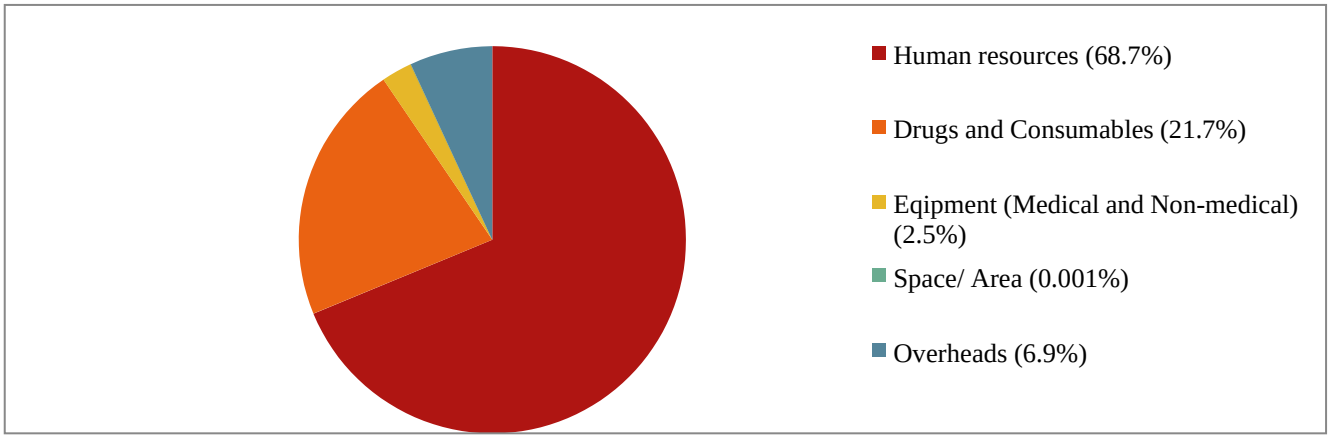


Figure 3.5: Distribution of unit costs for providing family planning and pregnancy-related services to women living with HIV from the OPD, IPD and OT of OB-GYN Department.

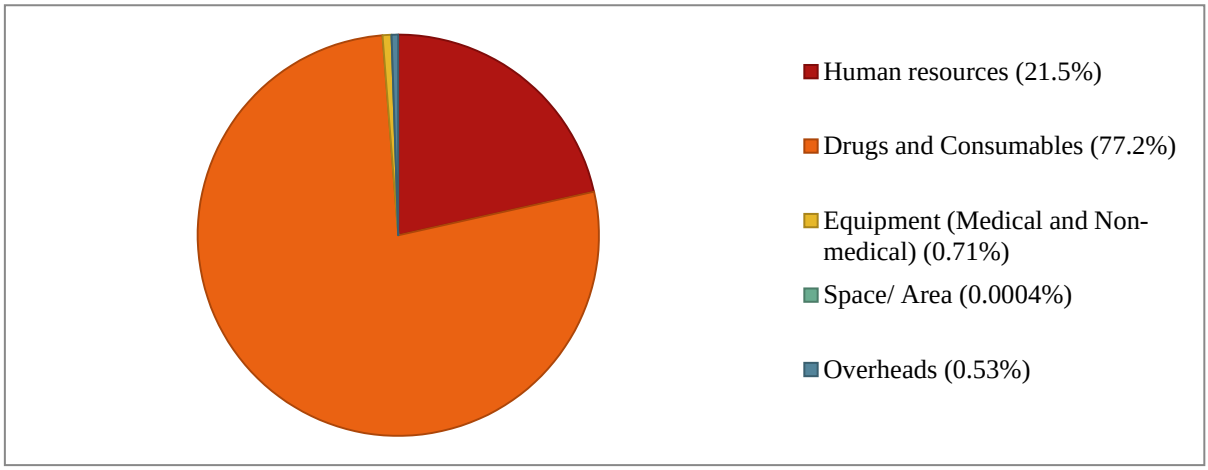


Figure 3.6: Distribution of unit costs for providing free ART services from the ART Centre to women living with HIV

3.2.5 Input Parameters:

Various parameters used for the construction and running of the model are presented in Table 2.11

Table 3.8: The input parameters used in the Markov model

Input parameter		Value	Source		
Proportion of WLHIV in various health states at the start of the model	Non-user	54%	MSACS PLHIV data for 2019-20		
	Condom user	29%			
	Reversible with condom user	11%			
	Reversible without condom user	0			
	Irreversible with condom user	0			
	Irreversible without condom user	0			
	Pregnant	4%			
	Death	3%			
Proportion of pregnant WLHIV	With intended pregnancy	49%	Shrinivas Dharak et al. [54]		
	With unintended pregnancy	51%			
Proportion of WLHIV on ART	With intended pregnancy	97%	MSACS PLHIV data for 2019-20		
	With unintended pregnancy	3%			
Proportion of WLHIV with live births	With intended pregnancy	60%	Shrinivas Dharak et al. [54]		
	With unintended pregnancy	24%			
Proportion of WLHIV with still births	With intended pregnancy	10%	Shrinivas Dharak et al. [54]		
	With unintended pregnancy	19%			
Proportion of WLHIV with abortions	With intended pregnancy	30%	Shrinivas Dharak et al. [54]		
	With unintended pregnancy	57%			
Proportion of infants initiated on ARV prophylaxis		87.3%	National Strategic Plan for HIV/ AIDS and STI: 2017-2024 [55]		
Proportion of infants tested for HIV within 6 months of birth		84.1%			
Proportion of infants diagnosed with mother on ART		4.35%			
Proportion of infants diagnosed with mother not on ART		0	Assuming that infants of mothers not on ART would not be receiving ART		
Proportion of infants positive due to not being on ART		20%	National Technical Guidelines on Anti-Retroviral Treatment- 2018 [56]		
Discount rate for outcome		3%	HTAIn Manual [57]		
Discount rate for costs		3%			
Input parameter		**Value**	**Lower limit**	**Upper limit**	**Source**
Age at menopause		46.2	36.4	56	Ahuja et al. [58]
	Non-user	0.976	0.968	0.985	
	Condom user	0.989	0.981	0.996	
	Reversible method user	0.951	0.742	1	

Utility scores	Irreversible method user	0.987	0.961	1	Primary cross-sectional study
	Pregnant	0.971	0.975	0.991	
Out of pocket expenditure	Infant ARV prophylaxis	0	0	0	ARV prophylaxis and testing is clubbed with other hospital visits (mothers ART visits, vaccination visits etc). Thus, OOPE for these are not expected.
	Infant testing	0	0	0	
Health system cost packages in standard of care (from primary study)	Non-user	0	0	0	Primary cross-sectional study
	Condom user	433.2	346.5	519.9	
	Reversible with condom user	760.4	608.3	912.5	
	Reversible without condom user	518.1	414.4	621.7	
	Irreversible with condom user	9254.6	7403.7	11105.5	
	Irreversible without condom user	9009.9	7207.9	10811.9	
	Pregnant	6757.2	5405.7	8108.6	
	Abortion	6918.3	5534.6	8301.9	
	ART	15564.9	12451.95	18677.92	
Health system cost packages when providing intervention (from primary study)	Non-user	0	0	0	After adding intervention costs spent for IEC, training and incentives to the basic health system costs
	Condom user	433.2	346.5	519.9	
	Reversible with condom user	760.4	608.3	912.5	
	Reversible without condom user	518.1	414.4	621.7	
	Irreversible with condom user	9254.6	7403.7	11105.5	
	Irreversible without condom user	9009.9	7207.9	10811.9	
	Pregnant	6757.2	5405.7	8108.6	
	Abortion	6918.3	5534.6	8301.9	
	ART	15564.9	12451.95	18677.92	
Health system cost for infant testing and ARV prophylaxis (from literature reference)	Infant testing	30	24	36	Samudyatha et al. [59]
	Infant ARV prophylaxis	2450	1960	2940	
Increment in dual method users in the intervention arm		22%	Joshi et al. [33]		
Risk of transmission from Pregnant mother on ART to infants		3%, 5%, 27.4%	[75,76]		

Data analysis:

The data was entered and analyzed in MS Excel. We estimated the annual and unit cost of all the cost centers. We used the HMIS data to identify the total number of appointments in 2019-20. The total cost was the sum of both capital and recurrent costs. We annualized the capital costs with an expected life of 15 years, a discount rate of 3%, and an annual maintenance rate of 10%. For

recurrent costs, we multiplied the unit price by the quantity. Finally, we added the supporting costs of the kitchen, laundry, and blood bank to obtain the total annual cost.

We prepared the summary sheets for all cost centers summarizing the distribution of annual costs among various cost heads for 2019-20. The unit costs were calculated by dividing the annual costs by the total number of patients availing of the services and multiplying the same with apportioning factors. We derived the unit health system cost for providing ART services at the ART center, and OB-GYN OPD, OT, and IPD services for WLHIV.

We combined the unit costs of all services from different hospitals by the weighted average method to arrive at a single unit cost. We used percentages of women seeking family planning and pregnancy-related services from various levels of healthcare as the weights. To obtain the weight, we used the National Family Health Survey-4 data [60].

