2018

Family Planning and HIV Interventions among Women in Low-income Settings

Steven P. Masiano

Family Planning and HIV Interventions among Women in Low-income Settings

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

By

Mwatiyesa Steven Pirirani Masiano

Master of Science, Brandeis University, 2013

Bachelor of Social Sciences, University of Malawi, 2007

Doctoral Candidate, 2018

Advisor: April D. Kimmel, PhD

Assistant Professor, Department of Health Behavior and Policy

Virginia Commonwealth University School of Medicine

Virginia Commonwealth University School of Medicine,

Richmond, Virginia

December 2018

To my lovely wife, Noella, and two beautiful children Winston and Condoleezza-Gwen.

Acknowledgments

First, thanks and praises to Jehovah for His love, care, and blessings throughout this dissertation research. You granted me the wisdom, health, and strength to undertake this research and saw me through till the end. You never abandoned me. As thou saith in the Book of Mathews 7:7-8 “Ask, and it shall be given to you; seek, and you shall find; knock, and it shall be opened unto you: For every one that asketh receiveth; and he that seeketh, findeth; and to him that knocketh it shall be opened,” Thank you, Jehovah.

This journey was long and winding but getting to the promised land would not have been possible without the tremendous support and guidance of several people. I deeply appreciate and many thanks to you all. I owe special thanks to my committee chair and advisor, April D. Kimmel, for her guidance, encouragement, and untiring support. Without her, this dissertation work would not have been completed. I would also like to express my profound gratitude to my committee: Bassam Dahman, Daniel Nixon, Tiffany Green, and the late Saba Masho. I deeply appreciate your guidance and insights which have helped me to become an independent researcher. I would also like to thank Kate Grant for her support and encouragement, as well as the dedication and commitment to help with activities and jobs outside the routine of her regular position. Kate, you are the best. I also gratefully acknowledge the support of Yangyang who oriented me to the Medicaid claims data. Without him, this journey could have been harder.

This work would not have been possible without the support of classmates and peers. I could not have asked for more supportive classmates and colleagues. Specifically, I would like to thank Anushree and Lauryn who were great pillars of support and cheerleaders in some of the most trying times on this journey. I will miss you.

To family and friends outside of VCU, what can I say? My wife, “Queen Noella as I like to call her”, stayed with me along this difficult journey, continued to love me, and gave me comfort when I needed it most. I will forever be grateful. To my two children, Winston and Gwen, I am very grateful for your love, patience, and understanding. I was not able to spend as much time with you as both of us would have wanted; I will make it up to you. To my mum, I say thank you. I know it was not easy not to see your son and grandchildren for nearly five years. But your phone calls and unceasing prayers gave me hope and courage. To my late father, Omar Steven Bitoni Masiano, and late uncle Joseph Lameck Kalulu, I say thank you. Although you could not live long enough to see the fruits of your hard work, your legacy lives on. To Bud and Susie Whitehouse, I say thank you. You gave us your love and trust without knowing us. You supported us morally, spiritually, and materially. It is through you that my faith in Jesus Christ strengthened. Through you, my family learned that you don’t have to know someone to help them. My family and I shall forever be grateful.

TABLE OF CONTENTS

Family Planning and HIV Interventions among Women in Low-income Settings

Abstract

This dissertation examines the effectiveness of interventions related to family planning and the uptake of HIV-related preventive services among women in low-income settings. Women in low-income settings and living with HIV face many barriers to care, including limited access to services for family planning and HIV-related preventive care. At the same time, national, regional, and global efforts are looking for interventions to help control rapid population growth, create an HIV-free generation, and provide adequate preventive care for those living with HIV. This dissertation cuts across these issues and can help to inform debate and policies to address these issues.

This dissertation comprises three discrete papers. Paper 1 (chapter 1) examines the effectiveness of a national scale-up of community-based distribution of family planning services on contraceptive use in Malawi's rural areas during the period 2005-2016. The national-scale up of the intervention followed the success of a pilot of a similar intervention implemented in the period 1999-2004. As in the pilot, the scaled-up program distributed condoms and oral contraceptives and provided family planning education. Further, because education and income are important determinants of individual contraceptive use, the paper also examines whether the effectiveness of the national scale CBDs varies over these dimensions. The paper uses the Malawi Demographic and Health Surveys. The study finds that the intervention increased contraceptive use by 6.8 percentage points and the effects were greater among uneducated and low-income women.

Paper 2 (chapter 2) conducts a cost-effectiveness analysis of a trial of cash incentives aimed at increasing the uptake of services for the prevention of mother-to-child transmission (PMTCT) of

HIV. The trial was conducted in the Democratic of the Congo (DRC) as part of an effort to find ways of increasing uptake of PMTCT services in sub-Saharan Africa where uptake of these services remains low. The study is conducted from the societal perspective, relies on multiple sources within and outside of the DRC for cost data, and reports economic costs in 2016 International Dollars (I$). At a threshold of 3*GDP per capita for the DRC (I$2409), the study finds that the intervention is cost-effective.

Paper 3 (chapter 3) examines the guideline concordance of the time to follow-up anal cancer screening in women living with HIV at high risk for anal cancer. In the US, the incidence of anal cancer in women living with HIV has increased significantly in the past 2-3 decades. However, early detection of anal cancer, through regular screening, can lead to effective secondary prevention of the disease. While guidelines for anal cancer screening exist, very little is known about the guideline concordance of the time to follow-up anal cancer screening in women at high risk of acquiring anal cancer. Hence this study. The study uses Medicaid Analytic eXtract files which compile claims of individuals enrolled in Medicaid—a public health insurance program largely for eligible low-income adults and the largest single payer for HIV/AIDS in the US. The study finds that time to follow-up screening is not guideline-concordant for most women living with HIV, particularly those with one of the two risk factors for anal cancer: a history of abnormal cervical test results or a history of genital warts.

Chapter 1: The effects of community-based distribution of family planning services on contraceptive use in Malawi

Abstract

Background: To address rapid population growth, Malawi implemented and scaled-up a pilot project of community-based distribution (CBD) of family planning services. However, the effects of the scaled-up (national) CBDs on contraceptive use remain unclear. To address this knowledge gap, we evaluated the effectiveness of the national CBDs of family planning on contraceptive use. We also investigated whether education and income, two important determinants of individual-level contraceptive use behaviors, moderate these effects.

Methods: We used the 2000/2004 and 2010/2016 Malawi Demographic and Health Surveys (N=57,978) and difference-in-differences analyses to estimate the effects of the 2005 national scale-up of CBDs on modern contraceptive use. We used rural and urban communities as the intervention and comparison groups since the national CBDs were implemented only in rural communities. Contraceptive use is defined as current use of any modern contraceptive method—e.g., pills—and was modeled using multilevel logistic regression.

Results: Prior to the national CBD scale-up (2000/2004), the probability of using contraceptives was 21.5% in rural communities and 26.3% in urban communities. In the post-scale-up period (2010/2016), the probability of using contraceptives increased in both rural and urban communities but was greater in rural communities (44.9% vs. 42.9%). The effect attributable to CBDs was 6.8 percentage points (95% CI=3.3, 9.7). The effects of the CBD scale-up were greater among uneducated and low-income women.

Conclusions: These findings suggest that national CBDs increase overall contraceptive use, particularly in rural communities. Poor and uneducated women benefit more from family planning interventions that reduce communication and financial barriers. Further research on the effects of national CBDs on fertility, as well as the value and affordability of the national CBDs, is needed.

1. Introduction

Since gaining independence from the British in 1964, Malawi has experienced rapid population growth [1], [2], which has strained the country's resources in important sectors of education and health and has undermined the country's efforts to reduce poverty [3]. Malawi's population grew by about 500%, from 3.7 million in 1964 to over 17 million in 2015 [1], [2]. To find ways to slow the population growth, the Malawi government with financial support from the World Bank rolled out a pilot of the Learning and Innovation Population and Family Planning (Pop/FP) Project [4]–[6]. The pilot's objective was to test the feasibility of implementing a comprehensive community approach aimed at increasing the demand for and improving access to family planning services among hard-to-reach populations [6], [7]. The project trained community-based distribution[1] (CBD) agents to carry modern contraceptive methods (pills and condoms) and conduct family planning education in local languages of their designated communities of service [5], [6]. Some CBD agents of family planning referred clients to health facilities for services the agents could not provide [4].

The pilot project was implemented from 1999 to 2003 in 3 districts, one in each region. The districts were Chiradzulu in the South, Dowa in the Center and Chitipa in the North [5], [6], **figure 1**. The districts were selected based on the presence of a committed District Health Management Team (DHMT), low contraceptive prevalence rate (CPR), high population density, and low literacy rates [7]. Each pilot district had one control selected based on proximity and comparable socio-demographic characteristics (e.g., education) [5], [7]. The controls were

[1] The idea of a community approach to delivering family planning services was not entirely new in Malawi. It was first introduced in the late 1980s [4]. In 1991, the Christian Health Association of Malawian—an umbrella body of faith organizations providing healthcare services in Malawi—started a similar initiative [4]. The difference, however, is that prior efforts were not well coordinated, did not have a large presence in the communities, and had little or no involvement of public sector institutions [4].

Mulanje for Chiradzulu, Ntchisi for Dowa and Karonga for Chitipa [5], [7]. An end-of-pilot evaluation in 2003 suggested that the pilot was effective in increasing contraceptive use [5], [6].

Given the pilot project's effectiveness, it was scaled-up to the national level in late 2004. However, no study has evaluated the effect of the national CBD scale-up. Therefore, the current study investigates the effect of the full national scale-up of the CBDs of family planning (henceforth, CBDs) on contraceptive use during the period 2005-2016. Furthermore, because education and income are important determinants of individual contraceptive use behavior [8]–[11] and the intervention was designed to reduce or eliminate information and financial barriers to accessing contraceptives [5], [6], we also examine whether the effect of the CBDs varies by the education or income of the target population. The first hypothesis is that CBDs increased the number of women using modern contraceptives. The second hypothesis is that the effects of CBDs on contraceptive use are moderated (influenced) by both the education and income of the women receiving the services and these effects greater among highly educated and high-income women. The scale of the CBDs was done simultaneously across the country [personal communication, Malawi's Ministry of Health, January 2016].

Understanding the effect of the full scale-up of Malawi CBDs is important for several reasons. First, many projects implemented in low- and middle-income countries (LMICs) show promise of success when implemented as pilots [12]–[16], [17, p. 360], [18], [19], but when scaled to the national level, the evidence on the performance of such projects is lacking. This makes it difficult for policymakers to respond to emerging challenges and set new goals for the countries to achieve. Moreover, the few studies that have evaluated large-scale or scaled-up CBDs in Africa were not rigorous enough to provide reliable evidence that can be extrapolated to Malawi for evidence-based decision making. The studies either lacked control groups [20], [21] or did

not use pre- and post-intervention study designs [22]. This study addresses the methodological shortcomings of the previous studies by implementing a difference-in-differences technique to mimic an experimental study design to identify the effect of the CBDs on contraceptive use.

The second reason for evaluating the effects of the national CBDs in Malawi is that the selection criteria of the pilot districts (e.g., the presence of a committed DHMT and low district CPR) predisposed the pilot of the CBDs to demonstrate a level of effectiveness higher than would have been the case had the districts been randomly selected [6], [7]. Therefore, as these criteria suggest that the pilot districts were systematically different from the non-pilot districts and that the effect of CBDs in the pilot project might have been overstated, it is important to investigate the effect of the CBDs in the non-pilot districts after the scale-up.

Third and importantly, the national scale-up was implemented as a variant of the pilot project as not all conditions in the pilot project were maintained in the national scale-up which raises questions about the effectiveness of the scaled-up CBDs. A comparison of the pilot and national CBDs is provided in **table 1**. Notably, a monthly $6 cash payment to each CBD agent during the pilot was discontinued. Moreover, during the pilot the CBDs were primarily supervised by project employees who were given adequate resources, including motorcycles; in the national scale-up, primary CBD supervisors are government employees (Health Surveillance Assistants [HSA]—a cadre of community health workers) who use push bicycles to conduct the supervision [6]. Without the cash incentives and questions about supervision adequacy in the national scale-up, it is unclear whether the CBDs continued to be as effective as they were in the pilot.

In sum, an investigation into the effects of Malawi CBDs is needed as evidence on the effectiveness of the CBDs at the national level is lacking, but this evidence is important to Malawi. The evidence can be used by the Malawi government in the reorganization of the

country's priorities as the country works to achieve its target of eliminating poverty, providing quality education, and ensuring healthy lives for Malawians [3].

The rest of the study is organized as follows. Section 2 presents a background to the community-based distribution of family planning. Sections 3 and 4 present the theoretical/conceptual framework and methods. Results are presented in section 5. A discussion of the study's findings, strengths and limitations, and implications for policy is presented in section 6. Section 7 concludes.

2. Background to community-based distribution of family planning services

Community-based distribution (CBD) refers to strategies that rely on community structures, including community leaders and trained non-professional members of the community, to provide health services in the communities [23], [24]. CBDs of family planning promote the use of simple and safe non-clinical family planning methods such as oral contraceptives and condoms [24]. CBDs were introduced to reduce the unmet need for family planning in many parts of the world, particularly in rural areas of LMIC where the healthcare workforce is limited, stock-outs of modern contraceptives are frequent, and travel distances to health facilities are long [25]–[29]. CBDs were started in Latin America in the 1960s, then in Asia in the 1970s and more recently after 1980 in Africa [24], [30].

The promotion of CBDs in LMICs is based on theory and evidence which suggest that the CBDs have many advantages over services received in clinical settings. First, by bringing services to the communities, CBDs are more convenient for many people to access family planning services [23], [24], [27]. Second, family planning services received from CBDs cost less because many CBD agents work as volunteers or accept a small payment for their services and do not require extensive training [27], [31]. Third, it is easier for people in the communities to accept family

planning messages from the CBD agents since in many cases, the CBD agents are respectable and trusted members of their communities, especially when they are selected by the communities themselves [24]. Moreover, because CBD agents usually have many commonalities (e.g., language and cultural beliefs) with the rest of the community, it is easier for them to overcome social customs and traditions hindering the uptake of contraceptives [24], [27], [29], [32], [33]. Fourth, there is repeated messaging: because the CBD agents often reside in communities in which they provide the family planning services, there are more opportune occasions (e.g., social gatherings) where they can talk about family planning [4], [27]. The CBD agents may also informally talk about family planning which can be more appealing than the demand-based and static clinical set-up [27].

2.1. The effectiveness of community-based distribution of family planning

Despite CBDs being considered an important innovation in the delivery of family planning services, evidence of their effectiveness is mixed and mainly comes from pilot projects. Data show that CBDs have increased contraceptive use in many parts of Africa [14]–[16], [21], [34], [35], and that the positive effects of the CBDs persist when the portfolio of methods carried by CBDs is expanded beyond the non-clinical methods to include depot medroxyprogesterone acetate (DMPA)—an injectable contraception [12], [17], [36]. Furthermore, CBDs are still effective even when the CBDs integrate family planning services with other services [36], or when social institutions are the medium for channeling family planning information [24], or in makeshift settings in times of crisis [37]. However, evidence suggests that CBDs have not increased contraceptive use in some parts of Africa [20], [38], [39].

The effectiveness of CBDs depends on many factors. CBDs are more effective in communities with low CPR [24], [29], in more rural and isolated communities [14], [27], and in earlier periods

of CBD implementation [14]. Characteristics of the CBD agents also affect the effectiveness of the CBDs, although this evidence is mixed. Reports show that CBD agents are less effective if the agents are not well educated [39], [40]. However, other evidence shows that the agents' age, education, and marital status have no association with CBDs' productivity [41], although the sex of the CBD agent is important in influencing the choice of the contraceptive method [29].

Despite the evidence that contextual factors and characteristics of the CBD agents influence the effectiveness of CBDs, it is unclear whether the education and income of the target population also affect the effectiveness of CBDs. It is important to understand the role of education and income of the people receiving services from the CBDs because education and income are important determinants of individual contraceptive use behavior [8]–[11], and the CBD agents disseminate family planning information in ways that are easier to understand and overcome financial barriers associated with accessing contraceptives [13], [24]. Therefore, apart from investigating the effects of Malawi CBDs on contraceptive use, we also investigate whether the education and income of the target population affect the effectiveness of the CBDs.

3. Theoretical and conceptual framework

To understand the effect of CBDs on contraceptive use, we draw upon the economic framework for fertility analysis and the human capital model of demand for health. The economic framework for fertility analysis expands on consumer choice approaches [42] by incorporating supply factors and the cost of regulating fertility to understand household fertility behavior [43]. The theory notes that a household's need to regulate fertility arises when its biological supply of children exceeds its demand for the children [43]. However, there are costs to fertility regulation. The costs could be objective (e.g., transportation and contraceptive costs) or subjective (e.g., coping with using contraceptives against one's beliefs) [44]. While having many children may

provide utility to some households [45] or alleviate the subjective feeling of poverty in some societies of LMICs [46], the relatively high costs of obtaining modern contraceptives prevent many households in LMICs from regulating their fertility [47]–[49]; this is where CBDs become relevant and important in Malawi. By bringing contraceptives to the communities, the CBDs bring down the objective costs of fertility regulation to almost zero. CBD clients are not required to pay for services received from the CBDs because public health services in Malawi are free at the point of delivery [50].

We also draw upon the human capital model of demand for health by Grossman which identifies two pathways through which education impacts health behaviors like contraceptive use. First, through productive efficiency: educated people are better decision makers and thus have higher marginal products in the health production process [51]. Second, through allocative efficiency: educated people tend to have more knowledge about health which helps them to change their set of choices as well as behaviors to produce more health [51], [52]. The information shared by CBDs adds to the knowledge educated people already had, making it easier for them to dispense with traditional customs and beliefs that may impede contraceptive use [8]. In sum, although both educated and uneducated people might have improved access to contraceptives through CBDs, educated people are likely to process family planning information better, discuss and follow recommendations for contraceptive use [8], [53], [54].

Based on the two economic theories, we developed a conceptual framework of the effect of CBDs on contraceptive use while incorporating contextual or community factors which may also influence contraceptive use as documented in the literature [8], [9], [55]–[58], **figure 2**. The conceptual framework is specific to rural communities as CBDs work in rural communities only. The framework shows that contraceptive use is influenced by CBDs, the intervention, as well as

individual-level characteristics (maternal and paternal) of the target population and community-level factors. As the study has hypothesized that the direct effect of CBDs on contraceptive use is moderated by education and income, education and income were extracted from the other individual-level characteristics so that their moderating effects on the effect of CBDs on contraceptive use could be depicted as hypothesized. Further, the framework shows that individual-level characteristics of the target population affect contraceptive use directly or indirectly via community characteristics.

4. Materials and methods

4.1. Overview

The study used data from four waves (2000, 2004, 2010, and 2016) of the Malawi Demographic and Health Surveys (MDHS) and the difference-in-differences (DD) method to estimate the effect of the CBDs on contraceptive use in a weighted sample of 52,768 women aged 15–49 years. As CBDs were implemented only in rural communities, the rural communities were designated as the intervention group and urban communities as controls; primary sampling units were used as a proxy for communities. As CBDs were introduced in 2005, data collected before 2005 (MDHS2000 and MDHS2004) represented the pre-intervention period while MDHS2010 and MDHS2015 represented the post-intervention period. Contraceptive use was defined as current use of any modern contraceptive method—for example, pills. Contraceptive use was modeled as a binary variable ("no method" and "modern method") in a multi-level logistic regression with women nested in communities and communities nested in districts.

4.2. Data sources

Four waves of the Malawi Demographic and Health Surveys (MDHS2000, MDHS2004, MDHS2010 and MDHS2016) were used in this study. The surveys were conducted by the

National Statistical Office (NSO) in partnership with the United States Agency for International Development (USAID) and the country's other development partners [57], [59]–[61]. In years 2000, 2004, 2010, and 2016, the surveys covered 14,213, 15,091, 27,000 and 26,361 households, respectively [57], [59]–[61]. From the selected households, eligible women aged 15-49 years and men aged 15-54 years in a sub-sample of about one-third of the households were interviewed. The surveys provided comprehensive up-to-date information on education, wealth, and contraceptive use, among other indicators [57], [59]–[61]. The surveys use two-stage stratified cluster sampling to produce representative samples of urban and rural populations at the district, regional and national levels. Urban areas are defined as any of the country's major cities or areas encompassing district administrative headquarters or any official town planning areas; all the other areas are rural [62].

4.3. Hierarchical structure of the data

Since the surveys use multi-stage sampling designs to generate nationally representative samples, data from the surveys have a hierarchical or clustered structure [63]–[65]. Elements sampled in the first-stage, districts, constitute the highest level while those sampled in the final-stage, women, are the lowest units [63]. Thus, women are nested in communities and the communities in districts. The nesting means that women from the same community or district are similar and do not act as independent observations in their use of contraceptives. The similarity might be due to unobserved factors, like having similar cultural and traditional beliefs, which can facilitate or hinder contraceptive use [66], [67]. Therefore, statistical modeling of these data should account for this dependence to avoid producing biased estimates [63], [68]. As discussed below, contraceptive use was modeled using a multilevel model to account for the hierarchical structure of the data.

4.4. Sample

The final sample comprised 57,524 women, representing about 79% of women in the four MDHS files, **figure 3**. The data for this study came from the "women recode" files. Figure 3 shows how the sample was derived and the number of women from each wave of the MDHS. Infecund women, defined as women wanting to have another child but not being able to get pregnant [69], were excluded. Pregnant women were also excluded because the dependent variable was constructed from a question which focused on current contraceptive use. All women, regardless of marital status, were included in the study as they can all demand contraceptives. However, the association between CBDs and contraceptive use was also examined in a subsample of married women to make the findings more comparable to those from the pilot of the CBDs which reported contraceptive use among married women only [5].

4.5. Variable definition

4.5.1. Dependent Variable

The dependent variable is current use of modern contraceptive methods, and it is binary (1=using a modern method and 0= not using a modern method). The women were asked this question:

> Are you currently [at the time of the interview] doing something or using any method to delay or avoid getting pregnant [70]?

Women answering "YES" to this question were further asked to mention the methods they were using [70]. The contraceptive methods were classified as either modern or traditional. Modern methods include injections, pills, intrauterine device, diaphragm, condoms, sterilization, implants, foam or jelly, and lactational amenorrhea; traditional methods include abstinence and withdrawal [69]. Abortion was not considered as contraception because contraception was

defined as any effort to reduce the risk of conception. The three categories of contraceptive use ("no method", "traditional method", and "modern method") were collapsed into two categories "no method" and "modern method" as <2% of the women used "traditional methods". A test for combining categories of the dependent variable proposed by Long and Freese [71] showed that "traditional methods" and "no method" could be collapsed into one category as the two categories were indistinguishable.

4.5.2. Explanatory variables

Consistent with the conceptual framework in figure 2, explanatory variables were classified into two broad groups: individual-level variables and community-level variables. Among the individual-level variables, the woman's partner's education and occupation were included as these may also affect contraceptive use regardless of the woman's characteristics [72], [73]. Community variables were also included because these may exert influence on women's behaviors related to contraceptive use [74], [75]. For example, community literacy was included because women without any education may get assistance or encouragement to use contraceptives from other women with education in the same community. All explanatory variables, including definitions and how they were constructed, are presented in **Appendix A1**.

4.6. Identification strategy: difference-in-differences

We used the difference-in-differences (DD) method to identify the effect of CBDs on contraceptive use. The method rests on the parallel paths assumption, which states that the intervention and comparison groups would have followed the same time trends were there no intervention [76]–[78]. An effective policy intervention, therefore, causes the intervention group to deviate from its time trend [76], [78], [79]. The assumption, however, requires that the policy change should be exogenous or that any of the groups should not systematically select to adopt

the policy change. The study identified rural and urban communities as the intervention and comparison groups, respectively, although the government did not explicitly say that it was introducing CBDs in rural communities. However, by the scope of their work and as corroborated by a family planning expert [personal communication, Directorate of Reproductive Health and Family Planning in Malawi, January 2017], CBDs operate in rural communities only. CBDs target populations residing in hard-to-reach communities and urban communities are not hard-to-reach; many urban communities have wealthier households, better roads, and a higher supply of both health facilities and healthcare workforce, all of which permit easy access to healthcare services [80], [81] and diminish the need for CBDs in the urban communities.

Furthermore, the period before 2005 was identified as the pre-CBD period while the period after 2005 was the post-CBD period, **figure 4**. The introduction of CBDs occurred from December 2004 to February 2005 while interviews for MDHS2004 started in October 2004 and were completed in February 2005 [59]. Although there was an overlap of two months (December and January) between the introduction of CBDs and the data collection process, the overlap was not expected to affect the identification strategy. This is because data collection for the MDHS2004 had just started when CBDs were being introduced, and it was likely that CBD effects had a time lag. Therefore, the assumption was that the data collected in December 2004 and January 2005 did not capture CBD effects on contraceptive use. So, MDHS2000 and MDHS2004 were designated as the baseline surveys and MDHS2010 and MDHS2016 as the post-intervention surveys. However, in sensitivity analysis (**Appendix A2**), the effect of the overlap was checked by redefining the pre-CBD period to the year 2000 and removing the year 2004 from the analyses.

Finally, the three districts (Chitipa, Ntchisi, and Chiradzulu) in which the pilot of the CBDs was conducted (1999 to 2003) were excluded from the analysis. A change in the trend of contraceptive use after 2004 in rural communities of these districts was not expected because CBDs operated almost continuously from 1999 through 2016. In sensitivity analysis (Appendix A2), the validity of the identification strategy was tested by examining contraceptive use in areas where CBDs were expected not to have significant effects, namely, in the three pilot districts and in urban communities.

4.7. Statistical analysis

Data were analyzed using univariable and multivariable statistical approaches. In univariable analyses, categorical variables were described using proportions and continuous variables using averages. In multivariable analyses, contraceptive use was modeled using multilevel logistic regressions to account for the hierarchical structure of the data, as done previously [74], [75], [82]. Multilevel modeling (MLM) was also warranted because CBDs were introduced at a higher level—the community. Since MDHS' do not have a defined geographic area for communities, primary sampling units (PSU) were used as a proxy for communities. On average, each PSU comprised 30 households [57], [59]–[61]. The appropriateness of MLM was tested using the likelihood ratio (LR) test in a comparison of the single-level to the MLM. The degree of clustering in contraceptive use among women at the community and district levels was assessed using the intra-class correlation (ICC)—a measure of the relative similarity among observations from a sampling process and is estimated by analysis of variance and variance components [83], [84].

All analyses were conducted incorporating weights to correct for the unequal probabilities of selection to permit nationally representative estimates of the population. The weights provided in

the MDHS public use files were scaled using a weight-scaling method which makes the cluster size equal to the effective sample size to make the weights more appropriate for adjusting estimations at higher levels of the model [63], [85]. The weight scaling method assumes that level-1 weights are non-informative and uncorrelated with covariates multiplying the random effect thereby yielding unbiased estimates [63].

All results are presented as log-odds and marginal effects. We did not use odds ratios because they are difficult to interpret when logistic regression includes interaction terms [86], [87]. Therefore, we relied the study relied heavily on the marginal effects to understand the effect of CBDs on contraceptive use and whether the effect depended on education or income. Statistical significance of the results was determined using p-values and confidence intervals. All analyses were performed in Stata 14.2 [88, p. 14].

4.7.1. Model specifications

4.7.1.1. Effect of CBDs on contraceptive use

To examine the effect of CBDs on contraceptive use, the study's primary objective, we first estimated a single-level logistic regression and then a multilevel logistic regression in the country's 25 districts in which the pilot of CBDs was not conducted. The multilevel logistic regression was a 3-level random intercept model and was estimated using Stata's "*melogit*" command [89]. Stata's melogit performs optimization using the "original metric of variance components" and was preferred to other candidate commands like the meqrlogit because model convergence time is much shorter using the melogit command than the meqr command [89], [90]. The single-level logistic regression for any woman is specified as follows:

$$log\left(\frac{\pi_i}{[1-\pi_i]}\right) = \beta_0 + \beta_1(Rural) + \beta_2(CBDA) + \beta_3(Rural * CBDA) + \lambda \boldsymbol{X}_i + \alpha \boldsymbol{P}_j + \gamma_k + \Gamma + \mathcal{E}_i \quad (1)$$

Extending the single-level logistic regression in equation 1, the 3-level random intercept model for the i[th] woman, in the j[th] community and k[th] district is specified as follows:

$$log\left(\frac{\pi_{ijk}}{[1-\pi_{ijk}]}\right) = \beta_0 + \beta_1(Rural_{jk}) + \beta_2(CBDA) + \beta_3(Rural_{jk} * CBDA) + \lambda \boldsymbol{X}_{ijk} + \alpha \boldsymbol{P}_{jk} + \Gamma + U_k + U_{jk} + \mathcal{E}_{ijk} \quad (2)$$

Where;

π_{ijk} is the proportion of women using contraceptives and $(1-\pi_{ijk})$ is the proportion of women not using any contraceptives.

Rural=1 if the community is in a rural area; *Rural*=0 for communities in urban areas.

CBD=1 if year =2010 or 2016; *CBD*=0 if year = 2000 or 2004.

$\boldsymbol{X}_{ijk}$ is a vector of individual-level variables e.g., age (see table A1) and $\boldsymbol{\lambda}$ is a vector of parameters corresponding to the individual-level characteristics.

$\boldsymbol{P}_{jk}$ is a vector of community-level variables e.g., community child mortality (see table A1) and $\boldsymbol{\alpha}$ is a vector of parameters corresponding to the community-level variables.

Γ captures fixed effects for the years 2000, 2004, 2010 and 2016.

U_k, $U_{jk,}$ and $\mathcal{E}_{ijk}$ are adjusted district random effects, community random effects, and individual-level residuals, respectively, and they are all assumed to be independent and normally distributed with zero means [76]. The district and community effects represent the unobserved district and community characteristics which influence contraceptive use.

It these unobserved factors which cause correlation in contraceptive use among women from the same community or district [75, 76].

Thus, for a binary outcome variable Y_{ijk}, in equation 2, $\pi_{ijk} = Pr(Y_{ijk}=1)$ is the probability that the i^{th} woman in the j^{th} community in the k^{th} district uses contraceptives and $log\ (\pi_{ijk}/[1-\pi_{ijk}])$ is the natural log of using contraceptives versus not using contraceptives.

We assessed the fitness of the model in equation 2 by comparing observed vs. predicted values of contraceptive use and deviance residuals.

4.7.1.2. Assessing moderation

To assess whether education or income moderate (influence) the relationship between CBDs and contraceptive use, we extended the model in equation 2 as follows:

Education as a moderator

$$log\left(\frac{\pi_{ijk}}{[1-\pi_{ijk}]}\right) = \beta_0 + \beta_1(Rural_{jk}) + \beta_2(CBDA) + \beta_3(Education_{ijk}) + \beta_4(Rural_{jk} * CBDA) + \beta_5(Rural * Education_{ijk}) + \beta_6(CBDA * Education_{ijk}) + \beta_7(Rural * CBDA * Education_{ijk}) + \lambda \boldsymbol{X}_{ijk} + \alpha \boldsymbol{P}_{jk} + \Gamma + U_k + U_{jk} + \mathcal{E}_{ijk} \quad (3)$$

Income as a moderator

$$log\left(\frac{\pi_{ijk}}{[1-\pi_{ijk}]}\right) = \delta_0 + \delta_1(Rural_{jk}) + \delta_2(CBDA) + \delta_3(Income_{ijk}) + \delta_4(Rural_{jk} * CBDA) + \delta_5(Rural * Income_{ijk}) + \delta_6(CBDA * Income_{ijk}) + \delta_7(Rural * CBDA * Income_{ijk}) + \lambda \boldsymbol{X}_{ijk} + \alpha \boldsymbol{P}_{jk} + \Gamma + U_k + U_{jk} + \mathcal{E}_{ijk} \quad (4)$$

We defined the parameters, variables, and variances in equations 3 and 4 as in equation 2 above.

5. Results

5.1. Trends in contraceptive use

We examined trends in contraceptive use among rural and urban women before and after implementation of CBDs, **figure 5**. Over the two periods, the proportion of women using contraceptives increased in both rural communities (where CBDs were implemented nationally) and urban communities. However, the increase was greater among rural women by about 8 percentage points.

5.2. Sample characteristics

We examined the characteristics of a weighted sample of 52,978 (unweighted sample=57,524) women aged 15-49 years, **table 2.** About 80% of the women were from rural communities. While the percent of women with primary or secondary education increased in both communities, in each period rural women were more likely not to have any education. The percent of low-income women declined in rural communities and stayed the same in urban communities, although in both periods rural women were still less likely to have higher incomes than urban women. In either period, both rural and urban women were more likely to be married but rural women were higher in the percent that was married. The percent of women exposed to family planning information declined in both rural and urban communities, but rural women were less likely to be exposed. Both rural and urban women were most likely not to want to have any more children in both periods, and the percent of women that wanted to delay fertility increased in both communities. Finally, rural communities were more likely to report problems of access to healthcare, higher community child mortality, be poor, illiterate, and want to have more children; these indicators, however, improved after introduction of CBDs.

5.3. Average community and district contraceptive use

We assessed contraceptive use among women from 2,567 communities in 25 districts and found that the odds of using contraceptives in an "average" community and district—given by the overall intercept when district and community effects are equal to zero—was about 0.55 (95% confidence interval (C.I.) =0.51, 0.60) corresponding to a probability of 0.36 (95% C.I.=0.34, 0.38). We also found between-district and between-community variations of 0.04 (95% C.I. = 0.02, 0.09) and 0.28 (95% C.I. = 0.23, 0.35), respectively. These estimates were obtained from an empty multilevel model, and we present caterpillar plots with 95% confidence intervals of average community and district contraceptive use in **figures 6 and 7**.

In figure 6 and 7, the line at zero represents average log-odds of using contraceptives. We found that in many communities the 95% confidence intervals of contraceptive use overlapped with the zero line, with about 15% of the communities significantly deviating from the overall average. Furthermore, nearly 40% of the districts had contraceptive use that differed significantly from the district average and one district—Mangochi—had below average outlying contraceptive use. In sum, we found significant heterogeneity in contraceptive use at the community and district levels, providing preliminary evidence supporting using an MLM so that each district and community could have its own intercept.

5.4. Appropriateness of multilevel models

When the single level and multilevel logistic regressions of contraceptive use were compared, we found that the multilevel logistic regression was more appropriate [LR Chi (2) =1852, $p<0.0001$]. Next, a comparison of two- and three-level logistic regressions showed that the three-level model should be preferred [LR Chi (1) =121, $p<0.0001$]. The evidence confirmed that women do not act as independent observations in contraceptive use; they are clustered at the

community and district levels. The clustering was about 4 times stronger among women in the same community than among women from different communities of the same district.

5.5. Effect of CBDs on contraceptive use

We present the effect of CBDs on contraceptive use estimated from the MLM in **table 3**. For comparison, we also include estimates from the single-level model. In all, the results from the two models are consistent with each other, although estimates from the MLM are slightly higher in many cases. Furthermore, the multilevel model had consistently larger standard errors and wider confidence intervals than the single-level model. This suggests that were we to use the single-level model, the probability of type 1 error (rejecting a true null hypothesis) would have been slightly higher than the nominal level as the statistical significance of our results would have been overstated [91], [92]. Our findings suggest that the effect of CBDs on contraceptive use was not homogenous in rural and urban communities as the coefficient of the interaction of CBDs and rural is statistically significant. The results also show that community factors explain the use of modern contraceptive methods in Malawi. The effect of the CBDs on contraceptive use is presented as marginal effects **in table 4**.

We found that CBDs increased contraceptive use by 6.8 percentage points among all women, table 5. The probabilities were predicted using the fixed part of the random coefficient model which is equivalent to setting the community and district random effects to zero. Thus, the average probabilities are for women in the median community [76]. Before CBDs were introduced, the probability of using contraceptives was 21.5% in rural communities and 26.3% in urban communities. After CBDs were introduced, however, the probability of using contraceptives in rural communities increased substantially and was higher than in urban communities (44.9% vs. 42.9%). Subtracting the urban-rural difference before CBDs from the

urban-rural difference after CBDs shows that CBDs increased contraceptive use by about 6.8 [95% C.I.=3.3, 9.7] percentage points, all other factors held constant. In a sub-sample of married women, CBDs increased the probability of using contraceptives by about 8.2 [95% C.I.=4.1,12.3] percentage points.

5.6. Assessing whether education and income are moderators of CBD effects

When we examined whether the association between contraceptive use and CBDs depended on education and income, we found that the association depended on both these factors, **table 5**. The effect of the CBDs varied by education and was significantly higher among women without any education followed by those with primary education in comparison with women with at least a secondary education. Similarly, the effect of CBDs was also moderated by income and was significantly greater among women with low and medium incomes compared to women with high income.

Figures 8 and 9 present the predicted probabilities of contraceptive use at various levels of education and income before and after the CBDs were introduced. The CBDs increased the probability of using contraceptives in each group of women and the percentage point changes were as follows: women without education (+22.8); women with primary education (+17.23); women with at least a secondary education (+9.69); low-income women (+19.85); medium-income women (+17.00); and high-income women (+10.05). Thus, women without any education benefitted the most from the CBDs with a 13-point net increase in the probability of contraceptive use over and above women with at least a secondary education. Compared to urban women, the change in contraceptive use was greater among rural women at every level of education. In terms of income, differences in contraceptive use were not statistically different between women in rural and urban communities.

5.7. Sensitivity analysis of the identification strategy

Because the data used for this study were not collected for evaluating the effect of CBDs, we performed three robustness checks to validate the identification strategy. To identify the effect of CBDs, we made three assumptions. First, we assumed that after the national rollout, the effect of CBDs was only in the 25 districts in which the pilot of the CBDs was not implemented. So, we tested this assumption by examining the effect of CBDs in the three districts in which the pilot of the CBDs was implemented, expecting the CBDs not to have significant effects in these districts. As expected, the coefficient of the interaction between CBDs and rural was not significant at 5% (log-odds=0.738, 95% C.I.= -0.418,1.894). A more detailed analysis of these results is presented in **appendix A2**.

Second, we assumed that the introduction of CBDs was exogenous and only in rural communities. Therefore, we expected CBDs not to have significant effects on contraceptive use in urban communities. We tested this assumption by examining the effect of CBDs in urban communities and whether education and/or income moderate the effect of CBDs on contraceptive use in urban communities. We found that CBDs and its interaction with education or income did not have a statistically significant effect on contraceptive use in urban communities at 5%, **Appendix A2**. However, these variables had significant effects in rural communities as reported earlier. This result reinforces the findings from the first sensitivity analysis and we conclude that our strategy identifies the effect of CBDs. A more detailed analysis of these results is presented in **Appendix A2**.

Third, we assumed that MDHS data collected in the years 2000 and 2004 served as the baseline for contraceptive use in the 25 districts in which the pilot of CBDs was not implemented. In these districts, CBDs were introduced after 2004, so MDHS2000 and MDHS2004 should not

capture CBD effects. We tested this assumption by examining the effect of changing the baseline years. We found that CBDs increased contraceptive use by 7.58 and 5.25 percentage points when the baseline years are 2000 and 2004, respectively, compared with 6.8 percentage points when both (2000+2004) are used as the baseline, **Appendix A2**. Thus using 2004 as the base year underestimated the effect of CBDs which suggests that the overlap between MDHS2004 and the introduction CBDs might be attenuating the effect of CBDs. In all, the sensitivity analyses showed that our identification strategy is valid, and in any case, we are underestimating the effect of the CBDs.

5.8. Model fitness

We tested model goodness-of-fit tests using two approaches both of which suggested that the model is a good fit for the data. First, we compared observed vs. predicted values of contraceptive use to understand how well the theoretical (binomial) distribution of the data fits the empirical distribution. We classified all women with a <0.5 probability of using contraceptives as not using contraceptives, while those with a ≥0.5 probability as using contraceptives. Second, we examined deviance residuals and identified outlying values. A residual was outlying if it lied outside two standard deviations of a mean residual value of zero. We found that our model correctly predicted about 75% of women as either using or not using contraceptives. However, the model had higher accuracy of predictions among nonusers of contraceptives compared to users (>80% vs. > 60%), possibly because there were more nonusers of contraceptives than there were users. Deviance residuals in **figure 9** also confirm that the model correctly predicted the status of contraceptive use for many women although less than 2% of predictions were outlying.

6. Discussion

Our primary objective was to estimate the effect of CBDs on contraceptive use in Malawi during the period 2005-2016. As hypothesized, we found that CBDs increased the probability of using modern contraceptives by 6.8 percentage points among rural women. Our finding is consistent with Kalanda's who reported that the pilot of CBDs in Malawi increased the probability of contraceptive use by 7 percentage points [5]. Because Kalanda reported contraceptive use among married women only and we report contraceptive use for all groups of women regardless of marital status, we also conducted a secondary analysis of the effect of CBDs in a sub-sample of married women only to make our findings more comparable. In the secondary analysis, we found that CBDs increased the probability of married women using contraceptives by about 8.2 percentage points, higher than reported in the pilot.

There are two possible explanations for the bigger effect of CBDs among married women in the national scale-up than in the pilot. First, the pilot was only for three years which may not have been adequate to see the full effects of the CBDs; to influence people to have positive attitudes towards contraceptives and for them to begin to use contraceptives consistently requires more time [93], [94]. Second, the scaled-up program has been evolving to include more contraceptive methods than there were in the pilot and increasing the number of contraceptive methods carried by CBDs is associated with increased contraceptive use [95]. USAID reported that from 2010 the Malawi Ministry of Health began to allow Health Surveillance Assistants—primary supervisors of CBDs—to administer DMPA [96]. Although few Health Surveillance Assistants administer the DMPA [96], it is probable that without this development fewer women would have reported using modern methods. This explanation is consistent with reports from pilot studies that including DMPA within the existing CBD programs increases contraceptive use, attracts new

users, and equally satisfies women as DMPA obtained in health clinic [12], [17, p. 360], [18], [36], [96], [97].

Our findings are also consistent with reports from previous studies examining the effect of community interventions in other parts of Africa. For example, contraceptive use increased in Mali following the introduction of village-level family planning promoters [15], in Ghana where health workers with basic training in curative health services were deployed with community volunteers to provide family planning services [14], in the Gambia where family planning was promoted through traditional social and religious institutions [24], and in South Sudan where a CBD program was implemented among displaced people [37].

Other studies have reported different results, however. In Ethiopia, Tawye et al. reported that community-based interventions, increased contraceptive use in some regions but not in others [20], perhaps because the study did not have a control group to serve as a counterfactual and/or may not have properly identified effects of the community intervention [20]. In Kenya, the African Medical and Research Foundation (AMREF) documented that traditional birth attendants and male herbalists working as CBDs did not increase contraceptive use [39], although AMREF attributed the null findings to the illiteracy of the CBDs. In the DRC, Bertrand et al. reported that CPR was relatively unchanged despite the introduction of CBDs [38]. Although the study was a pretest-posttest design, Bertrand et al. did not have a control group to fully and properly identify the effect of the intervention, unlike the current study which used a pre- and post-test design with a control group.

The current study also adds to the literature in its assessment of whether the effect of CBDs is moderated by education and income. As hypothesized, we found that the effect of CBDs is moderated by both education and income; we also found that the effect of CBDs varied more

strongly with education than with income. A surprising finding, however, was the finding that the effect of CBDs was strongest among women with no education and declined as the education level increased. There are two potential explanations for this finding. First, because CBDs provide family planning information in the simplest form possible, they may be seen to work to meet the needs of uneducated women. Second, CBDs carry a very limited number of contraceptives—in many cases pills and condoms only—which may be less appealing to highly educated women. As a result, highly educated women may be reluctant to seek services from CBDs. Since highly educated women are also more likely to have higher incomes, it means they can afford to pay for alternative methods of contraception or seek contraceptives elsewhere which is consistent with the finding that the effect of CBDs was strongest among low-income women. Low-income women are more likely to be receptive to commodities offered by CBDs because they have limited contraceptive choices and contraceptive sources.

6.1. Strengths and limitations

Findings from this study must be understood in the context of the following strengths and limitations. The key strength of our study is the use of nationally representative data to examine the effects of the CBDs on contraceptive use. Also, the incorporation of within- and between-community variation and unobserved community random effects makes our findings generalizable beyond the women from communities in the sample [98]. Additionally, by pooling independent cross-sections in different time periods, we can make inferences about changes in contraceptive use at the population level. Furthermore, our study produces more valid estimates of the effect of CBDs because the data were not reported by the CBDs themselves; data obtained directly from CBDs can be suspect or incomplete which can introduce bias [16], [95]. Moreover,

we performed a series of sensitivity analyses which validated our identification strategy and suggested that our findings are robust.

The study also has many limitations. First, because the MDHS' do not have defined geographic areas called communities, we used PSUs as a proxy for communities which might not be precise. Despite this limitation, it is still reasonable to think that women from the same PSU are more likely to have shared interests and attitudes and therefore constitute a community [9], [74], [75]. Second, while communities were dichotomized as rural or urban, communities occur on the urban-rural continuum. It is possible for some communities to have been misclassified and because the data come with PSU already classified as rural or urban, we were unable to perform a sensitivity analysis of our findings to changes in the urban-rural taxonomy.

Third, many variables used in the study, including contraceptive use, education, and income, are based on women's self-reports which may not accurately measure what we say they are measuring [99]–[101]. Our findings are thus biased to the extent of differential bias in self-reporting between rural and urban women and/or before and after CBD implementation and if the bias exists, its direction is unclear. Notwithstanding this limitation, we still used the self-reported measures because they are readily available and reflect the respondents' own view. Moreover, current contraceptive use has been validated before and women's self-reports were found to be more valid than men's [102]. A fourth limitation is that the data were not collected for purposes of evaluating the effect of CBDs on contraceptive use. Among women reporting contraceptive use, we do not know how many got the methods from CBDs or from other sources e.g., health centers. That said, the current analysis suggests that with a proper identification strategy it is possible to leverage national data (e.g., MDHS) collected for other purposes to answer programmatic questions.

Finally, due to data limitations, we were unable to check if CBD effects spilled over from the pilot districts to the neighboring districts during the CBD pilot project. Any spillovers are more likely to have occurred through the diffusion of family planning information than through contraceptive methods crossing district boundaries because the CBD agents had defined villages in which they worked; in Malawi, village boundaries do not transcend district boundaries. If spillover effects occurred, however, it means our estimates are biased towards the null as contraceptive use in the districts sharing borders with the pilot districts was higher than should have been at the time of the national scale-up of the CBDs.

6.2. Policy implications

From this research, several policy implications are evident. First, CBDs should be continued and strengthened if the country is to sustain the gains made in contraceptive use. Among other things, the government, the country's development partners, and stakeholders should ensure that supply of contraceptives to the communities is uninterrupted, CBDs receive refresher training regularly, supervision of the CBDs is active and frequent, provision of CBD agents' working kits (e.g., bicycles and gumboots) to facilitate follow-up of clientele. The availability of these facilities will help ensure that women relying on CBDs continue to get quality services and prevent intermittent use of contraceptives among the rural women.

Second, this work suggests that there may be a need to increase the portfolio of contraceptive methods carried by the CBDs. As noted, methods carried out by CBDs are not meeting the needs of women with more education and high income. With proper accountability and support, we suggest that all CBDs and their supervisors should be carrying DMPA and natural methods (e.g., cycle beads) in addition to the condoms and pills. Third, given the success of CBDs in rural communities, our results suggest that urban communities can benefit from the introduction of

CBDs or an equivalent of the CBDs in the urban communities. For example, health posts manned by Health Surveillance Assistants could be introduced in urban communities which have limited access to health centers or have high population densities. As the government of Malawi continues with efforts to increase contraceptive use, it is important that both urban and rural communities are targeted and that the efforts should not create or perpetuate rural/urban disparities in contraceptive use as noted in this study.

6.3. Future research

While we have reported that CBDs in Malawi increased contraceptive use, we make two recommendations for future research. First, the value of the CBDs should be established. Doing this would require analyzing both the costs and effects of the CBDs after the national scale-up; we have only examined their effectiveness. Examining costs and hence the value of the CBDs is important because prior evidence suggests that CBDs can add as much as 30% per capita to the primary healthcare budgets [103]. Second, this study has only reported the effect of CBDs on contraceptive use—a proximate determinant of fertility. The goal of introducing CBDs was to reduce fertility or at least increase birthing intervals in Malawi. Therefore, future studies should focus on evaluating the effects of CBDs on these outcomes.

7. Conclusion

Following the success of a pilot of CBDs from 1999 to 2003, the Malawi government scaled the CBDs to all rural communities of Malawi in 2005. We have found that CBDs increased contraceptive use during the period 2005 to 2016, and the intervention can help the country to achieve its long-term agenda of reducing population growth. Before the implementation of the CBDs, contraceptive use in rural communities was lower than in urban communities. After the implementation of the CBDs, however, contraceptive use increased significantly in the rural

communities to the extent that urban communities are now lagging. The effect of CBDs was strongest among uneducated and poor women suggesting that delivering messages and interventions using the communities' local languages and structures is important if any intervention is to reach the target population, particularly rural communities. While the CBDs should be continued and strengthened, it is important to establish whether the CBDs have also reduced fertility or are cost-effective.

Table 1. Comparison of the pilot and national CBDs in Malawi

Component	Pilot	National
Training	Yes	Yes
CBD incentives		
Certificates of recognition	Yes	Yes
Umbrellas, boots, raincoats, backpacks, and push bicycles	Yes	Yes
US$6 per month	Yes	No
Uniforms and badges	Yes	No
Dedicated resources for supervision*		
Motor vehicle (program-specific)	Yes	No
Motorcycles	Yes	No
Push bicycles	No	Yes
District Health Management Teams		
Commitment	Yes	Unknown
Information, education, and communication		
Health talks, dramas, leaflets, flyers, and posters	Yes	Yes
T-shirts, radio jiggles, cassette players, and, comic books	Yes	No
Family planning commodities		
Pills	Yes	Yes
Condoms	Yes	Yes

*In the pilot, project employees supervised CBDs. In national CBDs, Health Surveillance Assistants (community health workers) employed by the government conduct the supervision.