We derived the package cost for a condom-user, short-acting reversible method user, permanent method user, currently pregnant mother, vaginal delivery, C-section delivery, and abortion. We obtained expert opinions and did a literature review to formulate these packages. These costs include follow-up care, treatment of complications, and side effects.

Finally, we added the program costs for Intervention Education and Counseling (IEC), training, and incentives to the package cost to arrive at the total annual health system package cost. We derived the mean and standard deviation and 95% Confidence Interval (CI) by running a Probabilistic Sensitivity Analysis (PSA).

CHAPTER 4: RESULTS

Two of the study sites were tertiary care government hospitals. We conducted costing of both the ART center and OB-GYN department here. The third site was a district hospital from where we did the ART service costing alone. The number of beds in the facility was according to the Indian Public Health Standards. The patients availed ART services from the ART Centre and pregnancy-related services from the OB-GYN department. Both the ART Centre and OB-GYN department staff provided the family planning services.

4.1. **Estimation of transition probabilities**

We extracted the age-specific proportion of WLHIV in various health states from the data obtained from MSACS for the year 2019-20. The discontinuation rate, method failure, and switching rates were obtained from NFHS 4 as the data was available for the past five years preceding the survey among women in the reproductive age group [60].

We followed a hypothetical cohort of 782107 WLHIV [61] in the reproductive age group for a year. We observed the discontinuation and switching of contraception use and the incidence of pregnancies. Those women who got pregnant were followed up to access the desirability of the pregnancy and the pregnancy outcomes (live births, abortions, stillbirths, testing and diagnosis of the infant, ARV prophylaxis of the infant).

When a WLHIV used the same contraception methods for consecutive months till the end of the follow-up period, it was considered a contraceptive continuation. While if she stopped the use of contraception after being a prior user was termed contraception discontinuation. During the follow-up period, if the WLHIV changed the method of contraception used in consecutive months, it was termed as switching of contraception.

We began by determining the proportion of WLHIV in various health states at the beginning of the model to estimate the transition probabilities, and calculated the probabilities as the ratio of WLHIV in a health state to the total number of WLHIV. The probability of continuation, discontinuation and switching (obtained from the NFHS 4 data) was then incorporated into this data to obtain the final transition probabilities.

Table 4.1: Transition probabilities for various health states for the model in standard of care arm

Transition states (TS)	**Age groups (years)**						
	15-19	20-24	25-29	30-34	35-39	40-44	45-49
From non-user							
NU-NU	0.92427	0.79984	0.85048	0.91488	0.95128	0.96459	0.96707
NU-CU	0.00460	0.01839	0.02281	0.01522	0.00620	0.00277	0.00123
NU-Rev+C	0.00134	0.00750	0.01160	0.00924	0.00434	0.00166	0.00053
NU-Rev	0.00134	0.00750	0.01160	0.00924	0.00434	0.00166	0.00053
NU-Irr+C	0.00008	0.00385	0.00958	0.00677	0.00264	0.00106	0.00044
NU-Irr	0.00008	0.00385	0.00958	0.00677	0.00264	0.00106	0.00044
NU-Preg	0.04093	0.13923	0.06591	0.01564	0.00445	0.00095	0.00006
NU-Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From condom user							
CU-NU	0.41564	0.42316	0.40403	0.40599	0.40280	0.39864	0.39532
CU-CU	0.52800	0.52800	0.52800	0.52800	0.52800	0.52800	0.52800
CU-Rev+C	0.00000	0.00000	0.01026	0.00738	0.00806	0.00906	0.00898
CU-Rev	0.00000	0.00000	0.01026	0.00738	0.00806	0.00906	0.00898
CU-Irr+C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
CU-Irr	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
CU-Preg	0.02900	0.02900	0.02900	0.02900	0.02900	0.02900	0.02900
CU-Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From Reversible with condom user							
Rev+C -NU	0.35164	0.34600	0.35450	0.34795	0.34284	0.35276	0.34929
Rev+C -CU	0.00000	0.00940	0.00484	0.00147	0.00483	0.00000	0.00000
Rev+C - Rev+C	0.30183	0.30183	0.30183	0.30183	0.30183	0.30183	0.30183
Rev+C -Rev	0.30183	0.30183	0.30183	0.30183	0.30183	0.30183	0.30183
Rev+C - Irr+C	0.00000	0.00188	0.00060	0.00367	0.00362	0.00000	0.00000
Rev+C -Irr	0.00000	0.00188	0.00060	0.00367	0.00362	0.00000	0.00000
Rev+C -Preg	0.01733	0.01733	0.01733	0.01733	0.01733	0.01733	0.01733
Rev+C – Death	0.02736	0.01984	0.01845	0.02225	0.02409	0.02624	0.02971
From Reversible without condom user							
Rev-NU	0.351643	0.345996	0.354497	0.347946	0.34284	0.352756	0.349294
Rev-CU	0	0.009402	0.00484	0.001468	0.004829	0	0
Rev-Rev+C	0.301833	0.301833	0.301833	0.301833	0.301833	0.301833	0.301833
Rev-Rev	0.301833	0.301833	0.301833	0.301833	0.301833	0.301833	0.301833
Rev-Irr+C	0	0.00188	0.000605	0.00367	0.003622	0	0
Rev-Irr	0	0.00188	0.000605	0.00367	0.003622	0	0
Rev-Preg	0.017333	0.017333	0.017333	0.017333	0.017333	0.017333	0.017333
Rev-Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From Irreversible with condom user							

Irr+C -NU	NA	NA	NA	NA	NA	NA	NA
Irr+C -CU	NA	NA	NA	NA	NA	NA	NA
Irr+C -Rev+C	NA	NA	NA	NA	NA	NA	NA
Irr+C -Rev	NA	NA	NA	NA	NA	NA	NA
Irr+C -Irr+C	0.483822	0.487579	0.488273	0.486377	0.485456	0.484378	0.482647
Irr+C -Irr	0.483822	0.487579	0.488273	0.486377	0.485456	0.484378	0.482647
Irr+C -Preg	0.005	0.005	0.005	0.005	0.005	0.005	0.005
Irr+C -Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From Irreversible without condom user							
Irr-NU	NA	NA	NA	NA	NA	NA	NA
Irr-CU	NA	NA	NA	NA	NA	NA	NA
Irr-Rev+C	NA	NA	NA	NA	NA	NA	NA
Irr-Rev	NA	NA	NA	NA	NA	NA	NA
Irr-Irr+C	0.483822	0.487579	0.488273	0.486377	0.485456	0.484378	0.482647
Irr-Irr	0.483822	0.487579	0.488273	0.486377	0.485456	0.484378	0.482647
Irr-Preg	0.005	0.005	0.005	0.005	0.005	0.005	0.005
Irr-Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From pregnancy							
Preg-NU	0.417804	0.376982	0.410573	0.431472	0.435673	0.436278	0.435124
Preg -CU	0.194804	0.175771	0.191433	0.201177	0.203136	0.203418	0.20288
Preg -Rev+C	0.037167	0.033535	0.036523	0.038382	0.038756	0.03881	0.038707
Preg -Rev	0.037167	0.033535	0.036523	0.038382	0.038756	0.03881	0.038707
Preg -Irr+C	0.121112	0.109279	0.119016	0.125074	0.126292	0.126467	0.126132
Preg -Irr	0.121112	0.109279	0.119016	0.125074	0.126292	0.126467	0.126132
Preg -Preg	0.040926	0.139227	0.065909	0.015641	0.004455	0.000954	0.000058
Preg -Death	0.029908	0.022393	0.021006	0.024797	0.02664	0.028796	0.032258
From Death							
Death is the absorptive state							

Note: NU- Non user; CU- Condom User; Rev+C- Reversible method with condom user; Rev-Reversible method without condom user; Irr+C- Irreverisble methods with condom user; Irr- Irreversible method without condom user; Preg- Pregnancy

Table 4.2: Transition probabilities for various health states for the model in the intervention arm

Transition states (TS)	Age groups (years)						
	15-19	20-24	25-29	30-34	35-39	40-44	45-49
From non-user							
NU-NU	0.82086	0.22935	0.19277	0.36079	0.00000	0.55266	0.80468
NU-CU	0.08978	0.3822	0.4819	0.3608	0.6476	0.281136	0.120728
NU-Rev+C	0.02065	0.114673	0.096383	0.060132	0.16191	0.060356	0.018585
NU-Rev	0.00164	0.114673	0.096383	0.060132	0.16191	0.060356	0.018585
NU-Irr+C	0.00010	0	0.024096	0.060132	0	0.009145	0.003826
NU-Irr	0.00010	0	0.024096	0.060132	0	0.009145	0.003826
NU-Preg	0.03952	0.13923	0.06591	0.01564	0.00445	0.00095	0.00006
NU-Death	0.02736	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From condom user							
CU-NU	0.13882	0.14633	0.12872	0.12821	0.29591	0.62984	0.62984
CU-CU	0.43900	0.43900	0.69510	0.66669	0.59182	0.00000	-0.00346
CU-Rev+C	0.18292	0.18292	0.03862	0.07693	0.00000	0.15746	0.15746
CU-Rev	0.18292	0.18292	0.03862	0.07693	0.00000	0.15746	0.15746
CU-Irr+C	0.00000	0.00000	0.02574	0.00000	0.02959	0.00000	0.00000
CU-Irr	0.00000	0.00000	0.02574	0.00000	0.02959	0.00000	0.00000
CU-Preg	0.02900	0.02900	0.02900	0.02900	0.02900	0.02900	0.02900
CU-Death	0.027357	0.019841	0.018454	0.022246	0.024088	0.026244	0.029706
From Reversible with condom user							
Rev+C -NU	0.31648	0.31140	0.31905	0.31315	0.30856	0.31748	0.31436
Rev+C -CU	0.00000	0.01147	0.00590	0.00179	0.00589	0.00000	0.00000
Rev+C - Rev+C	0.36777	0.36492	0.36692	0.36664	0.36540	0.36789	0.36754
Rev+C -Rev	0.27165	0.27165	0.27165	0.27165	0.27165	0.27165	0.27165
Rev+C - Irr+C	0.00000	0.00229	0.00074	0.00448	0.00442	0.00000	0.00000
Rev+C -Irr	0.00000	0.00169	0.00054	0.00330	0.00326	0.00000	0.00000
Rev+C -Preg	0.01674	0.01674	0.01674	0.01674	0.01674	0.01674	0.01674
Rev+C – Death	0.02736	0.01984	0.01845	0.02225	0.02409	0.02624	0.02971
From Reversible without condom user							
Rev-NU	0.31602	0.30808	0.31773	0.31156	0.30572	0.31713	0.31367
Rev-CU	0.00000	0.01147	0.00590	0.00179	0.00589	0.00000	0.00000
Rev-Rev+C	0.36824	0.36824	0.36824	0.36824	0.36824	0.36824	0.36824
Rev-Rev	0.27165	0.27165	0.27165	0.27165	0.27165	0.27165	0.27165
Rev-Irr+C	0.00000	0.00229	0.00074	0.00448	0.00442	0.00000	0.00000
Rev-Irr	0.00000	0.00169	0.00054	0.00330	0.00326	0.00000	0.00000
Rev-Preg	0.01674	0.01674	0.01674	0.01674	0.01674	0.01674	0.01674
Rev-Death	0.02736	0.01984	0.01845	0.02225	0.02409	0.02624	0.02971
From Irreversible with condom user							

Irr+C -NU	NA	NA	NA	NA	NA	NA	NA
Irr+C -CU	NA	NA	NA	NA	NA	NA	NA
Irr+C -Rev+C	NA	NA	NA	NA	NA	NA	NA
Irr+C -Rev	NA	NA	NA	NA	NA	NA	NA
Irr+C -Irr+C	0.48382	0.48758	0.48827	0.48638	0.48546	0.48438	0.48265
Irr+C -Irr	0.48399	0.48775	0.48844	0.48655	0.48563	0.48455	0.48282
Irr+C -Preg	0.00483	0.00483	0.00483	0.00483	0.00483	0.00483	0.00483
Irr+C -Death	0.02736	0.01984	0.01845	0.02225	0.02409	0.02624	0.02971
From Irreversible without condom user							
Irr-NU	NA	NA	NA	NA	NA	NA	NA
Irr-CU	NA	NA	NA	NA	NA	NA	NA
Irr-Rev+C	NA	NA	NA	NA	NA	NA	NA
Irr-Rev	NA	NA	NA	NA	NA	NA	NA
Irr-Irr+C	0.48399	0.48775	0.48844	0.48655	0.48563	0.48455	0.48282
Irr-Irr	0.48382	0.48758	0.48827	0.48638	0.48546	0.48438	0.48265
Irr-Preg	0.00483	0.00483	0.00483	0.00483	0.00483	0.00483	0.00483
Irr-Death	0.02736	0.01984	0.01845	0.02225	0.02409	0.02624	0.02971
From pregnancy							
Preg-NU	0.30671	0.28024	0.30228	0.31583	0.31851	0.31884	0.31796
Preg -CU	0.23766	0.21444	0.23355	0.24544	0.24783	0.24817	0.24751
Preg -Rev+C	0.04534	0.04091	0.04456	0.04683	0.04728	0.04735	0.04722
Preg -Rev	0.04534	0.04091	0.04456	0.04683	0.04728	0.04735	0.04722
Preg -Irr+C	0.14776	0.13332	0.14520	0.15259	0.15408	0.15429	0.15388
Preg -Irr	0.14776	0.13332	0.14520	0.15259	0.15408	0.15429	0.15388
Preg -Preg	0.03952	0.13446	0.06365	0.01511	0.00430	0.00092	0.00006
Preg -Death	0.02991	0.02239	0.02101	0.02480	0.02664	0.02880	0.03226
From Death							
Death is the absorptive state							

Note: NU- Non user; CU- Condom User; Rev+C- Reversible method with condom user; Rev-Reversible method without condom user; Irr+C- Irreverisble methods with condom user; Irr- Irreversible method without condom user; Preg- Pregnancy

4.2 Markov Decision Model Analysis:

We constructed the model in MS Excel using appropriate commands. The model was run for a cohort of 15 to 49-year-old WLHIV. We calculated the desired outcomes from two alternatives, one was the standard of care with minimal/ no linkage of HIV and FP services and the second was intervention where linkage of HIV and FP was given importance and the use of dual methods was promoted to avoid unintended pregnancies.

We calculated the ICER value along with unintended pregnancies averted, unintended live births averted, unintended abortions averted, unintended stillbirths averted, and unintended infant infections averted.

We preferred to use ICER/clinical events such as pregnancies and child birth averted etc rather than per QALY gained as EQ5D measures are not expected to grossly vary due to single contraceptive use vs dual method users and as mentioned above we did not get adequate data to justify the difference)

Sensitivity analysis was conducted to evaluate uncertainties in the model parameters. Multiple parameter uncertainties were evaluated with PSA. Appropriate distributions like Beta/Gamma/Log-normal were used to run the PSA. For percentages, probabilities, and proportions, beta distribution was used. Gamma distribution was used for costs. The Monte Carlo method was used to simulate the results 1000 times. Median ICER estimate along with 2.5th and 97.5th percentile (as 95% confidence interval) was reported as an outcome of this analysis.

4.3 MARKOV MODEL:

The socio-demographic characteristics of the WLHIV as obtained from the MSACS data 2019-20 are presented in Table 4.3.

Table 4.3: Socio-demographic characteristics of the WLHIV as obtained from the MSACS data 2019-20

Characteristics	N (%)
Age group (N= 107341)	
15-19	2776 (3)
20-24	3942 (4)
25-29	2852 (5)
30-34	11735 (11)
35-39	20383 (19)
40-44	23050 (21)

45-49	16978 (16)
Deaths (All cause + HIV-specific mortality) (N= 3152)	
15-19	77 (2.4)
20-24	79 (3.5)
25-29	109 (3.4)
30-34	264 (8.4)
35-39	497 (15.8)
40-44	613 (19.4)
45-49	512 (16.2)
Pregnancies (N=1405)	
15-19	116 (8.3)
20-24	591 (42.1)
25-29	399 (28.4)
30-34	185 (13.2)
35-39	91 (6.5)
40-44	22 (1.6)
45-49	1 (0.07)
ART treatment and infant testing	
Number of pregnant WLHIV on ART treatment	1358 (96.7)
Number of infants tested for HIV	1011
Number of infants diagnosed with HIV	22
Number of infants initiated on ART	20

MSACS data included 107341 WLHIV. The highest percentage of participants was from the 40-44 age group (21%), while the least was from the 15-19 age group (3%). The data reported 3152 deaths due to all-cause and HIV-specific mortality. Out of the 1405 reported pregnancies, more than 70% were among 20-30-year-old women. Among the pregnant WLHIV, 96.7% received ART treatment. After the birth of the child, 1011 infants were tested for HIV within the first six months of birth. Among them, 22 were diagnosed with HIV, and ART was initiated among 20.

Table 4.4: Distribution of married WLHIV in the reproductive age group among various contraception uses as obtained from the MSACS data 2019-20

	Age group						
Method use (%)	**15-19**	**20-24**	**25-29**	**30-34**	**35-39**	**40-44**	**45-49**
NU	57.7	44.3	39.6	43.4	41.8	39.7	45.2
CU	30.8	41.7	43.8	33.4	31.3	30.9	28.9
Rev+ C	11.5	8.7	4.7	4.4	2.7	1.5	0.0
Rev	0.0	0.9	0.0	0.6	0.2	0.2	0.7
Irr+ C	0.0	1.7	6.3	10.3	10.2	16.2	14.4
Irr	0.0	2.6	5.7	7.9	13.8	11.5	10.8

Note: NU- Non user; CU- Condom User; Rev+C- Reversible method with condom user; Rev-Reversible method without condom user; Irr+C- Irreverisble methods with condom user; Irr- Irreversible method without condom user;

The non-users were highest in the youngest age group (15-19 years). The percentage of condom users remained relatively stable throughout the age groups. The proportion of women preferring to use the reversible or irreversible method of contraception increased with age.

4.4 Health Outcomes:

We followed a cohort of 782107 WLHIV [10] in the reproductive age group using the model and a time horizon of 31 years was considered. In table 4.5 we have presented the health outcomes of the two alternatives i.e. the standard of care (with no/ minimal focus on HIV-FP linkage) and the intervention (with a focus on HIV- FP linkage and promotion of dual methods).