Table 2: Descriptive statistics (Weighted sample size: n=52,978)

	Rural (n=42,707)		Urban (n=10,272)	
Variable	Pre-CBD (n=14,320)	Post-CBD (n=28,386)	Pre-CBD (n=3,200)	Post-CBD (n=7,073)
Personal-level factors				
Current contraceptive use*				
None	0.743	0.572	0.669	0.574
Modern	0.257	0.428	0.331	0.426
Education***				
None	0.276	0.149	0.083	0.046
Primary	0.636	0.682	0.505	0.411
Secondary	0.087	0.162	0.392	0.437
Higher	0.001	0.007	0.020	0.106
Income (wealth)***				
Low	0.410	0.406	0.045	0.036
Medium	0.355	0.374	0.079	0.109
High	0.235	0.219	0.876	0.856
Occupation***				
Not employed	0.428	0.385	0.602	0.532
Self-employed	0.449	0.506	0.093	0.102
Professional	0.123	0.110	0.305	0.366
Age (years)***				
15-19	0.217	0.229	0.248	0.225
20-29	0.423	0.374	0.481	0.423
30-39	0.233	0.268	0.189	0.254
40-49	0.127	0.129	0.081	0.098
Marital status***				
Never married	0.169	0.210	0.299	0.319
Currently married	0.706	0.659	0.598	0.572
divorced	0.092	0.104	0.062	0.078
Widowed	0.033	0.027	0.040	0.031
Fertility desire***				
wants child in < 1 year	0.091	0.056	0.085	0.056
wants child in >1 year but <3years	0.153	0.120	0.115	0.116
wants child after 3 years	0.315	0.410	0.346	0.434
no more children	0.440	0.415	0.454	0.393
Partner's education***				
None	0.313	0.373	0.343	0.399
Primary	0.549	0.439	0.297	0.199
Secondary	0.133	0.173	0.323	0.310
Higher	0.005	0.015	0.037	0.092
Exposure to family planning information*				
Not exposed	0.516	0.338	0.352	0.168
Some exposure	0.484	0.662	0.648	0.832
Autonomy**				

Little or no autonomy	0.476	0.378	0.479	0.358
Semi or complete autonomy	0.524	0.622	0.521	0.642
Religion***				
Catholic or Anglican	0.272	0.222	0.259	0.226
Other Christians	0.593	0.642	0.626	0.673
Muslims	0.135	0.137	0.115	0.102
Community-level factors				
Healthcare access problems**				
Yes	0.653	0.373	0.787	0.595
No	0.347	0.627	0.213	0.405
Community literacy***				
Not literate	0.519	0.263	0.048	0.039
Literate	0.481	0.737	0.952	0.961
Community income***				
Low	0.419	0.432	0.008	0.006
Medium	0.382	0.389	0.025	0.034
High	0.198	0.179	0.967	0.960
Community religion**				
Catholic or Anglican	0.171	0.092	0.069	0.032
Other Christians	0.700	0.777	0.895	0.929
Muslims	0.129	0.131	0.036	0.039
Community child mortality (mean)	209.167	136.050	135.498	106.898

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

All variables are categorical, except community child mortality, and proportions are presented in the table. For the categorical variables, we tested whether the proportion of women under each variable was the same in the periods before and after CBDs were introduced across both rural and urban communities. For the continuous variable, community child mortality, we tested whether the means were different in the two CBD periods across rural and urban communities. The tests were performed using the Wald test.

Table 3: Effect of CBDAs on contraceptive use in Malawi (2005-2016)

	Single-level model		Multi-level model	
	Coefficient	95% C.I.	Coefficient	95% C.I.
Dependent variable: Contraceptive use				
Main explanatory variables				
CBDAs	0.919***	[0.767,1.071]	0.954***	[0.706,1.202]
Rural	-0.411***	[-0.540,-0.281]	-0.314***	[-0.481,-0.147]
Ref: Urban, before CBDAs				
Rural, after CBDAs	0.421***	[0.272,0.571]	0.424***	[0.236,0.612]
Individual-level factors				
Age (ref: 15-19 years)				
20-29yr	0.568***	[0.470,0.666]	0.588***	[0.486,0.689]
30-39yr	0.555***	[0.446,0.663]	0.582***	[0.455,0.710]
40-49yr	0.357***	[0.234,0.479]	0.393***	[0.242,0.544]
Occupation (ref: unemployed)				
Self-employed/agriculture	0.093**	[0.036,0.149]	0.087*	[0.018,0.155]
Professional/formal	0.240***	[0.159,0.320]	0.251***	[0.190,0.312]
Marital status (ref: never married)				
Married	2.257***	[2.116,2.398]	2.353***	[2.086,2.619]
Divorced	1.356***	[1.210,1.502]	1.389***	[1.192,1.587]
Widowed	0.929***	[0.736,1.123]	0.978***	[0.757,1.200]
Exposure to family planning information (ref: no exposure)				
Some exposure	0.210***	[0.156,0.264]	0.216***	[0.163,0.269]
Fertility desire (ref: wants child <1y)				
>1y but <3y	1.777***	[1.615,1.940]	1.854***	[1.726,1.981]
Child after 3y	2.080***	[1.926,2.233]	2.170***	[2.023,2.317]
No more children	2.381***	[2.228,2.534]	2.454***	[2.319,2.590]
Autonomy (ref: no autonomy)				
At least some autonomy	0.113***	[0.053,0.173]	0.111*	[0.025,0.198]
Partner education (ref: no education)				
Primary	0.127***	[0.051,0.202]	0.120**	[0.040,0.201]
Secondary	0.189***	[0.099,0.280]	0.166***	[0.068,0.265]
Higher	0.244*	[0.055,0.432]	0.234*	[0.010,0.458]
Religion (ref: Catholic/Anglican)				
Other Christians	-0.107***	[-0.171,-0.044]	-0.093***	[-0.147,-0.039]
Muslims	-0.312***	[-0.428,-0.196]	-0.279***	[-0.411,-0.147]
Community-level factors				
Access problem (ref: no problem)				
Some problem	-0.061*	[-0.119,-0.002]	-0.082*	[-0.138,-0.026]
Literacy (ref: illiterate)				
Literate	0.055	[-0.009,0.120]	0.102**	[0.037,0.166]
Income (ref: low)				
Medium income	0.104***	[0.044,0.165]	0.126***	[0.069,0.182]

High income	0.135**	[0.054,0.217]	0.219***	[0.124,0.315]
Religion (ref: Catholic/Anglican)				
Other Christians	0.0601	[-0.022,0.142]	0.069	[-0.015,0.153]
Muslims	-0.299***	[-0.429,-0.169]	-0.185	[-0.382,0.012]
Community child mortality	-0.0001	[-0.0005,0.0003]	-0.0006*	[-0.001,-0.0001]
Year fixed effects (ref: 2000)				
2004	-0.015	[-0.110,0.079]	0.014	[-0.081,0.109]
2010	-0.776***	[-0.846,-0.707]	-0.775***	[-0.875,-0.675]
Constant	0.004***	[0.003,0.006]	0.003***	[0.002,0.004]
AIC	57312		56619	
BIC	57587		56833	
Number of districts	*25*		*25*	
Observations	*52978*		*52978*	

** p < 0.05, ** p < 0.01, *** p < 0.001*

†Effect of CBDAs was estimated in the 25 districts in which the CDBA pilot was not implemented.

The table summarizes and compares the effect of CBDs (community-based distribution) on contraceptive use modeled using a single-level logistic regression and a multilevel (3-level random intercept) logistic regression. While both models show that the CBDs increased contraceptive use, estimates from the multilevel model are generally larger and have wider confidence intervals. In both models, contraceptive use was significantly associated with both individual- and community-level explanatory variables, but the association was stronger with individual-level variables.

Table 4: Average predicted probabilities of contraceptive use before and after CBDs, by urban status

	Rural		Urban			
	Probability	95% C.I.	Probability	95% C.I.	First difference (D) [95% C.I.]	Second difference (DD) [95% C.I.]
Before CBDs	0.215	[0.199, 0.231]	0.263	[0.237, 0.288]	-0.048	
After CBDs	0.450	[0.430, 0.469]	0.429	[0.400, 0.459]	0.020	
First difference (D)	0.235		0.1668			**0.068 [0.031, 0.098]**

Table 5: Assessment of education and income (wealth) as moderators of CBD effects on contraceptive use in rural areas

	Model 1A (Education)		Model 1B (Income)	
	Coefficient	**95% C.I.**	**Coefficient**	**95% C.I.**
Ref: Before CBDs				
CBDs	1.500***	[1.310,1.691]	1.521***	[1.346,1.696]
Ref: No education				
Primary	0.128**	[0.0338,0.223]		
Secondary	0.113	[-0.0262,0.251]		
Ref: No education, before CBDs				
Primary, after CBDs	-0.172*	[-0.310,-0.0348]		
Secondary, after CBDs	-0.505***	[-0.657,-0.353]		
Ref: Low income				
Medium income			0.226***	[0.116,0.336]
High income			0.388***	[0.241,0.536]
Ref: Low income, before CBDs				
Medium income, after CBDs			-0.229***	[-0.323,-0.135]
High income, after CBDs			-0.575***	[-0.731,-0.419]
Observations	42865		42865	
Number of districts	*25*		*25*	

The table summarizes results of examining whether education and income influence the effect of CBDs on contraceptive use. For ease of interpretability and understanding, models for education and income were run separately. In both models, the coefficient of the interaction terms (CBD*education and CBD*income) is statistically significant at 5% which suggests that both education and income individually influence the association between CBDs and contraceptive use.

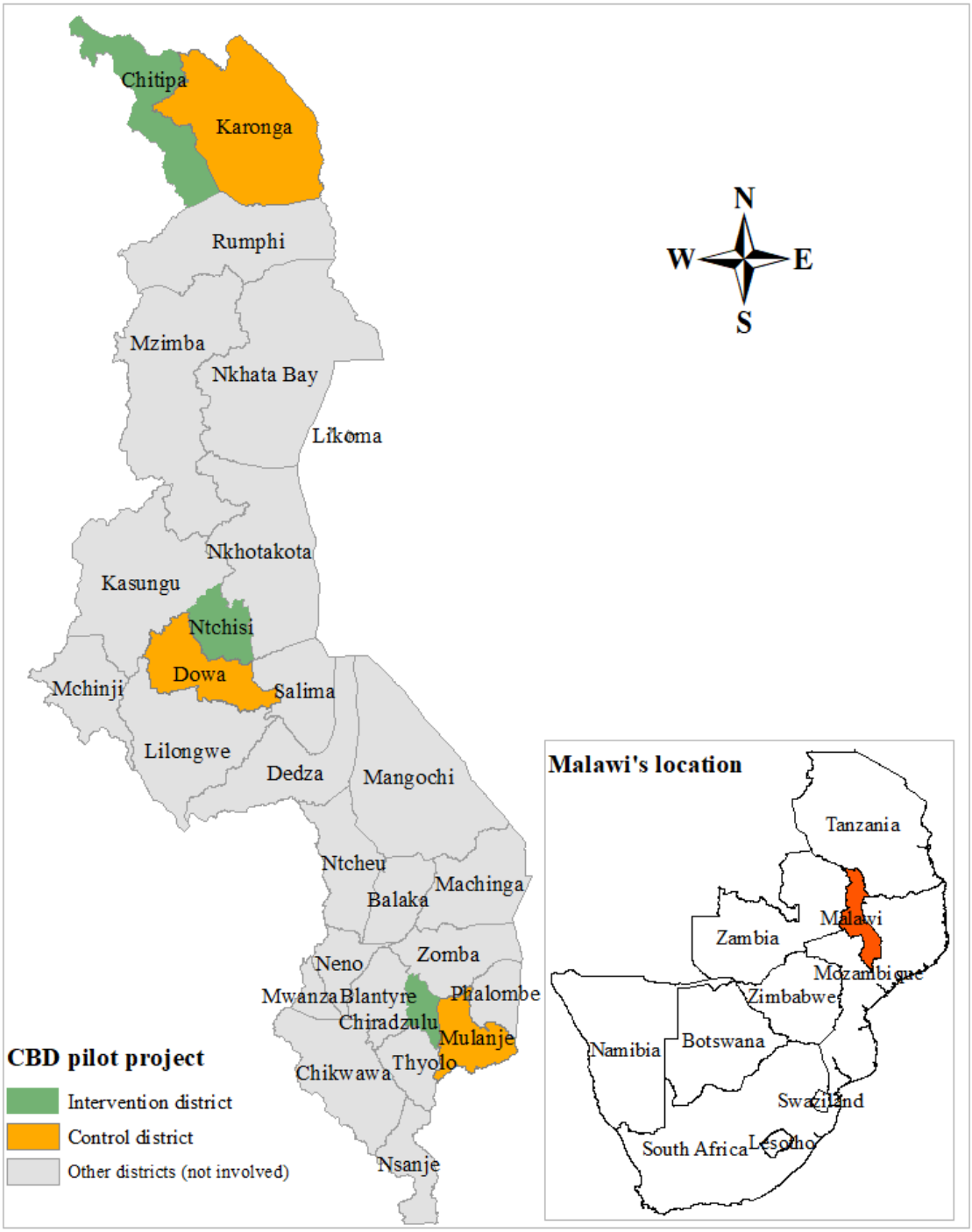
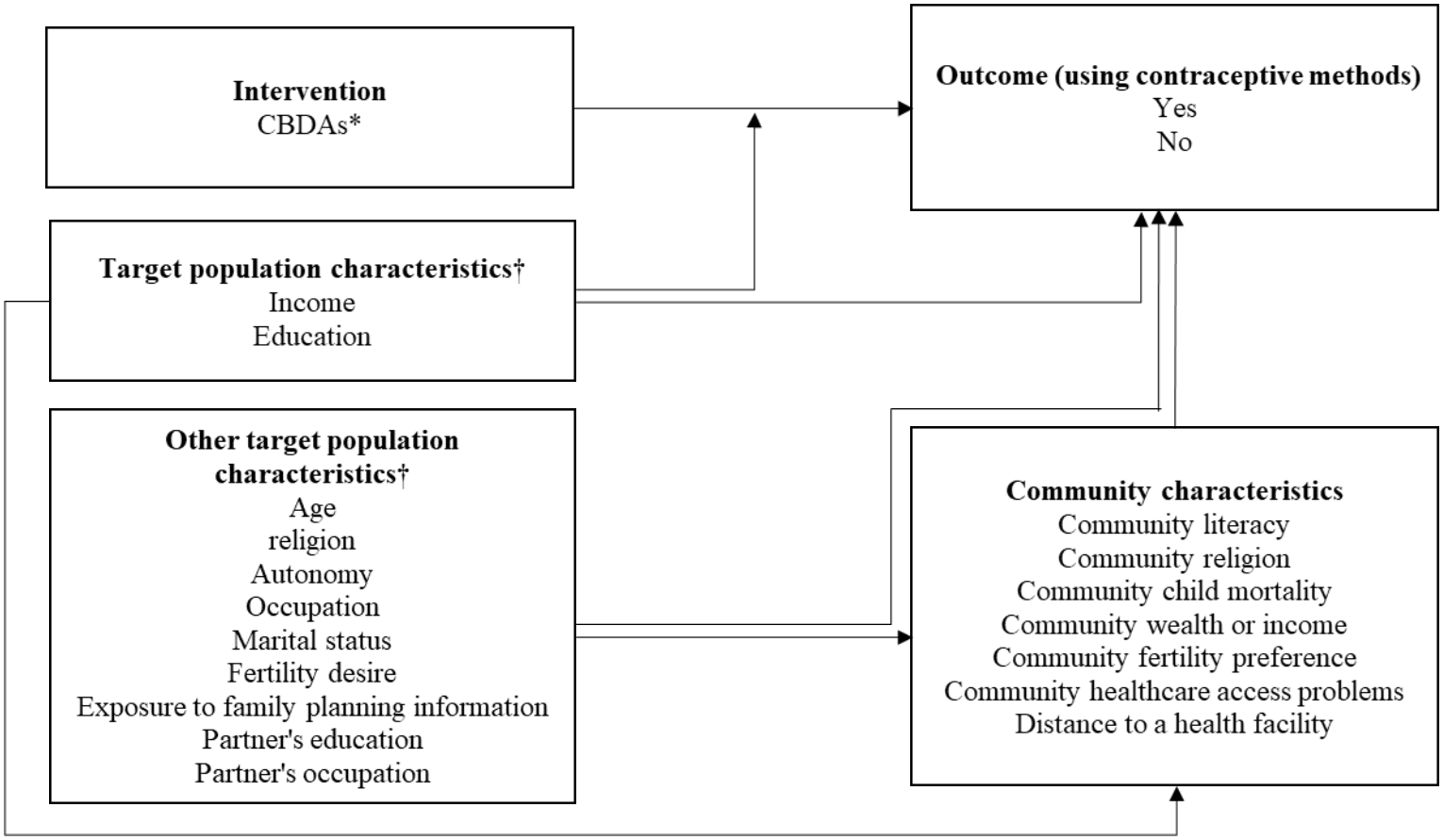


Figure 1: District participation in a community-based distribution (CBD) pilot of family planning services in Malawi, 1999-2003

This figure is a map of Malawi showing intervention and control districts in a pilot project testing whether a comprehensive community approach to family planning could increase contraceptive use in Malawi, 1999-2003.

Source of shapefiles: Global Administrative Areas (http://www.gadm.org)



*CBD stands for community-based distribution of family planning service.
†Refers to women's characteristics except when the word partner is used.

Figure 2. A conceptual framework for understanding the effect of CBDs on contraceptive use in rural areas of Malawi

The figure shows a conceptual framework of the effect of CBDs on contraceptive use in Malawi's rural areas. It also shows that the effect of CBDs on contraceptive use is moderated by both education and income. The figure also shows that individual-level characteristics may affect contraceptive use directly or indirectly via community characteristics.

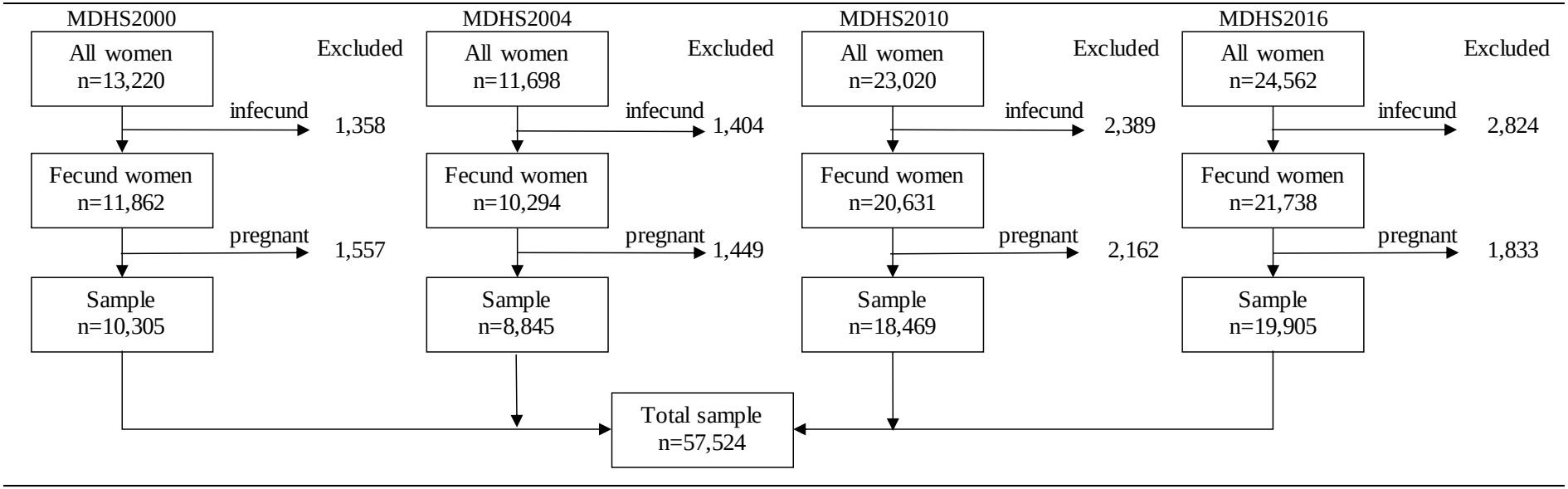


Figure 3: A flowchart for deriving a sample for examining the effect of community-based distribution (CBDs) on contraceptive use in Malawi

The flowchart shows the exclusions applied to derive a sample of women to examine the effect of community-based distribution agents (CBDs) of family planning on contraceptive use in Malawi. The data were drawn from four waves (2000, 2004, 2010 and 2016) of the Malawi Demographic and Health Surveys (MDHS). The data came from women recode files of the MDHS and contained responses from all women (ages 15-49 years) interviewed in the surveys.

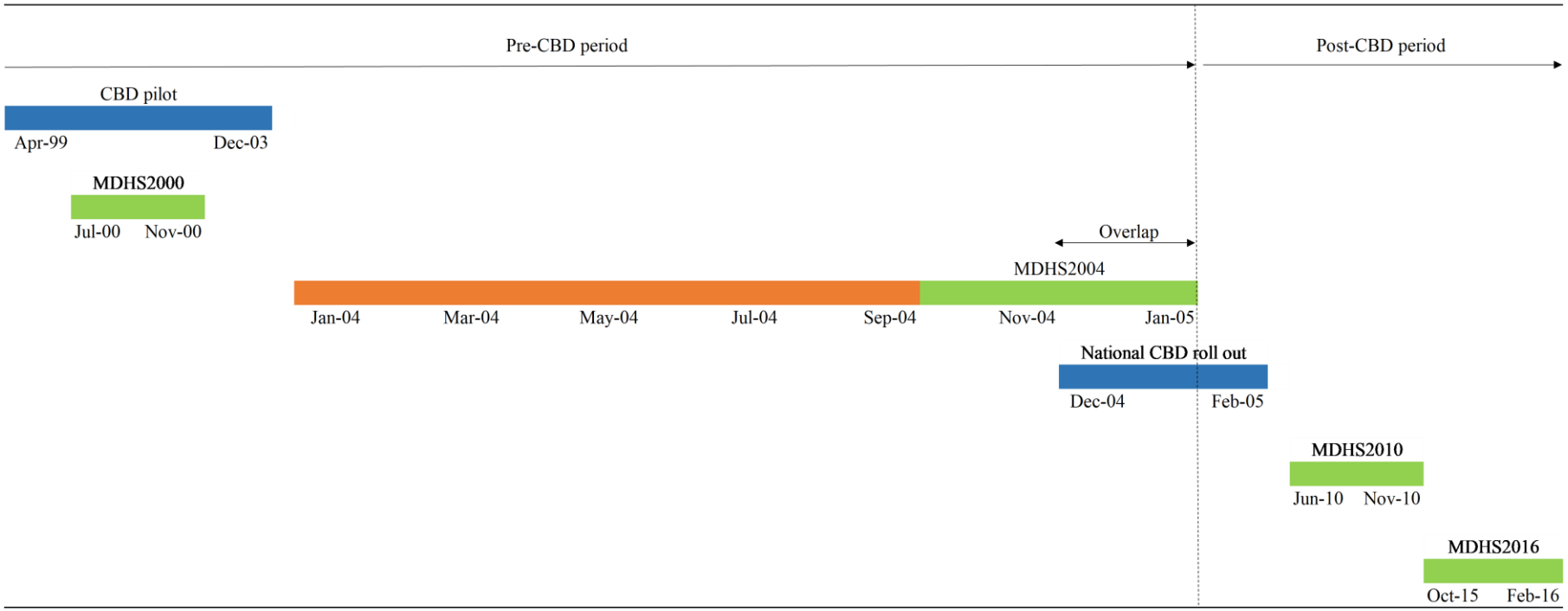


Figure 4. Timeline for implementation of community-based distribution (CBD) of family planning services and data collection in the Malawi Demographic and Health Surveys (MDHS)

This figure shows the timeline for the scale-up of national CBDs and MDHS data collection. The blue color (■) shows the timeline for pilot or national CBD implementation, orange color (■) shows the pre-CBD period while green color (■) shows the timeline for the MDHS. Thus, the study identified MDHS 2000/2004 as the pre-CBD period while MDHS 2010/2016 as the post-CBD period. Data collection for MDHS 2004 was from October 2004 to January 2005. CBD scale-up was from December 2004 to February 2005, overlapping in December 2004 and January 2005.

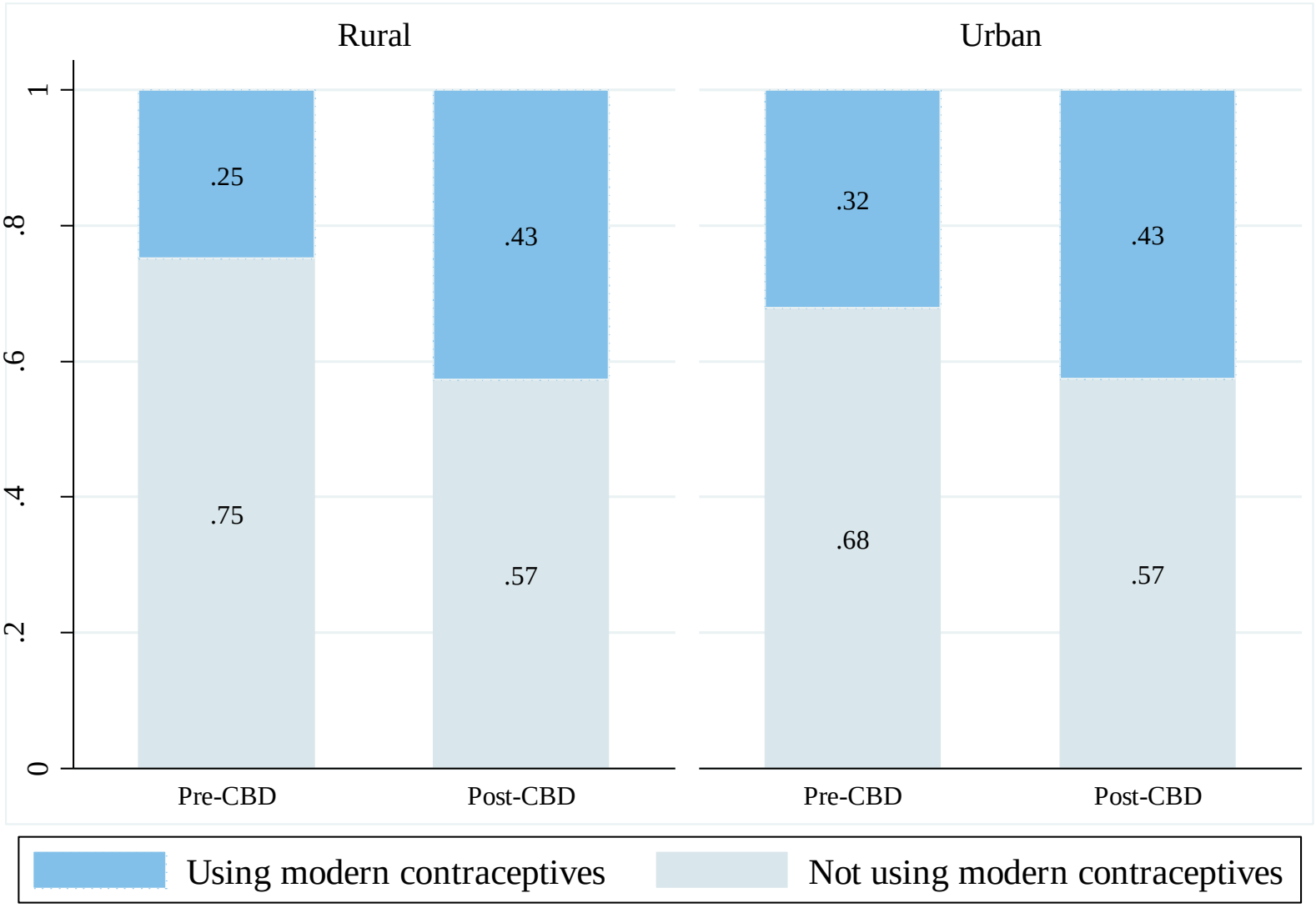


Figure 5: Urban-rural trends in contraceptive use before and after national CBDs in Malawi

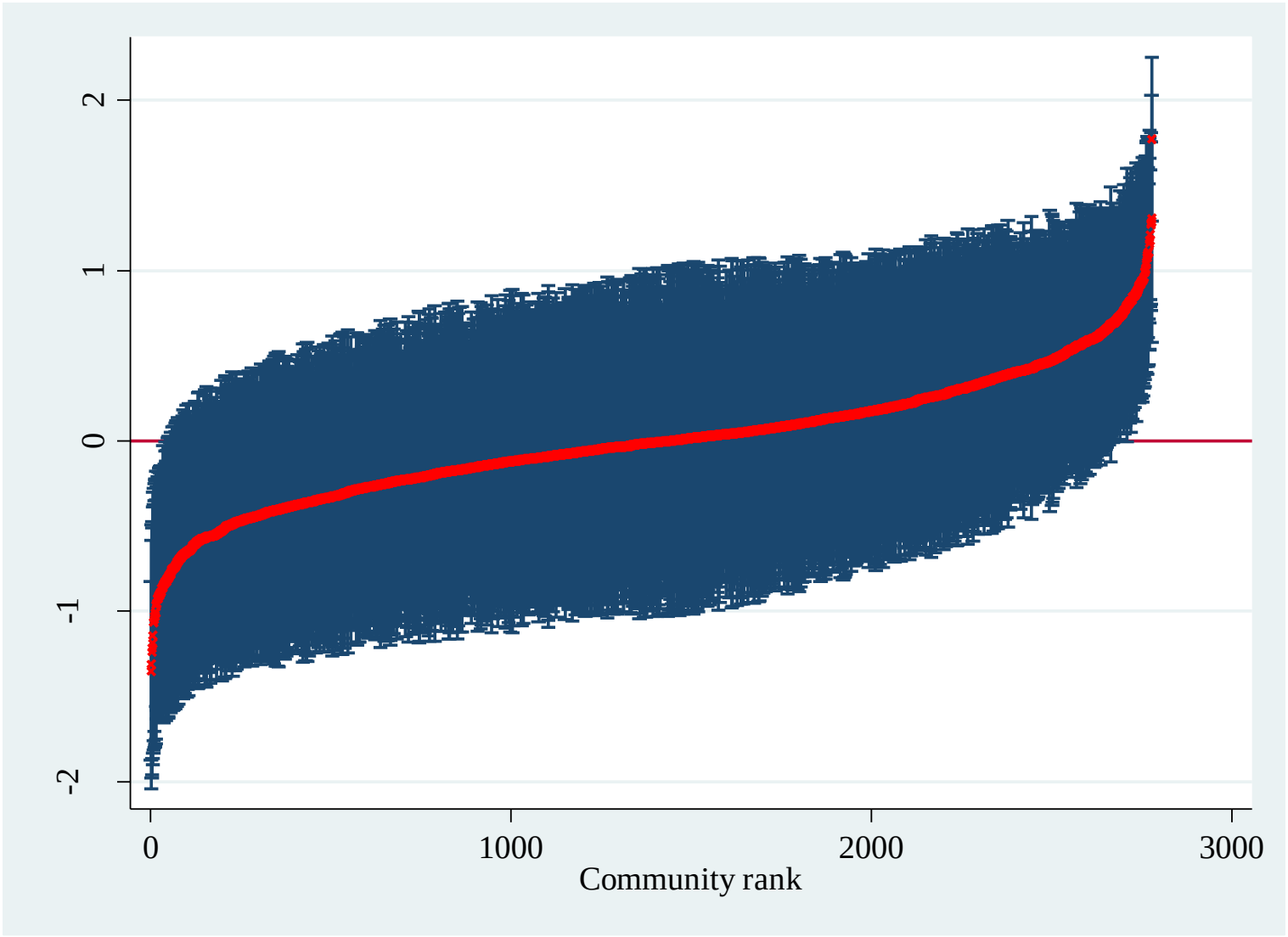


Figure 6: Average community contraceptive use

This figure shows contraceptive use in each community relative to the average contraceptive use in all the communities. The line at zero represents the average log-odds of using contraceptives. We found that in many communities the 95% confidence intervals of contraceptive use overlapped with the zero line, although a significant number deviated from the overall average.

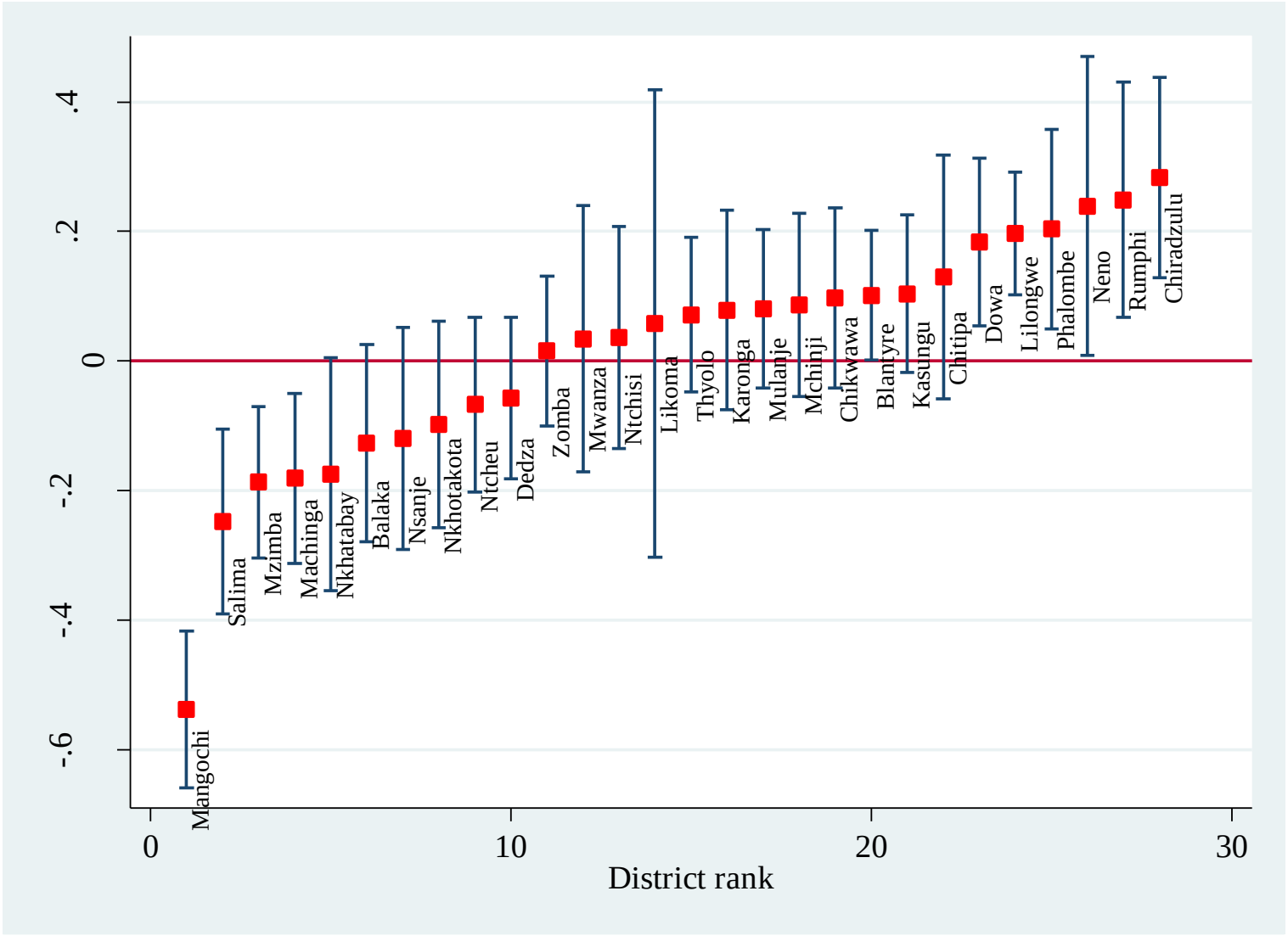


Figure 7: Average district contraceptive use

This figure shows contraceptive use in each district relative to the average contraceptive use in all the districts. The line at zero represents the average log-odds of using contraceptives in all the districts. We found that four districts had below average contraceptive use while 6 had above average contraceptive use.

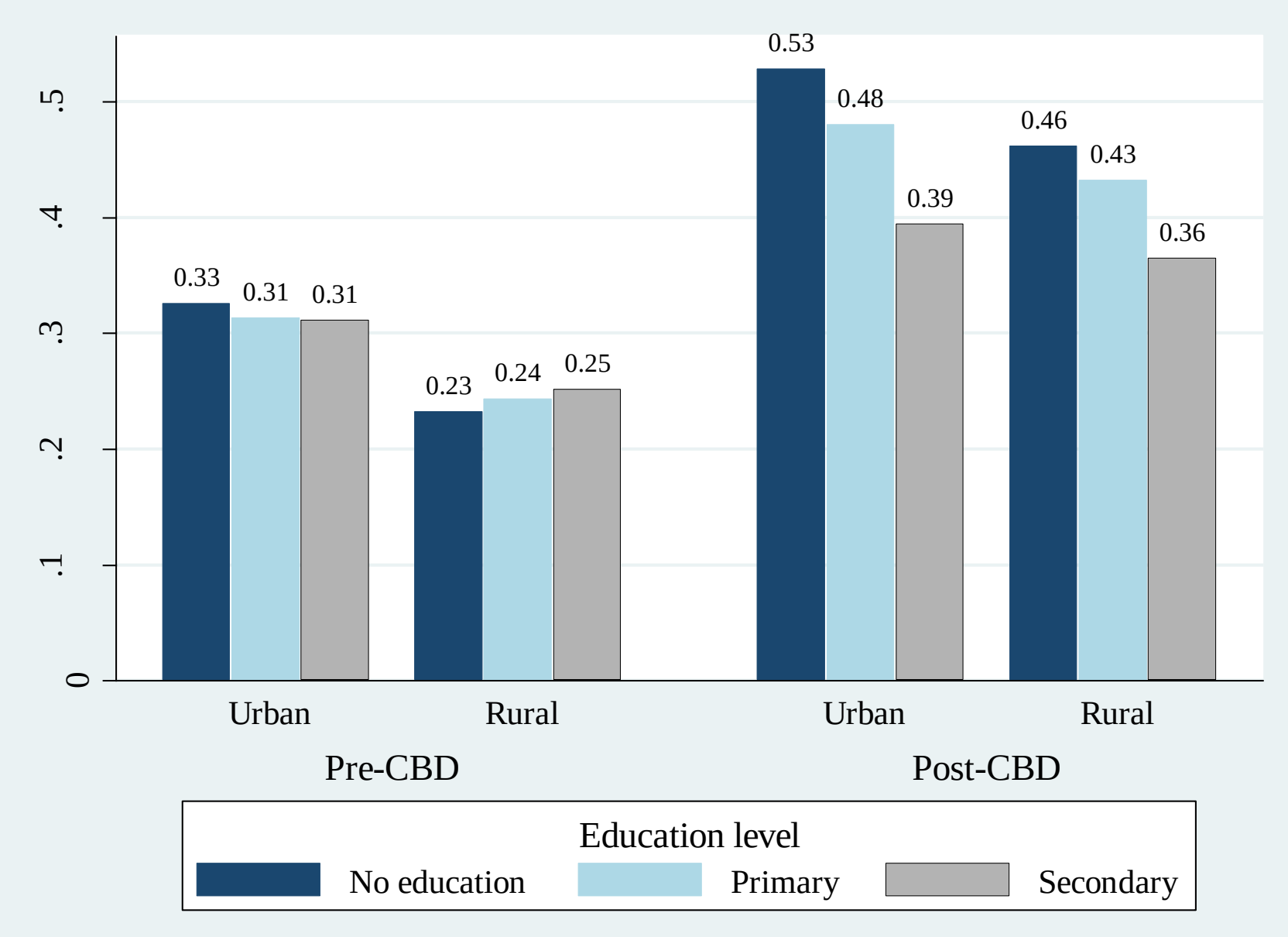


Figure 8: Predicted probability of contraceptive use by women's education.
This figure shows that contraceptive use increased among both rural and urban women, but the increases were greater among rural women with rural uneducated women benefitting the most from the scale-up of the CBDs.

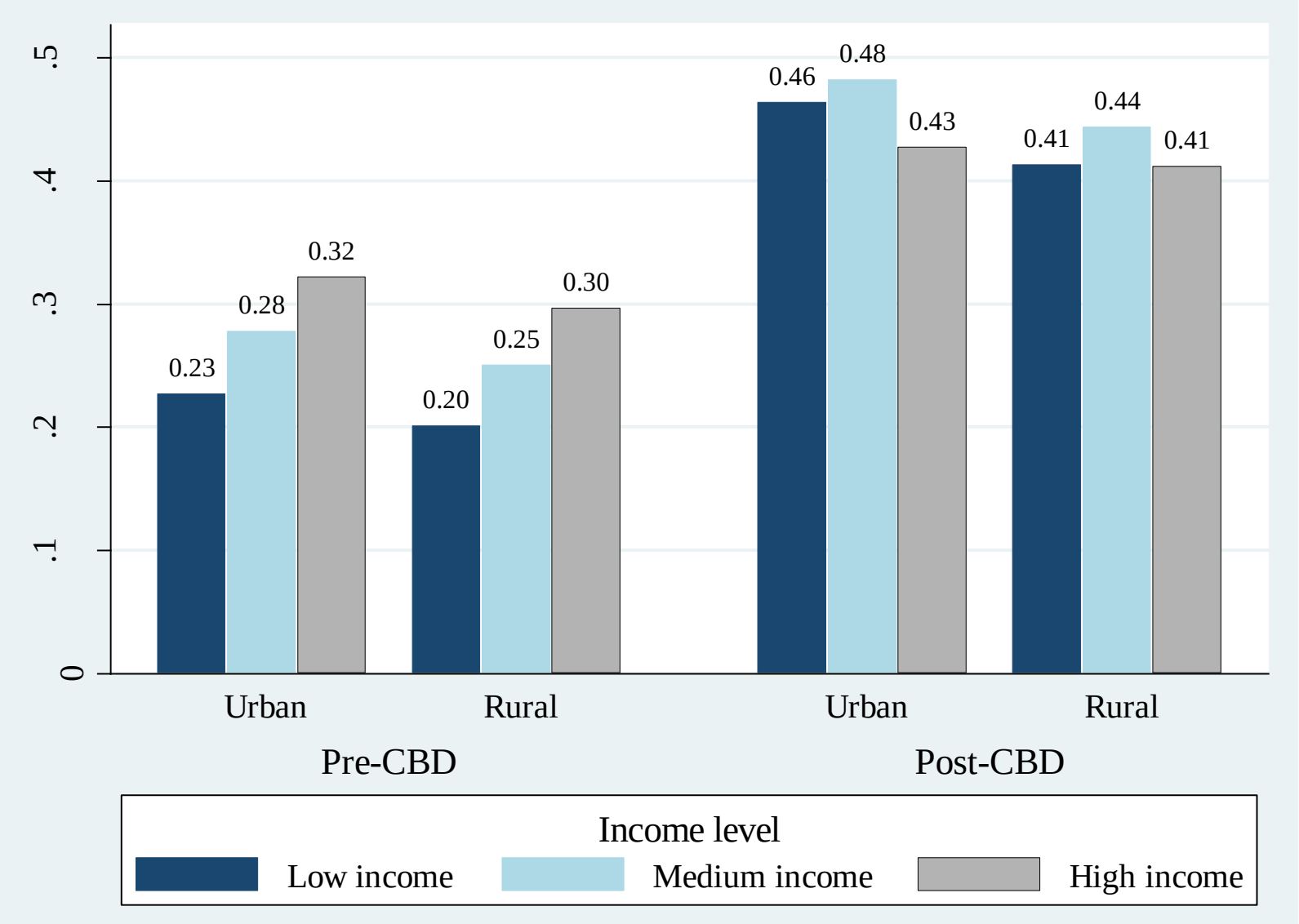


Figure 8: Predicted probability of contraceptive use by women's income.
This figure shows that contraceptive use increased among both rural and urban women, but the increases were greater among women with low incomes. The figure also shows that the increases in contraceptive use were similar for both rural and urban women at every level of income.

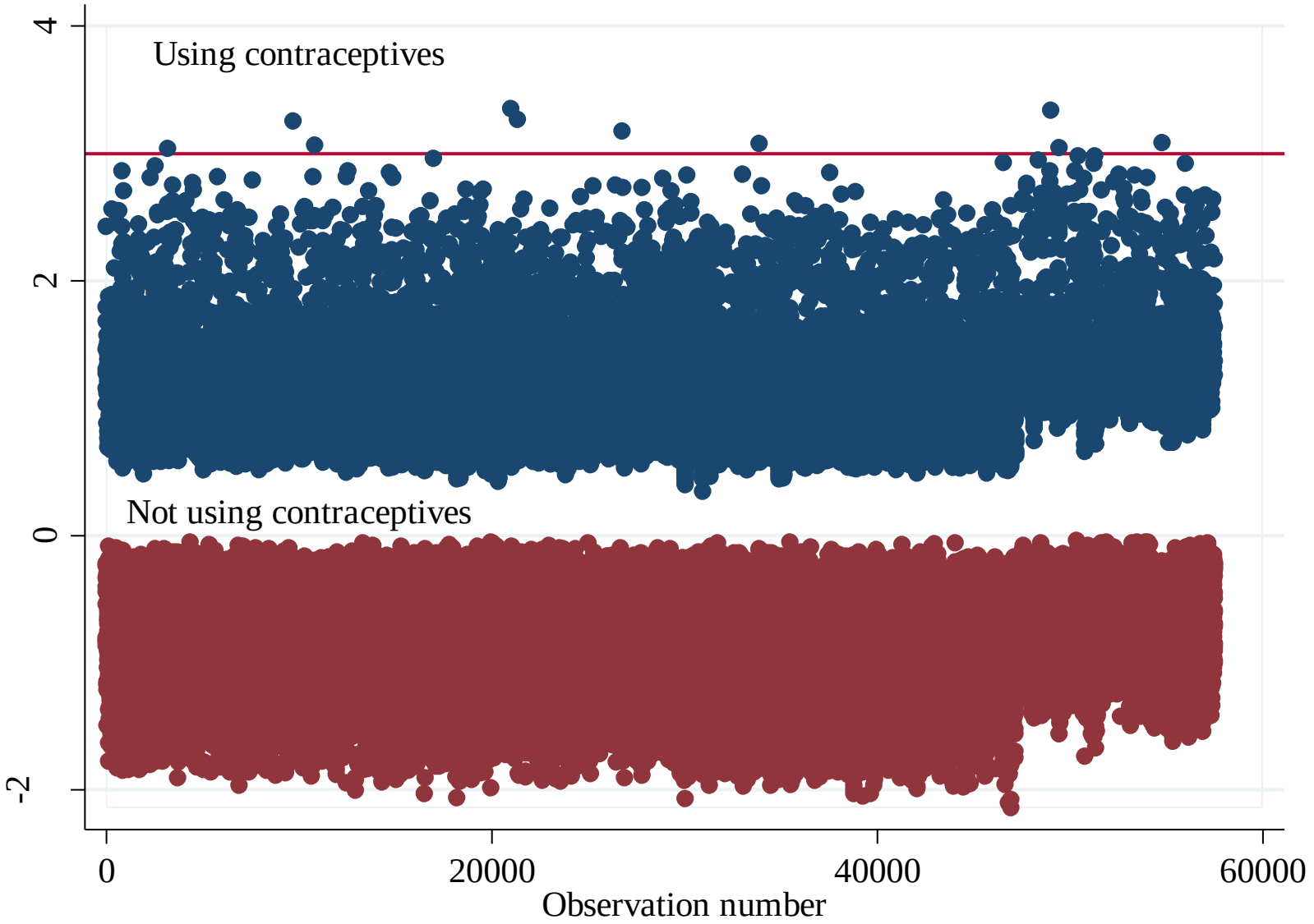


Figure 9: A goodness-of-fit test using deviance residuals
This figure shows that very few observations have outlying (above the red line) predictions, suggesting that the model is a good fit for the data.

Appendices

Appendix A1: Variable definition and construction

Table A1: Definition and construction of variables for examining the effect of community-based distribution agents on contraceptive use in Malawi

Variable	Type	Definition	Explanation/ justification
Key variables			
Current contraceptive use	Binary	Dependent variable: 1=using a modern method, 0=not using a modern method.	Women were asked if they were using any contraceptives at the time of the interview. We classified women using traditional methods (<2% of the total) as not using any contraceptive method.
Community-based distribution (CBD) of family planning services	Binary	CBD=1 if year is 2010 or 2016 (post-CBD period) and CBD=0 if year is 2000 or 2004 (pre-CBD period).	This is the key explanatory variable and it is the variable whose effect on contraceptive use we are assessing. Our hypothesis is that CBDs increased contraceptive use.
Rural/urban status	Binary	Rural=1, urban=0.	This is the second key explanatory variable. CBDs were introduced in rural communities only, so we designated the rural communities as the intervention and urban communities as the comparison group.
Individual-level variables			
Maternal education	Categorical	2=secondary or higher, 1=primary, 0=no education.	Highly educated women are more likely to use contraceptives. We grouped women with higher than secondary education with those with secondary education; <2% of the women had an education higher than secondary level.
Partner's education	Categorical	2=secondary or higher, 1=primary, 0=no education.	Women with highly educated partners are more likely to use contraceptives. We grouped partners with higher than secondary education with those with secondary education; fewer than 2% of the women's partners had an education higher than secondary level.
Income*	Categorical	3=high, 2=medium and 3=low.	High-income women are more likely to use contraceptives.
Age	Categorical	4="40-49yr", 3="30-39yr", 2="20-29yr", 1="15-19yr".	Contraceptive use among women increases with age but begins to decline after age 39. This age classification is consistent with other studies on contraceptive use in Africa [8], [104], [105].
Occupation (woman or her partner)	Categorical	2=professional employment, 1=self-employed or agriculture, 0=Unemployed.	This variable is highly correlated with education and income. Women in the professional sector or with partners in the professional are most likely to face a higher opportunity cost of raising children.
Marital status	Categorical	3=widowed, 2=divorced, 1=married, 0=never married.	Married women are most likely to use contraceptives.
Exposure to family planning methods†	Binary	1=Little or no exposure 0=moderate or substantial exposure.	Exposure to reproductive health messages via media in the month preceding the surveys. Women exposed to family planning information are more likely to use contraceptives.
Autonomy‡	Binary	0=Little or no autonomy, 1=semi or complete autonomy.	Autonomy is the woman's ability to consciously make decisions about her health and life without fear of reprisals. Autonomous women are more likely to use contraceptives.
Religion	Categorical	1=Catholic or Anglican, 2= other Christians, 3=Muslims, 4=no religion.	The religion to which a woman belongs. Some religions encourage contraceptive use while others do not.

Fertility desire	Categorical	4=wants no more children, 3=wants child after 3 years, 2= wants a child in >1 year but <3years, 1=wants child in < 1 year.	Women desiring to have children in less than one year are less likely to use contraceptives.
Community-level and residency variables			
Community literacy	Categorical	2=literate, 1=partly literate, 0=not literate.	Constructed from the maternal education variable by assigning the education category with the highest number of women to the whole community. We created this variable because women without any education may still get assistance from others with an education in the same community.
Community income	Categorical	3=high, 2=medium, 1=low.	We averaged wealth scores were averaged at the community level and created percentiles for each of the survey years.
Community religion	Categorical	1=Catholic or Anglican, 2= other Christians, 3=Muslims.	Assigned to the whole community based on which religion had the largest membership in that community.
Community access problems to care	Categorical	1=some problem, 0=no problem.	Women were asked to report if they had any problems accessing health care services in the 12 months preceding the study. Women with problems of access to care are less likely to use contraceptives.
Distance to health facility§	Continuous	n/a	Distance to a health facility. Women who travel longer distances to health clinics are less likely to use contraceptives.
Community child mortality¶	Continuous	n/a	Child deaths per 1,000 live births. Women in communities with high child mortality are less likely to use contraceptives.
District	Categorical	District dummy variables.	These are the country's 28 administrative districts.

*The Malawi Demographic and Health Surveys (MDHS) do not collect data on income; we used wealth as a proxy for the income. MDHS provides wealth scores reflecting ownership of durable goods and housing characteristics. We created the wealth categories separately for each year to reflect income distributions in the years of the surveys.
†Exposure to family planning variable was created from the following media: radio, TV, and newspaper. Exposure to each medium was given a score of 1 and then summed. In 2016, exposure to family planning messages via phone messages was added but for consistency with previous surveys, it was not included. Those with a zero score were regarded as not exposed.
‡The variable was constructed based on the extent to which the woman had a final say on the following: 1) Making large household purchases; 2) Making household purchases for daily needs; 3) Visiting family or relatives; 4) The woman's own health care; and 5) Meals prepared each day. For each of the five domains, there were 5 options on who made the decision: the woman alone; together with her partner; together with someone else; partner alone; someone else or decision was not made. The responses were scored on a scale of 1-5 (to be consistent with the response options) and then summed to get the total score for each woman. From the total scores, 2 groups were created with a cut-off point at the 50th percentile.
§Straight line distance (kilometers) from the community to the nearest health facility, calculated in ArcGIS 10.3.1. To calculate the distance, the MDHS files were joined to the Malawi 2012 Service Provision Assessment file (SPA)—also a public use file. The MDHS files provided coordinates for the communities while coordinates for health facilities came from the Malawi 2012 SPA. Since the Service Provision Assessment data only provided geographic coordinates for health facilities, we do not expect the temporal difference between the two surveys to influence the distances between the communities and health facilities.
¶Calculated at the community level and each household in the community is assumed to face this child mortality rate regardless of whether the household itself experienced child mortality. Community child mortality is used instead of household child mortality because the latter would be endogenous in a model of contraceptive use.

Appendix A2: Robustness of the identification strategy

Because the data used for this study were not collected for evaluating the effect of CBDs, we performed three robustness checks to validate our identification strategy. To identify the effect of CBDs, we made three assumptions. First, we assumed that after the national rollout, the effect of CBDs was only in the 25 districts in which the pilot of the CBDs was not implemented. So, we tested this assumption by examining the effect of CBDs in the three districts in which the pilot of the CBDs was implemented, expecting the CBDs not to have significant effects in these districts. Second, we assumed that the introduction of CBDs was exogenous and only in rural communities. We, therefore, expected CBDs not to have significant effects on contraceptive use in urban communities. We tested this assumption by examining the effect of CBDs in urban communities and whether education and/or income were moderators of the effect of CBDs on contraceptive use in the urban communities. Third, we assumed that MDHS data collected in the years 2000 and 2004 served as the baseline for contraceptive use in the 25 districts in which the pilot of CBDs was not implemented. In these districts, CBDs were introduced after 2004, so MDHS2000 and MDHS2004 should not capture CBD effects. We tested this assumption by examining the effect of changing the baseline years. In all, the sensitivity analysis showed that our identification strategy is valid, see detailed results below.

CBD effects in CBD-pilot districts

In the first sensitivity analysis, we applied the model in equation 2 to the three districts (Chitipa, Ntchisi, and Chiradzulu) in which the CBDs were piloted. In these districts, the nationwide adoption of CBDs was a continuation of the pilot. For emphasis, the model is repeated below:

$$log\left(\frac{\pi_{ijk}}{[1-\pi_{ijk}]}\right) = \beta_0 + \beta_1(Rural_{jk}) + \beta_2(CBDA) + \beta_3(Rural_{jk} * CBDA) + \lambda \boldsymbol{X}_{ijk} + \alpha \boldsymbol{P}_{jk} + \Gamma + U_k + U_{jk} + \mathcal{E}_{ijk} \quad (5)$$

For valid identification, β_3 was expected to be not statistically significant at 5% in equation 5. Results of this analysis are presented in **table A2**. In the three pilot districts, the effect of CBDs was not statistically significant at 5%. This suggests that our strategy properly identified the effects of CBDs on contraceptive use. However, some caution is warranted: the non-significant result of the interaction term could also be a result of the sample size being smaller in the pilot districts rather than the scale-up of the CBDs not having a statistically significant effect in the pilot districts. The estimate for the pilot districts was estimated with less precision, given the wider confidence interval, than the one for the non-pilot districts.

Table A2: Effect of CBDs on contraceptive use in CBD pilot and CBD non-pilot districts

	Non-pilot districts		**Pilot districts**	
	Coefficient	**95% C.I.**	**Coefficient**	**95% C.I.**
Contraceptive use				
Main explanatory variables				
CBDAs	0.954***	[0.706,1.202]	0.738	[-0.418,1.894]
Rural	-0.314***	[-0.481,-0.147]	-0.367	[-1.469,0.735]
Ref: Urban, before CBDAs				
Rural, after CBDAs	0.424***	[0.236,0.612]	0.871	[-0.248,1.990]
Individual-level factors				
Age (ref: 15-19 years)				
20-29yr	0.588***	[0.486,0.689]	0.287	[-0.011,0.586]
30-39yr	0.582***	[0.455,0.710]	0.146	[-0.178,0.470]
40-49yr	0.393***	[0.242,0.544]	-0.097	[-0.460,0.266]
Occupation (ref: unemployed)				
Self-employed/agriculture	0.087*	[0.018,0.155]	0.063	[-0.093,0.218]
Professional/formal	0.251***	[0.190,0.312]	0.119	[-0.113,0.352]
Marital status (ref: never married)				
Married	2.353***	[2.086,2.619]	3.010***	[2.576,3.445]
Divorced	1.389***	[1.192,1.587]	2.016***	[1.589,2.442]
Widowed	0.978***	[0.757,1.200]	2.012***	[1.462,2.561]
Exposure to FP information (ref: no exposure)				
Some exposure	0.216***	[0.163,0.269]	0.221**	[0.0714,0.370]
Fertility desire (ref: wants child <1 yr)				

>1yr but <3yr	1.854***	[1.726,1.981]	1.964***	[1.539,2.390]
Child after 3 yrs	2.170***	[2.023,2.317]	2.225***	[1.825,2.625]
No more children	2.454***	[2.319,2.590]	2.218***	[1.821,2.615]
Autonomy (ref: No autonomy)				
At least some autonomy	0.111*	[0.025,0.198]	0.061	[-0.119,0.241]
Partner education (ref: no education)				
Primary	0.120**	[0.040,0.201]	0.0521	[-0.197,0.301]
Secondary	0.166***	[0.068,0.265]	-0.055	[-0.324,0.214]
Higher	0.234*	[0.010,0.458]	-0.213	[-0.742,0.317]
Religion (ref: Catholic/Anglican)				
Other Christians	-0.0934***	[-0.147,-0.039]	-0.05	[-0.216,0.115]
Muslims	-0.279***	[-0.411,-0.147]	0.111	[-0.347,0.568]
Community-level factors				
Access problem (ref: no problem)				
Some problem	-0.082*	[-0.138,-0.026]	-0.164*	[-0.318,-0.009]
Literacy (ref: illiterate)				
Literate	0.102**	[0.037,0.166]	0.00454	[-0.232,0.241]
Income (ref: low)				
Medium income	0.126***	[0.069,0.182]	0.390***	[0.222,0.558]
High income	0.219***	[0.124,0.315]	0.457***	[0.223,0.691]
Religion (ref: Catholic/Anglican)				
SDA and Other Christians	0.069	[-0.015,0.153]	0.135	[-0.060,0.329]
Muslims	-0.185	[-0.382,0.012]	0.039	[-0.515,0.593]
Community child mortality	-0.0006*	[-0.001,-0.0001]	0	[-0.001,0.001]
Year fixed effects (ref: 2000)				
2004	0.014	[-0.081,0.109]	-0.099	[-0.486,0.288]
2010	-0.775***	[-0.875,-0.675]	-0.965***	[-1.143,-0.786]
Constant	0.003***	[0.002,0.004]	-5.947***	[-7.277,-4.618]
Number of districts	25		3	
Observations	52978		4546	

** p < 0.05, ** p < 0.01, *** p < 0.001.* †The results in non-pilot districts are the same as the multilevel results already presented in table 3, but they are duplicated here to facilitate comparison.

Education and income as moderators of CBD effects in urban communities

In the second sensitivity analysis, we examined the effect of CBDs in urban communities and whether this effect is moderated by education or income. This analysis was performed using the model in equation 2 but only in urban communities of the 25 non-pilot districts. Because CBDs were implemented in rural communities only, the effect of CBDs and the interaction of CBDs

and education, as well as that of CBDs and income in urban communities should not be statistically significant at 5%. In Panel 1 of **table A3**, we present the log odds of using contraceptives in urban communities while in Panel 2 we reproduce the log odds for rural communities (already presented in table 6). We found that CBDs and its interaction with education or income did not have a statistically significant effect on contraceptive use in urban communities; confidence intervals of these variables overlapped with a log-odds of 0 and the p-values were greater than 0.05. As reported earlier, however, these variables had significant effects in rural communities. This result reinforces our earlier findings from the first sensitivity analysis and we conclude that our strategy identifies the effect of CBDs.

Table A3: Sensitivity analysis of the moderating effects of education and income on the association between CBDs and contraceptive use

	Panel 1: Urban		Panel 2: Rural	
	M2A (Education)	**M2B (Income)**	**M1A (Education)**	**M1B (Income)**
	Coefficient [95% C.I.]	**Coefficient [95% C.I.]**	**Coefficient [95% C.I.]**	**Coefficient [95% C.I.]**
Ref: Before CBDs				
CBDs	1.18	0.945	1.500***	1.521***
	[-1.527,3.886]	[-2.499,4.389]	[1.310,1.691]	[1.346,1.696]
Ref: No education				
Primary	1.493		0.128**	
	[-0.654,3.639]		[0.0338,0.223]	
Secondary	1.382		0.113	
	[-0.746,3.509]		[-0.0262,0.251]	
Ref: No education, before CBDs				
Primary, after CBDs	-1.077		-0.172*	
	[-4.126,1.971]		[-0.310, -0.0348]	
Secondary, after CBDs	-0.669		-0.505***	
	[-3.705,2.367]		[-0.657, -0.353]	
Ref: Low income				
Medium income		-0.341		0.226***
		[-3.937,3.255]		[0.116,0.336]
High income		-0.346		0.388***
		[-3.579,2.887]		[0.241,0.536]
Ref: Low income, before CBDs				
Medium income, after CBDs		-0.656		-0.229***
		[-4.252,2.940]		[-0.323, -0.135]
High income, after CBDs		-0.56		-0.575***
		[-3.905,2.784]		[-0.731, -0.419]
Observations	10113	10089	42865	42865

The table summarizes sensitivity analysis results of examining whether education and income influence (moderate) the effect of CBDs on contraceptive use in urban areas. For ease of interpretability and understanding, models for education and income were run separately. In the urban panel, the coefficient of the interaction terms (CBD*education and CBD*income) is not statistically significant at 5% which suggests that both education and income do not individually influence the association between CBDs and contraceptive use.

Varying the definition of the pre-CBD period: 2000 or 2004

We earlier explained and showed in figure 4 that there was an overlap of about 2 months between the introduction of CBDs and data collection in MDHS2004. Although we expected CBDs not to have affected contraceptive use by the time the data were being collected, we still checked the effect of the overlap by defining the baseline as the year 2004 or 2000. If MDHS2004 captured the effects of the CBDs, our estimate would be biased towards the null. We first examined whether contraceptive use was different between years 2000 and 2004. We found that the log-odds of using contraceptives were lower in 2004 than in 2000, but the difference was immaterial. Thus either year (2000 or 2004) could be used to define the pre-CBD period.

We present results of defining the baselines as the year 2000 or 2004 in the **table A4**, while results in Panel A combine years 2000 and 2004 (like those presented earlier in table 3). We found that, for many coefficients, the direction and strength of association with contraceptive use were the same across the three models. We also found that CBDs increased contraceptive use by 7.58 and 5.25 percentage points when the baseline years are 2000 and 2004, respectively, compared with 6.8 percentage points when both are used as the baseline. Thus using 2004 as the base year underestimated the effect of CBDs which suggests that the overlap between MDHS2004 and the introduction CBDs might be attenuating the effect of CBDs. While this evidence points to using 2000 as the baseline, we preferred to use a model that combined 2000 and 2004 as the baseline. This is because estimates from the model in Panel A are measured with the most precision and this model allowed us to account for year fixed effects; the other models cannot do this because of collinearity problems among year, CBDs, and the intercept.

Table A4: Effect of CBDs on contraceptive use in response to changing the baseline

	A (main results) †		B		C	
	Baseline: 2000+2004		Baseline: 2000		Baseline: 2004	
	Coefficient	95% C.I.	Coefficient	95% C.I.	Coefficient	95% C.I.
Dep var contraceptive use						
Main explanatory variables						
CBDA	0.954***	[0.706,1.202]	0.870***	[0.638,1.102]	1.011***	[0.721,1.300]
Rural	-0.314***	[-0.481,-0.147]	-0.403***	[-0.587,-0.219]	-0.284*	[-0.536,-0.032]
Ref: Urban, before CBDAs						
Rural, after CBDAs	0.424***	[0.236,0.612]	0.483***	[0.278,0.688]	0.339**	[0.114,0.564]
Individual-level factors						
Age (ref: 15-19 years)						
20-29yr	0.588***	[0.486,0.689]	0.622***	[0.514,0.729]	0.558***	[0.449,0.667]
30-39yr	0.582***	[0.455,0.710]	0.585***	[0.447,0.722]	0.550***	[0.421,0.680]
40-49yr	0.393***	[0.242,0.544]	0.329***	[0.171,0.488]	0.338***	[0.162,0.513]
Occupation (ref: unemployed)						
Self-employed/agriculture	0.087*	[0.018,0.155]	0.098**	[0.024,0.172]	0.071	[-0.021,0.162]
Professional/formal	0.251***	[0.190,0.312]	0.261***	[0.184,0.338]	0.222***	[0.151,0.293]
Marital status (ref: never married)						
Married	2.353***	[2.086,2.619]	2.328***	[2.065,2.591]	2.480***	[2.159,2.800]
Divorced	1.389***	[1.192,1.587]	1.405***	[1.218,1.593]	1.482***	[1.277,1.686]
Widowed	0.978***	[0.757,1.200]	1.045***	[0.780,1.309]	1.131***	[0.866,1.396]
Exposure to FP information (ref: no exposure)						
some exposure	0.216***	[0.163,0.269]	0.203***	[0.145,0.261]	0.172***	[0.107,0.236]
Fertility desire (ref: wants child <1y)						
>1y but <3y	1.854***	[1.726,1.981]	1.900***	[1.741,2.058]	1.871***	[1.691,2.051]
Child after 3y	2.170***	[2.023,2.317]	2.198***	[2.042,2.354]	2.161***	[1.957,2.366]
No more children	2.454***	[2.319,2.590]	2.506***	[2.349,2.664]	2.429***	[2.222,2.635]
Autonomy (ref: No autonomy)						
Some or total autonomy	0.111*	[0.025,0.198]	0.134**	[0.039,0.228]	0.105	[-0.026,0.236]
Partner education (ref: no education)						
Primary	0.120**	[0.040,0.201]	0.116**	[0.040,0.192]	0.113*	[0.027,0.199]
Secondary	0.166***	[0.068,0.265]	0.118*	[0.0214,0.215]	0.107*	[0.008,0.206]
Higher	0.234*	[0.010,0.458]	0.183	[-0.039,0.405]	0.172	[-0.086,0.430]
Religion (ref: Catholic/Anglican)						
Other Christians	-0.093***	[-0.147,-0.039]	-0.0784*	[-0.145,-0.011]	-0.085**	[-0.145,-0.024]
Muslims	-0.279***	[-0.411,-0.147]	-0.265***	[-0.422,-0.108]	-0.305***	[-0.447,-0.163]
Community-level factors						
Access problem (ref: no problem)						
Some problem	-0.082*	[-0.138,-0.026]	-0.059	[-0.119,0.001]	-0.052	[-0.107,0.003]
Literacy (ref: illiterate)						
Literate	0.102**	[0.037,0.166]	0.128**	[0.043,0.212]	0.081*	[0.018,0.144]
Income (ref: low)						

Medium income	0.126***	[0.069,0.182]	0.120***	[0.052,0.187]	0.137***	[0.082,0.192]
High income	0.219***	[0.124,0.315]	0.189***	[0.090,0.289]	0.232***	[0.126,0.338]
Religion (ref: Catholic/Anglican)						
SDA and Other Christians	0.069	[-0.015,0.153]	0.056	[-0.053,0.165]	0.025	[-0.098,0.148]
Muslims	-0.185	[-0.382,0.012]	-0.219	[-0.443,0.005]	-0.305*	[-0.546,-0.064]
Community child mortality	-0.001*	[-0.001,-0.000]	-0.001**	[-0.001,-0.000]	-0.001	[-0.001,0.000]
Year fixed effects						
2004	0.014	[-0.081,0.109]				
2010	-0.775***	[-0.875,-0.675]	-0.762***	[-0.867,-0.658]	-0.766***	[-0.872,-0.659]
Constant	0.003***	[0.002,0.004]				
Observations	52978		44503		43162	

* p < 0.05, ** p < 0.01, *** p < 0.001. †These results are the are the same as the multilevel results already presented in table 3, but they are duplicated here to facilitate comparison.

Stata do file

```
///ANALYSIS

use analysis_cbda.dta, clear

set more off

log using contra_use, text replace


*setting the font for graphs to times roman new

 graph set window fontface "Times New Roman"


*trends in contraceptive use

*graph bar (mean) none (mean) modern, over(year) percentages blabel(bar,
size(small) format(%9.2g)) by(, title(Urban-rural trends in contraceptive use
in Malawi)) by(rural, total)

graph bar (mean) none (mean) modern, over(cbda, label(labsize(3.0))) stack
///

by(urban, note(" ") graphregion( color(white)) plotregion(fcolor(white)
ifcolor(white))) ///

subtitle(,  fcolor(white) lcolor(white)) ///

bar(1, lpattern(solid) color(bluishgray)) bar(2, lpattern(dot)
color(eltblue)) bar(3, lpattern(solid)) blabel(bar, size(3.0)
position(center) format(%9.2g)) ///

by(, title("Figure 3: Urban-rural trends in contraceptive use before and
after national CBDs in Malawi", size(3.0) color(black))) ///

ytitle("Proportion", size(3)) scheme(s2color) ///

legend(label(1 "Not using modern contraceptives ") label(2 "Using modern
contraceptives") order(2 "Using modern contraceptives" 1 "Not using modern
contraceptives" ))

graph save Graph "U:\Home\Health Behavior and
Policy\masianosp\Dissertation\Paper_1\Analyis\Graphs\urban-
ruraltrends_1.gph", replace

**Conducting a test of the IIA assumption

mlogit contra_use cbda##rural , base(0)

estimates store m_1

mlogit contra_use urban##education if (contra_use != 1), base(0) /*excludes
traditional methods*/

estimates store m_2
```

```
hausman  m_1 m_2, alleqs constant /*alleqs means to test using all
equations*/

*the test statistic from the above is negative so the more appropriate test
is suest

suest m_1 m_2

test [m_1_modern=m_2_modern],  common const /*we fail to reject the null, the
IIA assumption is met*/


*test for combining categories

mlogit contra_use comm_fertpref comm_wealth comm_literacy


*random effects model

set more off

use analysis_cbda, clear


*combining nonusers and traditional users

gen contra_use_orig= contra_use

recode contra_use 2=0


*setting weights


svyset community, weight(comm_wt) || _n, weight(sampweight)


/*checking the effect of weights*/

tab region

tab region  [iweight=sampweight]

tab region  [iweight=comm_wt]


*empty or null model with 3 levels

melogit contra_use if notpilot==1 [pw=sampweight] ||district: ||community:,
pw(comm_wt) or covariance(unstructured)

estimates store null_3levels

estat icc

gen _prob=exp(_b[_cons])/(1+ exp(_b[_cons]))
```

```
di _prob

drop _prob


*empty or null model with 2 levels

melogit contra_use if notpilot==1 [pw=sampweight] ||community:, pw(comm_wt)
or covariance(unstructured)

estimates store null_2levels


*single level logit

logit contra_use if notpilot==1 [pw=sampweight],  or

estimates store null_singlelevel


*comparing the two-level to the single-level

lrtest null_3levels null_singlelevel, force


*comparing the three level to the single level

lrtest null_3levels null_singlelevel, force


*comparing the 2-level and 3-level models

lrtest null_3levels null_2levels, force /*shows that the 3-level model should
be preferred*/



**drawing caterpiller plots from the variance components model

melogit contra_use if notpilot==1 [pw=sampweight] ||district: ||community:,
pw(comm_wt) or covariance(unstructured)

estimates replay null_3levels, or


*reffects and reses calculate the shrunken residuals/best linear unbiased
prediction of random intercepts and standard errors

predict u0dist u0comm, reffects reses(u0sedist u0secomm)


*district caterpillars

egen pickonedist=tag(district)
```

```
sort u0dist

gen u0rankdist=sum(pickonedist)

*to draw the caterpillar graph with 95% confidence band of intercept
residuals

serrbar u0dist u0sedist u0rankdist if pickonedist==1, scale(1.96) mvopts(
msymbol(square) mlabel(district) mlabcolor(black) ///

      mlabsize(*0.95) mlabposition(6) mlabgap(huge) mcolor(red)
mlabangle(vertical)) ytitle(District random effects) xtitle(District rank)
yline(0) ///

      title("Figure 4b: Average district contraceptive use" , size(medium
large))

      graph save Graph "J:\Home\Health Behavior and
Policy\masianosp\Dissertation\Paper_1\Analyis\Graphs\District_residuals.gph",
replace

      *counting the number of districts outside average district
contraceptive use

      count if ((u0dist + 1.96*u0sedist)<0 | (u0dist - 1.96*u0sedist)>0) &
pickonedist==1


*community caterpillars

egen pickonecomm=tag(community)

sort u0comm

gen u0rankcomm=sum(pickonecomm)

*to draw the caterpillar graph with 95% confidence band of intercept
residuals

serrbar u0comm u0secomm u0rankcomm if pickonecomm==1, scale(1.96) mvopts(
msymbol(smx) mcolor(red)) ///

      ytitle(Community random effects) xtitle(Community rank) yline(0) ///

      title("Figure 4a: Average community contraceptive use" , size(medium
large))

      graph save Graph "J:\Home\Health Behavior and
Policy\masianosp\Dissertation\Paper_1\Analyis\Graphs\comm_residuals.gph",
replace

      *counting the number of communities outside average average
contraceptive use

      count if ((u0comm + 1.96*u0secomm)<0 | (u0comm - 1.96*u0secomm)>0) &
pickonecomm==1 /*93*/

//effect of CBDS
```

```
*full model standard logistic regression

global controls "i.age_cat i.occup i.marstatus i.exp_fp_inf
i.fertility_desire i.autonomy i.ptnr_education i.religion i.access_prob
i.comm_literacy i.comm_wealth i.comm_religion comm_childmort i.year"


logit contra_use  cbda##rural $controls  if notpilot==1 [pw=sampweight], or

estimates store full_std


*full model with random effects

melogit contra_use  cbda##rural  $controls  if notpilot==1 [pw=sampweight]
||district: ||community:, pw(comm_wt) or covariance(unstructured)

estimates store full_re


//cluster specific margins or probabilities

margins, at(cbda=(0 1) rural=(0 1)) predict(mu fixed) noestimcheck post

margins r.cbda##r.rural, predict(mu fixed) contrast noestimcheck post


*average margins in a sub-sample of married women only

global controls "i.age_cat i.occup i.exp_fp_inf i.fertility_desire i.autonomy
i.ptnr_education i.religion i.access_prob i.comm_literacy i.comm_wealth
i.comm_religion comm_childmort i.year"


melogit contra_use  cbda##rural $controls  if notpilot==1 & marstatus==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store full_marriedonly


//cluster specific margins or probabilities

margins, at(cbda=(0 1) rural=(0 1)) predict(mu fixed) noestimcheck post

margins r.cbda##r.rural, predict(mu fixed) contrast noestimcheck post



//average margins, including random effects

drop u0dist u0comm u0sedist u0secomm pickonedist u0rankdist pickonecomm
u0rankcomm
```

```
estimates restore full

*reffects calculate the shrunken residuals/best linear unbiased prediction of
random intercepts

predict prmeandist prmeancomm, remeans reses(prsedist prsecomm)


*table 4, CBDA effects in single and multi-level models


esttab full_std full_re using CBDA_effect.rtf, nogaps wide eform b se  aic
bic replace  nonum label  ///

            refcat(cbda "Main explanatory variables" 1.cbda#1.rural "Ref:
Urban, before CBDAs"  ///

            2.age_cat "Age (ref: 15-19 years)" 2.occup "Occupation (ref:
unemployed)" 1.marstatus "Marital status (ref: never married)" ///

            1.exp_fp_inf "Exposure to FP inf (ref: no exposure)"
2.fertility_desire "Fertilify desire (ref: wants child <1 yr)" ///

            1.autonomy "Autonomy (ref: No autonomy)" 1.ptnr_education
"Partner education (ref: no education)" ///

            2.religion "Religion (ref: Catholic/Anglican)" 1.access_prob
"Access problem (ref: no problem)" ///

            1.comm_literacy "Literacy (ref: illiterate)" 2.comm_wealth
"Income (ref: low)"  ///

            2.comm_religion "Religion (ref: Catholic/Anglican)" 2004.year
"Year fixed effects (ref: 2000)" 0.education "Individual-level factors" ///

            0.access_prob "Community-level factors" , nolabel) ///

            mtitle("Single-level Logistic Regression" "Multi-level Logistic
Regression")  ///

            title( "Table 4: Effect of CBDAs on contraceptive use") ///

            collabels("Odds Ratio" "Standard errors" "95% Confidence
Interval" "Odds Ratio" "95% Confidence Interval") ///

            coeflabels (eq1 ""cbda "CBDAs" 1.cbda "CBDAs" 1.rural "Rural"
1.cbda#1.rural " Rural, after CBDAs" ///

            1.access_prob " Some problem" 2004.year " 2004" 2010.year " 2010"
comm_childmort "Community child mortality") ///

            drop (0.rural 0.cbda  0.cbda#0.rural 1.cbda#0.rural
0.cbda#1.rural 2000.year  ///

            2015.year 1.age_cat 1.occup 0.marstatus 0.exp_fp_inf 0.autonomy
///
```

```
            1.fertility_desire 1.religion 0.ptnr_education 1.comm_wealth
1.comm_religion 0.comm_literacy) obslast


//The effect of education


*Mediation

*unadjusted

melogit contra_use cbda i.education if notpilot==1 [pw=sampweight]
||district: ||community:, pw(comm_wt) or covariance(unstructured)

estimates store unadj_edu

coefplot,  xline(0)


*adjusted but without education

melogit contra_use cbda rural i.wealth $controls if notpilot==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store cbda_adj_noedu


*adjusted with education

melogit contra_use cbda i.education rural i.wealth $controls if notpilot==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store cbda_adj_edu

coefplot,  xline(0) keep(*education)




esttab cbda_only unadj_edu cbda_adj_noedu cbda_adj_edu using
edu_mediation.rtf, eform b ci noeqlines eqlabels(none)  keep(cbda
*.education) ///

            coeflabels (eq1 ""cbda "CBDA" ) ///

            drop(0.education) ///

            refcat(1.education "Ref: No education") ///

            title( "Table 6: Assessment of education as a mediator of CBDA
effects on contraceptive use") ///

            mtitle("Model 1A" "Model 1B" "Model 2A" "Model 2B") label replace
nonum
```

```
//the effect of wealth

*unadjusted

melogit contra_use cbda i.wealth if notpilot==1 [pw=sampweight] ||district:
||community:, pw(comm_wt) or covariance(unstructured)

estimates store unadj_wealth


*adjusted but without wealth

melogit contra_use cbda rural i.education $controls if notpilot==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store cbda_adj_nowealth


*adjusted with wealth

melogit contra_use cbda i.education rural i.wealth $controls if notpilot==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store cbda_adj_wealth


esttab cbda_only unadj_wealth cbda_adj_nowealth cbda_adj_wealth using
wealth_mediation.rtf, eform b ci noeqlines eqlabels(none) ///

        keep(cbda *.wealth) nogaps ///

            coeflabels (eq1 ""cbda "CBDA" ) ///

            drop(1.wealth) ///

            refcat(2.wealth "Income (Ref: Low income)") ///

            title( "Table 6B: Assessment of income (wealth) as a mediator of
CBDA effects on contraceptive use") ///

            mtitle("Model 1A" "Model 1B" "Model 2A" "Model 2B") label replace
nonum


*Moderation

global controls "i.age_cat i.occup i.exp_fp_inf i.fertility_desire i.autonomy
i.ptnr_education i.religion i.access_prob i.comm_literacy i.comm_wealth
i.comm_religion comm_childmort i.year"
```

```
recode education 3=2


melogit contra_use  cbda##ib0.education $controls if notpilot==1 & rural==1
[pw=sampweight] ||district: ||community:, pw(comm_wt)
covariance(unstructured)

estimates store moderation_education_r


melogit contra_use  cbda##ib1.wealth $controls if notpilot==1 & rural==1
[pw=sampweight] ||district: ||community:, pw(comm_wt)
covariance(unstructured)

estimates store moderation_wealth_r


coefplot (moderation_education_r, label("Education") keep(*:1.cbda
1.cbda#0.education 1.cbda#1.education )) (moderation_wealth_r,
label("Income") keep(*:1.cbda#1.wealth 1.cbda#2.wealth)), bylabel(Rural) ///

            ||, eform cismooth levels(95 90) msymbol(S) xline(1) xscale(r(1
2)) xlabel(1(0.5)4) ylab(, labsize(3)) ///

            xtitle("Odds ratios", size(2.5)) ytitle("CBDA effect by
education/income", size(3.5)) grid(none) ///

        title("Figure 6: Education and income as moderators of CBDA effects",
span size(4) color(black))

            graph save Graph
"U:\Dissertation\Paper_1\Analyis\Graphs\moderation_main2.gph", replace


*making a table of the moderating effects of education and wealth

esttab moderation_education_r moderation_wealth_r using
edu_wealth_moderation1.rtf, b ci wide noeqlines eqlabels(none) ///

            title( "Table 6: Assessment of education and income (wealth) as
moderators of CBDA effects on contraceptive use in rural areas") ///

            keep(*1.cbda *.wealth *.education) nogaps ///

            refcat(1.cbda "Ref: Before CBDAs" 0.education "Ref: No education"
1.cbda#1.education "Ref: No education, before CBDAs" 1.wealth ///

            "Ref: Low income" 1.cbda#1.wealth "Ref:Low income, before CBDAs")
///

            coeflabels (eq1 "" cbda "CBDAs" 1.cbda "CBDAs" 1.cbda#1.education
"Primary, after CBDAs" 1.cbda#2.education "Secondary, after CBDAs" ///

            1.cbda#2.wealth "Medium income, after CBDAs" 1.cbda#3.wealth "
High income, after CBDAs") ///
```

```
mtitle("Model 1A" "Model 1B") label replace nonum aic bic


*this makes bar graphs

*coefplot moderation_education moderation_wealth, eform keep(1.cbda#*)
vertical recast(bar) barwidth(0.25) fcolor(*.5) ciopts(recast(rcap)) citop
citype(logit) xtitle(Repair Record 1978) ytitle(Proportion)


**another moderation graph, strength of the association between education and
wealth


melogit contra_use  cbda##education##wealth $controls if notpilot==1 &
rural==1 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store moderation_2


gen education1=education

recode education1 3=2

label copy education education1

label values education1 education1


*predicting probabilities

predict predprob, fixedonly


*getting average probabilities by education and income

table education1 wealth cbda, c(mean predprob)


*setting the font

graph set window fontface "Times New Roman"


graph bar (mean) predprob if rural==1,  over(education1 ) over(wealth,
label(labsize(small))) over(cbda)   asyvars ///

      ytitle(Predicted probability) ///

      b1title("") ///

      legend(rows(1) ///
```

```
      subtitle(Education level)) ///

      bargap(0) ///

      bar(1, lpattern(solid) color(dkorange)) bar(2, lpattern(solid)
color(brown)) bar(3, lpattern(solid) color(green) fintensity(70) ) ///

      title("Figure 8: Predicted probability of contraceptive use by income
and education among rural women", size(3) color(black))

      graph save Graph "U:\Home\Health Behavior and
Policy\masianosp\Dissertation\Paper_1\Analyis\Graphs\moderationbyeducation2.g
ph", replace


//*Model diagnostics


use analysis_cbda, clear

global controls "age agesq i.occup i.marstatus i.exp_fp_inf
i.fertility_desire i.autonomy i.ptnr_education i.religion i.access_prob
i.comm_literacy i.comm_wealth i.comm_religion comm_childmort i.year"

melogit contra_use  cbda##rural i.education i.wealth $controls  if
notpilot==1 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store for_residuals


*goodness of fit test using predicted probabilities

predict probability, fixedonly

gen predicted_contra=0

replace predicted_contra=1 if probability>0.5

tab   contra_use predicted_contra if notpilot==1, row

count if contra_use==1 & predicted_contra==1 & notpilot==1 | contra_use==0 &
predicted_contra==0 & notpilot==1

drop probability predicted_contra


*goodness of fit test using residuals

gen n = _n

predict residuals, deviance

label var n "Observation number"

twoway (scatter residuals n if contra_use) (scatter residuals n if
!contra_use) if notpilot==1, ///
```

```
      yline(-2 2) legend(off) text(3.8 10000 "Using contraceptives") text(0.2
10000 "Not using contraceptives")  ///

      title("Figure 8: Goodness-of-fit test using deviance residuals",
size(4) color(black)) ///

      ytitle("Deviance residuals")

      graph save Graph "J:\Home\Health Behavior and
Policy\masianosp\Dissertation\Paper_1\Analyis\Graphs\deviance_residuals.gph",
replace

///***sensitivity analysis

global controls "i.age_cat i.occup i.marstatus i.exp_fp_inf
i.fertility_desire i.autonomy i.ptnr_education i.religion i.access_prob
i.comm_literacy i.comm_wealth i.comm_religion comm_childmort i.year"

melogit contra_use  cbda##rural $controls  if notpilot==1 [pw=sampweight]
||district: ||community:, pw(comm_wt) or covariance(unstructured)

estimates store sensitivity_pilot


melogit contra_use  cbda##rural $controls  if notpilot==0 [pw=sampweight]
||district: ||community:, pw(comm_wt) or covariance(unstructured)

estimates store sensitivity_notpilot


*joint test of the interaction term and the main effects

test _b[1.cbda]=_b[1.rural]=_b[1.cbda#1.rural]


esttab  sensitivity_pilot sensitivity_notpilot using Sensitivity_1.rtf,
nogaps wide b ci  replace  nonum label  ///

            refcat(cbda "Main explanatory variables" 1.cbda#1.rural "Ref:
Urban, before CBDAs"  ///

            2.age_cat "Age (ref: 15-19 years)" 2.occup "Occupation (ref:
unemployed)" 1.marstatus "Marital status (ref: never married)" ///

            1.exp_fp_inf "Exposure to FP inf (ref: no exposure)"
2.fertility_desire "Fertilify desire (ref: wants child <1 yr)" ///

            1.autonomy "Autonomy (ref: No autonomy)" 1.ptnr_education
"Partner education (ref: no education)" ///

            2.religion "Religion (ref: Catholic/Anglican)" 1.access_prob
"Access problem (ref: no problem)" ///

            1.comm_literacy "Literacy (ref: illiterate)" 2.comm_wealth
"Income (ref: low)"  ///
```

```
            2.comm_religion "Religion (ref: Catholic/Anglican)" 2004.year
"Year fixed effects (ref: 2000)" ///

            0.access_prob "Community-level factors" , nolabel) ///

            mtitle("Pilot districts" "Non-pilot districts")  ///

            title( "Table 4: Effect of CBDAs on contraceptive use") ///

            collabels("Odds Ratio" "95% Confidence Interval" "Odds Ratio"
"95% Confidence Interval") ///

            coeflabels (eq1 ""cbda "CBDAs" 1.cbda "CBDAs" 1.rural "Rural"
1.cbda#1.rural " Rural, after CBDAs" ///

            1.access_prob " Some problem" 2004.year " 2004" 2010.year " 2010"
comm_childmort "Community child mortality") ///

            drop (0.rural 0.cbda  0.cbda#0.rural 1.cbda#0.rural
0.cbda#1.rural 2000.year  ///

            2015.year 1.age_cat 1.occup 0.marstatus 0.exp_fp_inf 0.autonomy
///

            1.fertility_desire 1.religion 0.ptnr_education 1.comm_wealth
1.comm_religion 0.comm_literacy) obslast


**Moderation: effects of education and wealth

melogit contra_use  cbda##ib3.education##ib3.wealth $controls if notpilot==1
& rural==1 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store moderation_education_u


melogit contra_use  cbda##ib3.wealth $controls i.education if notpilot==1 &
rural==0 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store moderation_wealth_u


coefplot (moderation_education_u, label("Education") keep(*: 1.cbda
1.cbda#0.education 1.cbda#1.education) ) (moderation_wealth_u,
label("Income") keep(*: 1.cbda#1.wealth 1.cbda#2.wealth) ), bylabel(Panel A:
urban)  ///

            || (moderation_education_r, label("Education") keep(*:1.cbda
1.cbda#0.education 1.cbda#1.education)  ) (moderation_wealth_r,
label("Income") keep(*: 1.cbda#1.wealth 1.cbda#2.wealth)), bylabel(Panel B:
rural) ///

            ||,  eform xline(1) cismooth levels(99.999) byopts(xrescale)
msymbol(S) label ylab(, labsize(3)) ///
```

```
            xtitle("Odds ratios", size(3)) ytitle("CBDA effect by
education/income", size(3)) grid(none) ///

            graphregion(color(white)) ///

            title("Figure B1: CBDA effects and the role of education and
income as moderators of the effects", span size(3.3) color(black))

            graph save Graph
"U:\Dissertation\Paper_1\Analyis\Graphs\moderation_senstiv2.gph", replace


**Examining the effect of using 2000, 2004 as baselines

use analysis_cbda.dta, clear


global controls "i.age_cat i.occup i.marstatus i.exp_fp_inf
i.fertility_desire i.autonomy i.ptnr_education i.religion i.access_prob
i.comm_literacy i.comm_wealth i.comm_religion comm_childmort i.year"


quietly melogit contra_use  cbda##rural $controls  if notpilot==1 &
year!=2004 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store _2000


quietly melogit contra_use  cbda##rural $controls  if notpilot==1 &
year!=2000 [pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store _2004


quietly melogit contra_use  cbda##rural $controls  if notpilot==1
[pw=sampweight] ||district: ||community:, pw(comm_wt) or
covariance(unstructured)

estimates store full


esttab _2000 _2004 full using year_sensitivity.rtf , nogaps eform b ci wide
replace  nonum label ///

            refcat(cbda "Main explanatory variables" 1.cbda#1.rural "Ref:
Urban, before CBDAs"  ///

            2.age_cat "Age (ref: 15-19 years)" 2.occup "Occupation (ref:
unemployed)" 1.marstatus "Marital status (ref: never married)" ///

            1.exp_fp_inf "Exposure to FP information (ref: no exposure)"
2.fertility_desire "Fertility desire (ref: no more child)" ///
```

```
            1.autonomy "Autonomy (ref: No autonomy)" 1.ptnr_education
"Partner education (ref: no education)" ///

            2.religion "Religion (ref: Catholic/Anglican)" 1.access_prob
"Access problem (ref: no problem)" ///

            1.comm_literacy "Literacy (ref: illiterate)" ///

            2.comm_religion "Religion (ref: Catholic/Anglican)" 2004.year
"Year fixed effects" 0.education "Individual-level factors" ///

            0.access_prob "Community-level factors" , nolabel) ///

            mtitle("Baseline: 2000" "Baseline: 2004" "Baseline: 2000+2004")
///

            title( "Table S2: Effect of CBDAs on contraceptive use in
response to changing baseline") ///

            coeflabels (eq1 ""cbda "CBDA" 1.cbda "CBDA" 1.rural "Rural"
1.cbda#1.rural " Rural, after CBDAs" ///

            1.access_prob " Some problem" 2004.year " 2004" 2010.year " 2010"
comm_childmort "Community child mortality") ///

            drop (0.rural 0.cbda  0.cbda#0.rural 1.cbda#0.rural
0.cbda#1.rural 2000.year  ///

            2015.year 1.age_cat 1.occup 0.marstatus 0.exp_fp_inf 0.autonomy
///

            1.fertility_desire 1.religion 0.ptnr_education 1.comm_wealth
1.comm_religion 0.comm_literacy) obslast

estwrite * using results, replace

estread results

log close
```

Chapter 2: Conditional cash transfers to increase the uptake of services for the prevention of mother-to-child transmission of HIV: a trial-based cost-effectiveness analysis

Abstract

Background: Innovative strategies have been implemented to address the prevention of mother-to-child transmission (PMTCT) of HIV in sub-Saharan Africa (SSA). A recent randomized controlled trial found that conditional cash transfers (CCTs) to pregnant women with HIV increases the uptake of PMTCT services. The current study evaluates the cost-effectiveness of the CCTs.

Methods: A cost-effectiveness analysis, from the societal perspective, was conducted for a randomized controlled trial of CCTs in 89 clinics in the Democratic Republic of the Congo (DRC), 2013-2015. The trial had two arms. The intervention group (n=216) received the standard of care plus US$5 at the first visit and increased by US$1 at every scheduled visit. The control group (n=217) only received the standard of care. Health outcomes were measured using PMTCT uptake and PMTCT retention. We expressed incremental effectiveness using the number needed to treat (NNT). We evaluated economic costs by trial arm and relied on the trial, negotiated drug price lists, and the literature for cost estimates. We reported the costs in 2016 International Dollars (I$). The threshold for cost-effectiveness was based on 3x GDP per capita for the DRC in 2016 (I$2409). We used both deterministic sensitivity analyses and cost-effectiveness acceptability curves to examine the uncertainty associated with the ICERs.

Results: The CCTs increased PMTCT uptake and retention, but at a higher cost. The NNT was 7.0 (95% C.I.=6.7-7.6) for PMTCT uptake and 12.1 (95% C.I.=11.6-12.8) for PMTCT retention. The mean costs/participant in the intervention and control groups were I$516 and I$431, representing an incremental cost of I$85 (95% C.I.=59-111). The ICER was I$595 (95% C.I. =567-624) for PMTCT uptake and I$1026 (95% C.I.=960-1101) for PMTCT retention. In uncertainty analyses, the CCTs were still cost-effective even in the worst case.

Conclusion: CCTs are a cost-effective way to increasing uptake of PMTCT services in the DRC and similar settings. However, additional research is needed to understand the effectiveness and cost-effectiveness of the CCTs in larger populations and over a longer analytic time horizon before further scale-up of CCTs.

1. Introduction

Despite global progress in reducing the number of new HIV infections, mother-to-child transmission (MTCT) of HIV remains a challenge. The United Nations Joint Program on HIV/AIDS (UNAIDS) estimated that over 440 children (ages 0-14 years) were infected with HIV every day in 2016, mostly through vertical transmission [106]. Most of these infections (88%) occurred in sub-Saharan Africa (SSA) where nearly 70% (26 million) of all people with HIV lived in 2016 and uptake of services for the prevention of mother-to-child transmission of HIV (PMTCT) is low (<70 percent overall and as low as 32 percent in countries like Nigeria) [106], [107]. Evidence suggests that PMTCT services, which include the provision of highly efficacious preventive antiretroviral drugs to both the mother and the infant, can reduce the risk of MTCT to <5%. However, in the absence of PMTCT services, the risk of MTCT is about 40% [108]–[110].

The low uptake of PMTCT services despite the advantages and wide availability of the services in SSA poses challenges to global ambitions of eliminating the AIDS epidemic by 2030 [111]. This raises a need to find innovative and cost-effective approaches to help overcome barriers preventing the uptake of and demand for these services. One such approach is the use of conditional cash transfers (CCTs), an approach previously used to modify individual and household behaviors in health and other sectors like education [112]–[114]. To test whether CCTs can be used to increase the uptake of PMTCT services, a randomized controlled trial (RCT) of the CCTs was implemented in the Democratic of the Congo (DRC) [115]. The expectation was that the CCTs would help to overcome demand-side barriers, particularly transport costs—one of the major factors preventing the uptake of PMTCT services in SSA [116]–[119].

Results from the DRC trial suggested that CCTs can increase the number of women taking up PMTCT services [115], but it is unclear whether the CCTs are cost-effective. Therefore, the goal of the present study is to conduct a trial-based cost-effectiveness analysis of the CCTs to establish whether the CCTs represent a good value for the money. We emphasize that the main contribution of this study is in the cost and cost-effectiveness analysis and not in establishing the effectiveness of the intervention.

2. Overview of the trial

In 2013-2015, an RCT was launched in the DRC to test the effectiveness of paying pregnant women with HIV cash to help overcome demand-side barriers to healthcare [115]. These barriers include lack of transport money and the opportunity of time spent seeking PMTCT services [117], [118]. The trial, funded by the National Institutes of Health, was conducted in Kinshasa in 89 facilities already offering PMTCT services as part of maternal and child health clinics. All women newly diagnosed with HIV, <32 weeks of gestation, and registered for ANC at any of the 89 facilities were considered for participation.

The trial enrolled 433 women, with 216 randomized to the intervention group and 217 to the control group. The intervention group received standard PMTCT care plus the cash incentives while the control group only received the standard PMTCT care. At the initial visit, each participant in the intervention group received US$5 which increased by US$1 at the next visit but was reset to $5 if the participant missed a scheduled visit or refused a proposed service [115]. Option B+ was the standard of care at the time of the trial [115]. Under this protocol, pregnant women with HIV—irrespective of gestation age or HIV disease stage—are initiated on antiretroviral drugs and continue to take the drugs for life [120], [121]. **Table 1** lists the protocol's recommendations.

2.1. Trial outcomes

The trial had two primary health outcomes: uptake of PMTCT services and retention in PMTCT care. Uptake was defined as timely attendance (within 5 days) of all scheduled clinic visits from randomization through 6 weeks' postpartum and acceptance of all proposed services listed in table 1. Retention was defined as being in HIV care at 6 weeks' postpartum regardless of the reason for missing any prior scheduled visits [115].

3. Methods

3.1. Overview

We conducted a trial-based cost-effectiveness of CCTs aimed at increasing uptake of PMTCT services and retention in PMTCT care in the DRC. We conducted the study from both the societal and healthcare perspectives and largely followed recommendations by the World Health Organization (WHO) for cost-effectiveness analysis in resource-limited settings [122]–[124]. Data on resource utilization came from the trial but cost data came from multiple sources. We report economic costs in constant 2016 international dollars (I$). Costs in local currency were first adjusted for inflation using DRC's gross domestic product (GDP) deflator and then converted to 2016 I$. In line with the trial, we measured the effectiveness of the CCTs using two health outcomes: uptake of PMTCT services and retention in PMTCT care. We expressed incremental effectiveness in terms of the number needed to treat (NNT)—the number of participants needed to receive the cash incentives for one more participant to take up the services or be retained in care. We did not discount the costs or effects to net present value as participant follow-up was <1 year. The threshold for cost-effectiveness was based on 3x GDP per capita for the DRC in 2016 (I$2409). We used both deterministic sensitivity analyses and cost-effectiveness acceptability curves to examine the uncertainty in the ICERs. This study was

approved as exempt by the Internal Review Board of Virginia Commonwealth University (IRB#: HM20009283).

3.2. Study perspective

We conducted the study from a societal perspective as recommended by the WHO [122]. The perspective included formal healthcare sector costs (e.g., drugs) and informal healthcare sector costs (e.g., patient transport costs) [122]. We summarize the costs included in this study in **table 2**.

3.3. Identifying cost sources

As the trial was not designed for an economic evaluation and therefore, did not collect detailed cost data, we relied on multiple sources for the cost data. The sources included peer-reviewed studies and the grey literature from within and outside of the DRC. We searched Google, Google Scholar, PubMed, and Medline using the terms in **Appendix B1**. We also manually searched reference lists of identified studies for studies not captured by our search terms.

We restricted the search to cost sources contextually relevant to the DRC. We defined contextual relevance in three ways: the time of the study, geography, and income—measured using GDP per capita as classified by the World Bank. In terms of time, the search was restricted to studies conducted from the year 2005 onward as antiretroviral drugs and PMTCT strategies were widely introduced after 2004 [125], [126]. In terms of geography, the search was restricted to studies in SSA. In terms of income, the search was restricted to countries with low GDP per capita, similar to the DRC [127]. For prices of antiretroviral drugs, we relied on price lists of international negotiated prices publicly available through the Clinton Health Access Initiative (CHAI) [128]. **Appendix B2** lists the candidate cost sources.