Table 4.5: Health outcomes of the standard of care and intervention arms related to pregnancies, livebirths, abortions, and deaths averted as compared to current scenario

Outcomes	**Number of averted cases for the cohort**	**Number of averted cases per person**
Unintended pregnancies	72604	0.092
Unintended, Live births	17425	0.022
Unintended, Abortions	41610	0.053
Infant infection averted(2%)	2752	0.004
Infant infection averted(5%)	6880	0.009
Deaths averted	8722	0.011

* At the World Health Organization reported ideal parent-to-child transmission rate of 2% [7] and National AIDS Control Program reported parent-to-child transmission rate of 5% [8]

Interpretation: Table 4.5 column 3, shows that out of total cohort of 787107 PlHIV women,

number of unintended pregnancies, unintended, live births, unintended, Abortions, and deaths

could be averted when the intervention i.e., HIV and family planning linkage is being considered compared to current scenario.

. **4.5 Cost and cost effectiveness:**

The comparison of costs, maternal deaths averted, unintended pregnancies averted, unintended live births averted, and unintended abortions averted between the standard of care and intervention arm are presented in table 4.6 and 4.7.

Table 4.6: Costs of standard of care and the intervention arm

		Standard of care	Intervention	Incremental values
Costs	Undiscounted	4,16,231	4,19,037	2806
	Discounted	2,80,869	2,82,133	1264

There is a gain in costs in the intervention arm in comparison to the standard of care.

Incremental cost-effectiveness ratio:

- The ICER was calculated in terms of life years, unintended pregnancies, live births, abortions and still births averted. For example,

  ICER in terms of maternal deaths averted =

$$\frac{(Cost\ of\ intervention - Cost\ of\ standard\ of\ care)}{(Maternal\ deaths\ in\ intervention - Maternal\ deaths\ in\ standard\ of\ care)}$$

The ICER valued is presented in table 4.7 and 4.8.

Table 4.7: Incremental cost and outcomes of unintended pregnancies, livebirths, abortions, and deaths (based on per person findings i.e for a woman in cohort through 15-49 years of age)

		CS	Intervention	Intervention- SOC
Costs	**Undiscounted**	4,18,787	4,21,357	2,571
	Discounted	2,83,031	2,84,086	1,055
Unintended Pregnancies averted		0.445	0.352	-0.092
Live births averted		0.107	0.085	-0.022
Abortions Averted		0.255	0.202	-0.053
Deaths Averted		11.387	11.376	-0.011

Note: Ignore the negative sign for averted cases in the denominator for calculating ICER values.

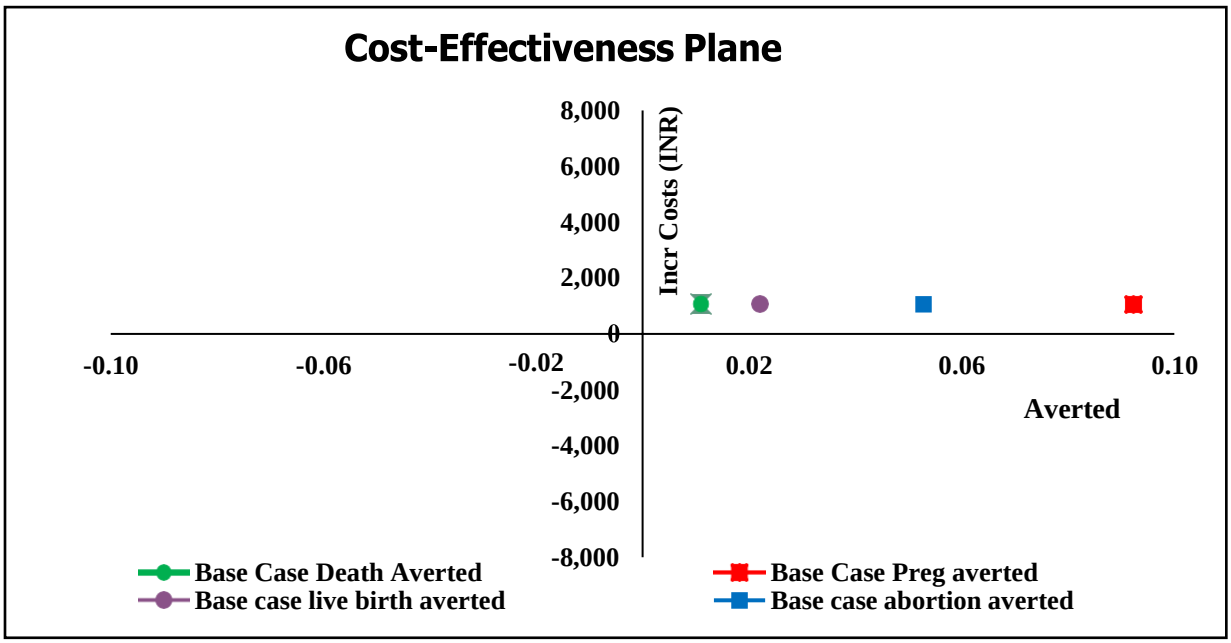
Table 4.8: ICER values of pregnancies, livebirths, abortions, and deaths (societal perspective)

	ICER (UD)	ICER (D)	% of Cost-effective from 1000 PSA simulations
Unintended Pregnancies averted	27868	11435	100%
Live births averted	116117	47647	71.7%
Abortions Averted	48626	19953	95.7%
Deaths Averted	231988	95192	57.1%

Note: Ignoring the negative sign for averted cases in the denominator for calculating ICER values.

Interpretation: ICER 11,435 indicate that at an incremental cost of INR 11,435, an unintended pregnancy is averted by providing linked HIV-FP services that focuses on promoting dual methods of contraception. ICER value of INR 11,435 per unintended pregnancy averted is below the WTP threshold of 1 time Indian GDP per capita value. Hence, intervention is cost-effective. Similarly, at an incremental cost of INR 46647, INR 19553, and INR 96121 livebirths, abortions, and deaths are averted by providing linked HIV-FP services that focuses on promoting dual methods of contraception. And, ICER values of these livebirths, abortions, and deaths averted are below the WTP threshold of 1 time Indian GDP per capita value. Hence, intervention is cost-effective (See table 4.6 and Table 4.7).

4.5 ICER Planes:



Interpretation: The above ICER planes indicates unintended pregnancies (red dot), livebirths (orange dot), abortions (blue dot), and deaths (green dot) averted. The green dot indicates that

with intervention, 0.01 deaths are averted art incremental cost of 1000. So, 1 death is averted at an additional cost for 100,000. Similarly, the orange, blue and red dot indicates that with intervention, 0.02 live births, 0.05 abortions and 0.09 deaths are averted at incremental cost of 1000. Thus, making the intervention to be cost-effective.

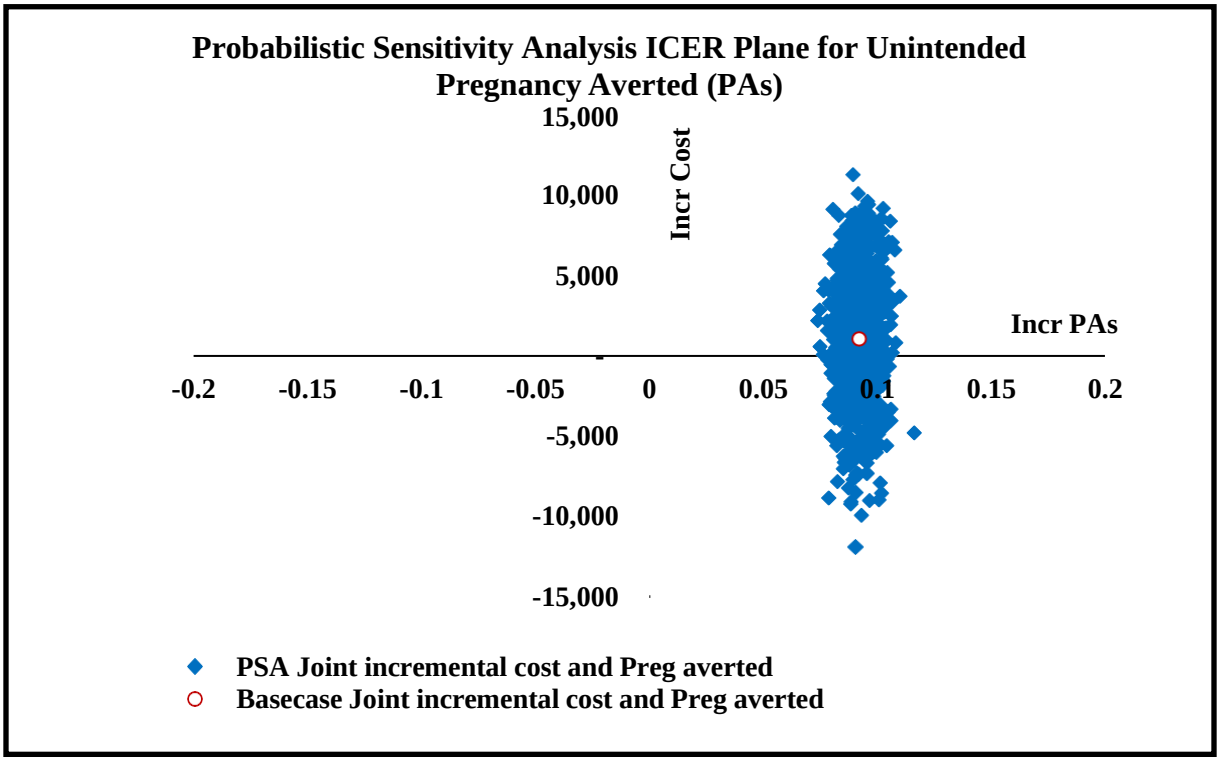
4.6 Sensitivity Analysis:

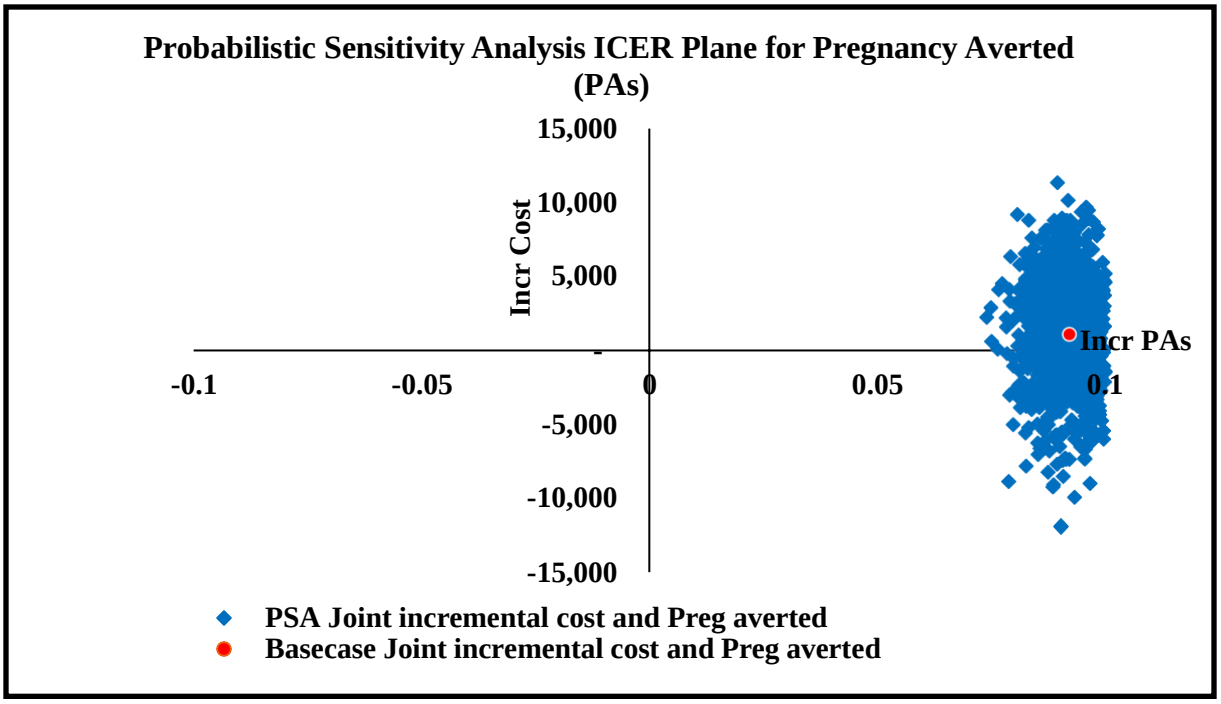
4.6.1 Probabilistic Sensitivity Analysis (PSA):

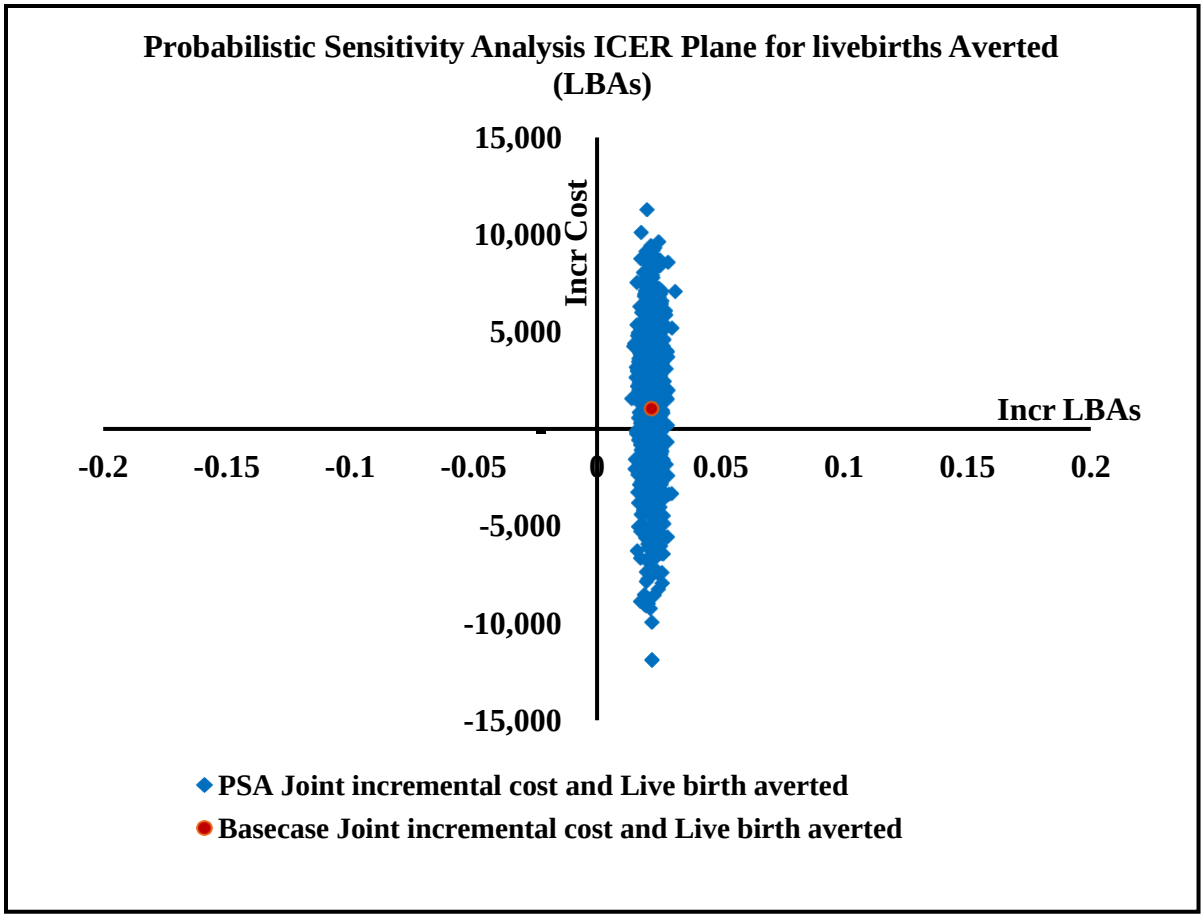
Since the inputs one uses for the model has uncertainties in relation to it, we use the PSA to address such uncertainties and increase our confidence in the results obtained from the model. PSA generates variable with varying values around the point estimate and a 1000 simulations were run. The PSA results are presented in the figure 4.3.

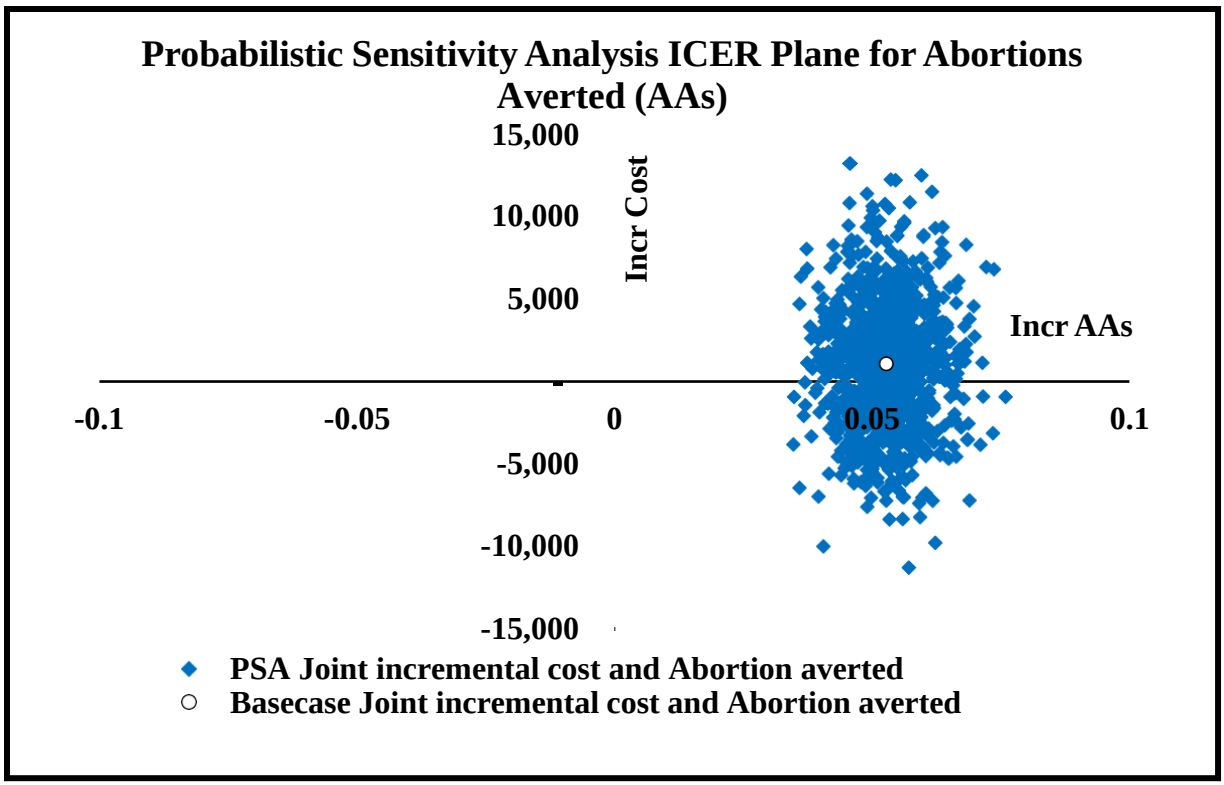
PSA Planes:

Interpretation: Of the 1000 simulations, pregnancies averted showed 100% cost-effective, 71.7% showed that livebirths averted is cost-effective, with 95.7% are cost-effective for abortions averted falling in upper right quadrant and only 57.1% of deaths averted is cost-effective (see table 3)**. Each blue dot in ICER plane, derived from 1000 Monte Carlo simulations. The red dot represents the base case ICER value.**




Probabilistic Sensitivity Analysis ICER Plane for Pregnancy Averted (PAs)
15,000
10,000
5,000
-5,000
-10,000
-15,000
Incr Cost
Incr PAs
-0.1
-0.05
0
0.05
0.1
PSA Joint incremental cost and Preg averted
Basecase Joint incremental cost and Preg averted


Probabilistic Sensitivity Analysis ICER Plane for livebirths Averted (LBAs)
15,000
10,000
5,000
-5,000
-10,000
-15,000
Incr Cost
Incr LBAs
-0.2
-0.15
-0.1
-0.05
0
0.05
0.1
0.15
0.2
PSA Joint incremental cost and Live birth averted
Basecase Joint incremental cost and Live birth averted



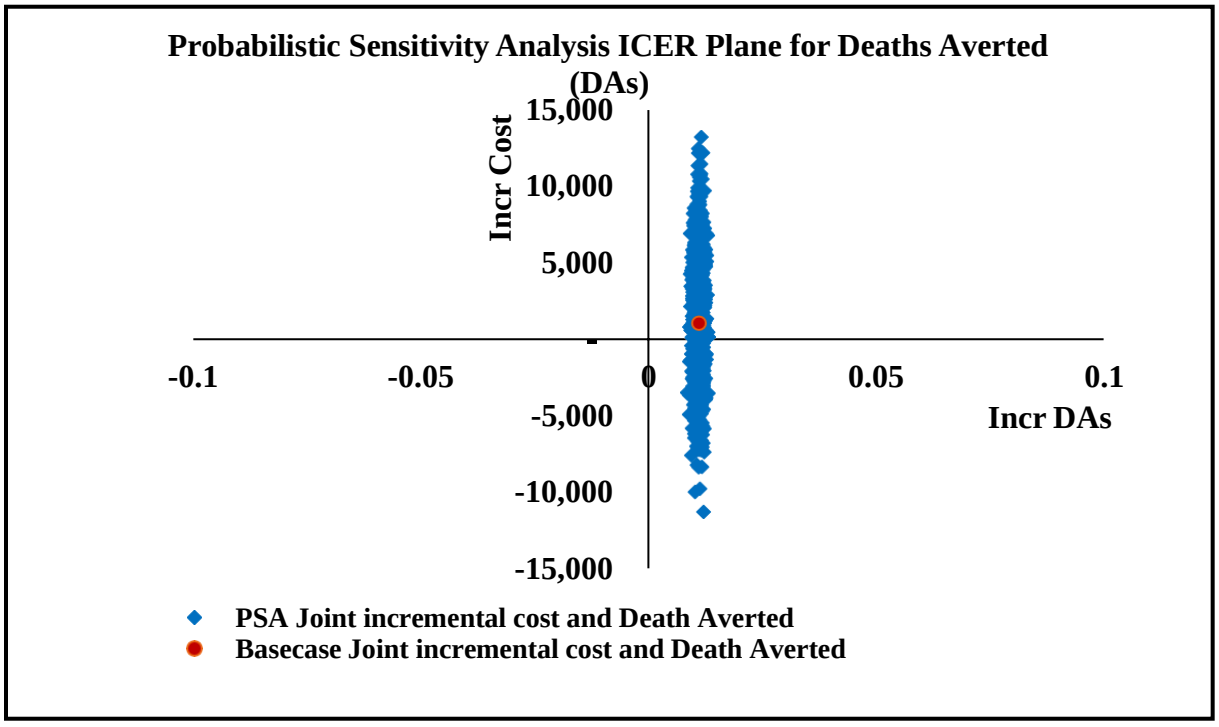
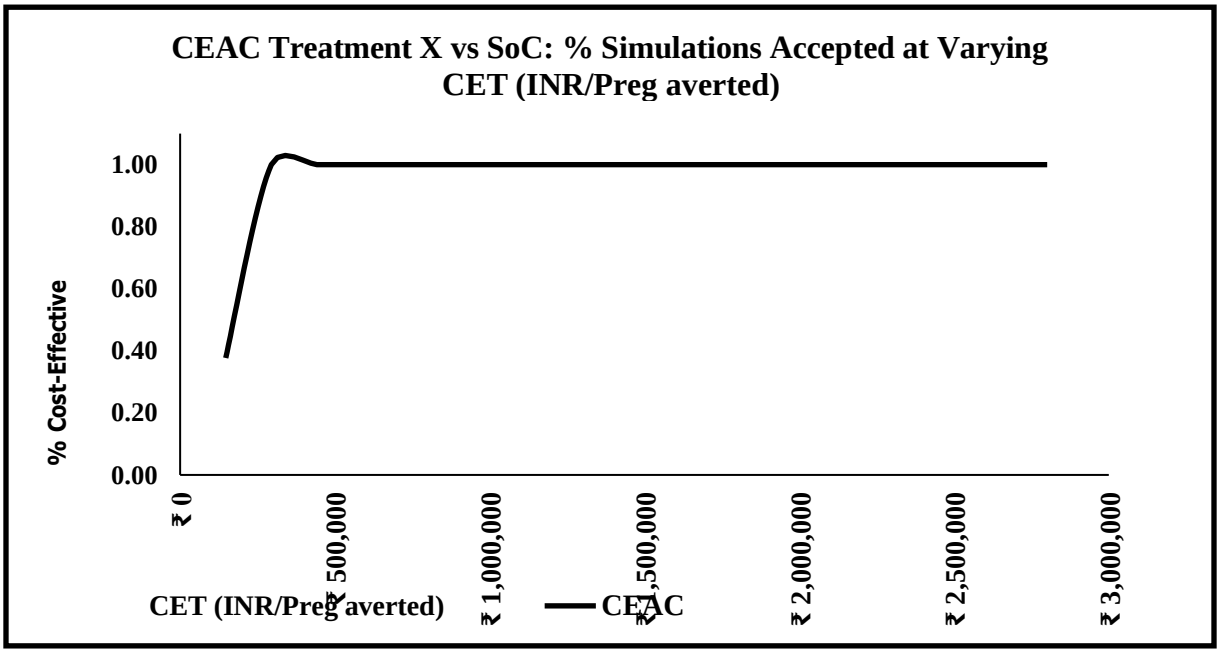
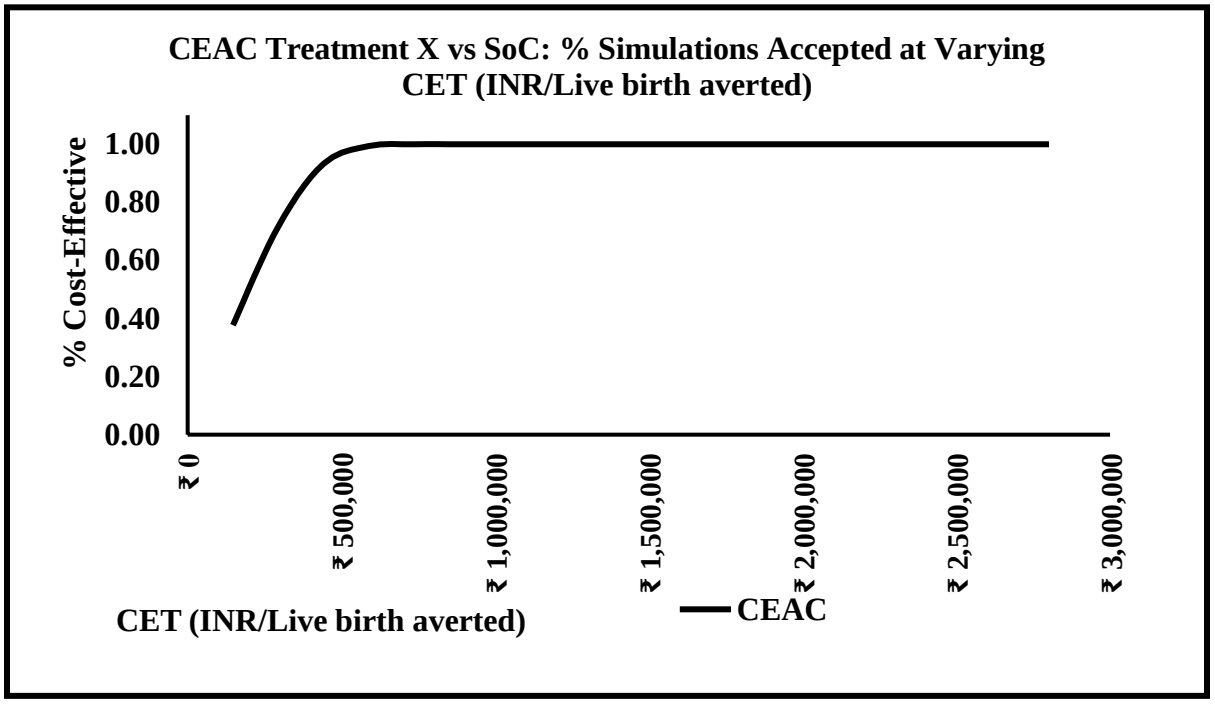