3.4. Identifying unit costs in base case analysis

From the list of candidate cost sources in appendix B2, we selected estimates from high-quality studies to represent base case unit costs, **table 3**. We defined high-quality studies as peer-reviewed studies and project reports which clearly articulated data sources, how costs were assigned, followed recommended guidelines for estimating costs in cost and cost-effectiveness analyses, and presented costs in disaggregated form—for example, cost per visit. If multiple high-quality sources were available, we selected estimates from studies closest to 2016 as they are likely to be more applicable to the current context.

3.5. Valuation of goods and services, inflation adjustment, and discounting

We valued the cost of the CCTs in international dollars (I$)—a hypothetical currency with the same purchasing power as the US$ has in the United States [122], [123]. The I$ reflects the correct value of goods because it distinguishes between tradable and non-tradable goods; without this distinction, non-tradable goods would be undervalued countries with higher purchasing power such as the DRC [122], [124]. Tradable goods (e.g., medications) are those goods that can be imported or exported and converted their estimates using nominal (official) exchange rates. On the other hand, non-tradable goods are produced locally and cannot be imported or exported (e.g., labor) [122], [124] and converted their estimates using purchasing power parity (PPP) exchange rates. All exchange rates came from a World Bank database [129].

As the trial was conducted for >1 year and cost estimates were extrapolated from multiple time periods [122], we adjusted the costs for inflation and reported the costs in constant 2016 I$—the year with the most recent conversion factors at the time of this study. To adjust for inflation, we used the implicit gross domestic product (GDP) deflator accessible through the World Bank database [130]. Unlike other candidate inflation-adjustment tools like the consumer price index,

the GDP deflator covers price changes in a broader range of economic activity, including the health sector [36]. We first applied inflation adjustment and then converted the inflation-adjusted estimates to I$. We did not discount costs or effects as participant follow-up was <1 year [131].

3.6. Cost assignment

We assigned costs to participants based on the number of visits or services utilized and used both micro-costing and gross-costing to estimate the costs. For example, we assigned the cost of transport and drugs based on micro-costing and the cost of utilities and staff wages using gross-costing. Micro-costing entails conducting a detailed identification and measurement of all activity inputs to value costs [132], [133]. Micro-costing can yield more precise estimates [132], but it was not possible to use this method to value all costs. Thus, we also used gross-costing—use of mean costs aggregated at a higher level from other studies to determine the value of an activity [132]. Gross-costing is simple, tractable and quick to use [132], although it may produce biased estimates because of overgeneralization [132], [134].

3.6.1. Medications and laboratory costs

To assign the cost of medications, we multiplied the number of days a participant was on the medications by the unit cost of the medications. We calculated the number of days on the medications by taking the difference between the date a participant was started on the medication and the date the participant was last followed-up. Participants lost to follow-up at six weeks were assumed to have taken the medications for 3 weeks (half-way between the first visit date and the would-have-been visit at six weeks). We also estimated the cost of infant NVP suspension but only for six weeks after delivery because thereafter participants were not followed-up. Unit prices of medications, which came from CHAI and represent drug acquisition costs only, were increased by 15% to cover shipping costs [135].

Among laboratory tests, we estimated the cost of CD4 cell counting and DNA PCR testing of infant dried blood sample (DBS). We also estimated the cost of transporting the DBS to a central laboratory in Kinshasa where the testing was done. We did not cost HIV testing and counseling as these services were provided to all pregnant mothers attending ANC clinics, regardless of study participation and therefore, would not contribute to incremental costs. We did not cost viral load tests because these tests were not performed or recorded systematically during the trial.

3.6.2. Delivery and post-delivery counseling

We estimated the cost of health facility deliveries as an episode. Separately, we also estimated the cost of post-delivery counseling on family planning and safe infant feeding practices. We assumed two post-delivery counseling sessions—one session soon after delivery but before the participant was discharged from the clinic and the other at six weeks' postpartum. We calculated the cost of the two counseling sessions separately because some participants who delivered in health facilities did not return at six weeks' post-partum.

3.6.3. Labor and overhead costs

We assigned labor costs to each visit, except the visit for hospital delivery which we assumed was included in the overall cost of the deliveries. We separately estimated labor costs for clinical and support staff. We used a nurse salary to approximate the labor cost of clinical staff. We assumed that a nurse saw 20 patients in a day [136] and worked for 22 days in a month. Therefore, we divided a nurse monthly salary by 440 (20*22) to find the labor cost of each visit. Using a similar approach, we derived the labor cost of support staff for each visit.

At each visit, we also calculated the cost of overheads—resources shared by other programs—which included utilities and equipment. Many of the studies from which we abstracted overhead

costs assigned costs to participants per month [137]–[139], so we assumed that the monthly cost was for one visit. We summed the costs per visit then multiplied by the number of visits to find the total cost of all visits per participant.

3.6.4. Patient and peer/family support costs

We also included costs incurred by participants and their supporters (peers or family) in the form of transport costs and the opportunity cost of time spent seeking PMTCT services [133]. Evidence suggests that women with HIV receiving PMTCT services are accompanied by their peers/family to the health facilities and they value their time and effort [140]. The trial recorded self-reported one-way transport costs which we doubled to get the transport cost per visit. We assigned the peer/family member the same transport cost as the participant. We also assumed that one clinic visit took one working day of the participant's time and that a participant's support lost an equal amount of time. Further, assumed the participant and their support lost 2 days for delivering in health clinics. We used a minimum day's wage for the DRC of 1680 FC in 2016 as the opportunity cost of time [141].

3.7. Missing data

In preliminary analyses, we found that about 40% of the participants had missing transport costs which we replaced using multiple imputations to introduce variation in the imputed values and derive asymptotically consistent estimates [142]. We assessed the pattern of data missingness and found that the missingness was not systematic—a key assumption is multiple imputations [143]. We performed the multiple imputations using predictive mean matching which does not make any assumptions about the distribution of the data [144], [145]. We included the dependent variable and all explanatory variables from equation 1 (below) in the imputation, as recommended [146].

3.8. Analysis

All analyses were by intention-to-treat. That is, all participants were kept in the groups to which they were randomized, regardless of deviations from the trial's protocol [147]. For example, one participant assigned to the control group and randomly selected to receive the cash incentives was still analyzed as part of the control group. We analyzed effects and costs using univariable and multivariable approaches and then estimated the incremental effectiveness and incremental costs. We then multiplied the incremental effectiveness and incremental costs to derive ICERs.

3.8.1. A general statistical model for analyzing effectiveness and costs

To model the effectiveness and costs of the CCTs, we used marginal models estimated via generalized estimating equations (GEE) and adjusted for potential clustering at the clinic level. Ignoring the potential clustering could have led to a narrower 95% confidence interval [148] and thus increasing the probability of type 1 error [91]. We also adjusted for baseline participant characteristics as randomization might still fail to equalize trial arms due to sampling error [77]. GEEs produce population-averaged coefficients which are desirable because they can inform policymakers, on average, the effectiveness or cost of the CCTs were all pregnant HIV-positive women to receive the intervention. Other candidate models like the generalized linear mixed models produce cluster-specific coefficients and not population-averaged coefficients [66], [149]. Another advantage of GEE is that the coefficients from these models are robust to misspecification of the variance structure making them appropriate for studies interested in estimating coefficients and not the variance itself; GEEs treat the variance as a nuisance thereby making correct variance specification less important [66], [149], [150]. While GEEs may produce biased estimates when the number of clusters is small (<10) and study arms are not balanced [148], [151], we have confidence in the estimates as the trial had a high number of

clusters (89 clinics) and the arms were balanced (216 vs. 217). We implemented the models using "*xtgee*" in Stata 14.2 [152].

The following was the generalized linear model:

$$F^{-}(Outcome_{ij}) = \beta_0 + \beta_1 Intervention_{ij} + \boldsymbol{X}_{ij}\mathbf{A} \qquad (1)$$

where:

$Outcome_{ij}$ was either PMTCT uptake or PMTC retention or cost for the i^{th} participant at the j^{th} clinic;

Intervention=1 if the participant received CCTs and 0 otherwise; β_1 was the coefficient of interest.

X_{ij} is a vector of participant characteristics and **A** a corresponding vector of coefficients.

We specified an exchangeable within-group correlation structure for both effectiveness and costs, but the links and distributions were different. An exchangeable structure means that the correlation between any pair of participants receiving PMTCT services at the same clinic was equal but non-zero [66], [149].

3.8.2. Effectiveness

To model the effectiveness of the CCTs, we specified a Poisson distribution and a logarithmic link in equation 1. We specified a Poisson distribution because a log-binomial model could not converge within the GEE environment in Stata 14.2. While the Poisson and log-binomial regressions produce identical estimates, standard errors from the Poisson are larger [153], [154] which increases the probability of failing to reject the null (type 2 error) [91]. To make the

standard errors smaller and comparable to those from a log-binomial model, we estimated the Poisson model with robust error variances [154].

To duplicate published results from the trial [115], we reported the effectiveness using relative risks. Thus, for PMTCT uptake in equation 1, participants who received the CCTs had β1 times the risk of taking up PMTCT services compared with participants who did not receive the CCTs. Similarly, for PMTCT retention, participants who received the CCTs had β1 times the risk of being retained in PMTCT care compared with participants who did not receive the CCTs.

3.8.3. Incremental effectiveness

Next, we estimated the incremental effectiveness of the CCTs expressed using NNT, like several other studies in the HIV literature[155], [156]. NNT is an epidemiological measure that quantifies the number of participants needed to receive a treatment to avoid a poor outcome [157], for example, not taking up PMTCT services. NNT is a natural number and therefore easier to interpret clinically than other candidate measures of incremental effectiveness like risk differences [157]. Thus, a higher NNT means that the treatment is less effective in avoiding the unwanted outcome. We were unable to use traditional measures of incremental effectiveness like the disability-adjusted life years (DALY) averted because participant follow-up time was too short, and the study was not powered to detect the effect of the CCTs on survival.

Calculation of NNT, like for relative risks, was based directly on the underlying risk of PMTCT uptake or PMTCT retention in each trial arm. We emphasize that we could not directly estimate the NNT using the relative risks from the Poisson regression. Therefore, after estimating the Poisson regression in equation 1, we derived the NNT in the following steps:

1. Predicted the absolute risk for each participant.

2. Calculated the mean absolute risk in each arm.
3. Calculated the mean absolute risk difference between the intervention and control arms.
4. Calculated the NNT, which is the reciprocal of the mean absolute risk difference [158].

We interpreted the NNT as the number of participants needed to receive the cash incentives for one more participant to take up PMTCT services, compared to standard of care. We made a similar interpretation for PMTCT retention.

3.8.4. Economic costs

To determine total costs in each trial arm, we multiplied resources used by each participant by the unit cost of that resource and then added. We described costs using both the median and mean but in multivariable regressions modeled mean costs only. While reporting of median costs is recommended as cost data are almost always positively skewed [131], we also report mean costs because budgeting and policy decisions are made based on expectation [159]. We tested differences in means and medians using t-tests and rank sum tests. The t-test, which assumes a normal distribution, is still robust when the sample size is greater than 150 or when the number of participants in the intervention and control groups is similar [160], as in this study.

3.8.5. Incremental costs

To estimate incremental costs, we also used equation 1 with cost as the outcome. We specified an exchangeable within-group correlation structure, a gamma distribution, and an identity link. These specifications were based on results of testing several correlation structures and cost distributions using the quasi-likelihood under the independence model criterion (QIC) [161]. By specifying an identity link, $\beta 1$ was in the original cost values and represented the difference in costs between the intervention and the control arms—or the incremental cost of the CCTs.

3.8.6. Incremental cost-effectiveness ratio

To derive ICERs, we multiplied incremental costs and incremental effectiveness (incremental costs*NNT)[2]. Because the ICER is a ratio and therefore does not have standard errors to use in calculating the 95% confidence intervals, we used Fieller's theorem to generate the confidence intervals [131], **Appendix B4**. Unlike other parametric methods which assume a normal distribution of the ratio, Fieller's method considers the skewed distribution of the ICER [131], [162].

3.8.7. Are the CCTs cost-effective?

To determine whether the CCTs are cost-effective, we compared the ICER of the CCTs to cost-effectiveness thresholds based on 3x the GDP per capita for the DRC in 2016 (I$2409) [163]. Thus, I$2409 represented the maximum willingness-to-pay for an additional participant to take up PMTCT services or be retained in care. However, because of concerns that a threshold of 3x GDP per capita may be too high [164]–[166], we also considered a lower threshold (1.5x the GDP per capita for the DRC in 2016 or I$1205).

3.8.8. Uncertainty analysis

We also assessed uncertainty in the cost variables and the estimated ICER[122], [133], [167]. Sources of the uncertainty included: abstraction of cost data in different unit costs outside of the trial, use of gross costing, and imputation of transport costs [143], [167], [168]. We used deterministic sensitivity analyses to examine uncertainty in cost variables and cost-effectiveness acceptability curves to examine uncertainty in ICERs.

[2] In the traditional approach, ICER=ΔC/ΔE, where ΔC is the incremental cost and ΔE is the incremental effectiveness. Estimating effectiveness using absolute risk means that the ΔE is the risk difference (RD). Thus, ICER=ΔC/RD= ΔC*1/RD. But 1/RD=NNT. Therefore, ICER=ΔC*NNT.

3.8.8.1. One-way sensitivity analysis

In one-way sensitivity analyses, we identified the main cost drivers by varying the cost of key components one at a time across a plausible range of values, holding other cost components at their base values [133], [169]. A component was key if it had high unit costs or high utilization relative to the other components, and therefore, more likely to substantially affect costs if varied [170]. We selected values for lower and upper bound unit costs from the sources of the base case unit costs [170]. We used the limits of the 95% confidence intervals of the base case unit costs as the upper and lower bounds in the sensitivity analyses. If the base unit cost did not have a 95% confidence interval, we decreased and increased base case estimate by 50% to derive the lower and upper bound estimates, as done previously [169], [171], [172]. In each one-way sensitivity analysis, we calculated new ICERs and report the results using tornado diagrams [173], [174]. **Table 3** presents the key components and the unit costs in the sensitivity analysis.

3.8.8.2. Multi-way sensitivity analyses: best- and worst-case scenarios

Since multiple variables may be uncertain, we examined the effect of simultaneously varying key cost variables in multi-way sensitivity analysis [169]. We created best- and worst-case scenarios. We combined the most optimistic unit costs (lower bound unit costs) in table 3 to create the best case and the most pessimistic unit costs (upper bound unit costs) to create the worst case. In each scenario, we calculated new ICERs and the associated 95% confidence intervals.

3.8.8.3. Cost-effectiveness acceptability curve

To examine the uncertainty associated with the ICERs in the base case, we used cost-effectiveness acceptability curves. These give the probability that an intervention is cost-effective compared with the alternative, for varying levels of willingness-to-pay [175]. To derive the cost-effectiveness acceptability curves, we implemented the following steps:

1. Using simple random sampling with replacement, we drew a sample of 216 observations from the trial data, similar to the size of the intervention arm [162], [176], [177].
2. From the resampled data, we calculated the mean cost and effectiveness [162], [176], [177].
3. We repeated steps 1 and 2 to obtain the mean cost and effectiveness in the control arm.
4. Next, we combined the resampled datasets and calculated a new ICER.
5. We repeated steps 1-4 for 4000 times although 1500 times is recommended [178]. This is because the bootstrapped costs and effects were normally distributed after 4000 samples. We bootstrapped costs and effects together because of their interdependence.
6. From the 4000 ICERs, we estimated differences in costs and differences in effects.

From the differences in costs and effects in step 6, we derived the cost-effectiveness acceptability curves. We also plotted the joint distribution of the differences in costs and effects on a cost-effectiveness plane. To construct the CEAC, we modified an existing Stata program by changing the program's default confidence limits and maximum values [179].

4. Results

4.1. Effectiveness of CCTs

We found that CCTs significantly increased the uptake of PMTCT services and retention in PMTCT care. About 68% (146/216) of women in the intervention group took up PMTCT services compared with 53% (116/217) in the control group. About 81% (174/216) of women in the intervention group were retained in PMTCT care compared with 72% (157/217) in the control group. Compared to participants who did not receive the cash incentives, participants who received the cash incentives were 28% and 12% more likely to take up PMTCT services and

being retained in PMTCT care, respectively, **table 4**. Further, women with a secondary education and those who walked to clinics were significantly more likely to take up PMTCT services.

4.1.1. The incremental effectiveness of CCTs (number-needed-to-treat)

We present incremental effectiveness (NNT) of the CCTs and the values at each step of deriving the NNT in **table 5**. We emphasize that NNT cannot be derived directly from relative risks and therefore, results in table 4 could not have been used to derive the NNT. The NNT for PMTCT uptake was 7.0 (95% C.I.=6.7-7.6)—that is 7 participants needed to receive the cash incentives for one more participant to take up the PMTCT services. For PMTCT retention, the NNT was 12.1 (95% C.I.=11.6-12.8).

4.2. The economic cost of the CCTs

We summarize economic costs in **table 6**. The mean total cost ± SD per participant in the intervention group was I$516 (116), compared with I$431 (132) in the control group (p-value <0.001). The median cost was also higher in the intervention group (I$540, IQR (485-590) vs. I$ 468, IQR (392-512)) (p-value <0.001). As a share of mean total costs, the cost of delivering in a health facility was the highest in both arms, although lower in the intervention group (52% vs. 58%). In the intervention arm, the cost of the CCTs ranked second tied with the cost of medications (10%). Overall, participants in the intervention group made 35 visits (934 vs. 899), with a mean cost per visit of I$119 (vs. I$104 in the control group).

4.2.1. The incremental cost of the CCTs

Table 7 presents the incremental costs of the CCTs. The CCTs had an incremental cost of I$85 (95% C.I.=59-111). The Incremental costs did not differ significantly by participant

characteristics although the costs were higher among those who were married, without any education, and walked to the clinics.

4.3. Incremental cost-effectiveness ratios of CCTs

In the following subsections, we present incremental cost-effectiveness ratios in the base case and in uncertainty analyses.

4.3.1. Base case analysis

Table 8 presents the incremental cost-effectiveness ratios of the CCTs in the base-case analysis. The incremental cost-effectiveness ratio of the CCTs with respect to PMTCT uptake was I$595 (95% C.I. =567-624) and I$1026 (95% C.I.=960-1101) with respect to PMTCT retention. Thus, the CCTs were very cost-effective in increasing PMTCT uptake (ICER <1x DRC GDP per capita or I$803) and cost-effective in increasing PMTCT retention (ICER> I$803 but <3x DRC GDP per capita or I$2409).

I$595 (95% C.I. =567-624) for PMTCT uptake and I$1026 (95% C.I.=960-1101)

4.3.2. One-way sensitivity analysis

Figure 1, a tornado diagram, presents the results of the one-way sensitivity analysis and the associated ICERs. The vertical line in the diagram corresponds to the ICER in the base case. The variables are ranked so that the most influential variable is at the top. The x-axis measures the change in ICER from the base case while the labels of the bars are the lower and upper bound unit costs used in the sensitivity analysis. The CCTs followed by delivery in health facilities were the main drivers of the incremental cost-effectiveness ratios. For example, paying each participant I$20 (or US$11) at every visit while holding other variables constant increases the

ICER from I$1026 per additional HIV+ mother retained in PMTCT care in the base case to I$1,570, but still cost-effective.

4.3.3. Multi-way sensitivity analysis

Table 9 presents results of multi-way sensitivity analysis. In the best-case, the ICERs were <1x GDP per capita and therefore very cost-effective. In the worst case, the CCTs were still cost-effective as the 95% confidence intervals of the ICERs were < I$2409 (PMTCT uptake: ICER=I$1175, 95% C.I. (1118-1235); PMTCT retention: ICER=I$2027, 95% C.I. (1893-2178).

4.3.4. Cost-effectiveness acceptability curves and willingness to pay for CCTs

We present the joint distribution of differences in costs and effects for PMTCT uptake in **figure 2** and for PMTCT retention in **figure 3**. In both figures, all the data points (incremental cost-effectiveness ratios) are in the northeast quadrant of the cost-effectiveness plane—thus the CCTs increased both effectiveness and costs in all the resampled datasets. Furthermore, the clustering of ICERs in the same part of the quadrant shows that the values of the ICERs from the resampled datasets were close and did not greatly vary from the ICER estimate from the original trial data.

Based on the joint distribution of incremental costs and effects, we capture the uncertainty surrounding the incremental cost-effectiveness of CCTs at different willingness-to-pay thresholds in **figure 4**. This acceptability curve shows the level of uncertainty surrounding the ICER estimate and the probability that the CCTs were cost-effective, compared to the control group, for a given level of willingness-to-pay. Points B and F correspond to the ICER point estimates[3] reported in table 7 and all points on the solid black line in figures 2 and 3. These

[3] The ICER point estimates in figures 2, 3, and 4 are slightly different from the ICERs in the main results (table 8). This is because in resampling the original trial data 4000 times, each resampled dataset had its own ICER.

points have 0.5 probabilities of being cost-effective. The steep slope and the rapid rise of the curves (A to C and E to G) suggest small deviations from the original ICER estimate, and therefore, a high degree of certainty associated with the ICERs.

In addition to showing a high degree of certainty surrounding the ICERs, figure 4 also shows that the CCTs were cost-effective at many of the thresholds of willingness-to-pay proposed in this study. For example, if the willingness-to-pay is I$2409 (3x GDP per capita in 2016), the probability that the CCTs were cost-effective is almost 1. At a threshold of I$1205 (1.5x GDP per capita in 2016), the probability that the CCTs were cost-effective is almost 1. At a threshold of I$803 (1x GDP per capita in 2016), the probability that the CCTs were cost-effective in increasing PMTCT uptake is almost 1 (point D), but for PMTCT retention the probability is almost zero. At any threshold < I$570, the CCTs have no chance of being cost-effective.

5. Discussion

Uptake of PMTCT services in SSA remains low despite scale-up of Option B+ in the region [106], posing challenges to global ambitions of eliminating MTCT of HIV. Coupled with inadequate domestic funding and lack of growth in international financing towards the HIV/AIDS response [181], [182], it is imperative to find innovative and cost-effective strategies that can increase the uptake of the PMTCT services. We examined the cost-effectiveness of a trial of one such strategy—small but increasing cash incentives aimed to increase PMTCT uptake and PMTCT retention in the DRC. The findings suggest that the cash incentives were cost-effective from the societal perspective. To our knowledge, this is the first study to evaluate

Therefore, figures 2, 3, and 4 present the mean of the ICERs while table 8 presents ICERs from the original trial data. It is not unusual for ICERs from the original trial data and resampled datasets to differ slightly [180].

the cost-effectiveness of cash incentives aimed to increase the uptake of PMTCT services and retention in PMTCT care.

From the societal perspective, the estimated incremental cost of the cash incentives was I$85, with corresponding ICERs of I$585 for PMTCT uptake and I$1081 for PMTCT retention. For a willingness-to-pay threshold of 3x DRC GDP per capita in 2016 (I$2409), these estimates suggest that the cash incentives were very cost-effective in increasing PMTCT uptake but cost-effective in increasing PMTCT retention. In a sensitivity analysis, the cash incentives were the main cost drivers and the intervention was still cost-effective even in the worst case.

The study's finding that the cash incentives were cost-effective is consistent with reports from previous studies which examined the cost-effectiveness of other strategies aimed at increasing uptake of PMTCT services although some of the studies predate the Option B+ era. We emphasize that literature on interventions aimed at increasing uptake of PMTCT services is limited. Instead, the literature is replete with cost-effectiveness studies comparing different treatment protocols (for example, no intervention vs Option A vs. Option B vs. Option B+) or different HIV testing and counseling strategies [183]–[185]. For example, universal HIV testing of all pregnant mothers during ANC clinics was cost-effective in multiple countries [186], as were HIV rescreening late in pregnancy in South Africa [187] and couple counseling in Kenya [188]. Evidence from studies of non-conventional models for the delivery of PMTCT services suggests that these models are also cost-effective, although comparability is still limited because of health outcomes used. The Futures Institute reported that low and high levels of integration of PMTCT services with maternal, neonatal, and child health within antenatal care clinics in Malawi, Uganda, and Mozambique were cost-effective [189]. The study reported health outcomes using number of HIV infant infections averted over a period of 100 years [189].

Similarly, the JSI Research and Training Institute, which used data from Kenya and reported health outcomes using number of infant infections averted and QALYs gained, reported that Civil Society Organizations delivered PMTCT services more cost-effectively than did public health facilities [190]. Peer mentors like Mother2mothers—initially implemented in South Africa and later scaled to other parts of SSA [191], [192]—increased uptake of PMTCT services, improved health outcomes, and represent a good value for the money according to another report by the JSI Research and Training Institute [193]. However, comparability of findings is limited because the study had a longer analytic time horizon and was a cost-benefit analysis—that is, it expressed incremental effectiveness in monetary terms [193].

This study contributes to a broader, although limited, literature on the cost-effectiveness of cash incentives to improve individual/household behaviors and well-being. The findings from this limited literature are mixed overall but suggest that the cash incentives are cost-effective in resource-limited settings [194]–[196] or when the analytic time horizon is longer—for example over a lifetime [197]. The lack of evidence that cash incentives are cost-effective is largely for two reasons. First, the lack of comprehensive data about costs and effects. Second, not considering the effects of the cash incentives more broadly [198], [199]. This is particularly true for effects because the impact of the cash incentives is likely to go beyond the specific sector of interest [198]–[201]. For example, in Malawi, cash incentives averted one HIV infection among school going girls aged 13-22 years at a cost more than 15 times Malawi's GDP per capita [202], and therefore less cost-effective. However, the cash the incentives also increased retention of the girls in school [202]. Thus, although less cost-effective when considered more narrowly (via the lens of HIV financing only), the cash incentives could be cost-effective and make economic sense when co-financing models (for example, including resources from education) are

considered [203]. Given that this study did not include all the possible benefits of the cash incentives, for example, increases in uptake of family planning services and improvements in overall health-seeking behaviors, it is likely that the current study underestimates the cost-effectiveness of the CCTs. Further, the evidence suggests that cash incentives are less-cost effective in high-income countries perhaps because the size of the incentives relative to household income is not large enough to be effective [204], [205], [206, p.]. On the other hand, cash incentives do appear to be cost-effective in developing countries where the cash incentives increased school enrollment and attendance and improved secondary school outcomes [194], [195]. Cash incentives were also cost-effective in increasing household food security and child development [196] and preventing undernutrition in emergency situations [171]. Therefore, although the evidence is mixed, this study adds to the building evidence that cash incentives are cost-effective and can be used to promote good social behaviors, particularly in resource-limited settings like in many countries in SSA.

5.1. Limitations

This study has limitations. First, because the trial did not collect detailed data for each cost component, there may be bias in the cost estimates. We relied on external sources, made a series of assumptions, and imputed missing data to estimate the costs. However, recognizing that this may have introduced bias [207], we conducted sensitivity analyses and the findings suggest that the cash incentives were still cost-effective even in the worst of circumstances.

Second, we were unable to use traditional health outcome measures for incremental effectiveness analysis like the number of DALYs [163] or HIV-infections averted. This is because participant follow-up, which was up to six weeks post-partum, was not long enough to have definitive results about the HIV status of infants in each trial arm. This limits the comparability of the

study's findings with other cost-effectiveness analysis studies. Despite the limitation, these findings serve as a foundation for future cost-effectiveness studies that can incorporate final, versus intermediate, health outcomes. Moreover, the success of PMTCT services in achieving the desired goals begins with the uptake of the PMTCT services [108]–[110] and the findings from this study suggest that the cash incentives increase PMTCT uptake and do so cost-effectively.

Third, the thresholds based on GDP per capita have been criticized in the literature for not reflecting the opportunity cost of local resources used in the interventions [164]–[166], as recommended [208]. This suggests that most interventions deemed effective using these thresholds, may not be cost effective if the thresholds reflected the opportunity cost of the local resources used in the interventions. Furthermore, we emphasize that these thresholds based on GDP per capita were developed for cost-effectiveness analyses using final health outcome like DALYs averted or QALYs gained [163], and not intermediate outcomes like NNT. Noting these limitations, we considered a more conservative threshold (1.5x DRC GDP per capita) in uncertainty analysis and found that the cash incentives were still cost-effective. Moreover, results from studies using thresholds based on GDP per capita continue to help inform policy. For example, Option B+, an intervention already adopted and expanded by the DRC and many countries in SSA was found to be cost-effective based on these thresholds [209]–[211].

5.2. Implications for future research

While these findings suggest that the cash incentives are cost-effective, additional research is needed before any recommendations to scale-up the intervention can be made. First, we need to understand the cost-effectiveness of the cash incentives using final health outcomes like DALYs averted or life-years saved, as might be done in mathematical modeling studies. Such studies can

also examine whether the cash incentives are still cost-effective in larger populations and with different HIV profiles. Second, there is a need to understand whether the cash incentives can be combined with other cost-effective strategies also aimed at increasing the uptake of PMTCT services. This is important because the cash incentives, even if scaled widely, cannot overcome all barriers preventing the uptake of PMTCT services. Overcoming barriers to uptake of PMTCT services like stigmatization of people living with HIV and lack of partner support [118], [212] would require other interventions, particularly those that are community-based. Several of these interventions have shown effectiveness in increasing uptake of PMTCT services in Tanzania [213], South Africa [214], [215], Nigeria [216], Malawi [217], Zimbabwe [218], and Uganda [219]. Therefore, if these interventions are also cost-effective, future research should focus on whether some of these interventions can be combined with the cash incentives.

6. Conclusion

Low uptake of PMTCT services is a challenge in SSA, with implications on global efforts of realizing an HIV-free generation. Based on WHO's thresholds for cost-effectiveness, conditional cash transfers are cost-effective in increasing uptake of PMTCT services and retention in PMTCT care in the DRC and similar settings. Additional research is needed to understand the effectiveness and cost-effectiveness of the cash incentives using final health outcomes and in larger populations before further scale-up of the intervention. Given that the cash incentives can overcome financial, vs. social barriers like stigmatization, considerations to combine the cash incentives with other cost-effective community-based strategies should also be made.

Table 1: Definition of standard PMTCT care

HIV counseling and testing
HIV posttest counseling
CD4 cell count
Cotrimoxazole prophylaxis
AZT if CD4 cell count ≥350 cells/mm3 or triple ARV therapy if <350 cells/mm3*
Delivery in a health facility
Post-partum care, including counseling on infant feeding options
Nevirapine suspension for the infant
Cotrimoxazole prophylaxis for infants
DNA PCR and Serologic testing for infants

*Participants with CD4 cell counts <350 cells/mm3 were referred to an HIV clinic where they received AZT. *Source: Yotebieng et. al, 2016.*

Table 2: Included costs, societal perspective*

Sector	Type of impact
Formal healthcare sector	
	Health outcomes (effects)†
	Uptake of PMTCT services
	In PMTCT care six weeks' postpartum
	Medical costs
	Medications
	Laboratory tests
	Transportation of infant dried blood samples‡
	Health facility deliveries
	Post-delivery counseling
	Labor (wages for clinical and support staff)
	Overhead costs (utilities)
	Capital costs (equipment)
Informal healthcare sector	
	Patient time costs
	Peer/family support time costs
	Patient transportation costs
	Peer/family support transportation costs

*This table is based on recommendations by the second US Panel on Cost-effectiveness in Health and Medicine [220] and not the World Health Organization. † The study had two primary outcomes: uptake of PMTCT services and retention in PMTCT care. Uptake of PMTCT services was defined as timely attendance (within 5 days) of all scheduled clinic visits from randomization through 6 weeks' postpartum and accepting all proposed services listed in box 1. ‡ Infant dried blood samples from all clinics participating in the study were transported to a central laboratory in Kinshasa for DNA PCR testing.

Table 3. Unit Costs, in I$2016

Cost component	Unit of measurement	Base case*	Lower bound†	Upper bound†	Reference
Cash Incentives	Per visit	9-20‡	9.00	20.00	Trial data
Medications					
AZT (mother)	Per dose (30 days)	7.48	3.74	10.87	[128]
ART (mother)	Per dose (30 days)	7.83	3.92	12.58	[128]
Cotrimoxazole (mother)	Per dose (30 days)	1.08	0.51	3.25	[221]
Nevirapine (infant)	Per dose (6 weeks)	11.63	5.82	17.45	[128]
Cotrimoxazole (infant)	Per dose (6 weeks)	4.14	2.07	6.21	[222]
Laboratory tests					
CD4 count	Per test	15.3	7.65	22.95	[138]
DNA PCR (infant)	Per test	45.28	22.64	67.92	[138]
Transportation of DBS§	Per sample	2.33	1.16	3.49	[223]
Health facility deliveries ‖					
Delivery	Per delivery	281.31	28.13	843.92	[224]
Post-delivery counselling	Per session	0.47	-	-	[184]
Labor					
Wages for clinical staff	Per visit	3.32	-	-	[225]
Wages for support staff	Per visit	1.61	-	-	[226]
Capital and overhead costs					
Equipment	Per visit	1.70	-	-	[227]
Utilities	Per visit	0.90	-	-	[138]
Patient and peer/family support costs					
Time	Per day	3.00	1.50	4.49	[141]
Transportation (varies by patient)	Per visit	0.19-5.75	0.19	5.75	Trial data

*Base-case values were used to derive total mean costs in each trial arm for the main analysis. †Lower and upper bounds were created from 95% confidence intervals of the base case unit costs. If a base unit cost did not have a 95% confidence interval, the base unit cost was decreased by 50% to derive the lower bound and increased by 50% to derive the upper bound unit cost. The lower and upper bounds were individually used in one-way deterministic sensitivity analysis and in combination to create best- and worst-case scenarios in multi-way sensitivity analysis. ‡This range in USD is 5-11. §DBS (dry blood sample) was transported from the study clinics to a central laboratory in Kinshasa. ‖ Health facility deliveries: as the trial did not collect data on facility type, delivery method, and employment status, we made the following assumptions. For the base case unit cost, we assumed that all study participants delivered in secondary health centers, the baby was delivered normally and that all participants were unemployed. For the lower bound unit cost, we assumed that all study participants delivered in primary health centers, delivery was normal and that they were all were unemployed. For the upper bound unit cost, we assumed that all study participants delivered in primary health centers, delivery was through cesarean section and that all study participants were employed.

Table 4: Effectiveness of conditional cash transfers

	PMTCT Uptake†		PMTCT Retention‡	
	Relative risk	**95% C.I.**	**Relative risk**	**95% C.I.**
Intervention	1.276**	[1.09,1.50]	1.12*	[1.01-1.23]
Age	1.003	[0.99,1.02]	0.99	[0.99,1.00]
Marital status (ref: not married)				
Married	0.975	[0.83,1.15]	1.00	[0.89,1.13]
Education (ref: no education)				
Primary	0.916	[0.73,1.15]	1.04	[0.90,1.21]
Secondary or higher	1.396**	[1.14,1.71]	1.10	[0.94,1.29]
Wealth (ref: first quintile (poorest))§				
Second quintile	0.939	[0.74,1.19]	0.98	[0.83,1.15]
Third quintile	1.07	[0.86,1.331]	1.02	[0.87,1.19]
Fourth quintile	0.91	[0.69,1.20]	0.99	[0.84,1.16]
Fifth quintile (richest)	1.092	[0.85,1.40]	0.99	[0.84,1.17]
Transport mode (ref: other means)				
Walk	1.209*	[1.04,1.40]	1.091	[0.99, 1.20]
Constant	0.423***	[0.27,0.66]	0.80	[0.61,1.04]
Observations	433		433	

Abbreviations: PMTCT, prevention of mother-to-child transmission of HIV.
* p<0.05, ** p<0.01, *** p<0.001. † PMTCT uptake was defined as meeting the following conditions: attended all scheduled clinic visits from enrollment date through 6 weeks' postpartum, gave birth in a study clinic, accepted all proposed services including providing blood samples for CD4 cell count and dried blood spot sample for early infant diagnosis of HIV at six weeks' postpartum. ‡ PMTCT retention was defined as being in HIV care at 6 weeks' postpartum regardless of the reason for missing any prior scheduled visits [115]. §Wealth quintiles were created from twelve variables using principal components analysis (PCA). The following variables were included in the PCA: maternal education, average number of household members per room, number of beds in the household, water source for the household (private or communal) and cooking fuel type (electrical stove, or firewood/charcoal). Ownership status of the following durable assets was also used in the PCA: radio, television, mobile telephone, refrigerator, and car [115].

Table 5: Number-needed-to-treat (NNT), and steps for deriving the NNT

	PMTCT uptake	PMTCT retention
Steps		
Predicted mean absolute risk in the treatment group	0.68	0.81
Predicted mean absolute risk in the control group	0.53	0.72
Calculated absolute risk reduction*	0.14	0.08
Number-needed-to-treat (NNT) †	**7.01 (6.69-7.57)‡**	**12.11 (11.55-12.81)‡**

The values in the table may not be exact due to rounding *We subtracted the predicted mean absolute risks between the intervention and control groups to derive the absolute risk reduction. †We took the reciprocal of the absolute risk reduction to derive the NNT. ‡These numbers represent the 95% confidence intervals and were generated using Fieller's method.

Table 6. Mean cost per participant, by trial arm (2016 I$)

	Intervention		Control		
Cost	**Mean**	**95% C.I.**	**Mean**	**95% C.I.**	**p-value***
Cash Incentives	51.10	[48.56-53.64]	0.31†	[0.00-0.93]	<0.001
Medications					
AZT (mother)	18.27	[16.19-20.34]	17.40	[15.33-19.47]	>0.1
ART (mother)	13.45	[11.18-15.73]	11.96	[9.81-14.1]	>0.1
Cotrimoxazole (mother)	5.04	[4.79-5.29]	4.86	[4.58-5.13]	>0.1
Nevirapine (infant)	10.12	[9.6-10.65]	9.43	[8.82-10.05]	<0.1
Cotrimoxazole (infant)	3.91	[3.78-4.04]	3.68	[3.51-3.86]	<0.05
Laboratory tests					
CD4	35.99	[33.98-38]	31.66	[29.65-33.67]	>0.1
DNA PCR (infant)	30.61	[27.75-33.46]	24.21	[21.17-27.24]	<0.01
Transportation of dry blood sample	1.57	[1.43-1.72]	1.24	[1.09-1.4]	<0.01
Health facility deliveries	265.68	[257-274.36]	250.19	[238.33-262.05]	<0.05
Post-delivery counselling	0.44	[0.43-0.46]	0.42	[0.4-0.44]	<0.05
Labor					
Wages for clinical staff	11.21	[10.63-11.8]	10.80	[10.18-11.41]	>0.1
Wages for support staff	4.97	[4.71-5.23]	4.79	[4.52-5.06]	>0.1
Capital and overhead costs					
Equipment	5.74	[5.44-6.04]	5.52	[5.21-5.84]	>0.1
Utilities	3.04	[2.88-3.2]	2.93	[2.76-3.1]	>0.1
Patient and peer/family support costs					
Patient and family support's time	35.96	[34.74-37.18]	34.02	[32.73-35.31]	<0.05
Transportation (varies by patient)	18.83	[17.22-20.43]	18.00	[16.28-19.73]	>0.1
Total cost	**515.94**	**[500.37-531.51]**	**431.43**	**[413.75-449.11]**	**<0.001**

*The p-values were from tests of medians based on the Wilcoxon rank sum tests. †The mean cost of cash incentives in the control group is not zero because one randomly selected participant in the control group received an incentive of I$ 82 (or US$ 45). We truncated the confidence interval for the cash incentives in the control group at zero; the actual confidence interval was [-0.31-0.93].

Table 7. Adjusted costs of conditional cash transfers, I$2016

	Cost	95% C.I.
Intervention	84.77***	[58.72,110.82]
Age	-1.68	[-3.64,0.28]
Marital status (ref: not married)		
Married	22.8	[-9.12,54.64]
Education (ref: no education)		
Primary	-1.97	[-29.94,26.00]
Secondary or higher	-0.13	[-56.11,55.84]
Wealth (ref: first quintile (poorest))†		
Second quintile	-8.90	[-45.27,27.47]
Third quintile	-1.63	[-33.14,29.89]
Fourth quintile	-28.90	[-70.35,12.47]
Fifth quintile (richest)	-28.80	[-70.33,12.70]
Transport mode (ref: other means)		
Walk	13.00	[-13.45,39.48]
Constant	469.00***	[408.31,529.71]
Observations	433	

* p<0.05, ** p<0.01, *** p<0.001. †Wealth quintiles were created from twelve variables using principal components analysis (PCA). The following variables were included in the PCA: maternal education, average number of household members per room, number of beds in the household, water source for the household (private or communal) and cooking fuel type (electrical stove, or firewood/charcoal). Ownership status of the following durable assets was also used in the PCA: radio, television, mobile telephone, refrigerator, and car.

Table 8. Incremental cost-effectiveness ratios of conditional cash transfers

	PMTCT Uptake		PMTCT Retention	
	Estimate	95% C.I.	Estimate	95% C.I.
Incremental effectiveness (NNT)*	7.01	[6.69-7.57]	12.11	[11.55-12.81]
Incremental cost (I$)	84.77	[58.72-110.82]	84.77	[58.72-110.82]
ICER*†	**594.54**	**[567.04-624.26]**	**1026.23**	**[959.99-1101.26]**

Abbreviations: PMTCT, prevention of mother-to-child transmission of HIV; NNT, number-needed-to-treat); ICER, incremental cost-effectiveness ratio.
*Confidence intervals generated using Fieller's theorem. †At a cost-effectiveness threshold 3x DRC GDP per capita in 2016 (I$2409), the conditional cash transfers were cost-effective.

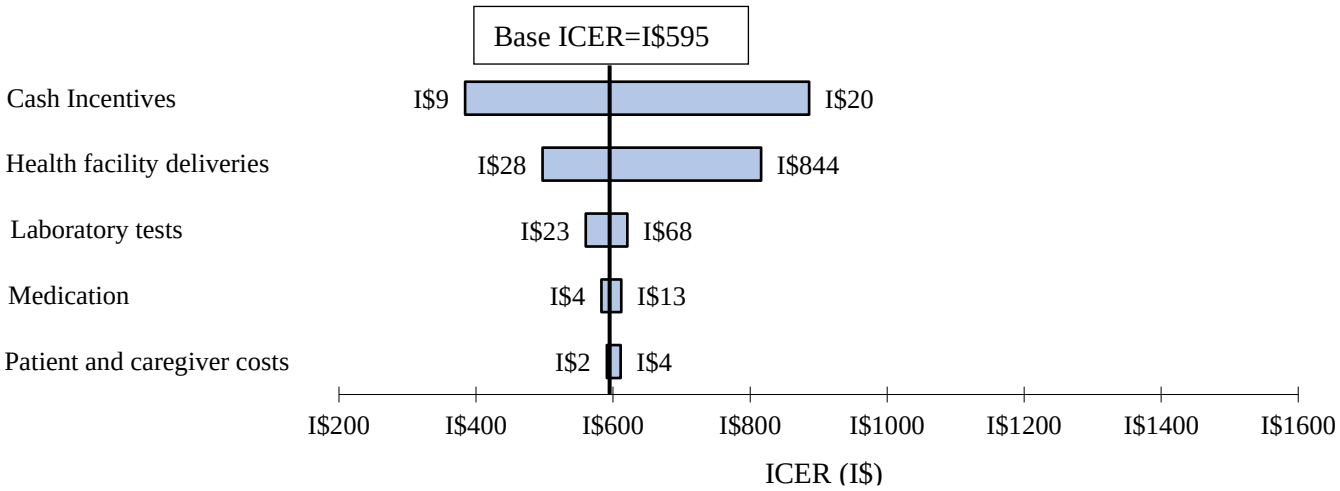
Table 9. Multi-way sensitivity analysis of the cost-effectiveness of CCTs: best and worst cases

	PMTCT Uptake		PMTCT Retention	
	ICER	95% C.I.*	ICER	95% C.I.*
Base case	594.54	[567.04-624.26]	1026.23	[959.99-1101.26]
Best case†	219.78	[210.01-230.37]	379.36	[355.36-406.62]
Worst case‡	1174.51	[1118.11-1235.32]	2027.34	[1893.95-2178.09]

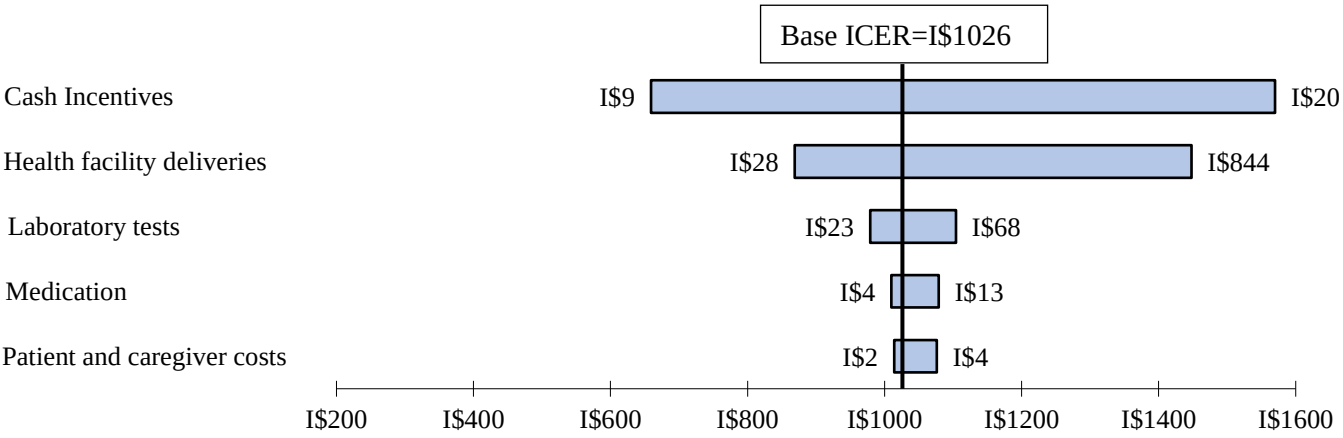
Abbreviations: PMTCT, prevention of mother-to-child transmission of HIV; ICER, incremental cost-effectiveness ratio.

*The 95% confidence intervals generated using Fieller's theorem. †The best case was created by combining lower-bound unit costs of the key cost components. ‡ Worst-case scenario created by combining upper-bound unit costs of the key components. At a cost-effectiveness threshold 3x DRC GDP per capita in 2016 (I$2409), the conditional cash transfers were still cost-effective.

Panel 1: PMTCT uptake



Panel 2: PMTCT retention



This figure shows how ICERs respond to changes in unit costs of one variable while holding costs of other variables at their baseline values. The thick vertical lines in the graphs correspond to the ICERs derived using unit costs in the base case. The labels at the end of each bar are the lower and upper bound unit costs used in the sensitivity analysis. The length of the bar on either side of the vertical line represents the new ICER associated with each of the unit costs, and its value can be read from the x-axis. Cash incentives followed by health facility deliveries were the most influential variables in determining the ICER

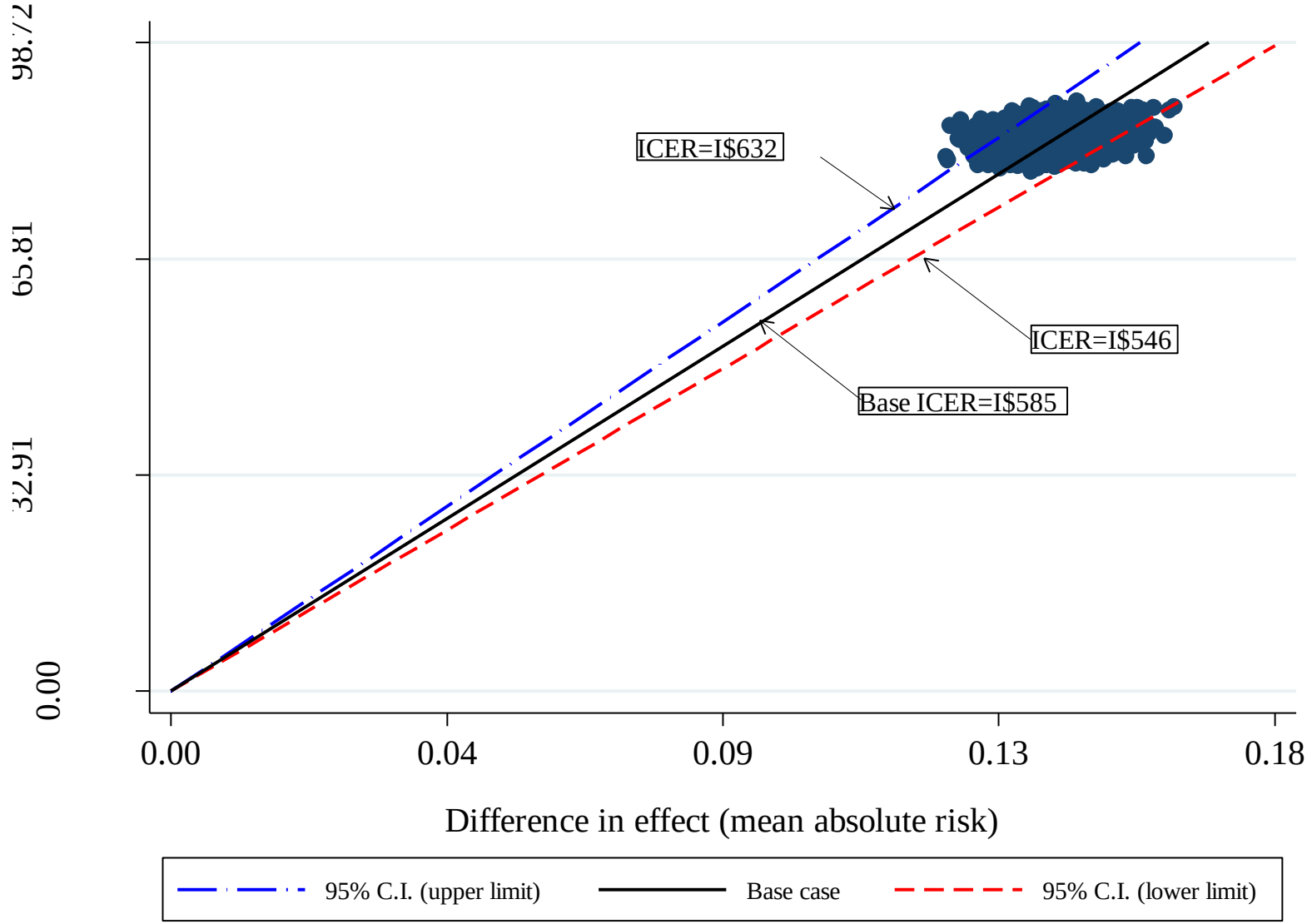


Figure 2: Differences in costs and effects, PMTCT uptake

This figure shows a joint distribution of differences in costs and effects associated with uptake of PMTCT services. A total 4000 replications of the original trial data were performed, and each dot in the graph represents one incremental cost-effectiveness ratio.