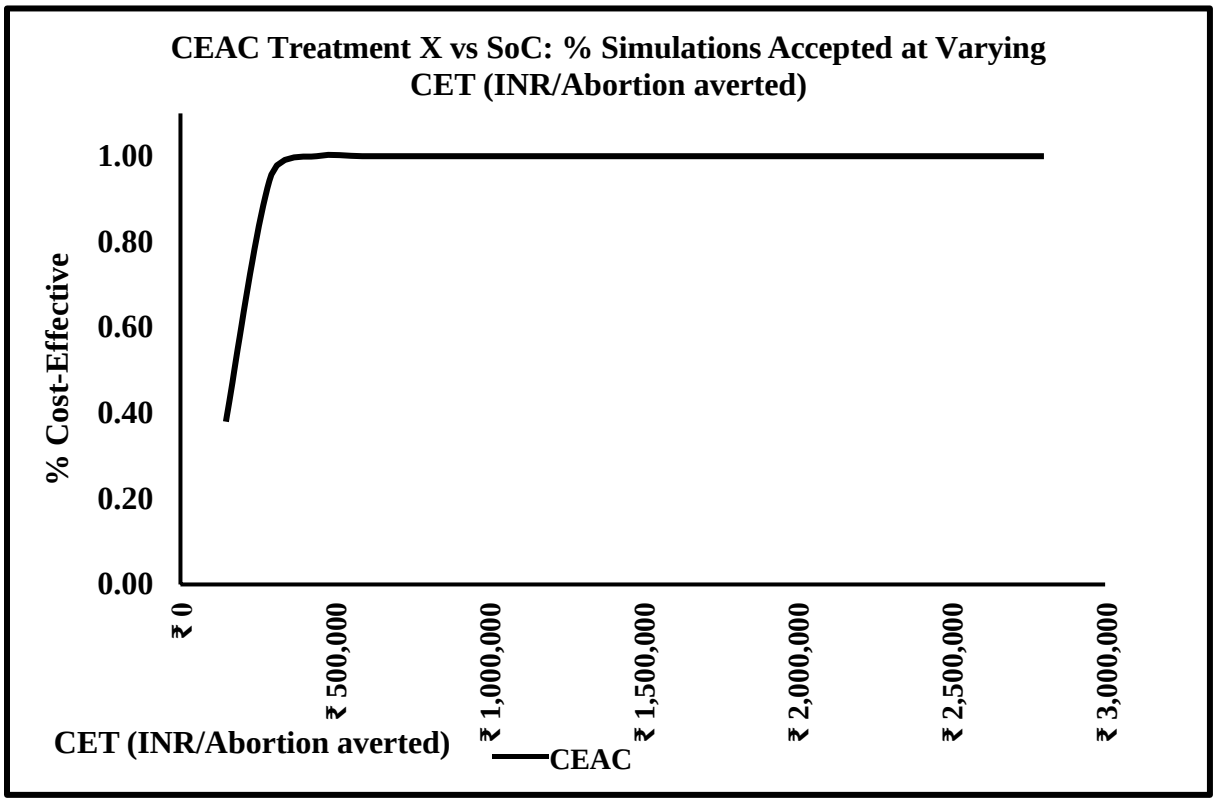
Figure 4.3: Cost-effectiveness plane showing the 1000 ICER values obtained from the PSA

4.6.2 CEAC Planes:

Interpretation: This curve shows that as willingness to pay increases, the proportion of simulations that shows pregnancy averted, livebirth averted, abortion and death averted increases. The curve plateaus at about 90-96%, the maximum proportion of simulations that can be cost-effective in this model for pregnancies averted, livebirths averted, abortions and deaths averted respectively (figure 4.4).







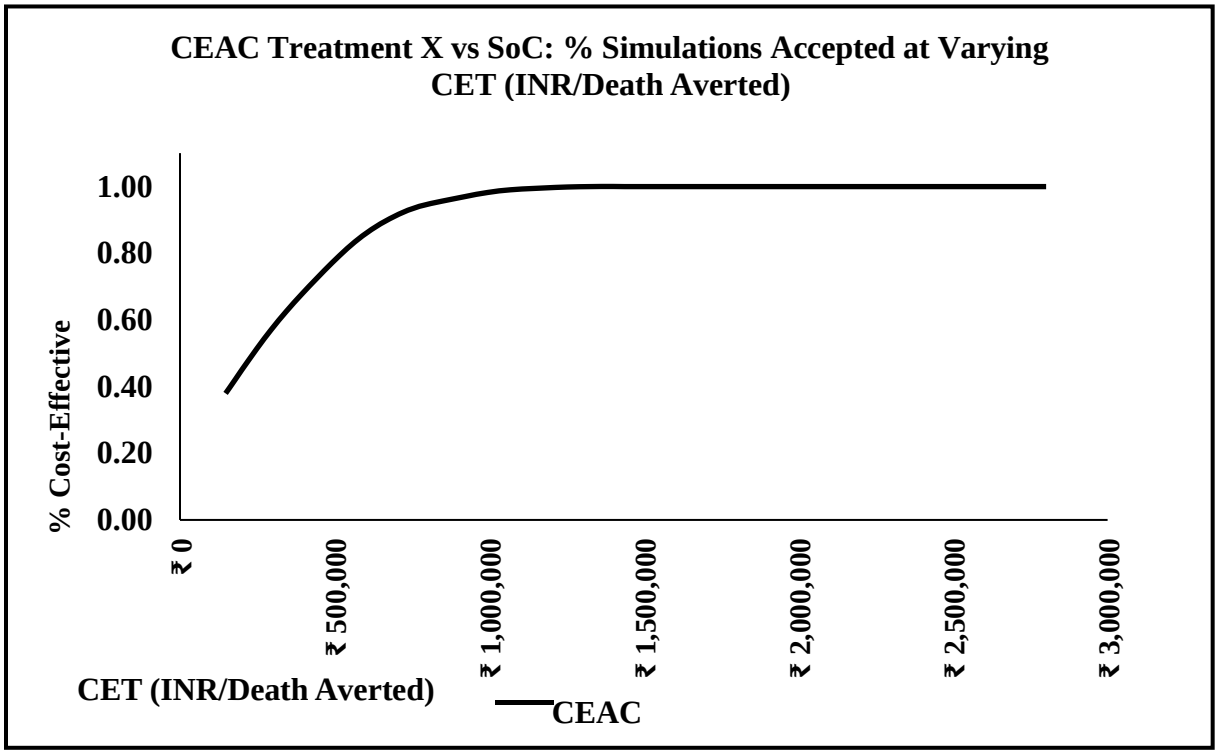


Figure 4.4 Cost-effectiveness acceptability curve (CEAC) for adding the Nexplanon intervention to the Current scenario

CHAPTER 5: EQUITY ISSUES

Equity upholds social justice and rights. Its emphasis is on the fair and just distribution of the technology assessed using the Health Technology Assessment project. There is a methodological challenge in the HTA process as the results are interpreted solely based on costs and QALYS. Equity consideration opens the moral and ethical dimension of the intervention of interest.[57]

In this HTA study, the sample population is WLHIV, who are a vulnerable group in society. Previous literature from global and Indian settings shows that PLHIV in general and WLHIV in specific are stigmatized and discriminated against in the context of health as well as social inclusion [62] [63] [64] [65] [66]. This discrimination could be reflected in the unavailability of proper and timely family planning services. Access to effective contraception is a matter of right for PLHIV as is for the general population. Misconceptions among the service providers are a major factor contributing to this gap in HIV care.

Targeted Intervention (TI) [67] is an effective method of preventing infection transmission from mother to child and partner to partner, especially in low-level concentrated epidemics, like HIV/AIDS. The method aims at focusing the intervention on high-risk groups (HRGs). The HRGs include female sex workers, MSM, IDU, etc. Linkage of HIV care and FP services could enhance the availability and reach of such TI.