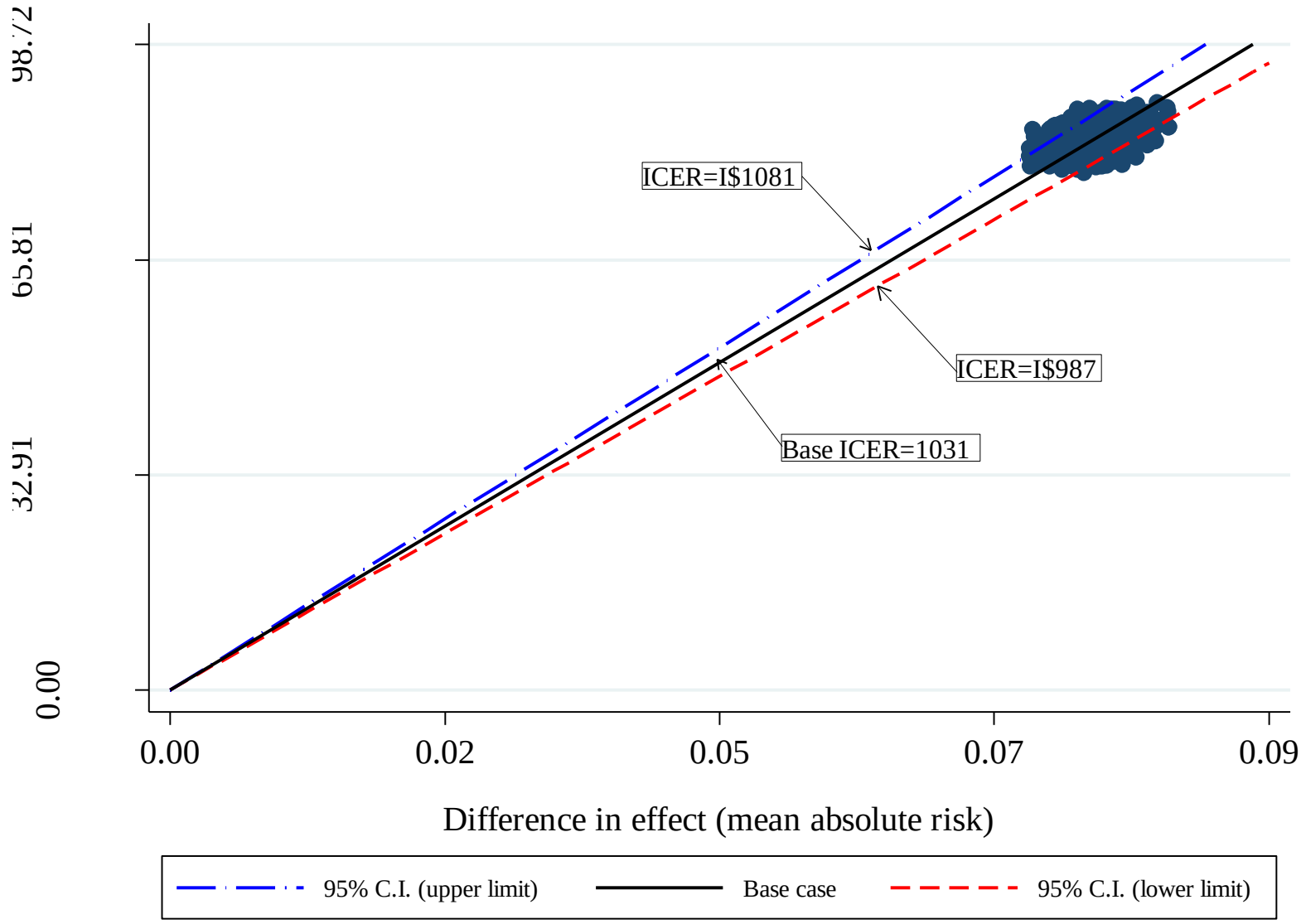


Figure 3: Differences in costs and effects, PMTCT retention

This figure shows a joint distribution of differences in costs and effects associated with retention in PMTCT care. A total 4000 replications of the original trial data were performed, and each dot in the graph represents one incremental cost-effectiveness ratio.

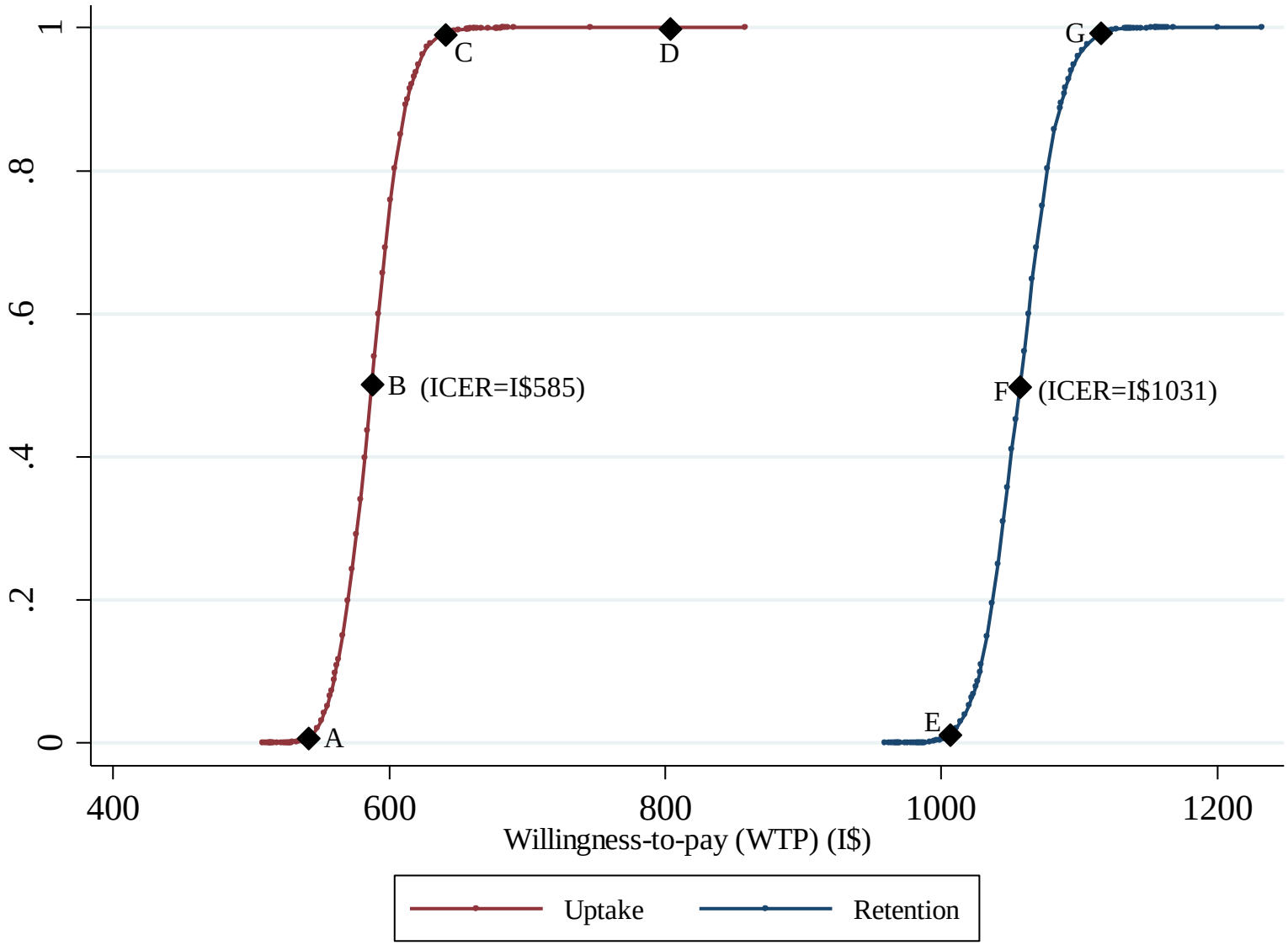


Figure 4: Society's willingness-to-pay for uptake of PMTCT services and retention in PMTCT care
This figure shows the uncertainty surrounding the mean incremental cost-effectiveness ratios (ICER) of the cash incentives with respect to PMTCT uptake and PMTCT retention. The steep slopes of the curves suggest a high degree of certainty surrounding the mean ICERs.

Appendices

Appendix B1: Overview of search terms for cost estimates

"prevention of mother-to-child transmission of HIV" OR "prevention of mother-to-child transmission" OR "PMTCT of HIV" OR "PMTCT" OR "vertical transmission of HIV" OR "Maternal and infant interventions in HIV" OR "prevention of vertical transmission of HIV" OR "mother-to-child transmission of HIV" OR "vertical transmission of HIV" OR "HIV"

AND

"cost" OR "cost analysis" OR "cost-effectiveness" OR "cost-utility" or "economic evaluation" or "cost-benefit analysis"

The study used these terms to search for cost estimates in Google, Google Scholar, Medline, and PubMed

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref
Recurrent costs								
Wages								
Clinical staff*	IntraHealth International	DRC	2016 USD	145.00	per nurse per m	per visit	0.33	[228]
	Becker-Dreps	DRC	2005 USD	1.15	per hour	per visit	0.58	[225]
	Adebeyi & Waldron	Zambia	2011 USD	1.32	per visit	per visit	1.32	[137]
	Mccoy et al.	Burkina Faso	2006 USD	204.50	per nurse per m	per visit	0.46	[229]
	Arise Project	Zimbabwe	2012 USD	1.10	per patient per m	per visit	1.10	[230]
	Scott et al.	Zambia	2011 USD	0.52	per nurse visit	per visit	1.04	[221]
	Maheswaran et al	Malawi	2014 USD	1.00	per visit	per visit	1.00	[139]
	Tagar et al.	Malawi	2011 USD	365.00	per nurse per m	per visit	0.83	[231]
	Tagar et al.	Ethiopia	2011 USD	117.00	per nurse per m	per visit	0.27	[231]
	Tagar et al.	Zambia	2011 USD	386.00	per nurse per m	per visit	0.88	[231]
	Tagar et al.	Rwanda	2011 USD	806.00	per nurse per m	per visit	1.83	[231]
	Jain et al.	Uganda	2012 USD	240.00	per nurse per m	per visit	0.55	[138]
Support staff†	Binagwaho et al.	Rwanda	2009 USD	3.30	per 18 m	per visit	0.55	[184]
	Bratt et al.	Zambia	2008 USD	0.41	Per visit	Per visit	0.41	[226]
Lab tests‡								
CD4 count	Toure et al.	Rwanda	2009 USD	11.20	per test	per test	11.20	[232]
	Bikilla et al.	Ethiopia	2005 USD	6.92	per person year	per test	3.46	[233]
	Jain et al.	Uganda	2012 USD	8.50	per test	per test	8.50	[138]
	Dutta et al.	LIC	2014 USD	5.40	per person-year	per test	2.70	[234]
	Ishikawa et al.	Zambia	2013 USD	5.00	per test	per test	5.00	[235]
	Scott et al.	Zambia	2011 USD	10.60	per test	per test	10.60	[221]
DNA PCR	Jain et al.	Uganda	2012 USD	42.00	per test	per test	42.00	[138]

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref
	Ishikawa et al.	Zambia	2013 USD	10.00	per test	per test	10.00	[235]
	Fasawe et al.	Malawi	2010 USD	32.50	per test	per test	32.50	[209]
	Khamadi et al.	Kenya	2007 USD	21.50	per test	per test	21.50	[223]
Medications‡								
HIV drugs (mothers) §								
Zidovudine	CHAI reference prices	LMIC	2016 USD	6.30	60 tablets per m	per m	6.30	[128]
	Perriens et al.	LMIC	2012 USD	121.00	per patient per y	per m	10.08	[236]
Zidovir	CHAI reference prices	LMIC	2016 USD	6.30	60 tablets	per m	6.30	[128]
	Perriens et al.	LMIC	2012 USD	140.00	per patient per y	per m	11.67	[236]
Zidolam-N (AZT/3TC/NVP)	CHAI reference prices	LMIC	2016 USD	8.20	60 tablets per m	per m	8.20	[128]
	Dutta et al.	LMIC	2014 USD	96.00	per patient y	per m	8.00	[234]
	Perriens et al.	LMIC	2012 USD	118.00	per patient per y	per m	9.83	[236]
Zidolam (AZT/3TC)	CHAI reference prices	LMIC	2016 USD	6.60	60 tablets per m	per m	6.60	[128]
	Scott et al.	Zambia	2011 USD	8.41	per patient m	per m	8.41	[221]
	Perriens et al.	LMIC	2012 USD	140.00	per patient per y	per m	11.67	[236]
Efavirenz (EFV)	CHAI reference prices	LMIC	2016 USD	3.80	30 tablets per m	per m	3.80	[128]
	Dutta et al.	LIC	2014 USD	93.00	per patient y	per m	7.75	[234]
	Scott et al.	Zambia	2011 USD	4.30	per patient m	per m	4.30	[221]
	Perriens et al.	LMIC	2012 USD	183.00	per patient per y	per m	15.25	[236]
Cotrimoxazole (mothers)	Fasawe et al.	Malawi	2010 USD	0.40	per m	per m	0.40	[209]
	Scott et al.	Zambia	2011 USD	0.93	per patient m	per m	0.93	[221]

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref
HIV drugs (infants)								
Nevirapine	CHAI reference prices	LMIC	2016 USD	7.00	per infant m	6 w	9.80	[128]
	Maclean et al.	Zambia	2003 USD	6.00	per m	6 w	8.40	[237]
	Kuznik et al.	Uganda	2011 USD	11.20	per 6 w	6 w	11.20	[185]
	Ciaranello et al.	Zimbabwe	2008 USD	4.50	per m	6 w	6.30	[238]
Cotrimoxazole (infants)	WHO	LMIC	2006 USD	0.03	per d	6 w	1.26	[222]
	Binagwaho et al.	Rwanda	2009 USD	12.30	per y	6 w	1.42	[184]
	Chitah	Zambia	2015 USD	0.20	per dose	6 w	0.60	[239]
Health facility deliveries‖	Kongo Emmanuel†	DRC	2016 FC	15000.00	per delivery (normal, PHC, unemployed)	per delivery	15000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	25000.00	per delivery (dystocia, PHC, unemployed)	per delivery	25000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	300000.00	per delivery (cesarean, PHC, unemployed)	per delivery	300000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	50000.00	per delivery (normal, PHC, employed)	per delivery	50000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	100000.00	per delivery (dystocia, PHC, employed)	per delivery	100000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	450000.00	per delivery (cesarean, PHC, employed)	per delivery	450000.00	[224]

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref
	Kongo Emmanuel	DRC	2016 FC	150000.00	per delivery (normal, SHC, unemployed)	per delivery	150000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	40000.00	per delivery (dystocia, SHC, unemployed)	per delivery	40000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	870000.00	per delivery (cesarean, SHC, unemployed)	per delivery	870000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	200000.00	per delivery (normal, SHC, employed)	per delivery	200000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	100000.00	per delivery (dystocia, SHC, employed)	per delivery	100000.00	[224]
	Kongo Emmanuel	DRC	2016 FC	950000.00	per delivery (cesarean, SHC, employed)	per delivery	950000.00	[224]
	The World Bank	DRC	2005 USD	3.00	per delivery	per delivery	3.00	[240]
	The World Bank	DRC	2005 USD	10.00	per delivery	per delivery	10.00	[240]
	The World Bank	DRC	2005 USD	5.00	per delivery	per delivery	5.00	[240]
	The World Bank	DRC	2005 USD	15.00	per delivery	per delivery	15.00	[240]
	The World Bank	DRC	2005 USD	10.00	per delivery	per delivery	10.00	[240]
	The World Bank	DRC	2005 USD	125.00	per delivery	per delivery	125.00	[240]
	Gibbons et al.	DRC	2008 USD	131.40	per delivery (cesarean)	per delivery	131.40	[241]
Counseling after delivery	Binagwaho et al.	Rwanda	2009 USD	0.16	per session	per session	0.16	[184]

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref
Transportation of DBS	Khamadi et al.	Kenya	2007 USD	0.50	per sample	per sample	0.50	[223]
Utilities	Adebeyi & Waldron	Zambia	2011 USD	3.15	per visit	per visit	3.15	[137]
	Menzies et al.	5 PEPFAR countries¶	2009 USD	4.85	per y, minimum	per visit	0.40	[227]
	Menzies et al.	5 PEPFAR countries¶	2009 USD	14.34	per y, mean	per visit	1.19	[227]
	Jain et al.	Uganda	2012 USD	0.50	per m	per visit	0.50	[138]
	Galarraga et al.	Benin	2009 USD	21.10	per y	per visit	1.76	[242]
	Maheswaran et al	Malawi	2014 USD	0.48	per visit	per visit	0.48	[139]
Opportunity cost of time #	US Department of State	DRC	2016 FC	1680.00	per day	per day	1680.00	[141]
Capital costs								
Equipment (Office & Medical)	Adebeyi & Waldron	Zambia	2011 USD	2.01	per visit	per visit	2.01	[137]
	Menzies et al.	5 PEPFAR¶ countries	2009 USD	6.97	per y, minimum	per visit	0.58	[227]
	Menzies et al.	5 PEPFAR countries¶	2009 USD	20.61	per y, mean	per visit	1.72	[227]

Abbreviations: DRC (Democratic Republic of the Congo); LMIC (Low-and-middle income countries); PCR (polymerase chain reaction); USD (United States Dollar); FC (Congolese Francs); WHO (World Health Organization); CHAI (Clinton Health Access Initiative); PEPFAR (Presidential Emergency Plan for AIDS Relief); PHC (primary health center); SHC (secondary health center). * We assumed that a patient was seen by one clinical staff (assumed to be a nurse) at each antenatal care (ANC) visit. We further assumed that a nurse takes care of 20 patients in a day and divided the monthly wage of a nurse by 22 because we also assumed that, as in many countries, normal work hours exclude weekends. The study by Becker-Dreps [225] provided an hourly cost estimate, so we assumed that each visit or interaction between the nurse and the patient lasted for 30 minutes and divided the hourly estimate by 2. † We assumed that one support staff was adequate at each ANC visit. ‡ Goods and services classified as tradable—goods that can be imported or exported[122], [124]; the rest were classified as non-tradable. § To estimate monthly costs for drugs, we divided annual costs by 12 or multiplied daily costs by 30. We assumed 15% for shipping and handling of the drugs [135] which we added to the estimates published by CHAI or Medicines Sans Frontier (MSF). We did not add the shipping and handling costs to estimates from peer-reviewed literature because these were assumed to have been included in the studies. ‖Estimates in local currency for health facility deliveries were not available, except for one study by Emmanuel Kongo [224] which did not indicate when the estimates were collected. So, we assumed that the estimates were collected in 2015—one year before the study was

Appendix B2: Candidate cost sources

Costs	Cost source	Country	Currency and year	Estimate	Original Unit	Common Derived Unit	Estimate common unit	Ref

published. ¶ The 5 PEPFAR countries were Uganda, Nigeria, Botswana, Ethiopia, and Vietnam. # We assumed that both the patient and their support spent one day traveling and receiving (waiting plus actual interaction with a nurse) health care services at the clinic and quantified the cost of this time in terms of lost wages or earnings. Because there was no data on earnings, we assumed that the patient and her support each lost the equivalent of the statutory minimum wage (1680 Congolese Francs) for the DRC[141], [243], in 2016.

Appendix B3: Analytic decisions and recommendations for conducting cost-effectiveness analyses

In this appendix, we outline a series of analytic decisions for estimating economic costs in the current study which were largely informed by CEA recommendations by WHO under the Cost Effectiveness and Strategic Planning[122], [124]. For completeness, we also present recommendations from two other organizations: The World Bank under the Disease Control Priorities Project (DCPP) [244], [245] and The US Panel on Cost-effectiveness in Health and Medicine[220], [246].

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	**Concept**	**Recommendations**	**Debate/commentary**	**Decision implemented**
Perspective	This is the viewpoint for conducting a CEA. Examples include: societal, payer (including donor, employer, insurer, and/or government), healthcare, clinical provider, or patient.	*WHO*: The study can be conducted from multiple perspectives, but the societal perspective should be primary. The societal perspective means that all costs associated with an intervention must be valued, regardless of who is paying for the intervention or service [122]. The rationale for this approach is that health and consumption of healthcare services contribute to social welfare [122]. *World Bank/DCPP*: The primary perspectives are the donor or partner and beneficiary (e.g., patient) perspective, although other perspectives like an implementer's may also be specified [245]. The rationale is that the donor	While many experts do not disagree with using the societal perspective as the primary perspective in CEA, they disagree on the extent of the societal perspective [247]. This is because including every aspect of the society affected by a health intervention may be burdensome to the analyst (thereby violating the "rule of reason"), particularly for interventions which extend survival or improve the quality of life. Additionally, while some experts do not agree with including future health-unrelated consumption or productivity benefits or losses, the position and guidance from other panels have been evolving on this matter. For example, the first US Panel (1996) on CEA recommended excluding	We used a societal perspective which was limited to the inclusion of transport costs and the opportunity cost of time for both the patient and her support. Productivity costs were not included because the RCT of the CCTs was not powered to estimate effects of the CCTs on averting new HIV infections or

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	Concept	Recommendations	Debate/commentary	Decision implemented
		and the beneficiary of an intervention or program face different costs and an intervention which is cost-effective from the beneficiary's perspective may not be cost-effective from the donor's perspective [245]. *US Panel*: CEA studies must be conducted from two perspectives: healthcare and societal perspectives [220].	productivity losses associated with an illness because such costs will have been captured in measures of quality life [246]. However, the second US Panel (2016) says that productivity gains or losses should be included whenever it is possible because there is no evidence suggesting that the quality of life measures reflect the productivity costs [220].	quality of life through increased survival.
Cost components	This decision is about which cost components to include in the analysis. The question is: should the analysis include direct (health-related) costs only or direct and indirect (health-unrelated) costs?	*WHO*: Include both direct and indirect costs. The rationale is that costs like caregiving, travel time, and waiting time need to be valued as they can determine whether an intervention is effective or whether people will seek healthcare services. Additionally, health and healthcare also affect families' consumption of other goods and services, either immediately or in the future[122], [124].	Many low-income countries, like the DRC, do not have properly functioning health systems or adequate healthcare infrastructure which pose barriers to accessing healthcare services[250], [251]. The trial of the CCTs was borne as an effort to help overcome barriers (e.g., transport costs) to accessing PMTCT services.	We included both direct and indirect costs.

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	Concept	Recommendations	Debate/commentary	Decision implemented
		World Bank/DCPP: Include direct costs only. The World Bank assumes that a properly functioning health system, defined as a health system that does not impose additional costs on consumers, is in place[244]. Furthermore, because some of the indirect costs can be higher than the cost of an intervention, some interventions may erroneously be deemed to be not cost-effective[244], [248]. *US Panel*: Include both direct and indirect costs. The rationale is the same as with WHO[249].		
Price level	This refers to whether resources consumed by the intervention should be valued at international or local prices.	*WHO:* Two recommendations are made by the WHO. First, to value the cost of an intervention using local prices when detailed cost data about the intervention have been collected. Furthermore, to use local prices when the intervention is more local that international comparisons are not necessary or meaningful [122], [124]. Second, to value the costs of the intervention at	The decision about price levels is often confused with the decision of currency choice[124], although in many cases the international prices are the US$ or the I$ (international dollar). Methods for deriving I$ are described below in a discussion of tradable and non-tradable and currency choice.	We used international price levels (in I$) because the results of the CEA might also be relevant to other countries, particularly those in Sub-Saharan Africa, where

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	Concept	Recommendations	Debate/commentary	Decision implemented
		international prices. The rationale is that the use of international prices can facilitate comparison of results from multiple studies across countries [122], [124]. *World Bank/DCPP:* Like WHO, the recommendation is to value the costs of an intervention at international prices. The rationale is also to facilitate comparison of results from multiple studies across countries[244].		mother-to-child transmission of HIV remains a challenge.
Distinguishing between tradable vs. nontraded goods.	Tradable goods—for example, medications—are those goods that can be imported or exported while non-tradable goods (for example, labor) are those that are produced locally and cannot be imported or exported [122], [124].	*WHO:* Tradable goods should be distinguished from non-tradable goods. The rationale is that these goods must be costed differently to reflect the correct value of the good, otherwise non-tradable goods will be undervalued if they are treated like tradable goods in countries with higher purchasing power [122], [124]. *World Bank/DCPP:* Distinguish between tradable and non-tradable	The difference between the WHO and World Bank/DCPP recommendations is in the valuation of non-tradable goods. According to the World Bank, if the cost of a non-tradable good is in local currency, then it must be converted to US$ using the nominal (official) exchange rate of that country's local currency to the US$. s that if the cost estimate of a non-tradable good (e.g., buildings) is being extrapolated from another setting with the estimate already in US$, then no further conversion is required. On the other hand,	We distinguished between tradable and non-tradable goods.

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	Concept	Recommendations	Debate/commentary	Decision implemented
		goods. The rationale is that tradable (imported) goods are already in US$ while the cost of non-tradable goods must be converted to US$ using exchange rates[244]. *US Panel:* Not discussed	the WHO recommendation is that all non-tradable goods should be converted using purchasing power parity (PPP)—the number of units of a local currency required to buy the same quantities of goods and services as one US$ would do in the United States[122]. The unit cost of goods and services valued this way is the international dollar (I$) and 1I$=1US$. WHO also recommends that non-tradable goods quoted in US$ should be converted using the ratio of the PPP conversion factor to the official exchange rate of that country to the USD in the year of the cost estimate. Thus, using the PPP exchange rates eliminates price differences when converting or transferring costs across countries[123], [124]. The World Bank argues against using the PPP because the I$ is hypothetical and is not informative of how much an intervention costs which is important for budgeting purposes[244].	
Currency choice	This refers to the choice of currency for reporting costs. This is particularly important	*WHO:* 1) When the analyst has decided to use international price levels and to distinguish between tradable and non-tradable goods, the recommendation is	While both the US$ and I$ may facilitate international comparisons of results from different studies, the World Bank notes that the I$ is hypothetical and is not	We used I$ because, as argued by the WHO, the US$ only tells you

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	Concept	Recommendations	Debate/commentary	Decision implemented
	as this study draws estimates from multiple sources with the cost estimates in different currencies. Furthermore, the choice of currency is informed by two analytic decisions presented above: price levels and distinguishing between tradable and non-tradable goods.	to use I$ which is derived when the PPP exchange rate is used (see discussion on tradable vs. non-tradable goods). The rationale is that using the PPP exchange rates eliminates price differences when converting or transferring costs across countries [122], [124]. *World Bank/DCPP:* To use the US$. The rationale is that the US$ is informative of how much an intervention actually costs[244].	informative of how much an intervention costs and is not relevant to decision makers interested in budgeting or expanding interventions[244]. But the argument by WHO is that, in many cases, the I$ accurately reflects what people can purchase given a certain amount of resources and the US$ fails to convey this information.	the cost of an intervention but it does not tell you its value.
Year for reporting costs.	This refers to the year for reporting results of the CEA	This varies from study to study and depends on the analyst's assessment of what the aims of the CEA are, so there are no clear guidelines on which year to use.	For the current study, there are three options: 1) 2013: Start date of the RCT of the CCTs in the DRC; 2) 2015: End date of the RCT in the DRC; and 3) 2016: Year for which the most current data for inflation adjustment and currency conversion are available.	We used 2016 as the base year because it is the year for which the most recent conversion data were available.

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	**Concept**	**Recommendations**	**Debate/commentary**	**Decision implemented**
Inflation adjustment	Adjusting for inflation removes the effect of price changes and is necessary when the original cost data are reported in different years. Inflation adjustment will allow us to obtain estimates in a constant currency. Thus, the data from years prior to the chosen year will be inflated while data from later years will be deflated.	*WHO:* Inflation adjustment to be done using the GDP (gross domestic product) deflator—an index number comparing real GDP to nominal GDP. The GDP deflator is recommended because it covers price changes in a broad range (almost everything) of economic activity, including health sector costs [122], [124], [252]. *World Bank/DCPP:* Not discussed *US Panel:* Inflation adjustment to be done using the medical price index[249]. The rationale is that, unlike the general consumer price index (CPI), the medical price index more accurately reflects changes in prices in the healthcare sector as it is specific to that sector.	The main problem with the GDP deflator is that in many low-income countries, like the DRC, it fails to account for heterogeneity among sectors and can lead to wrong conclusions[253]. Although the medical CPI is recommended, it is not available for the DRC.	We adjusted for inflation using the GDP deflator as it is the only recommended inflation-adjustment method which is readily available.
Order for inflation adjustment and	When transferring costs across time and space, the order in which inflation	*WHO:* Adjust for inflation before applying exchange rates. The rationale is that inflation in countries like the DRC also depends on exchange rates,	The issue of whether inflation adjustment is done before currency conversion is almost a settled issue.	We first adjusted for inflation before

Appendix B3: Recommendations for cost analysis and analytic decisions

Analytic decision	**Concept**	**Recommendations**	**Debate/commentary**	**Decision implemented**
exchange rate application	adjustment and exchange rates are applied can affect the eventual cost estimates and whether an intervention is cost-effective.	and because of weaker currencies, the inflation rate is much higher than in developed countries. This means that adjusting for inflation after currency conversion will more likely overvalue non-tradable goods[123]. Julia Fox-Rushby, who has published some of the CEA guidelines by the World Bank, also recommend adjusting for inflation before applying exchange rates[254].		applying exchange rate conversion.

Appendix B4: Fieller's theorem for estimating confidence intervals for incremental cost-effectiveness ratios.

Note: This appendix draws heavily from Glick, 2014.

Fieller's method is a parametric method for estimating confidence intervals for ratios like the incremental cost-effectiveness ratio (ICER). Compared to other parametric methods such as the normal distribution interval, Fieller's method has one advantage: the method takes into account the skewness of the ratio as it does not require the distribution of the ICER to be normal or symmetrical [131], [159], [162]. Briefly, the parametric Fieller's method proceeds as follows: let the bivariate normal distribution of the difference in mean costs and effects be represented by the expression RQ-C with a mean of zero [131]. In this expression, R=C/Q and Q is the difference in the mean effect and C is the difference in the mean cost [131]. Glick (2015) notes that when this expression is standardized using its standard error and setting it equal to a critical *t-value*, the result is a quadratic equation in R. If we take the square root of the quadratic equation in R, which also includes the Pearson correlation coefficient (ρ) between C and Q, we obtain the lower and upper confidence limits of the ICER [131]. The confidence intervals are as follows:

$$Lower\ Limit = \frac{[\mathrm{CQ} - (t_{\frac{\alpha}{2}})^2 \rho se_c\ se_q] - \{[\mathrm{CQ} - (t_{\frac{\alpha}{2}})^2 \rho se_c\ se_q] - [Q^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_q)(C^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_c]\}^{0.5}}{Q^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_q}$$

$$Upper\ Limit = \frac{[\mathrm{CQ} - (t_{\frac{\alpha}{2}})^2\ \rho\ se_c\ se_q] + \{[\mathrm{CQ} - (t_{\frac{\alpha}{2}})^2\ \rho\ se_c\ se_q] - [Q^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_q)(C^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_c]\}^{0.5}}{Q^2 - (t_{\frac{\alpha}{2}})^2 se^2{}_q}$$

In these equations:

C and Q are the differences in mean costs and mean effects in the two groups.

$t_{\frac{\alpha}{2}}$ is the critical value from a student's t-distribution; $t_{\frac{\alpha}{2}}$ = 1.96 for 95% C.I.

ρ is the Pearson correlation coefficient between C and Q.

se_c and se_q are the standard errors for C and Q, respectively.

Interpretation of the confidence limits:

- A statistically significant difference in effects between the two groups exists only when the denominator is positive and the interval is lower to upper limit [131].
- Negative denominators mean there is no statistically significant difference between the two groups. In that case, the upper limit is smaller than the lower limit [131].
- If there is no statistically significant difference in both effects and costs part of the numerator for which we are taking the square root (the term in brackets) will likely be negative, making the lower and upper limits undefined as negative numbers do not have square roots [131].

Stata do file

```
/*capture log close
set more off
log using cea.log, text replace
insheet using cea_new.csv, comma clear

*listing all the variables
ds

format %12s observations

*generating treatment
gen treatment=.
replace treatment=0 if group=="Soins habituels"
replace treatment=1 if group=="Intervention - Cash"
label define treatment 0 "Control" 1 "Treatment", replace
label values treatment treatment
tab treatment
tab treatment group

*working with the variables
codebook marital_status
encode marital_status, gen(marstatus)


*transport cost has some values missing
order transportcost transportcostart
tab transportcost transportcostart , m

replace transportcost=transportcostart if transportcost==.

*multiple imputation of missing transport costs
misstable patterns transportcost, bypatterns

mi set mlong
mi register imputed transportcost /*registers transportcost as the variable
to be imputed*/

mi misstable summarize treatment ses transportcost

mi impute pmm transportcost treatment uptakepmtct incaresixweek i.ses
yearofeducation ///
earlyancvisit traveltime i.transportmode i.marstatus age gestationalage,
add(20) knn(5) rseed(2232)

mi estimate: regress transportcost treatment uptakepmtct incaresixweek i.ses
///
yearofeducation earlyancvisit traveltime i.transportmode i.marstatus age
gestationalage

*checking how the imputation worked
mi estimate, vartable dftable /*as expected only travel time and SES
siginificantly predicted transport cost*/
```

```
*keeping a single dataset of imputed transport cost data
keep if _mi_m > 0
collapse (mean) transportcost , by( pidc)

save cea_imputed, replace
export excel using "cea_imputed", firstrow(variables) replace

log close*/

***ANALYSIS BEGIN HERE
capture log close
set more off
log using cea_analysis, replace

insheet using cea_DRC_PPP_final.txt, tab clear

*formatting column widths
format %12s obs

*listing all the variables
ds

*ordering variables
order pidc group amountpaid ltfubydelivey incaresixweek ltfuat6wk uptakepmtct
///
cost_pp cost_sp datepremierevisit visitnumber artstartdate aztstartdate
cotrim_final ///
deliverydate gestationalage

*generating treatment
gen treatment=.
replace treatment=0 if group=="Control"
replace treatment=1 if group=="Intervention"
label define treatment 0 "Control (No CCTs)" 1 "Intervention (CCTs)" 2
"Control (No CCTs)", replace
label values treatment treatment
tab treatment
tab treatment group
drop if treatment==.

*correcting the variable incare at 6 wks postpartum. It seems 1s should be 0s
ans 0s 1s
tab treatment incaresixweek
recode incaresixweek 0=2
recode incaresixweek 1=0
recode incaresixweek 2=1
label define incaresixweek 0 "Not in care" 1 "In care", replace
label values incaresixweek incaresixweek
tab treatment incaresixweek

*Uptake of PMTCT services
tab treatment uptakepmtct
label define uptakepmtct 0 "No uptake" 1 "Uptake", replace
label values uptakepmtct uptakepmtct
tab  uptakepmtct treatment

*Early ANC visit
```

```
tab earlyancvisit treatment
label define earlyancvisit 0 "Late ANC" 1 "Early ANC", replace
label values earlyancvisit earlyancvisit
tab earlyancvisit treatment

*marital status and cohabitation
codebook marital_status
encode marital_status, gen(marstatus)
codebook marstatus
tab marstatus treatment
replace marstatus=0 if marstatus!=1
replace marstatus=1 if cohabitation=="yes" /*assumes that cohabiting is
marriage*/
label define marstatus 1 "Married" 0 "Not married", replace
label values marstatus marstatus
tab marstatus treatment

*first pregnancy
tab primiparus
rename primiparus firstpregnancy
label define firstpregnancy 0 "Not first pregnancy" 1 "First pregnancy",
replace
label values firstpregnancy firstpregnancy

*HIV disclosure
codebook disclosure
encode disclosure, gen(disclosure1)
drop disclosure
rename disclosure1 disclosure
recode disclosure 1=0 2=1
label define disclosure 0 "No" 1 "Yes", replace
label values disclosure disclosure
tab disclosure

*Transport mode
tab transportmode treatment
recode transportmode 2=0 3=0
label define transportmode 0 "Other means" 1 "Walk", replace
label values transportmode transportmode
tab transportmode treatment

*education
tab educlevel
rename educlevel education
label define education 0 "No education" 1 "Primary" 2 "Secondary or higher",
replace
label values education education
tab education treatment

*SES
rename ses wealth
codebook wealth
label define wealth 4 "Fifth (richest)" 3 "Fourth" 2 "Third" 1 "Second" 0
"First (poorest)", replace
label values wealth wealth
tab wealth treatment
```

```
*labelling variables
label var pidc "Pateint ID"
label var treatment "Intervention"
label var amountpaid "Incentive paid"
label var age "Age"
label var incaresixweek "PMTCT Retention"
label var cost_pp "Cost (Payer perspective)"
label var cost_sp "Cost (Society perspective)"
label var datepremierevisit "Enrollment date"
label var disclosure "HIV disclosure"
label var gestationalage "Gestational age"
label var uptakepmtct "PMTCT Uptake"
label var traveltime "Travel time"
label var earlyancvisit "Early ANC visit"
label var yearofeducation "Education (years)"
label var wealth "Wealth quintile"
label var incentive "Incentive paid"
label var transportmode "Travel mode"


*SUMMARIZING DATA
*TABLE OF DEMOGRAPHIC CHARACTERISTICS

*checking the distribution of costs
sum cost_pp

recode treatment 0=2

hist cost_sp, by(treatment, note("")) freq subtitle(, size(medium)) ///
      by(, title("Figure 1: Cost distribution in the intervention and Control
groups, societal perspective", size(medium large) col(black))) ///
      xtitle(Cost (2016 I$)) ///
      legend(rows(1)) ///
      graphregion(fcolor(white)) ///
      ylab(, nogrid)
      *graphregion(color(white))
      graph save "cost_distribution_sp", replace

hist cost_pp, by(treatment, note("")) freq subtitle(, size(medium)) ///
      by(, title("Figure 1: Cost distribution in the intervention and Control
groups, payer perspective", size(medium large) col(black))) ///
      xtitle(Cost (2016 I$)) ///
      legend(rows(1)) ///
      graphregion(fcolor(white)) ///
      ylab(, nogrid) graphregion(color(white))
      graph save "cost_distribution_pp", replace

*graph combine cost_distribution_sp.gph cost_distribution_pp.gph

recode treatment 2=0

count if cost_sp<200 & treatment==1
count if cost_sp>=450 & treatment==1
count if cost_sp>600 & treatment==1

count if cost_sp<200 & treatment==0
count if cost_sp>=450 & treatment==0
```

```
count if cost_sp>600 & treatment==0

gen g_than_450=0
replace g_than_450=1 if cost_sp>=450
tab treatment g_than_450, row

*dpplot costparticipant, dist(gamma) param(`e(alpha)' `e(beta)')

*sample characteristics
tabstat cost_pp cost_sp, by(treatment) stats(mean sd median p25 p75)
tabstat cost_pp cost_sp age gestationalage yearofeducation traveltime,
by(treatment) stats(mean sd median p25 p75)
ttest cost_pp, by(treatment)
ttest cost_sp, by(treatment)
ranksum cost_pp, by(treatment)
ranksum cost_sp, by(treatment)

*summary of number of visits
sum visitnumber, d
tab treatment, sum(visitnumber)
hist visitnumber, by(group)
ttest visitnumber , by(treatment) level(90)
tabstat visitnumber, by (treatment) stats(mean median sum)

*cost per visit
bysort treatment: egen cost_per_visit=mean(cost_sp/visitnumber)

*TABLE SUMMARIZING COSTS
*checking the distribution of continuous variables
mvtest normal cost_pp cost_sp age traveltime yearofeducation incentive
gestationalage , bivariate univariate stats(all)

*performing the Mann-Whitney test

foreach var of varlist incentive cost* {
ranksum `var', by(treatment)
}

foreach var of varlist yearofeducation age traveltime gestationalage {
ranksum `var', by(treatment)
}



foreach var of varlist  uptakepmtct incaresixweek education wealth marstatus
earlyancvisit firstpregnancy disclosure transportmode {
tab  `var' treatment, col chi2
}
*effectiveness

*unadjusted risk ratios
cs incare treatment, exact
cs uptake treatment, exact

order pid cost_* incare uptake treatment treatment incentive traveltime
education marstatus firstpregnancy earlyancvisit  disclosure wealth
transportmode
```

```
*exporting the dataset to SAS for comparing analyses in Stata and those
performed in SAS
save cea_analysed_forsas, replace
saveold cea_analysed_forsasv12, version(12) replace
fdasave cea_analysed_forsas, rename replace
outsheet using cea_analysedforsas.txt, comma replace

*putting controls in a global macro
global controls "treatment earlyancvisit disclosure age i.marstatus
i.education i.wealth firstpregnancy transportmode"


*exploratory OLS multivariate model
mvreg cost_sp cost_pp = $controls

**GEE MODELS
xtset clinic

*EFFECTIVENESS
xtgee incaresixweek $controls, family(poisson) link(log) corr(exch) robust
eform
*xtgee incaresixweek $controls, family(bin) link(log) corr(exch)

estimates store incare
estimates replay, eform

/*xtgee uptake $controls, family(poisson) link(log) corr(exch) vce(robust)
eform
estimates store uptake*/

xtgee uptake $controls, family(poisson) link(log) corr(exch) robust
estimates store uptake
estimates replay, eform


**Getting the number needed to treat (this will be used in the CEA)
*incare
global controls "treatment age i.marstatus yearofeducation"
binreg incaresixweek $controls, rd vce(robust)
gen rd_incare=_b[treatment]
gen sd_rd_incare=0.0404129
gen NNT_incare=1/_b[treatment]
list NNT_incare in 1/1
*predicting risk of being in care
predict risk_incare, xb
tab treatment, sum(risk_incare)

*uptake
binreg uptake $controls, rd vce(robust)
gen rd_uptake=_b[treatment]
gen sd_rd_uptake=0.0462205
gen NNT_uptake=1/_b[treatment]
list NNT_uptake in 1/1
*predicting risk of taking up PMTCT services
predict risk_uptake, xb
tab treatment, sum(risk_uptake)
```

```
**COSTS
*identifying the family using the modified park test
global controls "treatment age i.marstatus i.education i.wealth
transportmode"
glm cost_pp $controls, family(gamma) link(identity) vce(robust)
predict resid, dev
predict yhat, xb
gen resid_sq=resid^2
glm resid_sq yhat, family(gamma) link(identity) vce(robust)
test yhat=0
test yhat=2 /*shows that the gamma should be used. See this link for this
test:
http://www.uphs.upenn.edu/dgimhsr/documents/ispor15.glmworkshop.glick.2.pdf*/
drop resid* yhat

**Payer perspective
xtgee cost_pp $controls, family(gamma) link(identity) corr(exch) vce(robust)
estimates store cost_pp
*incremental cost
gen Inc_cost_pp=_b[treatment]
gen sd_cost_pp=11.52162 /*standard errors*/
gen sample_size=217 /*sample size*/

*predicted costs
predict pred_cost_pp, xb

**Society perspective
xtgee cost_sp $controls, family(gamma) link(identity) corr(exch) vce(robust)
estimates store cost_sp
*incremental cost
gen Inc_cost_sp=_b[treatment]
gen sd_cost_sp=13.29177 /*standard errors*/
*predicted costs
predict pred_cost_sp, xb

/*table of costs*/
esttab cost_pp cost_sp using costs.csv , plain nogaps b(a2) ci(a4)  wide
replace  label obslast star ///
      refcat (treatment "Ref: Control group" 1.wealth "Ref: First
quintile(poorest)" ///
      1.education "Ref: No education" 1.marstatus "Ref: Not married"
transportmode "Ref: Other means") ///
      collabels("2016 I$" "2016 I$") ///
      drop (0.wealth 0.marstatus 0.education) brackets ///
      addnote("95% Confidence intervals in brackets; * p<0.05, ** p<0.01, ***
p<0.001") ///
      title( "Table 5: Adjusted costs and effectiveness of conditional cash
transfers")

*table of effectiveness
esttab uptake incare using effectiveness.csv, plain eform nogaps b(a3) ci
replace  label wide obslast star ///
      refcat (treatment "Ref: Control group" 1.wealth "Ref: First
quintile(poorest)" ///
      1.education "Ref: No education" 1.marstatus "Ref: Not married"
transportmode "Ref: Other means") ///
```

```
      collabels("Relative risk" "Relative risk") ///
      drop (0.wealth 0.marstatus 0.education) brackets ///
      addnote("95% Confidence intervals in brackets; * p<0.05, ** p<0.01, ***
p<0.001") ///
      title( "Table 5: Adjusted effectiveness of conditional cash transfers")

**generating incremental cost effectiveness ratios
*incare
*payer perspective
gen ICER_pp_incare=Inc_cost_pp*NNT_incare

*society perspective
gen ICER_sp_inccare=Inc_cost_sp*NNT_incare

*uptake
*payer perspective
gen ICER_pp_uptake=Inc_cost_pp*NNT_uptake

*society perspective
gen ICER_sp_uptake=Inc_cost_sp*NNT_uptake

list NNT_incare NNT_uptake ICER_pp_incare ICER_sp_inccare ICER_pp_uptake
ICER_sp_uptake in 1/1

**caculating confidence intervals using the Fieller's theorem
*payer perspective
list Inc_cost_pp sd_cost_pp sample_size rd_uptake sd_rd_uptake sample_size in
1/1
list Inc_cost_pp sd_cost_pp sample_size rd_incare sd_rd_incare sample_size in
1/1

*society perspective
list Inc_cost_sp sd_cost_sp sample_size rd_uptake sd_rd_uptake sample_size in
1/1
list Inc_cost_sp sd_cost_sp sample_size rd_incare sd_rd_incare sample_size in
1/1

***BOOTSTRAPPING 95% FOR THE ICER
*recall that the following are the steps involved

*1. Generate a sample of nt cost and effect pairs from the experimental group
data with replacement. The cost and effect pairs need to be resampled
together as they are inter-dependent.
*2. Generate a sample of nc cost and effect pairs from the control group data
with replacement
*3. Calculate the ICER for this bootstrap resample.
*4. Repeat this procedure 1000 times, to get 1000 bootstrap estimates of the
ICER. These estimates then define the empirical sampling distribution of the
ICER.

*1&2. Bootsrapping to create treatment and control groups of sizes similar to
the trial
bootstrap pred_cost_pp pred_cost_sp  risk_incare risk_uptake  if
treatment==0, reps(217) cluster(clinic) saving(control, replace) seed(1980):
summarize
bootstrap pred_cost_pp pred_cost_sp risk_incare risk_uptake if treatment==1,
reps(216) cluster(clinic) saving(treat, replace) seed(1980): summarize
```

```
save cea_analysed, replace

*combining the resampled datasets of treatment and control groups
use control, clear
gen treatment=0
save control, replace

use treat, clear
append using control
replace treatment=1 if treatment==.
rename _bs_1 cost_pp
rename _bs_2 cost_sp
rename _bs_3 risk_incare
rename _bs_4 risk_uptake

*3. Calculating the ICER and 95% C.I. from the bootstrap resample
program icer, rclass
          version 14.2
              ****costs
              ***payer perspective
              summarize cost_pp if treatment==0, meanonly
          local a = r(mean)
          summarize cost_pp if treatment==1, meanonly
          local b = r(mean)
              return scalar Inccost_pp=`b'-`a'
              **incare
              summarize risk_incare if treatment==0, meanonly
              local c=r(mean)
              summarize risk_incare if treatment==1, meanonly
              local d=r(mean)
              *NNT
              return scalar diff_incare= `d'-`c'
              return scalar NNT_incare=1/(`d'-`c')
              *ICER
              return scalar ICER_incarePP =(`b'-`a')/(`d'-`c')
              **uptake
              summarize risk_uptake if treatment==0, meanonly
              local e=r(mean)
              summarize risk_uptake if treatment==1, meanonly
              local f=r(mean)
              *NNT
              return scalar diff_uptake=`f'-`e'
              return scalar NNT_uptake=1/(`f'-`e')
              *ICER
              return scalar ICER_uptakePP =(`b'-`a')/(`f'-`e')
              *society perspective
              summarize cost_sp if treatment==0, meanonly
              local g=r(mean)
              summarize cost_sp if treatment==1, meanonly
              local h=r(mean)
              return scalar Inccost_sp=`h'-`g'
              *in care
              return scalar ICER_incareSP=(`h'-`g')/(`d'-`c')
              *uptake
              return scalar ICER_uptakeSP =(`h'-`g')/(`f'-`e')
end
```

```
*4. Bootstrapping the ICERs.
bootstrap r(Inccost_pp) r(Inccost_sp) r(diff_uptake) r(NNT_uptake)
r(diff_incare) r(NNT_incare) r(ICER_incarePP) r(ICER_uptakePP)
r(ICER_incareSP) r(ICER_uptakeSP), saving(trial, replace) bca reps(1000)
seed(1980) strata(treatment) nodots: icer summarize
program drop icer
save CEA_with_CI, replace

**GENERATING CEA ACCEPTABILITY CURVES
*bootstraping differences in mean costs and mean effects. Note that above
what was bootstrapped was the ICER itself.
capture program drop bscer
program define bscer

            sum `1' if `5'==1,meanonly
            scalar meancostpp=r(mean)
            sum `1' if `5'==0,meanonly
            scalar diffcostPP=meancostpp-r(mean)


            sum `2' if `5'==1,meanonly
            scalar meancostsp=r(mean)
            sum `2' if `5'==0,meanonly
            scalar diffcostSP=meancostsp-r(mean)

            sum `3' if `5'==1,meanonly
            scalar meanriskincare=r(mean)
            sum `3' if `5'==0,meanonly
            scalar diffriskincare=meanriskincare-r(mean)

            sum `4' if `5'==1,meanonly
            scalar meanriskuptake=r(mean)
            sum `4' if `5'==0,meanonly
            scalar diffriskuptake=meanriskuptake-r(mean)

            scalar ICER_incarePP= diffcostPP/diffriskincare
            scalar ICER_uptakePP=diffcostPP/diffriskuptake
            scalar ICER_incareSP= diffcostSP/diffriskincare
            scalar ICER_uptakeSP=diffcostSP/diffriskuptake

end

scalar exper=0

clear
use CEA_analysed
bootstrap "bscer pred_cost_pp pred_cost_sp risk_incare risk_uptake treatment
clinic " "diffcostPP diffcostSP diffriskincare diffriskuptake ICER_incarePP
ICER_incareSP ICER_uptakePP ICER_uptakeSP", reps(4000) saving(Cost&Effects)
replace strata(treatment) cluster(clinic)

clear
quietly do bsceaprogs
use Cost&Effects
sum
corr
```

```
quietly do bsceagraphs
*uptake
bscicer _bs_2 _bs_4 .95
bscicergraph
bsaccept  _bs_2 _bs_4 .95
bsaccgraph
*incare
bscicer _bs_2 _bs_3 .95
bscicergraph
bsaccept  _bs_2 _bs_3 .95
bsaccgraph

*CEA curve
clear
import excel "Willingess-to-pay_final.xlsx", sheet("Sheet1") firstrow
case(lower) clear
keep wtpacceptp retention uptake
scatter retention uptake wtpacceptp,  connect(dot dot) msize(tiny tiny) ///
    xtitle("Willingness-to-pay (WTP)", size(3.0)) ///
      ytitle("% acceptable", size(3.0) height(7)) ///
      graphregion(color(white)) ///
      xline(402 803 1205) ///
      yline(0.1 0.5 0.8) ///
      legend(order(2 "Uptake" 1 "Retention")) ///
      title("Figure 2: Willingness-to-pay for uptake of PMTCT services and
retention in PMTCT care", size(3.5) col(black))
graph save WTP_final, replace

log close
log2html cea_analysis, replace
**sensitivity analysis
```

Chapter 3: Guideline concordance of time to follow-up of anal cancer screening in women living with HIV at high-risk for acquiring anal cancer

Abstract

Background: In the past 2-3 decades, the incidence of anal cancer has increased significantly among women with HIV. This calls for a better understanding of receipt of anal screening in this population, particularly among those at increased risk of acquiring anal cancer. While some evidence suggests that these women receive initial anal cancer screening, it is unclear whether they also receive follow-up screening consistent with the guidelines for anal cancer screening in this population. This study examines the guideline concordance of the time to follow-up for anal cancer screening in women with HIV with histories of abnormal cervical tests or genital warts.

Methods: Data for this analysis came from administrative claims of Medicaid beneficiaries ages 19–64 years who qualified for Medicaid based on income and disability and who were continuously enrolled for ≥ 24 months. We created a 4-year retrospective cohort (2009-2012) of high-risk women using ICD-9 codes for abnormal cervical tests or genital warts. We estimated the follow-up time as the time from the date of the first anal cancer screen (after a high-risk diagnosis) to the date of the second screen. Follow-up time was guideline-concordant if the follow-up screening was performed in ≤ 6 months for those with abnormal results on the first screen and ≤ 12 months for those with normal results on the first screen. We used the Kaplan-Meier to estimate the follow-up time and modeled the guideline concordance of the follow-up time using logistic regressions. In sensitivity analysis, we restricted the sample to those continuously enrolled for 4 years, expanded the number of ICD-9 codes used to define a sample of high-risk women with HIV, and examined follow-up time of anal cancer screening at thresholds higher than those stipulated in the guidelines.

Results: A total of 3,779 high-risk women were eligible for follow-up screening and contributed 4,458 person-years. The median time to follow-up screening was 16.1 months (95% C.I.=15.2,17.6) and was shortest among women with histories of both risk factors (median=9.3, 95% C.I.=7.6,11.0 months). The time to follow-up screening was guideline-concordant for 47.3% (95% C.I.=42.0,53%) of high-risk women with abnormal results on the first screen and for 40.0% (95% C.I.=38.0,41.4%) for those with normal results. The time to follow-up screening was not guideline concordant for women with one risk factor. The odds that time to follow-up screening was guideline concordant were more than twice among women with two risk factors compared with those with a single risk factor for anal cancer (OR=2.06, 95% C.I.=1.73,2.46). These findings persisted in sensitivity analyses.

Conclusions: Time to follow-up anal cancer screening is not guideline-concordant overall and for nearly two-thirds of women with a single risk factor. Training providers in high-resolution anoscopy, gathering more evidence about the benefits of anal cancer screening to clarify the guidelines for anal cancer screening, and creating a billable procedural code for anal cancer screening could help to increase the rates of follow-up anal cancer screening in high-risk women.

1. Introduction

Among all non-AIDS-defining cancers[4], anal cancer has recorded the largest increase in incidence over the past 2-3 decades [256]. These increases have been observed in all groups of people living with HIV (PLWH), including women [257]–[259]. In that period, the incidence of anal cancer among women with HIV increased by 40% and is still increasing [257]–[260]. The high and rising incidence of anal cancer in women with HIV suggests that screening for anal cancer is critical in this population. This is particularly true in this era of combination antiretroviral therapy when PLWH have life expectancies similar to the general population but who are at a higher risk for many diseases, including anal cancer [261]–[263]. For example, data show that the incidence of anal cancer is 30 per 100,000 person-years in women with HIV, which is 15 times greater than in women without HIV [264].

Anal cancer screening leads to early detection of abnormal anal cells otherwise known as anal intraepithelial neoplasia (AIN[5]), making effective secondary prevention possible [267], [268]. The evidence suggests that rates of abnormal anal test results range from 12 to 42% [269]–[275] and that AIN can develop quickly in women with HIV [273] even if the women have normal anal cells at baseline [270]. Further evidence suggests that untreated low-grade AIN can progress to high-grade AIN within 2 years in many PLWH [267] and that untreated high-grade AIN can progress to anal cancer in less than one year [268]. However, among those screened and treated for AIN, the rates of progression are much lower [267], [268]. Additional evidence also suggests

[4] A cancer is AIDS-defining if its onset marks progression from HIV to AIDS [255]
[5] AIN is used to describe biopsy-confirmed results of anal cancer screening. Less severe lesions are classified as AIN1 while more severe ones are classified as AIN2 or AIN3 [265], [266]. On the hand, cytology results are reported as squamous intraepithelial lesions (SIL) and are classified as low-grade or high-grade SIL [265], [266]. These classifications are based off the terminology used in cervical cancer screening [265], [266].

that early detection of cancerous anal cells has survival benefits. The 5-year survival rates for localized, regional, and metastatic anal cancers are 0.78, 0.56, and 0.18, respectively [276].

While guidelines exist for anal cancer screening [277], little is known about the timing of screening for this cancer in women with HIV. This is particularly true for time to follow-up of anal cancer screening among women living with HIV at increased risk of acquiring anal cancer. Regular anal cancer screening is recommended for these at-risk women including those with histories of abnormal cervical tests or genital warts [277]–[279], two groups whom we collectively define as high-risk. Previous studies of anal cancer screening frequency in PLWH mainly focused on men who have sex with other men (MSM) [280]–[286], with women rarely included in those studies. While the few studies that included women provide some evidence of initial anal cancer screening in high-risk women with HIV [269]–[275], it is unclear whether high-risk women also receive follow-up screening and whether the timing of the follow-up screening is concordant with the guidelines. Studies that examined follow-up anal cancer screening in women with HIV had small sample sizes, were limited in geographic scope [270], [273], [275], [282], [283], or did not stratify findings by anal cancer risk factors [287], [288].

Guidelines for anal cancer screening by the HIV Medical Association recommend screening at baseline in all PLWH but thereafter, the screening depends on the outcome of the initial test and the risk of the individual [277]. When abnormal anal cells are detected at the initial test, follow-up screening is recommended in 6 months. When the initial test is normal, a follow-up test is recommended in 12 months but only in PLWH at high-risk for acquiring anal cancer, **figure 1**. This includes women with histories of abnormal cervical tests or genital warts, two groups of women at the center of this study.

Given these guidelines and the limitations of previous studies, the goal of the current study is to examine the guideline concordance of the time to follow-up of anal cancer screening in high-risk women, and whether this varies by the risk factors for anal cancer. We overcome limitations of previous studies by creating a large retrospective cohort of high-risk women from Medicaid administrative claims data in the US South.

1.1. Conceptual framework

We adapted Andersen's behavioral model of healthcare utilization to develop a conceptual framework for understanding the frequency of follow-up anal cancer screening in high-risk women [289], **figure 2**. The framework consists of three domains: individual and population characteristics, use of health services, and outcomes. It posits that health service utilization is a result of the interplay of three individual/population characteristics—predisposing factors, enabling resources, and need [289]. We emphasize that the focus of the current study is on the utilization of follow-up anal cancer screening services and not the benefits of the screening.

From left to right, the first part of the framework consists of predisposing factors—factors which exist before a person's need for healthcare arises. Although these factors do not define a person's health service utilization, they suggest the propensity that a person will need health services. The predisposing factors—for example, age—are exogenous and only affect healthcare utilization through enabling resources [289]–[291]. Next, enabling resources are necessary—although insufficient—for health services utilization to occur [289], [290]. These resources, for example, income, can facilitate follow-up anal cancer screening if available or impede it if unavailable.

Finally, individuals must have a need for healthcare if services are to be utilized. The need can be perceived (subjective) or evaluated (objective) [289]–[291]. While women with HIV have a need for anal cancer screening overall [292]–[296], the need is greater among those with one risk

factor for acquiring anal cancer and much greater among those with multiple risk factors [277]–[279]. Therefore, we expect the timing of follow-up anal cancer screening to be shorter in high-risk women with both risk factors for anal cancer but guideline-concordant in all high-risk women, regardless of the type or number of risk factors.

2. Methods

2.1. Overview

We examined the guideline concordance of the time to follow-up anal cancer screening in a retrospective cohort of high-risk women with HIV continuously enrolled in Medicaid for ≥ 24 months. Data for this analysis came from the Medicaid Analytic eXtract (MAX) files, which included administrative claims of beneficiaries ages 19–64 years and who qualified for Medicaid based on income and disability in the US South[6] (2009-2012). We used the International Classification of Diseases, Ninth Revision (ICD-9) codes to identify women with HIV, genital warts, abnormal cervical tests, and abnormal anal cells. To identify high-risk women screened for anal cancer, we used Current Procedural Terminology (CPT) codes for anal cytology and high-resolution anoscopy. We estimated the time to follow-up screening as the time from the date of the first anal cancer screen after a high-risk diagnosis (henceforth, the first screen) to the date of the second (follow-up) screen. In each group, we estimated the percentage with guideline-concordant time to follow-up screening. To determine whether the time to follow-up was guideline-concordant for the whole group and to be consistent with the literature, we compared the median follow-up time in that group to the follow-up time in the guidelines. We compared the odds that time to follow-up screening was guideline-concordant across the groups

[6] The US South encompasses 16 states (Delaware, Florida, Maryland, North Carolina, Georgia, South Carolina, Virginia, West Virginia, Alabama, Kentucky, Mississippi, Tennessee, Arkansas, Louisiana, Oklahoma and Texas) plus the District of Columbia.

using logistic regressions. In sensitivity analysis, we redefined the sample of high-risk women and examined follow-up time at thresholds higher than recommended in the guidelines.

2.2. Data sources

MAX files, available through the Centers for Medicare and Medicaid Services (CMS), were the primary data source. These data contain person-level information on Medicaid eligibility, utilization of healthcare services, and payments [297]. We used three MAX files: the MAX Personal Summary (PS) file to obtain enrollees' demographic information; MAX Other Therapy (OT) file to identify PLWH, high-risk women, those screened for anal cancer and outcomes of the screening; and the MAX Prescription Drug (RX) file to verify, using antiretroviral prescriptions, enrollees with HIV. Claims for services provided to PLWH are submitted to states by healthcare providers and in turn, each state's health department sends the claims to CMS every quarter [297]. MAX data is a reliable source for services received by PLWH [298], [299], and CMS regularly validates these data [300].

We supplemented the MAX data with data from the Area Health Resources File (AHRF) and AIDSVu for additional county-level information. In the MAX data, person-level socio-demographic information is limited to age, sex, and race/ethnicity. The AHRF, maintained by the Health Resource Service Administration, has county-level data on income, education, and availability of healthcare workforce [301]. We controlled for county-level education, income, and the healthcare workforce because these variables are positively associated utilization of health services [289], [302], [303]. AIDSVu, constructed by the Centers for Disease Control and Prevention and maintained by Emory University, consists of county-level HIV surveillance data in the US [304]. We controlled for county-level HIV prevalence because PLWH in counties with a high HIV burden are more likely to access HIV providers and receive appropriate HIV care

[305]. The study was approved by the institutional review board of Virginia Commonwealth University and used the data in accordance with a data use agreement with the CMS (IRB#: HM20008091, DUA#: RSCH-2017-51616)

2.3. Sample selection and eligibility criteria

We identified high-risk women from a sample of people verified to be living with HIV. Briefly, the sample of PLWH was derived as follows: Enrollees with HIV/AIDS were identified using ICD-9 codes 042 (AIDS diagnosis) and V08 (HIV diagnosis) [306]. In this sub-sample of enrollees living with HIV, we excluded enrollees for whom we could not verify and confirm an HIV-positive diagnosis. These included enrollees who only received HIV counseling, had HIV-associated ICD-9 codes that occurred <twice during the analytic time horizon or had first and last HIV-associated claims <30 days, only received Truvada—a pre-exposure prophylaxis for HIV. From this sample, we retained non-elderly women with HIV using the sex variable (el_sex_cd) and restricted ages of 19-65 years[7]. We also excluded women enrolled in both Medicare and Medicaid. Next, we identified high-risk women using ICD-9 codes for abnormal cervical tests and genital warts [307], [308], **Appendix C2**. We also excluded those diagnosed as high-risk before the date of the first HIV-associated ICD-9 code or on their last verified date of service. Finally, we excluded women enrolled for <24 months to permit enough time to observe ≥2 anal cancer screens after a high-risk diagnosis.

2.4. Identifying high-risk women screened for anal cancer

We identified high-risk women who received anal cancer screening using CPT codes for anal cytology and high-resolution anoscopy, **Appendix C3**. We used these codes because there were

[7] Although the data requested from the CMS was for Medicaid beneficiaries aged 19-64 years, we applied this exclusion because transitions from Medicaid to Medicare may not be instantaneous and some beneficiaries may receive services under Medicaid and Medicare during the transition period.

no CPT codes for anal cancer screening during the current study's analytic time horizon, 2009-2012 [309], [310]. At that time, the practice was for providers to bill payers for services and components that constituted anal cancer screening—for example, direct smear (CPT code 88104) or anoscopy (CPT code 46600). Although CPT code 88112 (anal cytology, liquid-based preparation) is the most commonly used for anal cytology [311], we included the other codes because specimens for anal cancer screening can be obtained in multiple ways and each of these codes reflects the method used [312].

2.5. Statistical analysis

We estimated time to follow-up anal cancer screening as the time from the date of the first screen (after a high-risk diagnosis) to the date of the second screen. We used Kaplan-Meier to estimate the time to follow-up screening overall and by risk group to make our findings comparable to the literature. The Kaplan-Meier estimator produces unbiased estimates even if the data are censored or have gaps [313], [314]. Data are censored if the observation of time-to-event is incomplete while gaps mean that a participant disappears from the study and then reappears at a later date [315]. These issues were important because of some enrollees moving in and out of the Medicaid program (churning) or not receiving any follow-up screening at the end of the analytic time horizon. To report the time to any follow screening, we used the median because the follow-up time was right-skewed ($\chi 2 = 1777(2)$, p-value <0.001). We tested the statistical significance of the differences in the time-to follow-up screening between the groups using the log rank test.

2.5.1. Guideline-concordant time to follow-up screening (unadjusted)

In each of the groups of high-risk women, we report the percent of women receiving follow-up screening at the times stipulated in the guidelines for anal cancer screening. We report these percentages at 6 and 12 months if on the first screen the results were, respectively, abnormal and

normal. However, for comparability with previous studies, we also report the median time—the time at which 50% of the group received follow-up screening. We tested whether the median time to follow-up screening was guideline-concordant by comparing it to the follow-up time recommended in the guidelines. Therefore, a group of high-risk women (for example, women with both risk factors) was considered to have had guideline-concordant time to follow-up screening if the median time was ≤ 6 months for those with abnormal results on the first screen and ≤ 12 months for those with normal results on the first screen. To ascertain whether the result on the first screen was normal or abnormal, we used the ICD-9 codes in **Appendix C4**.

2.5.2. Guideline-concordant time to follow-up screening (adjusted)

We modeled the likelihood that time to follow-up screening was guideline-concordant using logistic regressions, adjusting for other factors that can potentially influence the time to follow-up of anal cancer screening. We reported the results as odds ratios and probabilities. The odds ratios compared the guideline concordance of time to follow-up screening between groups while the probabilities determined if the time to follow-up in each group was guideline-concordant. Time to follow-up screening was guideline-concordant if the average predicted probability for a given group was ≥ 0.5. We created a binary variable "concordance" based on the follow-up time recommended in the guidelines. Concordance was equal to one if the time to follow-up screening was guideline-concordant and zero otherwise. We specified the following model:

$$log\left(\frac{\pi_i}{[1-\pi_i]}\right) = \beta_0 + \lambda \boldsymbol{X}_i + \alpha \boldsymbol{P}_j + \boldsymbol{\Gamma} + \mathcal{E}_i \text{ --- (1)}$$

Where;

π_i is the proportion with guideline-concordant time to follow-up screening; *(1-π_i)* is the proportion with time to follow-up screening not guideline-concordant.

$\boldsymbol{X}_i$ is a vector of individual-level variables, for example, age (**Appendix C1**); $\boldsymbol{\lambda}$ is a vector of parameters corresponding to the individual-level characteristics.

$\boldsymbol{P}_j$ is a vector of county-level variables, for example, the prevalence of HIV (Appendix C1); $\boldsymbol{\alpha}$ is a vector of parameters corresponding to the county-level variables.

Γ captures state fixed-effects for the 16 Southern states plus the District of Columbia.

ε_i is residuals—assumed to be independent and normally distributed with zero means.

Tests of model fitness using the Hosmer-Lemeshow test which compares observed vs. expected frequencies and deviance residuals which can identify outlying observations [316, p. 3] suggested the model was a good fit of the data: Hosmer-Lemeshow, χ^2 (8) =6.29 ($p>0.05$) and <5% (129/3,779) of observations were outlying (±2 standard deviations of the residuals' mean—zero). Test of multicollinearity suggested this was not a problem (mean VIF=6.10) [316], [317].

2.6. Sensitivity analysis

We conducted three sensitivity analyses. First, we restricted the sample of high-risk women to only those continuously enrolled in Medicaid for the entire study period (2009-2012). Redefining the sample this way helped to understand whether Medicaid enrollment length and churning influenced the frequency of anal cancer screening. In the second sensitivity analysis, we redefined the sample of high-risk women by including additional ICD-9 codes that might also be used to indicate a diagnosis of abnormal cervical test or genital warts. We conducted this sensitivity analysis to account for differences in practices in deciding which diagnoses might qualify an individual for anal cancer screening. For example, women with a diagnosis of "other abnormal Pap smear of cervix and cervical HPV (ICD-9 code 795.09)" may be considered as high-risk by some practitioners but not by others. All the supplementary codes used in the

sensitivity analysis are presented in **Appendix C2**. In the third sensitivity analysis, we modeled the time to follow-up screening at thresholds higher than stipulated in the guidelines to account for logistical delays in seeking care. We assumed a 2-month delay. Thus, in equation 1, we examined the likelihood of follow-up screening at ≤ 14 months among women with normal results and ≤ 8 months among those with abnormal results on the first screen.

3. Results

3.1. Descriptive statistics

Overall, we identified 6,086 high-risk women continuously enrolled in Medicaid for ≥ 24 months. Sixty-two percent (3,779/6,086) were screened for anal cancer after a high-risk diagnosis. Therefore, we examined time to follow-up screening in 3,779 high-risk women who accounted for a total of 4,458 person-years, **table 1**. Approximately three-quarters qualified for Medicaid via the disability path, with nearly two-thirds continuously enrolled in Medicaid for 4 years. The mean (±SD) age (years) was 41.5±10.4. The sample largely comprised women with histories of abnormal cervical tests (74%) followed by those with histories of both risk factors (18%). Most were non-Hispanic black (68%) followed by other races/ethnicities (for example, Pacific Islanders, Hawaiians, and Asians) (15%), non-Hispanic whites (12%), and Hispanics (5%). The incidence of anal cancer screening was 0.39 (95% C.I.=0.26,0.37) per person-year overall but much higher among high-risk women with both risk factors (0.62 (95% C.I.=0.57,0.68) per person-year). The time to follow-up screening was guideline-concordant for 46% of those with abnormal results and 37% among those with normal results. Women with both risk factors were highest in the proportion with guideline-concordant time to follow-up screening, regardless of the result on the first screen.

3.2. Time to any follow-up anal cancer screening (unadjusted)

The overall median time to any follow-up screening was 16.1 months (95% C.I.=15.2,17.6) but differed by risk group ($\chi^2(2) = 115.8$, p-value<0.001). The follow-up time was shortest among women with histories of both risk factors, with a median time almost half that of the next most screened group (women with histories of abnormal cervical tests only) (median=9.3, 95% C.I.=7.6,11.0 months vs. median=18.6, 95% C.I.=17.6,19.9 months). Among women with histories of genital warts only, the median follow-up time was two years (median=24.4, 95% C.I.=16.3,39.0 months). When examined collectively, the median time to follow-up screening for women with any single risk history was 18.9 (95% C.I.=17.8,20.3) months, **figure 3**. By 24 months, >75% of women with both risk histories had received follow-up screening compared with <60% among women with only one risk factor.

3.3. Guideline concordance of the time to follow-up screening (unadjusted)

Receipt of guideline-concordant follow-up anal cancer screening—defined as receiving follow-up screening within 6 months and 12 months for those with normal and abnormal results after the first screen, respectively—also differed by risk group. The time to follow-up screening was guideline-concordant for 47.3% (95% C.I.=42.0,53%) of high-risk women with abnormal results on the first screen and for 40.0% (95% C.I.=38.0,41.4%) for those with normal results. When stratified by risk group, the time to follow-up screening was guideline-concordant for more than half of high-risk women with both risk factors, **figure 4 (points A and C)**. The percent of women with guideline-concordant time to follow-up screening was lowest for women with a single risk factor and normal results on the first screen (36.8%, 95% C.I.=35.0,38.7%), **figure 4 (point D)**.

3.4. The odds of any follow-up anal cancer screening (adjusted)

In adjusted analyses, the odds of receiving any follow-up anal cancer screening differed by the number of risk factors, **table 2 (panel 1).** The odds were significantly higher in women with both risk factors than in women with one factor (OR=2.57, 95% C.I.=2.12,3.12). At the same time, high-risk women with an abnormal anal test on the first screen had significantly higher odds of receiving any follow-up screening compared with those who had normal results (OR=3.22, 95% C.I.=2.39,4.34). We also found that the odds of receiving any follow-up screening were significantly higher among those who qualified for Medicaid via the disability path and increased with increasing years of enrollment and age. Compared to non-Hispanic whites, Hispanics had significantly higher odds of receiving any follow-up anal cancer screening. Non-Hispanic blacks had similar odds of receiving any follow-up screening as non-Hispanic whites.

3.5. The odds and probability of guideline-concordant follow-up screening (adjusted)

The odds that the time to follow-up of anal cancer was guideline-concordant differed by risk group, **table 2 (panel 2)**. Compared with women with a single risk factor, women with both risk factors had double the odds of having guideline-concordant time to follow-up screening (OR=2.06, 95%=1.73,2.46). The odds were also higher among women with abnormal results on the first screen compared with women with normal results (abnormal vs. normal, OR=1.27, C.I.=1.00,1.63).

These results are also presented as predicted probabilities in **table 3** (base case analysis). From first to last, the average probabilities that the timing of the follow-up screening was guideline-concordant were as follows: both risk factors and abnormal result, 56.7% (95% C.I.=50.7,62.8%); both risk factors and normal result, 50.9 (95% C.I.=47.0-54.8%); one risk

factor and abnormal result, 39.3% (95% C.I.=33.7,44.9%); one risk factor and normal result, 33.8% (95% C.I.=32.2,35.6%).

We also found that the odds that time to follow-up screening was guideline-concordant differed on some individual- and county-level variables. The odds were significantly higher for older enrollees and those who qualified for Medicaid via the disability path. However, the odds did not significantly differ by years of continuous enrollment or race/ethnicity. In terms of county-level variables, the odds were higher for those living in counties with higher HIV prevalence but lower for those living in counties with more specialists. Finally, the odds were lower for high-risk women in states with higher proportions of Medicaid managed care enrollment although the difference was not significant.

3.6. Sensitivity analysis

When we restricted the sample of high-risk women to only those continuously enrolled in Medicaid for the entire study period (2009-2012), the percent of women with guideline-concordant time to follow-up screening increased but only marginally (within five percentage points), **table 3 (continuously enrolled for 4 years)**. For example, among women with both risk factors and abnormal results the percent with guideline-concordant follow-up time to screening increased from 57% (95% C.I.=51%,63%) in the main analysis to 62% (95% C.I.=56%,68%) in the sensitivity analysis.

Table 4 presents the results of the second sensitivity analysis in which we increased the number of ICD-9 codes used to create a sample of high-risk women, thereby relaxing the approach for constructing our sample. The pattern suggests that the percent with guideline-concordant time to follow-up screening decreased but was still higher in high-risk women with both risk factors. The decreases ranged from zero to three percentage points. Overall, the percent with guideline-

concordant time to follow-up decreased by two percentage points among high-risk women with normal results on the first screen after a high-risk diagnosis but did not decrease among those with abnormal results. Similar patterns were observed when the time to follow-up was analyzed by risk group.

In the third sensitivity analysis, which examined follow-up screening at the guideline-recommended times plus 2 months, the probability of follow-up anal cancer screening increased but marginally. The increases were by three to five points in each group, **table 5**. As in the main analysis, the probability of receiving follow-up screening at the higher thresholds was highest among women with both risk factors and abnormal results on the first screen, followed by those with both risk factors and normal results. In these two groups, the probabilities were >0.5. In high-risk women with one risk factor, the probabilities were <0.5, regardless of the result on the first screen.

4. Discussion

To our knowledge, this is the first study to examine and report, by anal cancer risk factors and screening result, the guideline concordance of the time to follow-up of anal cancer screening in women with HIV at high-risk for acquiring anal cancer. These women include those with histories of abnormal cervical tests or genital warts. We found that the time to any follow-up of anal cancer screening was longer overall, although shorter among high-risk women with histories of both risk factors. The time to follow-up screening was not guideline-concordant for most high-risk women although it was for most high-risk women with both risk factors. These findings persisted in sensitivity analyses. Among women at high risk of acquiring anal cancer, the odds of guideline-concordant screening are lower in those who are younger and qualified for Medicaid through the disability pathway.

Overall, we found that the time to follow-up of anal cancer screening was much longer among high-risk women with one risk factor, and it was not guideline-concordant for nearly two-thirds of them. However, the time to follow-up was guideline-concordant for high-risk women with both risk factors, regardless of the result on the first screen after a high-risk diagnosis. The lack of guideline concordance of the time to follow-up overall and among high-risk women with one risk factor is not surprising and might be for several reasons. One possible explanation is that the guidelines for anal cancer screening are not very clear on what to do next after the initial screening, particularly when a positive test is obtained [277], [318]. As a result, opinions and practice patterns of experts tend to influence institutions' anal cancer screening processes. For example, for people treated for severe lesions (AIN2/3), the University of San Francisco's screening protocol recommends follow-up screening every six months with high-resolution anoscopy (HRA)—the same as for those with untreated AIN1 [319], [320]. On the other hand, John's Hopkins does not have formal recommendations on follow-up time for those treated for AIN2/AIN3 but does recommend that follow-up screening with HRA be performed every six months in those with AIN1 [318]. Another area of uncertainty and debate is when the result of a pap smear is determined to be ASC-US—atypical squamous cell of undetermined significance or ASC-H— atypical squamous cell, cannot rule out high-grade lesion. For ASC-US, the University of San Francisco recommends follow-up screening with HRA screening and if lesions not found, an annual Pap test is recommended [319]. On the other hand, Johns Hopkins does not make any recommendations on ASC-US. However, if the result is ASC-H, it recommends HRA and if there is no lesion or AIN1, repeat HRA should be performed every 3 months [318]. The University of San Francisco has no formal recommendations for ASC-H. The position of the HIV Medical Association is unclear on these grey areas. This lack of clarity in the guidelines

suggests that the time to follow-up will vary by providers and some providers may not recommend follow-up screening to their clients even if the results on the initial screen are positive.

Given the lack of clarity in the guidelines, another possible explanation is that the guidelines may not have been sufficiently popularized and therefore, some providers may not be fully aware of the guidelines for anal cancer screening. This lack of awareness about the guidelines would most likely affect rates of anal cancer screening among women with histories of abnormal cervical tests or genital warts. This is because these risk factors for anal cancer are not the most well-known or most extensively studied. Receptive anal intercourse is [321] and hence the large literature on anal cancer screening in MSM with HIV [267], [280]–[283]. Thus, it is probable that providers not aware of the guidelines may prioritize anal cancer screening in MSM and overlook high-risk women, particularly those with a single risk factor.

Another potential explanation for the low rates of follow-up screening is that while HRA is considered the gold standard for anal cancer screening and strongly recommended for follow-up screening [318], [320], [322], several challenges limiting its use remain. These challenges include a shortage of colposcopies, shortage of well-trained personnel, and a long learning curve for the technique [278], [323], [324]. For example, data show that it takes examining about 200 cases for a provider to competently detect all high-grade lesions using HRA [324]. These technological limitations suggest that high-risk women, particularly those with abnormal results on the first screen after a high-risk diagnosis, may not receive the follow-up screening even if they want to.

An additional potential explanation is that physicians, particularly specialists, may not have enough time to provide the follow-up screening services. In multivariable regressions, we found

that high-risk women in counties with more specialists are significantly less likely to have guideline-concordant time to follow-up screening. At the same time, the likelihood of receiving guideline-concordant follow-up screening is higher, although not significant, in counties with more primary care physicians. This suggests that high-risk women relying on specialists, vs. primary care physicians, may face delays in receiving the follow-up anal cancer screening. These delays could be due to the involvement of multiple specialties vs. a single specialty in providing this care [325], [326]. Finally, it is possible that those with one risk factor may downplay the risk of anal cancer given that they have one and not multiple risk factors. Therefore, they may procrastinate in seeking follow-up screening, thinking the problem is not serious enough and may naturally disappear.

The pattern of the time to follow-up screening among those with abnormal and normal results (on the first screen) is consistent with reports from previous studies, although we emphasize that the overall median follow-up time in this study is not always consistent with those studies. Similar to the current study, previous studies reported higher follow-up screening frequencies among women with abnormal results compared to those with normal results [273], [275], [287]. The study's overall median follow-up time (18 months) compares favorably with findings from a study in California which reported a follow-up time of 17 months in women with HIV [287]. In New York, women with HIV and normal results on the previous screen received follow-up anal cancer screening in 12 months [275], which is guideline-concordant but inconsistent with this study's findings. Studies of women with HIV in Boston, Connecticut, and Massachusetts, reported a follow-up time of 6 months if the previous screen was normal [270], [273]. We emphasize that comparisons with these studies are limited because the studies did not restrict

their samples to women at high risk for anal cancer, had smaller sample sizes (<100 in many cases) or were limited in geographic scope.

Finally, the finding that time to follow-up screening was guideline-concordant for <50% of the high-risk women is consistent with other studies on the guideline concordance of care among PLWH. Among women with HIV, <50% receive guideline-concordant depression care [328] and <40% receive guideline-concordant cervical cancer screening [329]. Among PLWH, <40% receive guideline-concordant opioid therapy [330], <30% receive timely medical care for HIV symptoms [331], and <50% receive regular HIV care [332]. Therefore, this study contributes to a broader literature suggesting that there is room for improvement in the delivery of HIV-related care.

4.1. Limitations

This study has limitations. First, we were unable to examine the guideline concordance of the time to follow-up screening in women with HIV and histories of receptive anal intercourse due to data limitations. These women are also at high risk of acquiring anal cancer and are recommended for regular follow-up screening [277]. Although ICD-9 codes for high-risk sexual behaviors were available, we could not identify specific diagnoses of receptive anal intercourse in the MAX data. Despite this limitation, it is likely that we captured some of these women among those with histories of genital warts. This is because individuals with high-risk sexual behaviors like receptive anal intercourse are more likely to acquire sexually transmitted infections, including genital warts [333].

Second, we were unable to know if any women received follow-up anal cancer screening not paid for by Medicaid and therefore, not captured in the MAX data. This problem was likely to occur because of churning. Data show that individuals who churn tend to have health service

utilization patterns different from those continuously enrolled in Medicaid [334], [335]. Thus, the estimates are biased to the extent that the frequency of follow-up screening among those who churned systematically differed by risk group. To mitigate this problem, we limited the study's sample to high-risk women continuously enrolled in Medicaid for ≥ 24 months. Moreover, the study's findings were robust in sensitivity analysis when we restricted the sample to only those continuously enrolled for the entire study period (48 months).

Third, we did not have access to individual-level socio-economic data like education and income—two factors that influence the utilization of preventive care and health outcomes among PLWH [302], [303]. To address this limitation, we supplemented the MAX data with the AHRF and controlled for county-level education and income.

Finally, the findings may not be generalizable to all women with HIV at high-risk of acquiring anal cancer. This is particularly true as we used a cohort of Medicaid enrollees in the US South and not a nationally representative sample. Thus, the time to follow-up screening reported here may not be observed in the country's other regions or among those privately insured or rely on Ryan White HIV clinics. Despite these limitations, it is likely the study adequately captured the frequency of follow-up anal screening in high-risk women with HIV given the large sample for the study and likely reflects regional trends in the receipt of follow-up screening in this population.

4.2. Implications for practice and policy

Time to follow-up anal cancer screening is not guideline-concordant for most high-risk women with histories of abnormal cervical tests or genital warts, although it is for most high-risk women with both risk factors. This problem can be addressed in several ways, including enhancing partnerships between primary care physicians and specialists and training more providers in

using HRA—a specialized test for anal cancer screening and recommended for follow-up screening particularly among those with abnormal cytologic results. Use of HRA in follow-up screening is critical because, unlike cytology, HRA can distinguish between low-grade and high-grade lesions and therefore, allows for the appropriate treatment and follow-up recommendations [318], [320], [322].

Second, it is critical to clarify the guidelines for anal cancer screening. This can be achieved by gathering more compelling evidence on the benefits of anal cancer screening, particularly in individuals at high-risk for acquiring anal cancer. While experts agree that anal cancer screening in high-risk individuals can prevent anal cancer or at least detect it early, the guidelines for anal cancer screening have not been adopted universally [336], [337]. This is mainly because of the lack of compelling evidence about the benefits of anal cancer screening [336], [337]. To address this gap, a randomized controlled trial evaluating the benefits of treating high-grade lesions in PLWH is currently in progress in the USA [338]. Thus, the evidence from that trial and perhaps additional observational studies can help to clarify the guidelines, lead to their universal adoption and popularization, and eliminate any confusions about the timing of follow-up screening.

Furthermore, re-examining the payment policy for anal cancer screening services can be useful since there is no CPT code for anal cancer screening [309], [310], [312]. Thus, clinicians cannot bill payers for anal cancer screening as a single service. The status quo is that clinicians bill payers the bits and pieces that comprise anal cancer evaluation and management (for example, anoscopy) [339], [340]. Payers argue that they cannot pay for anal cancer screening because its benefits have not been evaluated in any randomized controlled trial and the screening is not universally recommended [278], [336], [340]. It is noteworthy that payers reimburse clinicians for cervical cancer screening despite cervical and anal cancers having many similarities and both

lacking evidence of screening benefits from randomized controlled trials [336], [339]. The lack of a single CPT code for anal cancer screening creates difficulties in reimbursement for the services [309], [312] and therefore, a disincentive to the continued provision of anal cancer screening services. Thus, it is probable that creating a billable CPT code for anal cancer screening could eliminate the difficulties in reimbursements and increase rates of anal cancer screening overall.

Finally, high-risk women should be made aware of the benefits of anal cancer screening, regardless of the number of risk factors for anal cancer. Data show that 63% of people at risk for anal cancer do not know that anal cancer screening is recommended [341], a sizable proportion refuses the screening [341]–[343], and not all clinicians discuss this with their patients [344]. Therefore, discussions between providers and their clients at a high-risk for acquiring anal cancer about the benefits of anal screening can increase the uptake of anal cancer screening services.

4.3. Future research

While this study contributes to a broader literature suggesting that most PLWH do not receive guideline-concordant care, much remains to be done. Future research should focus on whether the timing of follow-up anal cancer screening varies by health service delivery model (managed care) or payment model (fee-for-service). This is important as many states have moved from Medicaid fee-for-service to Medicaid managed care [345]. However, it is unclear how such changes affect the receipt of anal cancer screening specifically and HIV-related preventive care in general. Future research should also examine racial/ethnic disparities in the timing of follow-up anal cancer screening overall and in each group of high-risk women. Evidence suggests that racial/ethnic minorities are less likely to receive HIV-related preventive care [346]–[348], be treated for anal cancer [349], and more likely to present with advanced disease stage [350],

[351], compared with non-Hispanic whites. Among MSM with HIV, non-Hispanic blacks are less likely to be screened for anal cancer [286], [343], [352]. It is unclear whether these disparities extend to follow-up anal cancer screening of high-risk women. We were unable to investigate this question because of inadequate sample sizes for high-risk non-Hispanic whites and Hispanics.

5. Conclusion

In the past 2-3 decades, the incidence of anal cancer among PLWH has increased significantly. We examined the guideline concordance of the timing of follow-up anal cancer screening in two groups of women at high-risk for acquiring anal cancer: women with HIV and histories of either abnormal cervical tests or genital warts. The timing of the follow-up screening is not guideline-concordant overall and among high-risk women with a history of one risk factor. However, it is guideline-concordant among those with histories of both risk factors. These findings suggest that high-risk women with one risk factor are in danger of being overlooked as also being at risk for anal cancer. As a result, they may present for screening with advanced disease, making secondary prevention difficult, and thereby limiting the chance of survival. In all, these findings provide support for efforts, including training providers in how to effectively use HRA and generating more evidence to help push for the universal adoption of the guidelines for anal cancer screening, to increase rates of follow-up anal cancer screening in those at high-risk of acquiring anal cancer.

Table 1: Summary statistics for high-risk women living with HIV followed-up for anal cancer screening, by risk group

Variable	All high-risk women (n=3,779)		Genital warts only (n=292)		Abnormal cervical only (n=2,809)		Abnormal cervical and genital warts (n=678)	
	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
First screen after a high-risk diagnosis***								
Abnormal	326	9%	34	12%	162	6%	130	19%
Normal	3453	91%	258	88%	2647	94%	548	81%
Time at risk (person-years)†	4458	100%	349	8%	3438	77%	672	15%
Received follow-up screening***	2086	55%	129	44%	1454	52%	503	74%
Incidence of follow-up screening (per person-year)	0.39		0.31		0.35		0.62	
Time to follow-up screening guideline-concordant‡	1414	37%	91	31%	972	35%	351	52%
Abnormal anal test at first screening***	150	46%	10	29%	73	45%	67	52%
Normal anal test at first screening***	1264	37%	81	31%	899	34%	284	52%
Race/ethnicity***								
Non-Hispanic white	454	12%	45	15%	324	12%	85	13%
Non-Hispanic black	2570	68%	175	60%	1949	69%	446	66%
Hispanic	174	5%	28	10%	99	4%	47	7%
Others	581	15%	44	15%	437	16%	100	15%
Medicaid qualification***								
Income	994	26%	58	20%	788	28%	148	22%
Disability	2785	74%	234	80%	2021	72%	530	78%
Enrollment length***								
Continuously enrolled for 2 years	788	21%	62	21%	602	21%	124	18%
Continuously enrolled for 3 years	585	15%	48	16%	444	16%	93	14%
Continuously enrolled for 4 years	2406	64%	182	62%	1763	63%	461	68%
Age (mean and standard deviation) ***, years	41.9	10.2	42.2	9.9	41.6	10.6	40.7	9.9

*p-value<0.05; **p-value<0.01; ***p-value<0.001. †Percentages are by row, otherwise, percentages are by column. ‡ Receipt of follow-up anal cancer screening within 6 months for those with an abnormal anal test at the first test and within 12 months for those with normal results at the first test. §First column=mean and second column= standard deviation. For these variables tests of statistical significance were performed using the F-test; otherwise, Chi-square were tests used.

Table 2: Odds of guideline-concordant time to follow-up anal cancer screening in high-risk women with HIV

	Panel 1		Panel 2	
	Any follow-up anal cancer screening		Guideline-concordant follow-up anal cancer screening†	
	Odds Ratio	95% C.I.	Odds Ratio	95% C.I.
Individual-level factors				
Number of risk factors (ref: one risk factor)‡				
Both factors	2.57***	[2.12,3.12]	2.06***	[1.73,2.46]
Result at first anal cancer screen (ref: normal)				
Abnormal	3.22***	[2.39,4.34]	1.27*	[1.00,1.63]
Qualification for Medicaid (ref: income)				
Disability	1.23**	[1.03,1.47]	1.28***	[1.06,1.53]
Years of continuous enrollment (ref: 2 years)				
3 years	1.29**	[1.03,1.62]	1.11	[0.88,1.39]
4 years	1.37***	[1.16,1.64]	0.97	[0.81,1.16]
Age (ref: 19-34 years)				
35-44 years	1.39***	[1.16,1.67]	1.40***	[1.16,1.68]
45-54 years	1.30***	[1.07,1.58]	1.24**	[1.02,1.51]
55-64 years	1.58***	[1.22,2.04]	1.66***	[1.28,2.14]
Race/ethnicity (ref: non-Hispanic whites)				
Non-Hispanic Black	1.07	[0.86,1.34]	0.89	[0.71,1.11]
Hispanic	1.63**	[1.11,2.41]	1.14	[0.79,1.66]
Others	1.22	[0.87,1.70]	0.83	[0.59,1.16]
County/state level controls§				
Diagnosed HIV cases per 100,000 adults (ref: 0-54)				
55-138	1.84	[0.61,5.55]	2.82	[0.81,9.76]
139-2426	1.27	[0.44,3.69]	1.98	[0.59,6.65]
Primary care physicians per 10,000 population (ref: 0-3.7)				
3.8-6.3	1.35	[0.90,2.03]	1.22	[0.81,1.85]
6.4-47.6	1.22	[0.78,1.91]	1.18	[0.75,1.85]
Specialists per 10,000 population (ref: 0-0.92)				
0.93-3.4	0.43***	[0.24,0.76]	0.41***	[0.24,0.72]
3.5-147.8	0.45**	[0.24,0.83]	0.50**	[0.27,0.91]
Percent living the federal poverty level (ref:0.9%-13.5%)				
13.6%-18.9%	0.84	[0.60,1.17]	1.13	[0.81,1.59]
19%-63.2%	0.82	[0.56,1.20]	0.94	[0.64,1.37]
Percent with less than high school education (ref: 1%-11.4%)				
11.5%-18%	0.80*	[0.63,1.03]	0.86	[0.67,1.09]
18.1%-55	0.91	[0.66,1.27]	1.08	[0.78,1.51]
Percent with Medicaid managed care enrollment (ref: <=60%)¶				
61%-80%	1.02	[0.29,3.54]	0.33	[0.08,1.27]
>80%	1.1	[0.34,3.58]	0.38	[0.10,1.41]
Observations	3779		3779	

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$. †Receipt of follow-up anal cancer screening in 6 months for those with an abnormal anal test at the first test and within 12 months for those with normal results at the first test. ‡The risk factors are histories of abnormal cervical tests or genital warts. §The county and state control variables are tertiles. ¶State-level variable.

Table 3: The percent of women living with HIV with guideline-concordant time to follow-up screening at varying restrictions of years of continuous enrollment in Medicaid

	Base case analysis† (n=3,779)				Sensitivity analysis‡ (n=2,406)			
	Continuously enrolled for at least 2 years				Only those continuously enrolled for 4 years			
	Normal (≤12 months)		Abnormal (≤6 months)		Normal (≤12 months)		Abnormal (≤6months)	
Risk factors*	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**
Overall	37	[35-39]	42.00	[42-52]	39.61	[37-42]	46.96	[41-54]
One risk factor	34	[32-36]	39.33	[34-45]	36.30	[34-39]	44.39	[36-53]
Both risk factors	51	[47-55]	56.76	[51-63]	55.24	[50-61]	50.37	[41-61]

*Risk factors: a history of abnormal cervical tests or a history of genital warts. †The base case (main) analysis uses a sample of women living with HIV continuously enrolled in Medicaid for at least two years. ‡ This is a sensitivity analysis in which the guideline concordance of the follow-up time to anal cancer screening was examined only in women living with HIV continuously enrolled in Medicaid for 4 years (2009-2012)-the study's analytic time horizon.

Table 4: The percent of women living with HIV with guideline-concordant time to follow-up screening, using varying numbers of ICD-9 codes to define high-risk women

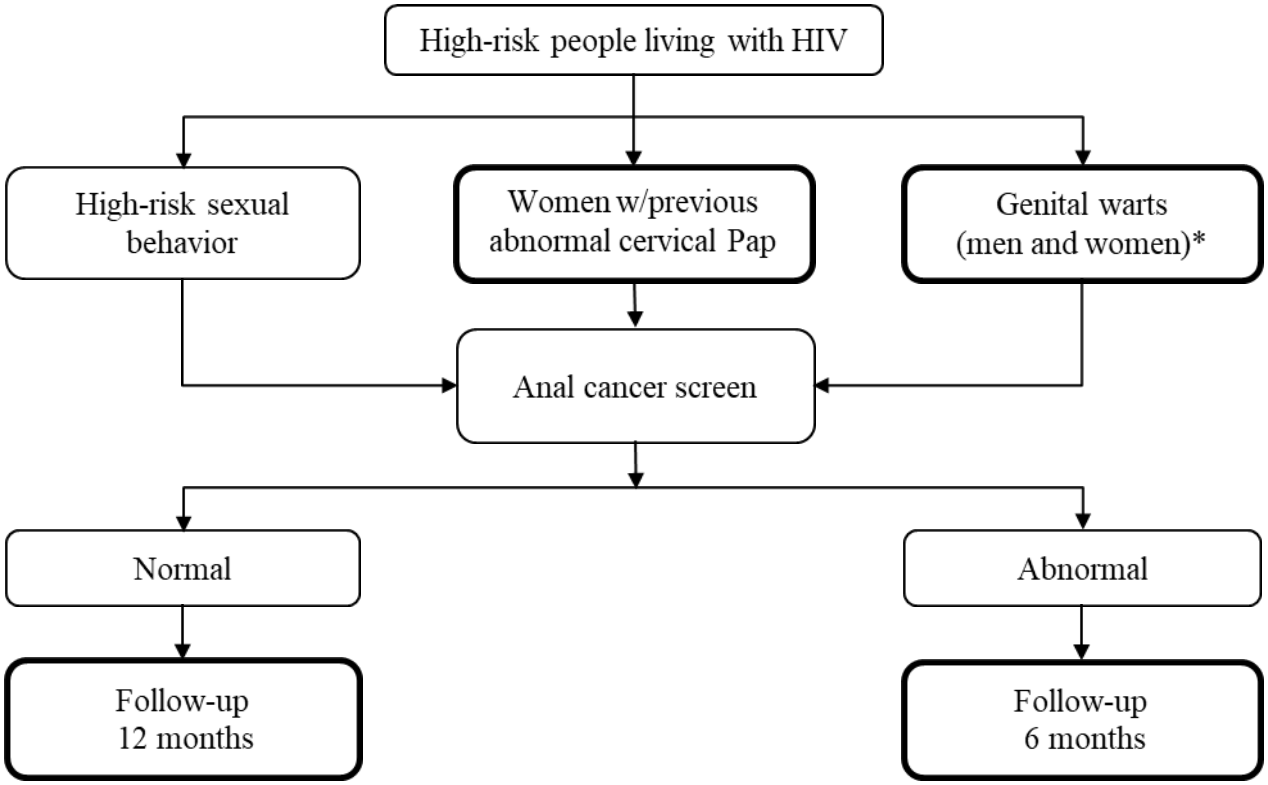
	Base case analysis† (n=3,779)				Sensitivity analysis (n=4,960)			
	Percent receiving follow-up screening†				Percent receiving guideline-concordant‡			
	Normal (≤12 months)		Abnormal (≤6 months)		Normal (≤12months)		Abnormal (≤6months)	
Risk factors*	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**	**Estimate (%)**	**95% C.I.**
Overall	40	[38-41]	47	[42-53]	38	[37-40]	47	[42-52]
One risk factor	37	[35-39]	44	[37-51]	36	[34-38]	42	[36-49]
Both risk factors	54	[50-58]	53	[44-61]	51	[47-55]	56	[48-64]

Abbreviation: ICD-9, International Classification of Diseases, Ninth Revision. *Risk factors: a history of abnormal cervical tests or a history of genital warts. †Estimates in the base case analysis were derived from a sample of high-risk women created using a more conservative definition (fewer ICD-9 codes) of high-risk. ‡In the sensitivity analysis, a sample of high-risk women was created using additional codes that may or may not conclusively suggest that an individual is high-risk. ‡Receipt of follow-up anal cancer screening within 6 months for those with an abnormal anal test at the first test and within 12 months for those with normal results at the first test

Table 5: Average predicted probability of receiving follow-up anal cancer screening in women with HIV at different cut-off points

	Base case analysis† (n=3,779)				Sensitivity analysis (n=3,779)‡			
	Normal (≤12 months)		Abnormal (≤6 months)		Normal (≤14 months)		Abnormal (≤8 months)	
Risk factors*	**Probability**	**95% C.I.**	**Probability**	**95% C.I.**	**Probability**	**95% C.I.**	**Probability**	**95% C.I.**
Overall	0.37	[0.35-0.39]	0.42	[0.42-0.52]	0.40	[0.39-0.42]	0.47	[0.42-0.53]
One risk factor	0.34	[0.32-0.36]	0.39	[0.34-0.45]	0.37	[0.35-0.39]	0.44	[0.38-0.50]
Both risk factors	0.51	[0.47-0.55]	0.57	[0.51-0.63]	0.55	[0.51-0.59]	0.62	[0.56-0.68]

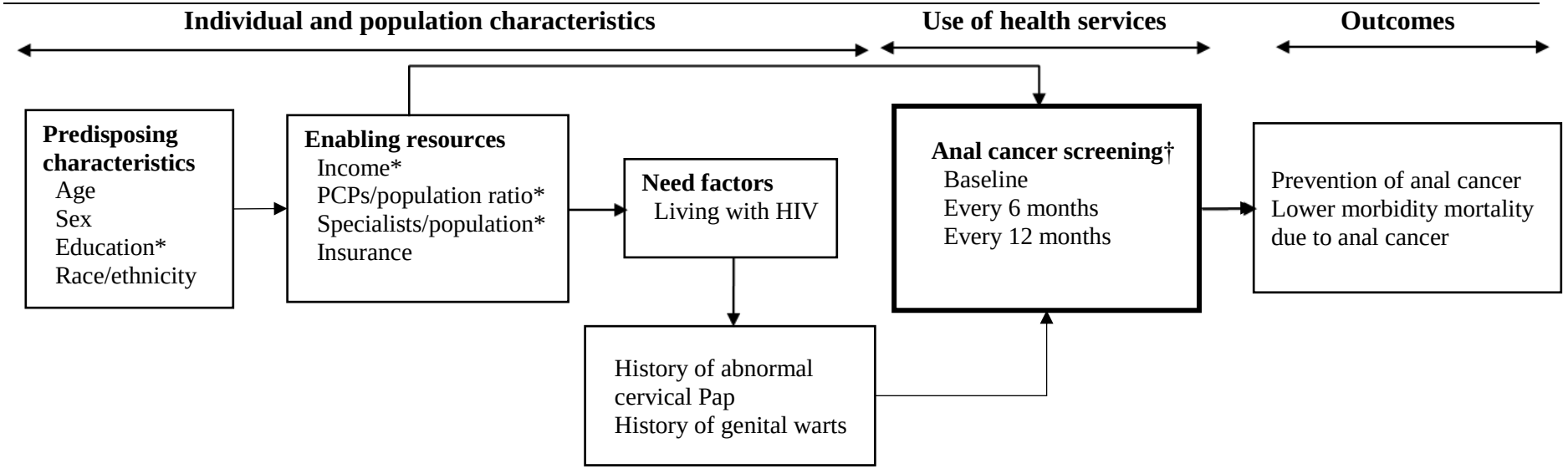
*Risk factors: a history of abnormal cervical tests or history of genital warts. †The base case analysis represents the time to follow-up recommended in the guidelines for follow-up anal cancer screening. ‡ The sensitivity analysis represents a relaxed threshold to account for logistical delays that may happen is seeking follow-up anal cancer screening services.