The need for addressing equity issues among eligible couples was always an issue that demanded attention in the Indian setting and more so among PLHIV. Socio-cultural barriers play a crucial role in this. To promote the linkage of FP services into the current HIV care system, we should consider:

- Special emphasis on counseling and BCC among HRGs, especially female sex workers with [68].
- There is a lacuna in what we know about dual method use among female sex workers and it is difficult to measure their contraceptive behavior as the condom use varies across partners [68].
- While the reversible methods of family planning, like OC pills, IUDs, etc gives the women the upper hand in controlling their fertility desires, the successful use of dual methods is dependent on the consistent use of a condom by the male partner.

CHAPTER 6: DISCUSSION

The analysis of the Markov model showed that the linkage of HIV and FP services aiming to improve the uptake of dual methods and reduce unintended pregnancies, abortions, livebirths, and deaths. The intervention gains the quality of life in terms of life years, QALYS, and averting maternal deaths, unintended pregnancies, live births, abortions, stillbirths, and new infant HIV infections. The costs associated with the intervention were mainly for the additional IEC and training activities. The intervention also gains costs in comparison to the SOC.

A cluster-randomized trial was conducted in Kenya by Shade et al. in 2013 [69] to determine the costs, cost-efficiency, and effectiveness of integrating HIV and FP services. In this study, it was found that the integration was a cost-efficient way to deliver FP services to WLHIV as the cost required to be spent for increased use of effective contraception methods was well within the threshold range of the country. The study reported that the intervention was cost-saving in larger health facilities due to the higher patient load and personnel.

Another African study from Zambia was conducted by Wall et al. in 2020 [70] to access the cost-effectiveness of integrating FP and HIV prevention services among couples attending HIV testing and counseling. The study reported that the integration of FP services into HIV testing centers with special emphasis on LARC was a cost-saving intervention. The integration program carried out 56407 LARC insertions.. The intervention was found to be cost-saving in terms of cost per unintended pregnancy averted, and cost per perinatal HIV infection averted.

Another study in 2006 by Reynold et al. [71] in a hypothetical Sub-Saharan population assessed the cost-effectiveness of incorporating FP programs to reduce unintended pregnancies which in turn would reduce HIV-positive births. The study reported that 28.6% more HIV-positive births were averted through FP programs in comparison to the nevirapine-oriented PPTCT program. When 10% more unmet family planning needs were addressed within the cohort, 1940 HIV-positive births were averted. The ICER for this was $663.47, which was lesser and therefore more effective than the nevirapine-oriented PPTCT program (ICER= $856.47). The study concludes that if they use $20000 for the FP program and nevirapine-oriented PPTCT program, the first would avert 30.1 HIV-positive births while the second would avert only 23.4 HIV-positive births which are 22.3% lesser than the former.

Our study findings resonate with the results of previous researches. There were several methodological challenges highlighted in these previous studies. We have tried to address this in our methodology and analysis. Shade et al. [69] had raised concerns that their study was not powered to detect cost-effectiveness concerning pregnancies averted. We have tried to measure the cost-effectiveness of the intervention in terms of not only averted unintended pregnancies but also averted unintended infant births, stillbirths, abortions, HIV-positive infant births, and maternal deaths. Wall et al. [70] mentioned that they had not considered the cost to patients for availing the services, and could have underestimated their cost-effectiveness. To address this, we conducted a primary study to collect the OOPE by the clients for availing the HIV, FP, and pregnancy-related services from Indian public health facilities. Reynold et al. [71] had raised concern whether the proportions used for unintended pregnancies and unmet needs were conservative and an under-estimation of the reality. We tried to address this by adhering to data from Indian settings for deriving the proportions and probabilities used in the model.

Various Indian studies highlighted the inadequate emphasis given to promotion of dual methods among WLHIV [33] [72]. While conducting the data collection for our primary studies, we observed that the number of dual method users (condom with reversible or irreversible method user) were low in the health setting. After screening more than 3000 WLHIV, we could extract data for only three reversible method users and eight irreversible method users, who used the said methods for the past year. Among them, the consistency of the condom use was questionable.

This study demonstrates that integrating HIV and family planning services is cost-effective and cost-saving in reducing new HIV-infections among infants by averting unintended pregnancies. Preventing unintended pregnancies among PLHIV could avert the burden on the health of women infected with HIV, the cost burden on the health system to manage HIV infection among pregnant women and newborns, and the families to raise these children. Access to integrated delivery of health care and efforts to curtail the spread of HIV could facilitate accomplishing the last difficult mile to reach the Sustainable Development Goal target [10] of ending epidemics like AIDS by 2030. Access to effective contraception is a matter of right for PLHIV, as is for the general population. HIV programs must invest in effective measures to prevent discrimination against this vulnerable population. Even though a logical conclusion, many studies have failed to emphasize the aspect of averting unintended pregnancies within the PPTCT program. This study presents a

cost-effective evidence to promote various family planning methods in general and dual methods in specific, among WLHIV.

CHAPTER 7: STRENGTHS AND LIMITATIONS

6.1 Strengths:

The conceptual, methodological, and statistical strengths of our study are enlisted here.

1) We have conducted a primary cross-sectional HRQoL study to estimate the utility scores.
2) The utility scores were calculated using the EQ-D-L generic tool, and the Indian tariffs.
3) We conducted a second cross-sectional study to estimate the OOPE incurred by the clients to avail the services of interest. This has helped us to obtain a complete picture of the "cost parameters" that were used for the model.
4) We also conducted a primary micro-costing study to determine the cost of providing HIV and family planning services to the WLHIV from a health system perspective. This study added to the reliability of these cost parameters.
5) We have used Indian study and data references for constructing the model, keeping in mind the necessity to replicate a real-life scenario. The input parameters have been obtained from WLHIV- specific data. Therefore, we have tried to simulate a real-life scenario in the Markov model.
6) We have validated the model by experts in the field to check and assure the quality of the models
7) We have tried to measure the outcomes in terms of multiple parameters like maternal deaths averted, unintended pregnancies, live births, stillbirths, and abortions averted and infant HIV infections averted. Even though these are not all the possible program outcomes, considering these parameters would have assisted in estimating more reliable results.
8) The results of the study apply to a high HIV prevalence setting with high TFR, like the North-East belt of India, Maharashtra, Andhra Pradesh, etc.

6.2 Limitations:

1. Our models measures a few benefits of the intervention (unintended pregnancies averted, new infant infections averted, etc). There could be much more benefits of the intervention. But measuring all the benefits would have increased the complexity of the analysis. This analysis could have under-estimated the benefits of the intervention.
2. The sample population of the primary studies was from the high HIV prevalence district of Mumbai. Therefore, the results generated would not be generalized to the entire country but specific settings with high HIV prevalence and fertility rates.
3. The data used for deriving the age-specific proportions and probabilities was the MSACS PLHIV data for 2019-20. The data had several limitations in itself. The reliability of this non-routine data could be questioned in several ways. However, due to the unavailability of any other relevant WLHIV-specific data from an Indian health setting, we went ahead with using this data. It would be appreciated if program data are collected with a more efficient and robust methodology and analyzed regularly to address such lacunae in the Indian research literature.
4. Contraceptive use is dependent on women/ couple behavior within the context of societal acceptance and quality of care available through the health system. The stigma and discrimination toward PLHIV in public health systems also contribute to the subjectivity of these outcomes and therefore the probabilities derived from the literature.
5. The utility scores and OOPE generated for dual method users have come from a smaller sample size than expected. Our methodology had aimed to collect data from 80 WLHIV who were dual method users for the past year, but the number of such clients was much lower.
6. As we have restricted to the event until childbirths, we have not evaluated the future costs of managing the HIV-positive child.
7. We have considered the OOPE for infant diagnosis and testing as zero considering that these procedures were conducted in coherence with the mother's ART visits and infant's vaccination visits. Even though this could hold for majority of the cases there may be exemptions.
8. We have considered the health system costs for infant testing considering that one WLHIV would give birth to one child. Mild differences could occur in case the women give birth to more than one child.

CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS

The WHO has recommended a four-prong strategy for the management of HIV. The HIV control programs have focused on prong 3, i.e. medical management of pregnant WLHIV, to reduce infant HIV infections. This strategy was found to be effective in reducing HIV transmission and is undoubtedly a successful component of the PPTCT program. But, the prevalence of unmet family needs is high among WLHIV in India [73] [74]. This highlights the necessity to address the WHO prong 2 strategies of promoting FP methods among WLHIV to avert unintended pregnancies and HIV-positive births.

The intervention of interest here is to integrate HIV care with FP services. The current FP component of the program focuses on condom promotion for the prevention of infection. This needs to be strengthened to promote use of dual methods.

Conclusions:

- The intervention to integrate HIV care and FP services was determined to be cost-effective and cost-saving.
- The intervention would reduce unintended pregnancies, live births, abortions, and maternal deaths and infant with HIV infections.

Recommendations

- Access to all contraceptives is a matter of right of PLHIV to be able to use effective methods, plan, when and how many children to born. This will reduce burden on the pregnant women as well as health system to manage HIV +ve pregnancies and their outcomes.
- The existing PPTCT program could be strengthened to promote dual methods among PLHIV women by holistic counseling and providing linked ART services to OBGYN department to address sexual and reproductive health needs
- Improve knowledge among service providers during training and correct any misconceptions regarding use of various contraceptives among PLHIV
- Inform and motivate the stakeholders regarding the efficiency and effectiveness of this simple intervention that could help achieve SDG targets of 0% new infections.

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