Adapted from Chin-Hong and Palefsky. *Clin Inf Dis* (2002) and Leeds and Fang. *World J Gastrointest Surg* (2016).
Thick boxes highlight the groups of people living with HIV and anal cancer screening frequencies of interest in this study.
*Both men and women with genital warts are recommended for regular screening, but the focus is on women with genital warts

Figure 1: Recommendations for anal cancer screening in people living with HIV at high risk for anal cancer

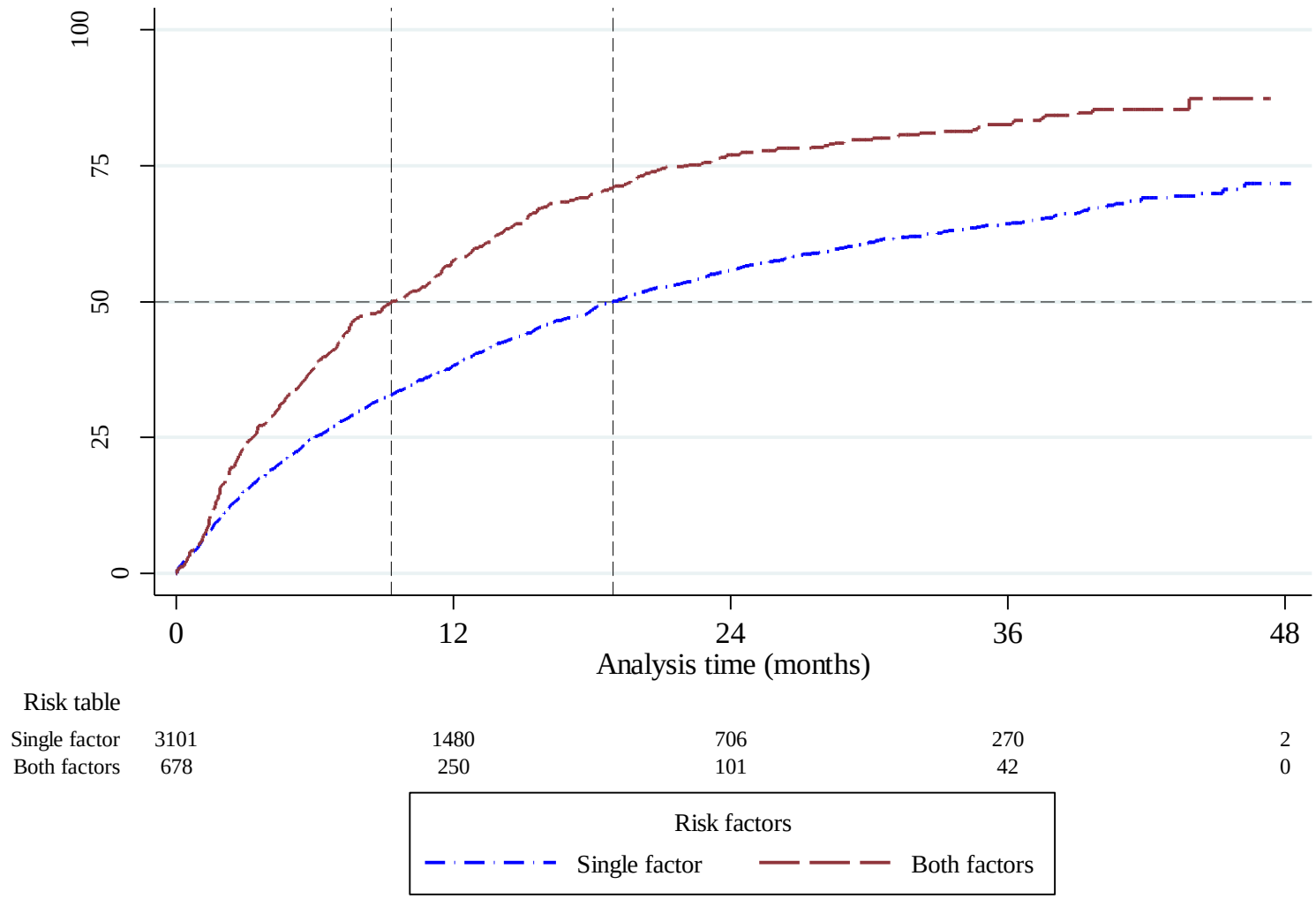
This figure summarizes recommendations for anal cancer screening in people with HIV at high-risk of acquiring anal cancer. Guidelines for anal cancer screening recommend regular screening in those with histories of high-risk sexual behaviors, abnormal cervical tests, or genital warts. Follow-up screening is recommended every 12 months if the initial result is normal or every 6 months if the result is abnormal.



Adapted from Andersen, *J. Health Soc. Behav., 1995*

The thick box highlights that the present study is interested in the frequency of anal cancer screening (utilization of health services) in high-risk people living with HIV. *Variable is only available at the county- and not individual-level. †The guidelines for anal cancer screening recommend screening of all people diagnosed with HIV at baseline and then those with histories of abnormal cervical Pap or genital warts should be screened annually if the anal cancer screening results are normal or bi-annually if the results are abnormal.

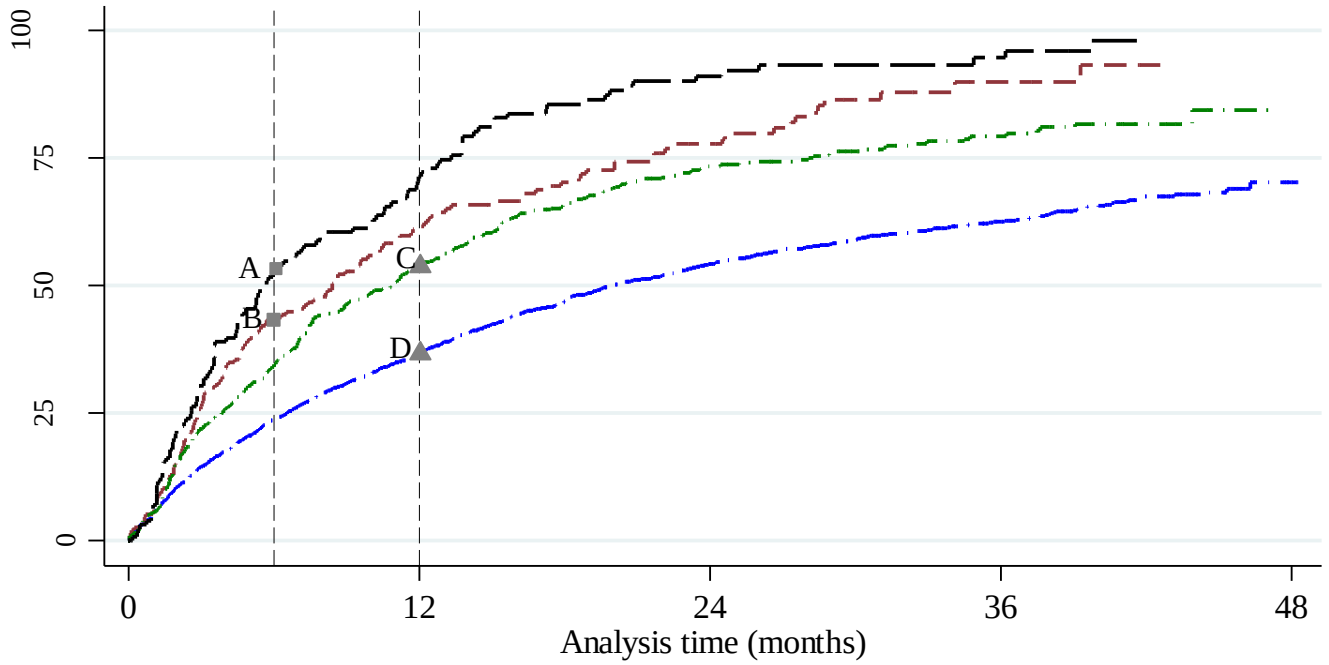
Figure 2: A framework for understanding the frequency of follow-up anal cancer screening in high-risk women living with HIV
This figure shows the interplay of individual/population factors and how they affect the utilization of anal cancer screening services. It also shows that while people living with HIV people have a need for anal cancer screening, risk factors like having a history of genital warts increase this need.



The risk factors are 1) history of abnormal cervical tests; 2) history of genital warts.

Figure 3: Kaplan-Meier estimates of the frequency of follow-up anal cancer screening, by risk group

This figure shows that the frequency of follow-up anal cancer screening was higher in women with HIV and histories of both abnormal cervical tests and genital warts.



Risk table

Single factor & normal	2905	1422	683	266	2
Single factor & abnormal	548	216	93	38	0
Both factors & normal	196	58	23	4	0
Both factors & abnormal	130	34	8	4	0

The risk factors are 1) history of abnormal cervical tests ; 2) history of genital warts.

Figure 4: Percent receiving guideline-concordant follow-up anal cancer screening, by risk group and the result of the first screen
This figure shows that the percent of women receiving guideline-concordant follow-up screening was highest among those with both risk factors, regardless of the result of the first anal cancer screen after a high-risk diagnosis (points A and C). The percent was lowest among those with a single risk factor and a normal result on the first test (point D).

Appendices

Appendix C1: Variable definitions

Table C1: Definition of variables in a study of guideline concordance of follow-up anal screening in high-risk women living with HIV

Variables	Type	Definition	Justification	Source	Year
Individual-level					
Frequency	Continuous	Time from first anal cancer screen after a high-risk diagnosis to the next screen.	Dependent variable.	MAX files	2008-2012
Concordance	Binary	Receipt of guideline-concordant follow-up screening: concordance=1 if guideline-concordant, concordance=0	Dependent variable	MAX files	2008-2012
Risk group	Categorical	1=history of abnormal cervical tests, 2=history of genital warts, 3=history of abnormal cervical tests and genital warts	Key explanatory variable. Anal cancer screening likely higher among women with both risk factors.	MAX files	2008-2012
Qualification for Medicaid	Binary	1= via income, 2= via disability.	Anal cancer screening likely higher among those qualified via the disability path.	MAX files	2008-2012
Continuous enrollment (years)	Ordinal	Years continuously enrolled in Medicaid: 1=2 years, 2=3 years, 3=4 years.	Anal cancer screening likely higher among those enrolled in Medicaid for longer periods.	MAX files	2008-2012
Age (years)	Categorical	1=19-34 years, 2=35-44 years, 3=45-54 years, 4=55-64 years.	Older participants more likely to be screened for anal cancer.	MAX files	2008-2012
Race/ethnicity	Categorical	1=non-Hispanic white, 2=non-Hispanic black, 3=Hispanic, 4=Others	Use of healthcare services differs by race [286], [343], [352].	MAX files	2008-2012
County-level					
HIV prevalence	Ordinal (tertiles)	HIV cases per 100,000 adult population.	People in high-burden HIV counties are more likely to receive HIV appropriate care as HIV providers are more likely to locate there [305].	AIDSVu*	2010
Primary care physician population (PCP) ratio	Ordinal (tertiles)	The ratio of primary care physicians per 10,000 population	Anal cancer screening services are more likely to be available in areas with a higher supply of PCPs.	AHRF	2010
Specialist population ratio	Ordinal (tertiles)	The ratio of specialists per 10,000 population	Anal cancer screening more likely to be available in areas with a higher supply of specialists.	AHRF	2010
Poverty	Ordinal (tertiles)	The percent of people in poverty.	Income is an enabler of health services use [289].	AHRF†	2010
Education	Ordinal (tertiles)	The proportion of residents with at least a high school education.	Education predisposes an individual to use healthcare services [289].	AHRF	2010
State-level					

Medicaid managed care enrollment.	Ordinal (tertiles)	The percent of Medicaid beneficiaries enrolled in managed care.	Beneficiaries in managed care are more likely to receive preventive care [353], like anal cancer screening.	KFF	2012

Abbreviations: MAX, Medicaid Analytic eXtract file; AHRF, AHRF Area Health Resources File; KFF, Kaiser Family Foundation. *AIDSVu, maintained by Emory University, consists of county-level surveillance data on diagnosed HIV cases in the US [304]. †AHRF is maintained by the Health Resource Service Administration [301].

Appendix C2: Identifying high-risk women from a sample of women living with HIV

To identify high-risk women among those with HIV, we used diagnosis codes for abnormal cervical tests or genital warts [307], [308]. We searched Google for commonly used ICD-9 codes for abnormal cervical tests or genital warts which we validated using the literature and expert opinions. For abnormal cervical tests, codes traditionally used for abnormal cervical Pap smears or cervical intraepithelial neoplasia were the main codes [354]–[357], **table C2**. However, other codes such as 795.01 (Papanicolaou smear of cervix with atypical squamous cells of undetermined significance) were also included to account for coding errors or misdiagnoses. The supplementary codes in table C2 were used in sensitivity analysis only. For genital warts, while ICD-9 code 078.11 is specific to genital warts, two codes are also commonly used: 078.10 for unspecified viral warts and 078.19 for other specified viral warts [358]. The supplementary codes were used in sensitivity analyses only. We did not restrict the ICD-9 code to a specific position.

Table C2: Codes for identifying women with HIV at high-risk for acquiring anal cancer

Identifying women living with HIV*	
ICD-9 Code	Description
042	AIDS diagnosis
V08	HIV diagnosis
Abnormal cervical Pap test/cervical intraepithelial neoplasia	
ICD-9 Code (Main)†	Description
795.02	Papanicolaou smear of cervix with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
795.03	Papanicolaou smear of cervix with low grade squamous intraepithelial lesion (LGSIL)
795.04	Papanicolaou smear of cervix with high grade squamous intraepithelial lesion (HGSIL)
795.05	Cervical high-risk human papillomavirus (HPV) DNA test positive
795.06	Papanicolaou smear of cervix with cytologic evidence of malignancy
622.10	Dysplasia of cervix, unspecified
622.11	Mild dysplasia of the cervix
622.12	Moderate dysplasia of the cervix
233.1	Carcinoma in situ of cervix uteri
233.32	Carcinoma in situ vulva
V13.22	History of cervical dysplasia
ICD-9 Code (Supplementary)‡	Description
622.1	Dysplasia of cervix, uteri
623	Dysplasia of vagina
79.4	HPV infection, unspecified site
795.00	Abnormal glandular Papanicolaou smear of cervix
795.01	Papanicolaou smear of cervix with atypical squamous cells of undetermined significance (ASC-US)
795.07	Satisfactory cervical smear but lacking transformation zone
795.08	Unsatisfactory cervical cytology smear
795.09	Other abnormal Pap smear of cervix and cervical HPV
History of genital warts	
ICD-9 Code (Main)	Description
078.11	Condyloma acuminatum
078.10	Viral warts, unspecified
078.19	Other specified viral warts
ICD-9 Code (Supplementary)‡	Description
078.12	Plantar warts

Abbreviations: ICD-9, International Classification of Diseases, Ninth Revision. *ICD-9 codes V01.79 (exposure to HIV virus) and 795.71 (nonspecific serologic evidence of HIV) were not included in identifying women with HIV because these codes do not confirm HIV disease. †These are the main codes for this diagnosis but added supplementary codes to account for coding errors. ‡ The supplementary codes were used in sensitivity analysis only.

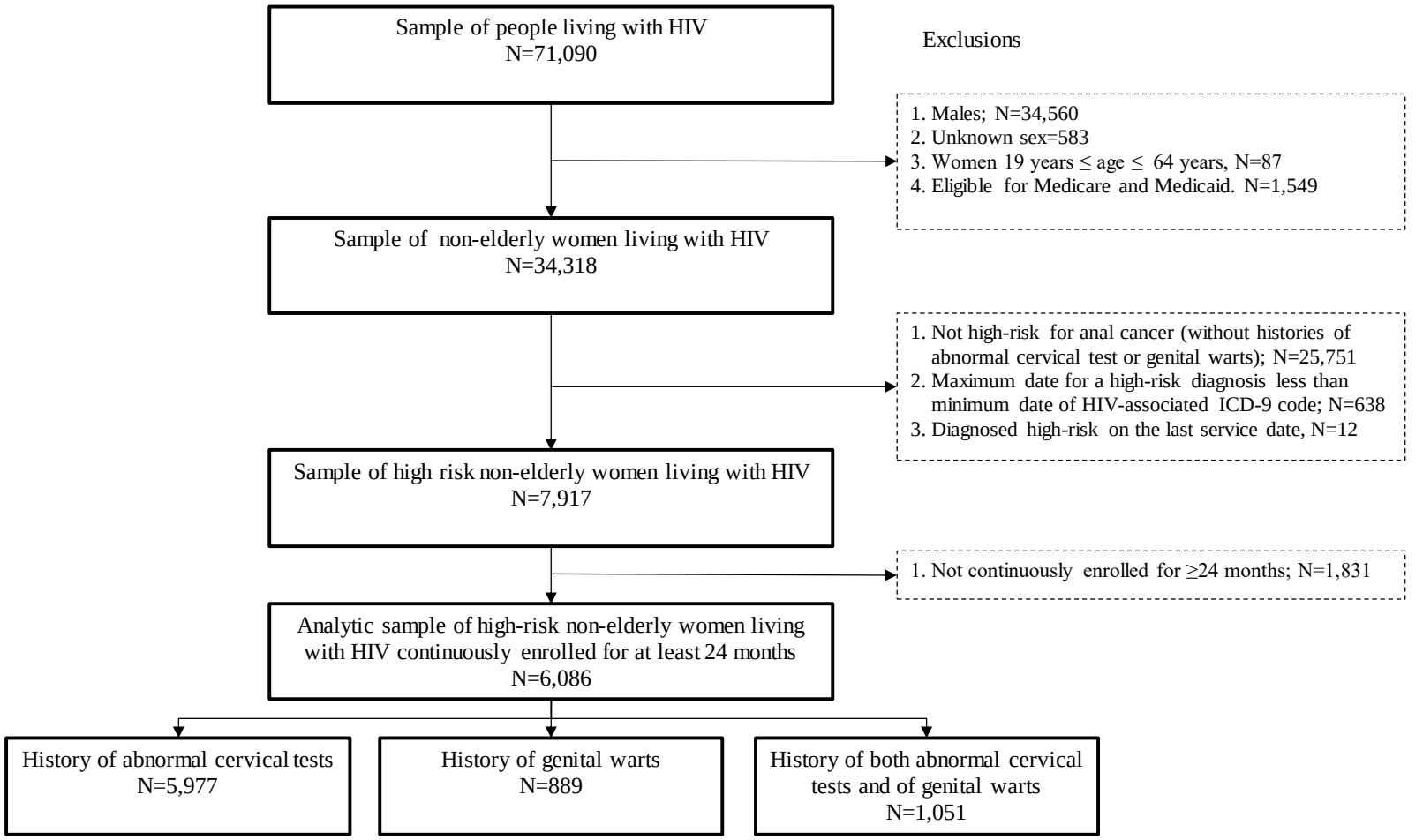


Figure C2: Algorithm for identifying high-risk HIV-infected women from Medicaid Analytic eXtract (MAX) files
This figure shows the process of deriving a sample of women at high-risk for acquiring anal cancer from a sample of women enrolled in Medicaid and validated to be living with HIV. The analytic sample comprised 6,086 of whom 5,977 had a history of abnormal cervical tests, 889 had a history of genital warts, and 1,051 had histories of both abnormal cervical tests and genital warts.

Appendix C3: Identifying high-risk women screened for anal cancer

To identify high-risk women screened for anal cancer, we used CPT codes that suggest that an anal cancer screen was performed, **table C3**. Unlike similar services such as cervical cancer screening, there is no single CPT code for anal cancer screening [309], [310], [312]. For example, CPT code 88104 "fluid requiring simple smear preparation" suggests that anal cancer screening was performed using a Pap smear. We searched Google, Google Scholar, and PubMed for commonly used CPT codes that suggest anal cancer screening was performed. Examples of terms used include "CPT code" used in combination with "anal cytology" or "anal cancer screen" or "high-resolution anoscopy".

Table C3: CPT codes for anal cancer screening

Anal cytology	
CPT* code	Description
87207	Stain for inclusion bodies
88104	Fluid requiring simple smear preparation
88108	Fluid requiring concentration technique
88112	Fluid requiring thin layer preparation
88160	Smear prepared by the client
88161	Smear requiring preparation
88162	Multiple smears (5 or more) requiring extended study
88172	Determination of adequacy of specimen
88173	FNA (fine needle aspiration) interpretation
88305	Fluid requiring cell block preparation
Anoscopy	
CPT code	
46600	Anoscopy, with or without collecting a specimen
46601	Anoscopy; diagnostic, with high-resolution magnification (HRA)
46606	Anoscopy with multiple biopsy specimens
46607	Diagnostic anoscopy and biopsy
HCPCS code†	Description
G2078	Anoscopy, high resolution (with magnification and chemical agent enhancement)
G6027	High-resolution anoscopy with specimen collection
G6028	High-resolution anoscopy with biopsy

Abbreviations: CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System. *CPT codes are used to report medical, surgical and diagnostic procedures rendered by physicians and other healthcare professionals. †HCPCS codes are in two levels. Level 1 comprises CPT codes while level 2 is for supplies, medications, and services provided to patients outside the physician's office and not included in the CPT code.

Appendix C4: Ascertaining whether a result of an anal cancer screen was abnormal

To ascertain whether the outcome of the anal cancer screen was abnormal, we used ICD-9 codes suggesting that an abnormal result was found during the screening. If an enrollee received the screening but none of the codes we found were recorded, we assumed that abnormal or suspicious anal cells were not found. We searched Google, Google Scholar, and PubMed for the ICD-9 codes. For the search, we used the terms "ICD-9 or in combination with "anal squamous intraepithelial lesion" or "dysplasia of anus" or "anal intraepithelial neoplasia", among other terms.

Table C4: ICD-9 codes for identifying women with abnormal results after anal cancer screening

ICD-9 Code	Description
796.70	Abnormal glandular Papanicolaou smear of anus
796.71	Papanicolaou smear of anus with atypical squamous cells of undetermined significance (ASC-US)
796.72	Papanicolaou smear of anus with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
796.73	Papanicolaou smear of anus with low grade squamous intraepithelial lesion (LGSIL)
796.74	Papanicolaou smear of anus with high grade squamous intraepithelial lesion (HGSIL)
796.75	Anal high-risk human papillomavirus (HPV) DNA test positive
796.76	Papanicolaou smear of anus with cytologic evidence of malignancy
796.77	Satisfactory anal smear but lacking transformation zone
796.78	Unsatisfactory anal cytology smear
796.79	Other abnormal Papanicolaou smear of the anus and anal HPV
569.44	Dysplasia of anus (mild, moderate, AINI and II)
230.5	Carcinoma in situ of the anal canal
230.6	Carcinoma in situ of anus, unspecified
211.4	Benign neoplasm of rectum and anal canal
569.49	Other specified disorders of rectum and anus

Abbreviation: ICD-9, International Classification of Diseases, Ninth Revision.

Stata do file

```
///Analysis of initial anal cancer screening

cd /mnt/isilon/data/hpr/yang/HIV/STEVEN/DATA/CLAIM/Working_folder/Stata/


log using summaries, replace


set more off


use hiv+_hirsk_patient_analysis, clear



*examining the characteristics of those enrolled for two years and those who
were not

tab continuously_2yr riskgroup, chi exp row

tab continuously_2yr race, chi exp row

tab continuously_2yr scrnd_for_AC, chi exp row

tab race scrnd_for_AC if continuously_2yr==0, chi exp row

tab race scrnd_secondtime if continuously_2yr==0, chi exp row



*keeping only those enrolled for at least two years

tab continuously_2yr, m

keep if continuously_2yr==1


*checking the association between routine care and anal cancer screening

tab routinecare

tab routinecare scrnd_for_AC, chi

tab routinecare scrnd_for_AC, col

tab routinecare scrnd_for_AC, col row


*setting the font

graph set window fontface "Times New Roman"
```

```
***********
*Initial anal cancer screening


**understanding the data


*tsetting the data
stset time_exit1, origin(time_entry1) failure(scrnd_for_AC ==1) id(msis_id)
scale(30)


tab _d, m
*tab _d scrnd_for_AC, m
gsort- _d
order scrnd_for_AC srvc_bgn_dt srvc_end_dt time* date_first_hirsk _d
srvc_date_first srvc_date_last



*describing the data
stdescribe


forval i=1/3 {
stdescribe if riskgroup==`i'
}


forval i=1/4 {
stdescribe if race==`i'
}


*summarizing the data
stsum, by(riskgroup)
stsum, by(race)
stsum, by(riskgroup race)
```

```
*checking if any of the variables are timevarying

stvary



*using the log-rank and unadjusted cox model to check variables for inclusion
///

*usually if p value >.2, the variable should not be included

*log rank test is for categorical variables, while Cox is for continuous one

*log rank

foreach var of varlist riskgroup race eligibility {

sts test `var'

}

* Cox

stcox age

stcox enrollment


***summary statistics

summarize  enrollment age


*Oneway ANOVA

oneway age riskgroup, tab

oneway enrollment riskgroup, tab



*kruskall Wallis test, by risk group

tabstat enrollment age, by(riskgroup) stats(p50 iqr)

kwallis enrollment, by(riskgroup)

kwallis age, by(riskgroup)



foreach var of varlist scrnd_for_AC scrnd_secondtime abnanal race eligibility
continuously_3 continuously_4 {

tab `var' riskgroup, chi
```

```
}

*ranksum tests
median age, by (riskgroup)
**
**table 2 of descriptives (by race)
*kruskall Wallis test, by race
tabstat enrollment age, by(race) stats(p50 iqr)
kwallis enrollment, by(race)
kwallis age, by(race)

oneway age race, tab
oneway enrollment race, tab



foreach var of varlist scrnd_for_AC scrnd_secondtime abnanal riskgroup
eligibility continuously_3 continuously_4 {
tab `var' race, chi
}
**the bivariate analyses
*the bivariate analyses will be only among those continuously enrolled for at
least 24 months

*table 3: bivariate analyses
foreach var of varlist riskgroup race continuously_3 continuously_4 {
stsum, by(`var')
stci, by(`var')
stci, rmean by(`var')
sts test `var'
}

*drawing Kaplan-Meier graphs: interest is in failure (success) and not
survival
```

```
sts graph, gwood failure risktable(, color(black) size(2.5) order(1 "All
women")  title("Risk table", size(3.0))) ///

yline(0.5, lwidth(0.002) lcolor(black) lpattern(-)) ylab(, labsize(2.5))
xline(13.6, lwidth(0.002) lcolor(black) lpattern(-)) ///

xtitle("Analysis time (months)", size(3.0)) ytitle("% screened for anal
cancer", size(3.0) height(7)) xlabel(,labsize(3.0)) ///

xlabel(0 (12) 48) ///

graphregion(fcolor(white)) ///

legend(rows(1) label(1 "(95% C.I.") label(2 "Screening function") size(2.5)
order(2 "Screening function" 1 "95% C.I.")) ///

title("Figure 1: Kaplan-Meier (KM) estimates of initial anal cancer screening
rates", size(3) color(black)) ///

graphregion(color(white))

graph save all_women, replace


*by riskgroup but I start by estimating unadjusted relative risks to see if
separate failure (sucess) curves are warranted

glm scrnd_for_AC i.riskgroup, fam(bin) link(log) eform /*shows that separate
success curves are warranted*/

stcox i.riskgroup


sts graph, failure by(riskgroup) risktable(, color(black) size(2.5) order(1
"Warts only" 2 "Abn. cerv only" 3 "Both")  title("Risk table", size(3.0)))
///

yline(0.5, lwidth(0.002) lcolor(black) lpattern(-)) ylab(, labsize(2.5)) ///

xline(4.2 14.8 43.9, lwidth(0.002) lcolor(black) lpattern(-)) ///

legend(rows(1) subtitle("Risk group", size(3.0)) label(1 "Warts only")
label(2 "Abn. cerv only") label(3 "Both") size(2.5)) ///

xtitle("Analysis time (months)", size(3.0)) ytitle("% screened for anal
cancer", size(3.0) height(7)) xlabel(,labsize(3.0)) ///

graphregion(fcolor(white)) ///

xlabel(0 (12) 48) ///

plot1opts(lpattern(longdash_dot) lcolor(blue)) ///

plot2opts(lpattern(dash) lcolor(maroon)) ///

plot3opts(lpattern(dash_dot) lcolor(green)) ///

caption("Abnormal cervical: HR=1.48, 95% C.I.=1.30-1.69; Both: HR=2.28, 95%
C.I.=1.97-2.63", size(3.0)) ///
```

```
title("Figure 1: KM estimates of initial anal cancer screening rates" "after
a high-risk diagnosis, by risk group", size(3.0) color(black)) ///

graphregion(color(white))

graph save byriskgroup_kaplan, replace


*estimating baseline hazards (read about this on page 142 and 143 of intro to
survival analysis using stata)

stcox i.riskgroup i.race i.eligibility log_enrol age number_pcp specialists
proportion_college med_hh_inc countycases


*stcurve, hazard at(riskgroup=1) at(riskgroup=2) at(riskgroup=3)
kernel(gaussian) width(4) noboundary


stcurve, cumhaz at(riskgroup=1) at(riskgroup=2) at(riskgroup=3) ///

legend(rows(1) subtitle("Risk group", size(3.0)) label(1 "Warts only")
label(2 "Abn. cerv only") label(3 "Both") size(2.5)) ///

xtitle("Analysis time (months)", size(3.0)) ytitle("Cumulative risk (hazard)
of anal cancer screening", size(2.5) height(7)) xlabel(,labsize(3.0)) ///

clpattern(longdash dash longdash_dot) clcolor(blue maroon green) ///

xlabel(0 (12) 48) ///

caption("Abnormal cervical: HR=1.51, 95% C.I.=1.32-1.72; Both: HR=2.48, 95%
C.I.=2.15-2.87", size(2.8)) ///

title("Figure 2: Adjusted risk of initial anal cancer screening (CPH)" "after
a high-risk diagnosis, by risk group", size(3.5) color(black)) ///

graphregion(color(white))

graph save byriskgroup_CPH, replace


*by race

glm scrnd_for_AC i.race, fam(bin) link(log) eform /*shows that separate
success curves are not warranted*/

stcox i.race

stcox i.riskgroup i.race i.eligibility log_enrol age number_pcp specialists
proportion_college med_hh_inc countycases


*unadjusted (KM)
```

```
sts graph, failure by(race) risktable(, color(black) size(2.5) order(1
"Whites" 2 "Blacks" 3 "Hispanics" 4 "Others")  title("Risk table",
size(3.0))) ///

yline(0.5, lwidth(0.002) lcolor(black) lpattern(-)) ylab(, labsize(2.5))
xline(6.3 8.2 8.5, lwidth(0.002) lcolor(black) lpattern(-)) ///

legend(rows(1) subtitle("Race/ethnicity", size(3.0)) label(1 "Whites")
label(2 "Blacks") label(3 "Hispanics") label(4 "Others")size(2.5)) ///

xtitle("Analysis time (months)", size(3.0)) ytitle("% screened for anal
cancer", size(3.0) height(7)) xlabel(,labsize(3.0)) ///

xlabel(0 (12) 48) ///

graphregion(fcolor(white)) ///

caption("Blacks: HR=0.95, 95% C.I.=0.87-1.04; Hispanics: HR=0.89, 95%
C.I.=0.76-1.04 Others: HR=0.45, 95% C.I.=0.41-0.51", size(2.2)) ///

title("Figure 2: KM estimates of initial anal cancer screening rates, by
race", size(3) color(black)) ///

plot1opts(lpattern(longdash_dot) lcolor(blue)) ///

plot2opts(lpattern(dash) lcolor(maroon)) ///

plot3opts(lpattern(dash_dot) lcolor(green)) ///

plot4opts(lpattern(longdash) lcolor(black)) ///

graphregion(color(white))

graph save byrace_kaplan, replace


*adjusted (CPH)

stcurve, cumhaz at(race=1) at(race=2) at(race=3) at(race=4) ///

legend(rows(1) subtitle("Race/ethnicity", size(3.0)) label(1 "Whites")
label(2 "Blacks") label(3 "Hispanics") label(4 "Others")size(2.5)) ///

xtitle("Analysis time (months)", size(3.0)) ytitle("Cumulative risk (hazard)
of anal cancer screening", size(2.5) height(7)) xlabel(,labsize(3.0)) ///

xlabel(0 (12) 48) ///

clpattern(longdash_dot dash dash_dot longdash) clcolor(blue maroon green
black) ///

caption("Blacks: HR=0.97, 95% C.I.=0.88-1.06; Hispanics: HR=0.84, 95%
C.I.=0.72-0.99; Others: HR=0.65, 95% C.I.=0.57-0.73", size(2.2)) ///

title("Figure 7: CPH adjusted risk of anal cancer screening, by
race/ethnicity", size(3.5) color(black)) ///

graphregion(color(white))

graph save byrace_CPH, replace
```

```
stci, rmean by(riskgroup)

stci, emean by(riskgroup)

stci, p(20) by(riskgroup)

stci, by(riskgroup)

stci, by(riskgroup abnanal)

stci, emean by(riskgroup) /*gives the extended mean*/


stci,  emean graph

stci,  emean tmax(100) graph



*estimating the hazard function using the adjusted Cox PH model

stcox i.riskgroup i.race i.eligibility enrollment age


*finding the correct functional form

predict mg, mgale

lowess mg age /*no major concerns here*/

lowess mg enrollment /*no major concerns here*/

drop mg



******overall hazards

stcox i.riskgroup i.race i.eligibility log_enrol age number_pcp specialists
proportion_college med_hh_inc countycases

estimates store overall


esttab overall using overall.rtf, nogaps wide eform b se  aic bic replace
nonum label


**hazards at different time periods

*estimating hazard rates at different time intervals
```

```
log using summaries1, replace

stptime,  by(riskgroup) at (1 6 12 24 48)

stptime,  by(race) at (1 6 12 24 48)

stsplit time, at(1 6 12 24)

stcox i.riskgroup i.race eligibility age log_enrol  number_pcp specialists
med_hh_inc proportion_college countycases

bysort time: stcox i.riskgroup i.race eligibility age log_enrol  number_pcp
specialists med_hh_inc proportion_college countycases

drop time

log2html summaries1, replace



*estimating the cumulative baseline hazard

stcox i.riskgroup i.race i.eligibility log_enrol age

predict H0, basechazard

line H0 _t, c(J) sort

label variable H0 "Warts only"

label variable _t "Analysis time (months)"


*getting the baseline hazard for each risk group

gen H2=H0*(exp(_b[2.riskgroup]))

label variable H2 "Abnormal cervical only"


gen H3=H0*(exp(_b[3.riskgroup]))

label variable H3 "Both warts and abnormal cervical"


line H0 H2 H3 _t, c(J J J) sort ///

legend(rows(1) size(2.0)) ///

xtitle(, size(3.0)) ytitle("Cumulative risk (hazard) of anal cancer
screening", size(2.5) height(7)) xlabel(,labsize(3.0)) ///

title("Figure 5: Adjusted risk of anal cancer screening", size(3.5)
color(black))


drop H0 H2 H3
```

```
*stcurve, cif at(riskgroup=1) at(riskgroup=2) at(riskgroup=3)

/*survivor functions (these might not be needed)
predict S0, basesurv
line S0 _t, c(J) sort

gen S2=S0*exp(_b[2.riskgroup])
gen S3=S0*exp(_b[3.riskgroup])
line H0 H2 H3 S0 S2 S3 _t, c(J J J J J J) sort
*/

*testing the PH assumption

*Global test for all and each variable after Cox regression
stphtest, rank detail


*graphs for each variable
stphtest, plot(age) ///
title("Age", position(12) ring(0) size(3.5) color(black)) ///
xtitle("Analysis time (months)", height(4) size(2.8) ) ///
xlabel(0 (12) 48) ///
ytitle(, height(7) size(2.8)) ///
graphregion(color(white)) ///
note("")
graph save age_ph.gph, replace

stphtest, plot(log_enrol) ///
title("Enrollment", position(12) ring(0) size(3.5) color(black)) ///
xtitle("Analysis time (months)", height(4) size(2.8)) ///
xlabel(0 (12) 48) ///
```

```
ytitle("scaled Schoenfeld - enrollment", height(7) size(2.8)) ///
graphregion(color(white)) ///
note("")
graph save enrollment_ph.gph, replace

stphplot, by(riskgroup) ///
title("Risk group", position(12) ring(0) size(3.5) color(black)) ///
ytitle(, height(7) size(2.8)) ///
xtitle(, height(4) size(2.8)) ///
plot1opts(lwidth(thin) msize(vsmall)) ///
plot2opts(lwidth(thin) msize(vsmall)) ///
plot3opts(lwidth(thin) msize(vsmall)) ///
graphregion(color(white)) ///
legend(off)
graph save riskgroup_ph.gph, replace

stphplot, by(race) ///
title("Race/ethnicity", position(12) ring(0) size(3.5) color(black)) ///
ytitle(, height(7) size(2.8)) ///
xtitle(, height(4) size(2.8)) ///
plot1opts(lwidth(thin) msize(vsmall)) ///
plot2opts(lwidth(thin) msize(vsmall)) ///
plot3opts(lwidth(thin) msize(vsmall)) ///
plot4opts(lwidth(thin) msize(vsmall)) ///
graphregion(color(white)) ///
legend(off)
graph save race_ph.gph, replace

graph combine riskgroup_ph.gph race_ph.gph age_ph.gph enrollment_ph.gph,
title("Figure 5: Test of PH assumption", size(4.0) color(black)) ///
graphregion(color(white))
graph save combined_ph.gph, replace
```

```
******
*testing overall fitness of the model
*Cox-snell residuals
*note that without the mgale option the results would be different
set more off

*before transforming enrollment
stcox i.riskgroup i.race i.eligibility enrol age, mgale(mg)

predict cs, csnell
stset cs, failure(scrnd_for_AC ==1)
sts generate H = na
line H cs cs, sort xlab(0 1 to 4) ylab(0 1 to 4) ///
title("Figure 7a: Overall model fitness using Cox-snell residuals" ///
"Before variable transformation", linegap(2) size(3.5) color(black)) ///
graphregion(color(white))
graph save gof_ph.gph, replace
drop mg cs H

*after transforming enrollment

stcox i.riskgroup i.race i.eligibility log_enrol age, mgale(mg)

predict cs, csnell
stset cs, failure(scrnd_for_AC ==1)
sts generate H = na
line H cs cs, sort xlab(0 1 to 4) ylab(0 1 to 4) ///
title("Figure 7b: Overall model fitness using Cox-snell residuals" ///
```

```
"After variable transformation (final model)", linegap(2) size(3.5)
color(black)) ///

graphregion(color(white))

graph save gof1_ph.gph, replace



stcox i.riskgroup i.race ib5.eligibility age enrollmnent, mgale(mg)


stcox i.riskgroup i.race ib5.eligibility age log_enrol, mgale(mg)

predict cs, csnell

stset cs, failure(scrnd_for_AC ==1)

sts generate H = na

line H cs cs, sort xlab(0 1 to 4) ylab(0 1 to 4) ///

title("Figure 7: Overall model fitness using Cox-snell residuals", size(3.5)
color(black))

drop mg cs H

*******LOGISTIC REGRESSIONS: EXAMINING GUIDELINE CONCORDANCE OF FOLLOW-UP
SCREENING****

cd /mnt/isilon/data/hpr/yang/HIV/STEVEN/DATA/CLAIM/Working_folder/Stata/


use for_logistic_regressions, clear


*tsetting the data

stset time_exit2, scale(30) origin(time_entry2) failure(scrnd_secondtime==1)
id(msis_id)

order _t _st

tab _st

keep if _st==1


*testing the normality/skewness of time

mvtest normal _t, univariate


****MAIN ANALYSIS****
```

```
**creating some variables

*any follow-up screening

tab scrnd_secondtime


gen any_fup_screen=scrnd_secondtime

label define any_fup_screen 0 "Not screened" 1 "Screened", replace

label values any_fup_screen any_fup_screen

tab any_fup_screen scrnd_secondtime


*concordance

gen concordant=.

replace concordant=1 if abnanal==0 & _t<=12 &  scrnd_secondtime==1 |
abnanal==1 & _t<=6 & scrnd_secondtime==1

replace concordant=0 if concordant==.

label define concordant 1 "Concordant" 0 "Not concordant", replace

labe values concordant concordant

order abnanal _t concordant

tab concordant abnanal, col chi exp

tab concordant riskgroup, col chi exp

tab concordant race, col chi exp


*Categorical age variable

gen age_cat=.

replace age_cat=1 if age<=34

replace age_cat=2 if age>34 & age<=44

replace age_cat=3 if age>44 & age<=54

replace age_cat=4 if age>54

label define age_cat 1 "19-34 years" 2 "35-44 years" 3 "45-54 years" 4 "55-64
years", replace

label values age_cat age_cat

tab age_cat

oneway age riskfactor, bonferroni tab
```

```
*enrollment_variable, categorical

gen continuous_enrollment=continuously_1yr + continuously_2yr +
continuously_3yr +continuously_4yr

label define continuous_enrollment 2 "2 years" 3 "3 years" 4 "4 years",
replace

label values continuous_enrollment continuous_enrollment

tab continuous_enrollment

tab concordant continuous_enrollment, chi exp row col


*summary statistics

tab abnanal riskfactor, chi

tab scrnd_secondtime riskfactor, chi

tab concordant riskfactor

tab concordant riskfactor  if abnanal==1, chi

tab concordant riskfactor  if abnanal==0, chi

tab race riskfactor, chi

tab eligibility riskfactor, chi

tab continuous_enrollment riskfactor, chi

stsum, by(riskfactor)

stptime,  by(riskfactor)


*working with MCO enrollment variable

gen mco=.

replace mco=1 if mco_enrollment <=0.6

replace mco=2 if mco_enrollment >0.6 & mco_enrollment<=0.8

replace mco=3 if mco_enrollment >0.8 & mco_enrollment<=1

label define mco 1 "<=60%" 2 "61%-80%" 3 ">80%", replace

label values mco mco

tab mco


*creating numeric state variable

encode state, gen(state_num)
```

```
*Any follow up screening


*without state fixed-effects

logit any_fup_screen  i.riskgroup i.abnanal i.eligibility
i.continuous_enrollment i.age_cat i.race i.HIVrate_tert i.pcp_tert
i.spec_tert i.poverty i.less_than_HS i.mco , noconst or

estimates store anyfup_no_fe


*with state-fixed effects

logit any_fup_screen  i.riskgroup i.abnanal i.eligibility
i.continuous_enrollment i.age_cat i.race i.HIVrate_tert i.pcp_tert
i.spec_tert i.poverty i.less_than_HS i.mco  i.state_num , noconst or

estimates store anyfup_with_fe



**guideline concordance

*without state fixed-effects

logit concordant  i.riskgroup i.abnanal i.eligibility i.continuous_enrollment
i.age_cat i.race i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty
i.less_than_HS i.mco  , or nocons

estimates store concordant_no_fe


*with state-fixed effects

logit concordant  i.riskgroup i.abnanal i.eligibility i.continuous_enrollment
i.age_cat i.race i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty
i.less_than_HS i.mco  i.state_num , or nocons

estimates store concordant_with_fe


margins abnanal

margins, at(riskgroup=(1 2) abnanal=(0 1)) post

margins abnanal


esttab concordant_with_fe anyfup_with_fe using logits.rtf, nogaps wide eform
b(2) ci(2) label replace  nonum star(* 0.10 ** 0.05 *** 0.01) ///

            collabels("Odds Ratio" "95% Confidence Interval" "Odds Ratio"
"95% Confidence Interval") ///
```

```
            mtitle("Guideline-concordant follow-up anal cancer screening"
"Any follow-up anal cancer screening") ///

        title( "Table 1: Predictors of guideline-concordant follow-up anal
cancer screening in high-risk women living with HIV") ///

            refcat(2.riskgroup "Risk factors (ref: one risk factor)"
1.abnanal "Result at first test (ref: normal)" ///

            2.race "Race/ethnicity (ref: non-Hispanic whites)" 2.eligibility
"Qualification for Medicaid (ref: income)" ///

            3.continuous_enrollment "Continuous enrollment (ref: 2 years)"
2.pcp_tert "Physician 10,000 population (ref: 0-3.7)" ///

            2.spec_tert "Specialists per 10,000 population (ref:0-0.92)"
2.less_than_HS "Less than high school (ref: 1%-11.4%)" ///

            2.poverty "Percent poor (ref:0.9%-13.5%)" 2.HIVrate_tert "HIV
prevalence per 100,000 adults (ref: 0-54)" ///

            2.mco "Medicaid managed care enrollment (ref: <=60%)" 2.age_cat
"Age (ref:19-34 years)", nolabel) ///

            drop (1.riskgroup 0.abnanal 1.race 1.eligibility
2.continuous_enrollment 1.pcp_tert 1.spec_tert 1.less_than_HS ///

            1.poverty 1.HIVrate_tert 1.mco 1.age_cat *state_num)



*checking for multicollinearity

collin riskgroup abnanal race eligibility continuous_enrollment age
number_pcp specialists proportion_college med_hh_inc countycases state_n


**goodness of fit measures

logit concordant  i.riskgroup i.abnanal i.race i.eligibility
i.continuous_enrollment age number_pcp specialists proportion_college
med_hh_inc countycases, or


*Hosmer lemeshow

estat gof, group(10)

lfit, group(20)


*predicted probabilities

predict probability , pr

gen conc_pred=0
```

```
replace conc_pred=1 if probability>=0.5

tab concordant conc_pred, row chi


*plotting residuals

gen n=_n

predict residuals, deviance

sum residual

gen county_n=countyname if residuals>2 & residuals<10

gen county_m=countyname if residuals<-2

label var n "Observation number"

twoway (scatter residuals n if concordant==1 , mlabel(county_n) mlabsize(2))
(scatter residuals n if !concordant, mlabel(county_m) mlabsize(2)), ///

      yline(-2 2) legend(off) text(1.9 1000 "Concordant") text(0 1000 "Not
concordant")  ///

      title("Fig 1: Goodness-of-fit test using deviance residuals", size(4))
///

      ytitle("Deviance residuals")

count if county_n!="" | county_m!=""


drop probability conc_pred residuals county_n county_m



tab  conc_pred concordant, chi

roctab  concordant conc_pred, detail table


/////SENSITIVITY ANALYSIS

//sensitivity analysis 2

*continuously enrolled for 4 years


sts list if continuously_4yr==1, failure by(abnanal) at (6 12)


sts list if continuously_4yr==1, failure by( riskgroup abnanal) at (6 12)
```

```
logit concordant  i.riskgroup i.abnanal i.eligibility i.age_cat i.race
i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty i.less_than_HS i.mco
i.state_num, or nocons

estimates store two_years_main

logit concordant  i.riskgroup i.abnanal i.eligibility i.age_cat i.race
i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty i.less_than_HS i.mco
i.state_num if continuously_4yr==1, or nocons

estimates store four_years


esttab two_years_main four_years, nogaps wide eform b(2) ci(2) label replace
nonum star(* 0.10 ** 0.05 *** 0.01) ///

            collabels("Odds Ratio" "95% Confidence Interval" "Odds Ratio"
"95% Confidence Interval") ///

            mtitle("Guideline-concordant follow-up anal cancer screening"
"Any follow-up anal cancer screening") ///

        title( "Table 1: Predictors of guideline-concordant follow-up anal
cancer screening in high-risk women living with HIV") ///

            refcat(2.riskgroup "Risk factors (ref: one risk factor)"
1.abnanal "Result at first test (ref: normal)" ///

            2.race "Race/ethnicity (ref: non-Hispanic whites)" 2.eligibility
"Qualification for Medicaid (ref: income)" ///

            2.pcp_tert "Physician 10,000 population (ref: 0-3.7)" ///

            2.spec_tert "Specialists per 10,000 population (ref:0-0.92)"
2.less_than_HS "Less than high school (ref: 1%-11.4%)" ///

            2.poverty "Percent poor (ref:0.9%-13.5%)" 2.HIVrate_tert "HIV
prevalence per 100,000 adults (ref: 0-54)" ///

            2.mco "Medicaid managed care enrollment (ref: <=60%)" 2.age_cat
"Age (ref:19-34 years)", nolabel) ///

            drop (1.riskgroup 0.abnanal 1.race 1.eligibility 1.pcp_tert
1.spec_tert 1.less_than_HS ///

            1.poverty 1.HIVrate_tert 1.mco 1.age_cat *state_num)



tab

*concordance

drop concordant

gen concordant=.
```

```
replace concordant=1 if abnanal==0 & _t<=14 &  scrnd_secondtime==1 |
abnanal==1 & _t<=8 & scrnd_secondtime==1

replace concordant=0 if concordant==.

label define concordant 1 "Concordant" 0 "Not concordant", replace

labe values concordant concordant

order abnanal _t concordant

tab concordant abnanal, col chi exp

tab concordant riskgroup, col chi exp


*without state fixed-effects

logit concordant  i.riskgroup i.abnanal i.eligibility i.continuous_enrollment
i.age_cat i.race i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty
i.less_than_HS i.mco  , or

estimates store concordant_no_fe


*with state-fixed effects

logit concordant  i.riskgroup i.abnanal i.eligibility i.continuous_enrollment
i.age_cat i.race i.HIVrate_tert i.pcp_tert i.spec_tert i.poverty
i.less_than_HS i.mco  i.state_num , or

estimates store concordant_with_fe

margins abnanal

margins, at(riskgroup=(1 2) abnanal=(0 1)) post

esttab concordant_with_fe, wide eform ci

log close
```

Chapter 5: Conclusion

This dissertation examined the effectiveness of interventions aimed at increasing uptake of family planning services and HIV-related preventive care among women in low-income settings. The studies show that uptake of these services is low overall but find that interventions at the clinic or community levels are effective in increasing the uptake of these services. However, the studies also emphasize several areas for future research. For example, paper 1 which reports that contraceptive use increased among rural women following the national scale-up of CBDs in rural Malawi, the paper suggests that future research should focus on examining the cost-effectiveness of the national CBDs given that resources in these settings are very limited. The trial-based cost-effectiveness of conditional cash transfers in the DRC suggests that future research should focus on examining the cost-effectiveness of the cash incentives in larger populations and over a longer analytic horizon before further scale-up of the intervention in sub-Saharan Africa. Similarly, gathering more evidence about the benefits of anal cancer screening in people living with HIV at high risk for anal cancer in the USA can help solidify the guidelines for anal cancer screening and improve the rates overall follow-up anal cancer screening.

References

[1] National Statistical Office, "Malawi population datasheet," 2012.

[2] The World Bank, "Data: Malawi," 2015.

[3] M. of E. P. and D. Malawi Government, "Why population matters to Malawi's development," 2012.

[4] J. Solo, R. Jacobstein, and D. Malema, "Malawi case study: Choice not chance," *A repositioning family planning case study*, no. Journal Article, 2005.

[5] B. Kalanda, "Repositioning family planning through community based distribution agents in Malawi," *Malawi Medical Journal*, vol. 22, no. 3, 2010.

[6] The World Bank, "Document of the World Bank. Malawi Population and Family Planning Project. Implementation Completion Report (IDA-31330): Report number 27059:," 2004.

[7] The World Bank, "Document of the World Bank: Project appraisal document on a proposed learning and innovation lending (credit) in the amount of SDR 3.8 million (US$5 million equivalent) to the Government of Malawi for a population and family planning project. Report number: 1792-MAI," 1998.

[8] B. Cohen, "Family planning programs, socioeconomic characteristics, and contraceptive use in Malawi," *World Dev.*, vol. 28, no. 5, pp. 843–860, 2000.

[9] J. Chintsanya, "Trends and Correlates of Contraceptive Use among Married Women in Malawi: Evidence from 2000-2010 Malawi Demographic and Health Surveys," no. Journal Article, 2013.

[10] M. Palamuleni, "Fertility decline in Malawi: an analysis of the proximate determinants," *Journal of social development in Africa*, vol. 25, no. 1, 2010.

[11] S. A. Adebowale, S. A. Adedini, L. D. Ibisomi, and M. E. Palamuleni, "Differential effect of wealth quintile on modern contraceptive use and fertility: evidence from Malawian women," *BMC Womens Health*, vol. 14, no. 1, p. 1, 2014.

[12] A. Brunie, T. H. Hoke, and B. Razafindravony, "Community-based distribution of injectable contraceptives in an African setting: community trial in Madagascar," *Sante*, vol. 21, no. 1, pp. 21–26, 2011.

[13] T. Hoke *et al.*, "Community-based distribution of injectable contraceptives: introduction strategies in four sub-Saharan African countries," *International perspectives on sexual and reproductive health*, vol. 38, no. 4, pp. 214–219, 2012.

[14] C. Debpuur, J. F. Phillips, E. F. Jackson, A. Nazzar, P. Ngom, and F. N. Binka, "The impact of the Navrongo Project on contraceptive knowledge and use, reproductive preferences, and fertility," *Stud.Fam.Plann.*, vol. 33, no. 2, pp. 141–164, 2002.

[15] K. R. Katz, C. G. West, F. Doumbia, and F. Kané, "Increasing access to family planning services in rural Mali through community-based distribution," *International Family Planning Perspectives*, no. Journal Article, pp. 104–110, 1998.

[16] M. Fayemi, G. Momoh, O. Oduola, G. Delano, O. Ladipo, and O. Adebola, "Community based distribution agents' approach to provision of family planning information and services in five Nigerian States: A mirage or a reality?," *African journal of primary health care & family medicine*, vol. 3, no. 1, 2011.

[17] FHI 360, "Research and Utilization: Expanding the community-based distribution of injectable contraceptives in Africa," 2008.

[18] A. Jacinto *et al.*, "Safety and Acceptability of Community-Based Distribution of Injectable Contraceptives: A Pilot Project in Mozambique," *Glob.Health.Sci.Pract.*, vol. 4, no. 3, pp. 410–421, 2016.

[19] N. Prata, A. Gessessew, A. Cartwright, and A. Fraser, “Provision of injectable contraceptives in Ethiopia through community-based reproductive health agents,” *Bull.World Health Organ.*, vol. 89, no. Journal Article, pp. 556–564, 2011.
[20] Y. Tawye, F. Jotie, T. Shigu, P. Ngom, and N. Maggwa, “The potential impact of community-based distribution programmes on contraceptive uptake in resource-poor settings: evidence from Ethiopia,” *Afr.J.Reprod.Health*, no. Journal Article, pp. 15–26, 2005.
[21] J. S. White and I. S. Speizer, “Can family planning outreach bridge the urban-rural divide in Zambia?,” *BMC health services research*, vol. 7, no. 1, p. 143, 2007.
[22] K. Krueger, A. Akol, P. Wamala, and A. Brunie, “Scaling up community provision of injectables through the public sector in Uganda,” *Stud.Fam.Plann.*, vol. 42, no. 2, pp. 117–124, 2011.
[23] World Health Organization, *Community-based distribution of contraceptives: A guide for programme managers*. World Health Organization, 1995.
[24] J. F. Phillips, W. L. Greene, and E. F. Jackson, *Lessons from community-based distribution of family planning in Africa*. Population Council New York, NY, USA, 1999.
[25] J. D. Shelton, L. Bradshaw, B. Hussein, Z. Zubair, T. Drexler, and M. R. McKenna, “Putting unmet need to the test: community-based distribution of family planning in Pakistan,” *International Family Planning Perspectives*, no. Journal Article, pp. 191–195, 1999.
[26] J. B. Casterline and S. W. Sinding, “Unmet need for family planning in developing countries and implications for population policy,” *Population and development review*, vol. 26, no. 4, pp. 691–723, 2000.
[27] N. Prata, F. Vahidnia, M. Potts, and I. Dries-Daffner, “Revisiting community-based distribution programs: are they still needed?,” *Contraception*, vol. 72, no. 6, pp. 402–407, 2005.
[28] R. J. Magnani, D. R. Hotchkiss, C. S. Florence, and L. A. Shafer, “The impact of the family planning supply environment on contraceptive intentions and use in Morocco,” *Stud.Fam.Plann.*, vol. 30, no. 2, pp. 120–132, 1999.
[29] J. R. Foreit, M. R. Garate, A. Brazzoduro, F. Guillen, M. del Carmen Herrera, and F. C. Suarez, “A comparison of the performance of male and female CBD distributors in Peru,” *Stud.Fam.Plann.*, no. Journal Article, pp. 58–62, 1992.
[30] S. L. Isaacs, “Nonphysician distribution of contraception in Latin America and the Caribbean,” *Fam.Plann.Perspect.*, no. Journal Article, pp. 158–164, 1975.
[31] A. J. Kols, M. J. Wawer, W. Quillin, and J. Kinsey, “Population reports. Community-based health and family planning.,” *Population reports.Series L, Issues in world health*, no. 3, 1982.
[32] J. Bongaarts and J. Bruce, “The causes of unmet need for contraception and the social content of services,” *Stud.Fam.Plann.*, no. Journal Article, pp. 57–75, 1995.
[33] N. Rutenberg and S. C. Watkins, “Conversation and contraception in Nyanza province Kenya.,” 1996.
[34] D. C. Kaseje, E. K. Sempebwa, and H. C. Spencer, “Community-based distribution of family planning services in Saradidi, Kenya,” *Annals of Tropical Medicine & Parasitology*, vol. 81, no. sup1, pp. 135–143, 1987.

[35] Z. Charyeva *et al.*, "Task Shifting Provision of Contraceptive Implants to Community Health Extension Workers: Results of Operations Research in Northern Nigeria," *Glob.Health.Sci.Pract.*, vol. 3, no. 3, pp. 382–394, 2015.
[36] T. H. Hoke *et al.*, "Community-based provision of injectable contraceptives in Madagascar: 'task shifting' to expand access to injectable contraceptives," *Health Policy Plan.*, vol. 27, no. 1, pp. 52–59, 2012.
[37] M. Tanabe *et al.*, "Community-Based Distribution of Family Planning Services in Humanitarian Settings: Identified Need and Potential from Malakal, South Sudan," *St Antony's International Review*, vol. 9, no. 2, pp. 114–132, 2014.
[38] J. T. Bertrand, M. E. McBride, N. Mangani, N. C. Baughman, and M. Kinuani, "Community-based distribution of contraceptives in Zaire," *International Family Planning Perspectives*, no. Journal Article, pp. 84–91, 1993.
[39] D. Nyamwaya, R. Morgan, M. Lukhando, A. Fisher, and L. Ndhlovu, "Expanding family planning delivery systems using traditional health practitioners: An operations research study in rural Kenya, Final Report," *AMREF & Nairobi, Kenya: The Population Council*, no. Journal Article, 1993.
[40] M. F. Gallo *et al.*, "Evaluation of a volunteer community-based health worker program for providing contraceptive services in Madagascar," *Contraception*, vol. 88, no. 5, pp. 657–665, 2013.
[41] J. N. Chege and I. Askew, "An assessment of community-based family planning programmes in Kenya," *Nairobi: Population Council*, no. Journal Article, 1997.
[42] G. S. Becker, "An economic analysis of fertility," in *Demographic and economic change in developed countries*, Book, Section vols., Columbia University Press, 1960, pp. 209–240.
[43] R. A. Easterlin, "An economic framework for fertility analysis," *Stud.Fam.Plann.*, vol. 6, no. 3, pp. 54–63, 1975.
[44] D. S. DeGraff, R. E. Bilsborrow, and D. K. Guilkey, "Community-level determinants of contraceptive use in the Philippines: a structural analysis," *Demography*, vol. 34, no. 3, pp. 385–398, 1997.
[45] A. G. Mairiga, A. A. Kullima, B. Bako, and M. A. Kolo, "Sociocultural factors influencing decision-making related to fertility among the Kanuri tribe of north-eastern Nigeria," *African journal of primary health care & family medicine*, vol. 2, no. 1, 2010.
[46] R. Mussa, "Impact of fertility on objective and subjective poverty in Malawi," no. Journal Article, 2010.
[47] S. Singh and J. E. Darroch, "Adding it up: Costs and benefits of contraceptive services," *Guttmacher Institute and UNFPA*, no. Journal Article, 2012.
[48] J. Bongaarts and S. W. Sinding, "A response to critics of family planning programs," *International Perspectives on Sexual and Reproductive Health*, vol. 35, no. 1, pp. 39–44, 2009.
[49] E. Lule, S. Singh, and S. A. Chowdhury, "Fertility Regulation Behaviors and Their Costs," *Contraception and unintended pregnancies in Africa and Eastern Europe and Central Asia.Washington: The International Bank for Reconstruction and Development.The World Bank*, no. Journal Article, 2007.
[50] Ministry of Health, "Malawi National Heath Accounts with Subaccounts for HIV/AIDS, Malaria, Reproductive Health, and Child Health for the Years 2009/10 , 2010/11, and 2011/12," 2014.

[51] M. Grossman, "On the concept of health capital and the demand for health," *Journal of Political economy*, vol. 80, no. 2, pp. 223–255, 1972.
[52] D. S. Kenkel, "Health behavior, health knowledge, and schooling," *Journal of Political Economy*, no. Journal Article, pp. 287–305, 1991.
[53] S. Saleem and M. Bobak, "Women's autonomy, education and contraception use in Pakistan: a national study," *Reproductive health*, vol. 2, no. 1, p. 1, 2005.
[54] C. Gordon, R. Sabates, R. Bond, and T. Wubshet, "Women's education and modern contraceptive use in Ethiopia," *International Journal of Education*, vol. 3, no. 1, p. 1, 2011.
[55] M. Ainsworth, K. Beegle, and A. Nyamete, "The impact of women's schooling on fertility and contraceptive use: A study of fourteen sub-Saharan African countries," *The World Bank Economic Review*, vol. 10, no. 1, pp. 85–122, 1996.
[56] C. L. Ejembi, T. Dahiru, and A. A. Aliyu, "DHS WORKING PAPERS," no. Journal Article, 2015.
[57] National Statistical Office and ICF Macro, "Malawi Demographic and Health Survey 2010," 2011.
[58] S. Pacqué-Margolis, C. Cox, A. Puckett, and L. Schaefer, "Exploring contraceptive use differentials in sub-Saharan Africa through a health workforce lens.," no. Journal Article, 2013.
[59] National Statistical Office and ICF Macro, "Malawi Demographic and Health Survey 2004," 2005.
[60] National Statistical Office and ICF Macro, "Malawi Demographic and Health Survey 2015-16: Key Indicators Report.," 2017.
[61] National Statistical Office and ORC Macro, *Malawi Demographic and Health Survey 2000*. Zomba, Malawi and Calverton, Maryland, USA: National Statistical Office, 2001.
[62] National Statistical Office, "2008 Malawi Population and Housing Census: Main census report," 2009.
[63] S. Rabe-Hesketh and A. Skrondal, "Multilevel modelling of complex survey data," *Journal of the Royal Statistical Society: Series A (Statistics in Society)*, vol. 169, no. 4, pp. 805–827, 2006.
[64] K. Jones, R. J. Johnston, and C. J. Pattie, "People, places and regions: exploring the use of multi-level modelling in the analysis of electoral data," *British Journal of Political Science*, vol. 22, no. 03, pp. 343–380, 1992.
[65] H. Goldstein, "Multilevel modelling of survey data," *Journal of the Royal Statistical Society.Series D (The Statistician)*, vol. 40, no. 2, pp. 235–244, 1991.
[66] F. Steele, "Module 7: Multilevel Models for Binary Responses: Concepts," *LEMMA VLE, University of Bristol, Centre for Multilevel Modelling.Accessed September*, no. Journal Article, 2010.
[67] J. Rasbash, "Module 4: Multilevel structures and classifications," 2008.
[68] A. C. Carle, "Fitting multilevel models in complex survey data with design weights: Recommendations," *BMC Medical Research Methodology*, vol. 9, no. 1, p. 1, 2009.
[69] ICF International, "Description of the Demographic and Health Surveys individual recode data file," 2008.
[70] ICF International, "Demographic and Health Surveys Methodology - Questionnaires: Household, Man's, and Woman's," 2011.

[71] J. S. Long and J. Freese, *Regression models for categorical dependent variables using Stata*. Stata press, 2006.
[72] E. B. Kaggwa, N. Diop, and J. D. Storey, "The role of individual and community normative factors: a multilevel analysis of contraceptive use among women in union in Mali," *International family planning perspectives*, no. Journal Article, pp. 79–88, 2008.
[73] Y. Oheneba-Sakyi and B. K. Takyi, "EFFECTS OF COUPLES'CHARACTERISTICS ON CONTRACEPTIVE USE IN SUB-SAHARAN AFRICA: THE GHANAIAN EXAMPLE," *J.Biosoc.Sci.*, vol. 29, no. 1, pp. 33–49, 1997.
[74] R. Stephenson, A. Baschieri, S. Clements, M. Hennink, and N. Madise, "Contextual influences on modern contraceptive use in sub-Saharan Africa," *Am.J.Public Health*, vol. 97, no. 7, pp. 1233–1240, 2007.
[75] K. M. Elfstrom and R. Stephenson, "The role of place in shaping contraceptive use among women in Africa," *PloS one*, vol. 7, no. 7, p. e40670, 2012.
[76] T. G. Conley and C. R. Taber, "Inference with 'difference in differences' with a small number of policy changes," *Rev.Econ.Stat.*, vol. 93, no. 1, pp. 113–125, 2011.
[77] W. R. Shadish, T. D. Cook, and D. T. Campbell, *Experimental and quasi-experimental designs for generalized causal inference*. Wadsworth Cengage learning, 2002.
[78] M. Bertrand, E. Duflo, and S. Mullainathan, "How much should we trust differences-in-differences estimates?," *The Quarterly journal of economics*, vol. 119, no. 1, pp. 249–275, 2004.
[79] J. Wooldridge, "What's new in econometrics? Lecture 10 difference-in-differences estimation," *NBER Summer Institute, available at: www.nber.org/WNE/Slides7–31–07/slides_10_diffindiffs.pdf, accessed April*, vol. 9, no. Journal Article, p. 2011, 2007.
[80] M. A. Manda, "SITUATION OF URBANISATION IN MALAWI REPORT," no. Journal Article, 2013.
[81] The World Bank, "Malawi public expenditure review," 2013.
[82] H. A. Khan, "A hierarchical model of contraceptive use in urban and rural Bangladesh," *Contraception*, vol. 55, no. 2, pp. 91–96, 1997.
[83] J. J. Bartko, "The intraclass correlation coefficient as a measure of reliability," *Psychol.Rep.*, vol. 19, no. 1, pp. 3–11, 1966.
[84] G. G. Koch, "Intraclass correlation coefficient," *Encyclopedia of statistical sciences*, no. Journal Article, 1982.
[85] D. Pfeffermann, C. J. Skinner, D. J. Holmes, H. Goldstein, and J. Rasbash, "Weighting for unequal selection probabilities in multilevel models," *Journal of the Royal Statistical Society: series B (statistical methodology)*, vol. 60, no. 1, pp. 23–40, 1998.
[86] E. C. Norton, H. Wang, and C. Ai, "Computing interaction effects and standard errors in logit and probit models," no. Journal Article.
[87] P. Karaca-Mandic, E. C. Norton, and B. Dowd, "Interaction terms in nonlinear models," *Health Serv.Res.*, vol. 47, no. 1pt1, pp. 255–274, 2012.
[88] StataCorp, "Stata Statistical Software: Release 14," vol. 14, no. Computer Program, 2015.
[89] StataCorp, "Stata multilevel mixed-effects reference manual release 15," 2017.
[90] Stata, "Meqrlogit — Multilevel mixed-effects logistic regression (QR decomposition)," 2014.
[91] A. Banerjee, U. Chitnis, S. Jadhav, J. Bhawalkar, and S. Chaudhury, "Hypothesis testing, type I and type II errors," *Industrial psychiatry journal*, vol. 18, no. 2, p. 127, 2009.

[92] M. Aitkin, D. Anderson, and J. Hinde, "Statistical modelling of data on teaching styles," *Journal of the Royal Statistical Society.Series A (General)*, no. Journal Article, pp. 419–461, 1981.
[93] M. A. Koenig, J. F. Phillips, R. S. Simmons, and M. A. Khan, "Trends in family size preferences and contraceptive use in Matlab, Bangladesh," *Stud.Fam.Plann.*, vol. 18, no. 3, pp. 117–127, 1987.
[94] M. A. Koenig, U. Rob, M. A. Khan, J. Chakraborty, and V. Fauveau, "Contraceptive use in Matlab, Bangladesh in 1990: levels, trends, and explanations," *Stud.Fam.Plann.*, vol. 23, no. 6, pp. 352–364, 1992.
[95] J. F. Phillips, W. S. Stinson, S. Bhatia, M. Rahman, and J. Chakraborty, "The demographic impact of the family planning--health services project in Matlab, Bangladesh," *Stud.Fam.Plann.*, no. Journal Article, pp. 131–140, 1982.
[96] USAID, "Three successful Sub-Saharan Africa Family Planning Programs: Lessons for meeting the MDGs.," 2012.
[97] R. A. Abdul-hadi *et al.*, "The effectiveness of community based distribution of injectable contraceptives using community health extension workers in Gombe State, Northern Nigeria," *Afr.J.Reprod.Health*, vol. 17, no. 2, pp. 80–88, 2013.
[98] L. Wu, *Mixed effects models for complex data*. CRC Press, 2009.
[99] J. M. Zenilman *et al.*, "Condom use to prevent incident STDs: the validity of self-reported condom use.," *Sex.Transm.Dis.*, vol. 22, no. 1, pp. 15–21, 1995.
[100] M. Pyra *et al.*, "Validity of self-reported hormonal contraceptive use among women with and at risk for HIV," *Obstet.Gynecol.*, vol. 217, no. 6, p. 737, 2017.
[101] J. D. Fishel, B. Barrère, and S. Kishor, "Validity of data on self-reported HIV status and implications for measurement of ARV coverage in Malawi.," no. Journal Article, 2012.
[102] S. Becker and E. Costenbader, "Husbands' and wives' reports of contraceptive use," *Stud.Fam.Plann.*, no. Journal Article, pp. 111–129, 2001.
[103] J. F. Phillips, A. A. Bawah, and F. N. Binka, "Accelerating reproductive and child health programme impact with community-based services: the Navrongo experiment in Ghana," *Bull.World Health Organ.*, vol. 84, no. 12, pp. 949–955, 2006.
[104] H. I. Awadalla, "Contraception Use among Egyptian Women: Results from Egypt Demographic and Health Survey in 2005," *J.Reprod.Infertil*, vol. 13, no. 3, pp. 167–173, 2012.
[105] Z. Griliches and W. M. Mason, "Education, income, and ability," *Journal of political Economy*, vol. 80, no. 3, pp. S74–S103, 1972.
[106] UNAIDS, "Start Free Stay Free AIDS Free — 2017 progress report," 2018.
[107] UNAIDS, "Fact sheet: Latest statistics on the status of the AIDS epidemic," 2018.
[108] A. Goga, T.-H. Dinh, and D. Jackson, *Evaluation of the effectiveness of the national prevention of mother-to-child transmission (PMTCT) programme on infant HIV measured at six weeks postpartum in South Africa*. South African Medical Research Council, National Department of Health South Africa and PEPFAR/US Centers for Disease Control & Prevention, 2012.
[109] C. L. Townsend, M. Cortina-Borja, C. S. Peckham, A. de Ruiter, H. Lyall, and P. A. Tookey, "Low rates of mother-to-child transmission of HIV following effective pregnancy interventions in the United Kingdom and Ireland, 2000-2006," *AIDS*, vol. 22, no. 8, pp. 973–981, 2008.
[110] UNAIDS, "How AIDS changed everything," 2015.

[111] UNAIDS, “Fast-Track - Ending the AIDS epidemic by 2030,” 2014.
[112] S. Diepeveen and C. van Stolk, “How effective are CCTs in low income settings?,” no. Journal Article, 2012.
[113] F. H. Ferreira and D. A. Robalino, “Social protection in Latin America: achievements and limitations,” *World Bank Policy Research Working Paper Series, Vol*, no. Journal Article, 2010.
[114] A. Fizbein and N. Schady, “The economic rationale for conditional cash transfers,” *Conditional Cash Transfers: Reducing Present and Future Poverty*, no. Journal Article, pp. 45–66, 2009.
[115] M. Yotebieng *et al.*, “Conditional cash transfers and uptake of and retention in prevention of mother-to-child HIV transmission care: a randomised controlled trial,” *The Lancet HIV*, vol. 3, no. 2, pp. e85–e93, 2016.
[116] F. Behets *et al.*, “Reducing vertical HIV transmission in Kinshasa, Democratic Republic of Congo: trends in HIV prevalence and service delivery,” *AIDS Care*, vol. 21, no. 5, pp. 583–590, 2009.
[117] L. Bwirire *et al.*, “Reasons for loss to follow-up among mothers registered in a prevention-of-mother-to-child transmission program in rural Malawi,” *Trans.R.Soc.Trop.Med.Hyg.*, vol. 102, no. 12, pp. 1195–1200, 2008.
[118] A. Gourlay, I. Birdthistle, G. Mburu, K. Iorpenda, and A. Wringe, “Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: a systematic review,” *Journal of the International AIDS Society*, vol. 16, no. 1, 2013.
[119] M. Kirere Mathe, D. Sondag-Thull, and P. Lepage, “Feasibility of prevention of perinatal HIV infection by nevirapine in rural areas of the northeast Democratic Republic of Congo, 2002–2004,” *J.Med.Virol.*, vol. 80, no. 5, pp. 772–776, 2008.
[120] UNICEF, “Options B and B+: Key considerations for countries to implement an equity-focused approach,” 2012.
[121] WHO, “Programmatic Update: Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants,” *WHO, Geneva, April*, no. Journal Article, 2012.
[122] T.-T. Edejer *et al.*, “WHO guide to cost-effectiveness analysis,” *Geneva: World Health Organization*, no. Journal Article, 2003.
[123] G. Hutton and R. Baltussen, “Valuation of goods in cost-effectiveness analysis: notions of opportunity costs and transferability across time and countries,” *Geneva, World Health Organization.Global Programme on Evidence for Health Policy Discussion Paper [forthcoming]*, no. Journal Article, 2003.
[124] G. Hutton and R. Baltussen, “Cost valuation in resource-poor settings,” *Health Policy Plan.*, vol. 20, no. 4, pp. 252–259, 2005.
[125] M. May, A. Boulle, S. Phiri, E. Messou, L. Myer, and R. Wood, “Prognosis of HIV-1 infected patients starting antiretroviral therapy in sub-Saharan Africa: a collaborative analysis of scale-up programmes. Lancet [Internet]. 2010 Aug 7 [cited 2012 Oct 9]; 376 (9739): 449–57,” 2010.
[126] J. S. Stringer *et al.*, “Rapid scale-up of antiretroviral therapy at primary care sites in Zambia: feasibility and early outcomes,” *Jama*, vol. 296, no. 7, pp. 782–793, 2006.
[127] The World Bank, “World Bank Country and Lending Groups: Country classification,” 2016.

[128] Clinton Health Access Initiative, "2015 Antiretroviral (ARV) CHAI reference price list," 2016.
[129] The World Bank, "Price level ratio of PPP conversion factor (GDP) to market exchange rate," 2017.
[130] The World Bank, "GDP deflator: Linked series (base year varies by country)," 2017.
[131] H. A. Glick, J. A. Doshi, S. S. Sonnad, and D. Polsky, *Economic evaluation in clinical trials*. OUP Oxford, 2014.
[132] W. A. Ghali, C. Donaldson, and B. J. Manns, "The impact of using different costing methods on the results of an economic evaluation of cardiac care: microcosting vs gross-costing approaches," *Health Econ.*, vol. 18, no. 4, pp. 377–388, 2009.
[133] M. C. Weinstein, J. E. Siegel, M. R. Gold, M. S. Kamlet, and L. B. Russell, "Recommendations of the Panel on Cost-effectiveness in Health and Medicine," *JAMA*, vol. 276, no. 15, pp. 1253–1258, 1996.
[134] J. Frappier, G. Tremblay, M. Charny, and L. M. Cloutier, "Costing bias in economic evaluations," *Journal of medical economics*, vol. 18, no. 8, pp. 596–599, 2015.
[135] J. E. McFayden, *International drug price indicator guide*. Management Sciences for Health, Drug Management Program, 2014.
[136] O. Mæstad, G. Torsvik, and A. Aakvik, "Overworked? On the relationship between workload and health worker performance," *J.Health Econ.*, vol. 29, no. 5, pp. 686–698, 2010.
[137] A. Adesina and J. Waldron, "Incremental Cost of Providing Key Services to Prevent Mother-to-Child Transmission (PMTCT) of HIV in Zambia," 2013.
[138] V. Jain *et al.*, "Estimated Costs for Delivery of HIV Antiretroviral Therapy to Individuals with CD4 T-Cell Counts> 350 cells/uL in Rural Uganda," *PloS one*, vol. 10, no. 12, p. e0143433, 2015.
[139] H. Maheswaran *et al.*, "Cost and quality of life analysis of HIV self-testing and facility-based HIV testing and counselling in Blantyre, Malawi," *BMC medicine*, vol. 14, no. 1, p. 1, 2016.
[140] L. S. Chiwaula *et al.*, "The value of informal care in the context of option B in Malawi: a contingent valuation approach," *BMC health services research*, vol. 16, no. 1, p. 136, 2016.
[141] US Department of State, "Democratic Republic of the Congo: 2016 Human Rights Report," 2017.
[142] M. Soley-Bori, *Dealing with missing data: Key assumptions and methods for applied analysis*, no. Journal Article, 2013.
[143] S. Ramsey *et al.*, "Good research practices for cost-effectiveness analysis alongside clinical trials: the ISPOR RCT-CEA task force report," *Value in health*, vol. 8, no. 5, pp. 521–533, 2005.
[144] R. J. A. Little, "Missing-Data Adjustments in Large Surveys," *Journal of Business & Economic Statistics*, vol. 6, no. 3, pp. 287–296, 1988.
[145] T. P. Morris, I. R. White, and P. Royston, "Tuning multiple imputation by predictive mean matching and local residual draws," *BMC medical research methodology*, vol. 14, no. 1, p. 75, 2014.
[146] J. A. Sterne *et al.*, "Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls," *BMJ*, vol. 338, no. Journal Article, p. b2393, 2009.

[147] S. K. Gupta, "Intention-to-treat concept: A review," *Perspect.Clin.Res.*, vol. 2, no. 3, pp. 109–112, 2011.
[148] M. Gomes, E. S.-W. Ng, R. Grieve, R. Nixon, J. Carpenter, and S. G. Thompson, "Developing appropriate methods for cost-effectiveness analysis of cluster randomized trials," *Medical Decision Making*, vol. 32, no. 2, pp. 350–361, 2012.
[149] J. W. (James W. Hardin, *Generalized estimating equations*, Second edition.. Boca Raton, FL : CRC Press, 2013.
[150] S. L. Zeger, K.-Y. Liang, and P. S. Albert, "Models for longitudinal data: a generalized estimating equation approach," *Biometrics*, no. Journal Article, pp. 1049–1060, 1988.
[151] Z. Feng, D. McLerran, and J. Grizzle, "A comparison of statistical methods for clustered data analysis with Gaussian error," *Stat.Med.*, vol. 15, no. 16, pp. 1793–1806, 1996.
[152] L. StataCorp, "Generalized estimating equations: xtgee."
[153] UCLA: Statistical Consulting Group., "How can I estimate relative risk using glm for common outcomes in cohort studies?"
[154] G. Zou, "A Modified Poisson Regression Approach to Prospective Studies with Binary Data," *Am.J.Epidemiol.*, vol. 159, no. 7, pp. 702–706, 2004.
[155] A. Chen and D. W. Dowdy, "Clinical effectiveness and cost-effectiveness of HIV pre-exposure prophylaxis in men who have sex with men: risk calculators for real-world decision-making," *PLoS One*, vol. 9, no. 10, p. e108742, 2014.
[156] B. J. Adamson, J. J. Carlson, J. G. Kublin, and L. P. Garrison, "The Potential Cost-Effectiveness of Pre-Exposure Prophylaxis Combined with HIV Vaccines in the United States," *Vaccines*, vol. 5, no. 2, p. 13, 2017.
[157] A. Laupacis, D. L. Sackett, and R. S. Roberts, "An assessment of clinically useful measures of the consequences of treatment," *N.Engl.J.Med.*, vol. 318, no. 26, pp. 1728–1733, 1988.
[158] R. J. Cook and D. L. Sackett, "The number needed to treat: a clinically useful measure of treatment effect," *BMJ*, vol. 310, no. 6977, pp. 452–454, 1995.
[159] D. Polsky and H. Glick, "Costing and cost analysis in randomized controlled trials: Caveat Emptor," *Pharmacoeconomics*, vol. 27, no. 3, pp. 179–188, 2009.
[160] J. A. Barber and S. G. Thompson, "Analysis of cost data in randomized trials: an application of the non- parametric bootstrap," *Stat.Med.*, vol. 19, no. 23, pp. 3219–3236, 2000.
[161] J. Cui, "QIC program and model selection in GEE analyses," *Stata journal*, vol. 7, no. 2, p. 209, 2007.
[162] M. A. Chaudhary and S. C. Stearns, "Estimating Confidence Intervals For Cost-effectiveness Ratios: An Example From A Randomized Trial," *Stat.Med.*, vol. 15, no. 13, pp. 1447–1458, 1996.
[163] World Health Organization, "Making choices in health: WHO guide to cost-effectiveness analysis," *Geneva: World Health Organization*, vol. 9, no. Journal Article, 2003.
[164] E. Marseille, B. Larson, D. S. Kazi, J. G. Kahn, and S. Rosen, "Thresholds for the cost–effectiveness of interventions: alternative approaches," *Bull.World Health Organ.*, vol. 93, no. Journal Article, pp. 118–124, 2014.
[165] B. Woods, P. Revill, M. Sculpher, and K. Claxton, "Country-level cost-effectiveness thresholds: initial estimates and the need for further research," *Value in Health*, vol. 19, no. 8, pp. 929–935, 2016.

[166] T. Loganathan, C.-W. Ng, W.-S. Lee, R. C. Hutubessy, S. Verguet, and M. Jit, "Thresholds for decision-making: informing the cost-effectiveness and affordability of rotavirus vaccines in Malaysia," *Health policy and planning*, vol. 33, no. 2, pp. 204–214, 2017.
[167] R. Jain, M. Grabner, and E. Onukwugha, "Sensitivity analysis in cost-effectiveness studies," *Pharmacoeconomics*, vol. 29, no. 4, pp. 297–314, 2011.
[168] A. Briggs, M. Sculpher, and K. Claxton, *Decision modelling for health economic evaluation*. OUP Oxford, 2006.
[169] L. Andronis, P. Barton, and S. Bryan, "Sensitivity analysis in economic evaluation: an audit of NICE current practice and a review of its use and value in decision-making," *Health Technol.Assess.*, vol. 13, no. 29, pp. iii, ix–xi, 1–61, 2009.
[170] D. Walker and J. Fox-Rushby, "Allowing for uncertainty in economic evaluations: qualitative sensitivity analysis," *Health Policy Plan.*, vol. 16, no. 4, pp. 435–443, 2001.
[171] L. Trenouth, T. Colbourn, B. Fenn, S. Pietzsch, M. Myatt, and C. Puett, "The cost of preventing undernutrition: cost, cost-efficiency and cost-effectiveness of three cash-based interventions on nutrition outcomes in Dadu, Pakistan," *Health Policy Plan.*, vol. 33, no. 6, pp. 743–754, 2018.
[172] R. Wilford, K. Golden, and D. G. Walker, "Cost-effectiveness of community-based management of acute malnutrition in Malawi," *Health Policy Plan.*, vol. 27, no. 2, pp. 127–137, 2011.
[173] A. Briggs, "Handling Uncertainty in Cost-Effectiveness Models," *Pharmacoeconomics*, vol. 17, no. 5, pp. 479–500, 2000.
[174] A. Sinha, O. Levine, M. D. Knoll, F. Muhib, and T. A. Lieu, "Cost-effectiveness of pneumococcal conjugate vaccination in the prevention of child mortality: an international economic analysis," *The Lancet*, vol. 369, no. 9559, pp. 389–396, 2007.
[175] E. Fenwick and S. Byford, "A guide to cost-effectiveness acceptability curves," *Br.J.Psychiatry*, vol. 187, no. Journal Article, pp. 106–108, 2005.
[176] R. M. Baltussen, R. C. Hutubessy, D. B. Evans, and C. J. Murray, "Uncertainty in cost-effectiveness analysis," *Int.J.Technol.Assess.Health Care*, vol. 18, no. 01, pp. 112–119, 2002.
[177] A. H. Briggs, D. E. Wonderling, and C. Z. Mooney, "Pulling cost-effectiveness analysis up by its bootstraps: A non-parametric approach to confidence interval estimation," *Health Econ.*, vol. 6, no. 4, pp. 327–340, 1997.
[178] R. Davidson and J. G. MacKinnon, "Bootstrap tests: How many bootstraps?," *Econometric Reviews*, vol. 19, no. 1, pp. 55–68, 2000.
[179] Penn Medicine, "Stata programs: Sampling Uncertainty for Cost-Effectiveness," 2015.
[180] D. J. Cohen and M. R. Reynolds, "Interpreting the results of cost-effectiveness studies," *J.Am.Coll.Cardiol.*, vol. 52, no. 25, pp. 2119–2126, 2008.
[181] S. Resch, T. Ryckman, and R. Hecht, "Funding AIDS programmes in the era of shared responsibility: an analysis of domestic spending in 12 low-income and middle-income countries," *The Lancet Global Health*, vol. 3, no. 1, pp. e52–e61, 2015.
[182] M. T. Schneider *et al.*, "Tracking development assistance for HIV/AIDS: the international response to a global epidemic," *AIDS*, vol. 30, no. 9, pp. 1475–1479, 2016.
[183] M. Johri and D. Ako-Arrey, "The cost-effectiveness of preventing mother-to-child transmission of HIV in low-and middle-income countries: systematic review," *Cost Effectiveness and Resource Allocation*, vol. 9, no. 1, pp. 1–16, 2011.

[184] A. Binagwaho *et al.*, "Prevention of mother-to-child transmission of HIV: cost-effectiveness of antiretroviral regimens and feeding options in Rwanda," *PLoS One*, vol. 8, no. 2, p. e54180, 2013.
[185] A. Kuznik *et al.*, "Evaluating the cost-effectiveness of combination antiretroviral therapy for the prevention of mother-to-child transmission of HIV in Uganda," *Bull.World Health Organ.*, vol. 90, no. 8, pp. 595–603, 2012.
[186] N. Ishikawa *et al.*, "Should HIV testing for all pregnant women continue? Cost-effectiveness of universal antenatal testing compared to focused approaches across high to very low HIV prevalence settings," *Journal of the International AIDS Society*, vol. 19, no. 1, 2016.
[187] S. Soorapanth, S. Sansom, M. Bulterys, M. Besser, G. Theron, and M. G. Fowler, "Cost-effectiveness of HIV rescreening during late pregnancy to prevent mother-to-child HIV transmission in South Africa and other resource-limited settings," *J.Acquir.Immune Defic.Syndr.*, vol. 42, no. 2, pp. 213–221, 2006.
[188] F. N. John, C. Farquhar, J. N. Kiarie, M. N. Kabura, and G. C. John-Stewart, "Cost effectiveness of couple counselling to enhance infant HIV-1 prevention," *Int.J.STD AIDS*, vol. 19, no. 6, pp. 406–409, 2008.
[189] L. Bollinger and A. Adesina, "Cost-effectiveness of integrating PMTCT and MNCH services: an application of the LiST model for Malawi Mozambique and Uganda.," no. Journal Article, 2013.
[190] C. Avila, J. Cali, A. Cico, and A. Yemaneberhan, "Evaluating service delivery models for prevention of mother-to-child transmission of HIV: Cost and effectiveness of providing PMTCT services in public private and civil society organizations.," no. Journal Article, 2016.
[191] M. Besser, "Mothers 2 Mothers," *S.Afr.J.Obstet.Gynaecol.*, vol. 12, no. 3, pp. 122–128, 2006.
[192] C. A. Teasdale and M. J. Besser, "Enhancing PMTCT programmes through psychosocial support and empowerment of women: the mothers2mothers model of care," *Southern African Journal of HIV Medicine*, vol. 9, no. 1, pp. 60–64, 2008.
[193] C. Zikusooka *et al.*, "External evaluation of the m2m mentor mother model as implemented under the STAR-EC Program in Uganda," *Cape Town: Mothers to Mothers*, 2014.
[194] D. P. Coady and S. W. Parker, "Cost-effectiveness analysis of demand-and supply-side education interventions: the case of PROGRESA in Mexico," *Review of Development Economics*, vol. 8, no. 3, pp. 440–451, 2004.
[195] S. García and J. E. Saavedra, "Educational Impacts and Cost-Effectiveness of Conditional Cash Transfer Programs in Developing Countries: A Meta-Analysis," *Review of Educational Research*, vol. 87, no. 5, pp. 921–965, 2017.
[196] D. Gilligan, A. Margolies, E. Quiñones, and S. Roy, "Impact evaluation of cash and food transfers at early childhood development centers in Karamoja, Uganda," *Final impact report.Washington (District of Columbia): International Food Policy Research Institute*, no. Journal Article, 2013.
[197] D. Mozaffarian *et al.*, "Cost-effectiveness of financial incentives and disincentives for improving food purchases and health through the US Supplemental Nutrition Assistance Program (SNAP): A microsimulation study," *PLoS medicine*, vol. 15, no. 10, p. e1002661, 2018.

[198] S. Handa and B. Davis, "The experience of conditional cash transfers in Latin America and the Caribbean," *Development policy review*, vol. 24, no. 5, pp. 513–536, 2006.
[199] S. M. Sultan and T. T. Schrofer, "5.4 Building Support to have Targeted Social Protection Interventions for the Poorest–The Case of Ghana," *Social Protection for the Poorest in Africa*, vol. 300, 2008.
[200] S. Devereux and P. White, "Pilots, principles or patronage: What makes social protection succeed in Southern Africa," presented at the Conference on Social Protection and Ideologies of Welfare in Southern Africa, 2007, vol. 6.
[201] R. L. Thornton, "The demand for, and impact of, learning HIV status," *American Economic Review*, vol. 98, no. 5, pp. 1829–63, 2008.
[202] S. J. Baird, R. S. Garfein, C. T. McIntosh, and B. Özler, "Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: a cluster randomised trial," *The Lancet*, vol. 379, no. 9823, pp. 1320–1329, 2012.
[203] M. Remme, A. Vassall, B. Lutz, and C. Watts, "Paying girls to stay in school: a good return on HIV investment?," *The Lancet*, vol. 379, no. 9832, p. 2150, 2012.
[204] U. Gneezy and A. Rustichini, "Pay enough or don't pay at all," *The Quarterly Journal of Economics*, vol. 115, no. 3, pp. 791–810, 2000.
[205] U. Gneezy, S. Meier, and P. Rey-Biel, "When and why incentives (don't) work to modify behavior," *Journal of Economic Perspectives*, vol. 25, no. 4, pp. 191–210, 2011.
[206] V. Paul-Ebhohimhen and A. Avenell, "Systematic review of the use of financial incentives in treatments for obesity and overweight," *Obesity Reviews*, vol. 9, no. 4, pp. 355–367, 2008.
[207] M. J. Sculpher, K. Claxton, M. Drummond, and C. McCabe, "Whither trial-based economic evaluation for health care decision making?," *Health Econ.*, vol. 15, no. 7, pp. 677–687, 2006.
[208] M. F. Drummond, M. J. Sculpher, K. Claxton, G. L. Stoddart, and G. W. Torrance, *Methods for the economic evaluation of health care programmes*. Oxford university press, 2015.
[209] O. Fasawe *et al.*, "Cost-effectiveness analysis of option B for HIV prevention and treatment of mothers and children in Malawi," *PLoS One*, vol. 8, no. 3, p. e57778, 2013.
[210] A. VanDeusen, E. Paintsil, T. Agyarko-Poku, and E. F. Long, "Cost effectiveness of option B plus for prevention of mother-to-child transmission of HIV in resource-limited countries: evidence from Kumasi, Ghana," *BMC infectious diseases*, vol. 15, no. 1, p. 130, 2015.
[211] H. Tweya *et al.*, "Comparative cost-effectiveness of Option B+ for prevention of mother to child transmission of HIV in Malawi: Mathematical modelling study," *AIDS (London, England)*, vol. 30, no. 6, p. 953, 2016.
[212] C. Wettstein *et al.*, "Missed opportunities to prevent mother-to-child-transmission: systematic review and meta-analysis," *AIDS*, vol. 26, no. 18, pp. 2361–2373, 2012.
[213] A. Gamell *et al.*, "Prevention of mother-to-child transmission of HIV Option B cascade in rural Tanzania: The One Stop Clinic model," *PloS one*, vol. 12, no. 7, p. e0181096, 2017.
[214] M. J. Rotheram-Borus *et al.*, "A cluster randomized controlled trial evaluating the efficacy of peer mentors to support South African women living with HIV and their infants," *PLoS One*, vol. 9, no. 1, p. e84867, 2014.

[215] L. Myer *et al.*, "Differentiated models of care for postpartum women on antiretroviral therapy in Cape Town, South Africa: a cohort study," *Journal of the International AIDS Society*, vol. 20, no. S4, 2017.
[216] N. A. Sam-Agudu *et al.*, "The impact of structured mentor mother programs on 6-month postpartum retention and viral suppression among HIV-positive women in rural Nigeria: a prospective paired cohort study," *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 75, no. Journal Article, pp. S173–S181, 2017.
[217] S. Phiri *et al.*, "Impact of facility-and community-based peer support models on maternal uptake and retention in Malawi's option B HIV prevention of mother-to-child transmission program: a 3-arm cluster randomized controlled trial (PURE Malawi)," *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 75, no. Journal Article, pp. S140–S148, 2017.
[218] G. Foster *et al.*, "Impact of Facility-Based Mother Support Groups on Retention in Care and PMTCT Outcomes in Rural Zimbabwe: The EPAZ Cluster-Randomized Controlled Trial," *J.Acquir.Immune Defic.Syndr.*, vol. 75 Suppl 2, no. Journal Article, pp. S207–S215, 2017.
[219] F. Cataldo, J. Seeley, M. J. Nkhata, Z. Mupambireyi, E. Tumwesige, and D. M. Gibb, "She knows that she will not come back: tracing patients and new thresholds of collective surveillance in PMTCT Option B," *BMC health services research*, vol. 18, no. 1, p. 76, 2018.
[220] G. D. Sanders *et al.*, "Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine," *JAMA*, vol. 316, no. 10, pp. 1093–1103, 2016.
[221] C. A. Scott *et al.*, "Retention in care, resource utilization, and costs for adults receiving antiretroviral therapy in Zambia: a retrospective cohort study," *BMC Public Health*, vol. 14, no. 1, p. 1, 2014.
[222] World Health Organization, "Taking stock: HIV in children," 2006.
[223] S. Khamadi *et al.*, "Rapid identification of infants for antiretroviral therapy in a resource poor setting: the Kenya experience," *J.Trop.Pediatr.*, vol. 54, no. 6, pp. 370–374, 2008.
[224] Kongo Innocent Emmanuel, "The Access to health care in the Democratic Republic of Congo: Major challenge for the poor," vol. Volume 1, no. 1, pp. 6–8, 2016.
[225] S. I. Becker-Dreps *et al.*, "Cost-effectiveness of adding bed net distribution for malaria prevention to antenatal services in Kinshasa, Democratic Republic of the Congo," *Am.J.Trop.Med.Hyg.*, vol. 81, no. 3, pp. 496–502, 2009.
[226] J. H. Bratt, K. Torpey, M. Kabaso, and Y. Gondwe, "Costs of HIV/AIDS outpatient services delivered through Zambian public health facilities," *Tropical Medicine & International Health*, vol. 16, no. 1, pp. 110–118, 2011.
[227] N. A. Menzies *et al.*, "The cost of providing comprehensive HIV treatment in PEPFAR-supported programs," *AIDS*, vol. 25, no. 14, pp. 1753–1760, 2011.
[228] IntraHealth International, "Strengthening health workforce information in the Democratic Republic of the Congo: Implementing IHRIS in Kasai and Kasai central provinces," 2016.
[229] D. McCoy *et al.*, "Salaries and incomes of health workers in sub-Saharan Africa," *The Lancet*, vol. 371, no. 9613, pp. 675–681, 2008.
[230] Arise Project, "Assessing costs and effectiveness of expanding high quality PMTCT services by community and facility strengthening in Mashonaland Central Province, Zimbabwe," 2013.

[231] E. Tagar *et al.*, "Multi-country analysis of treatment costs for HIV/AIDS (MATCH): facility-level ART unit cost analysis in Ethiopia, Malawi, Rwanda, South Africa and Zambia," *PLoS One*, vol. 9, no. 11, p. e108304, 2014.
[232] H. Touré *et al.*, "Public sector services for the prevention of mother-to-child transmission of HIV infection: a micro-costing survey in Namibia and Rwanda," *Bull.World Health Organ.*, vol. 91, no. 6, pp. 407–415, 2013.
[233] A. D. Bikilla, D. Jerene, B. Robberstad, and B. Lindtjorn, "Cost estimates of HIV care and treatment with and without anti- retroviral therapy at Arba Minch Hospital in southern Ethiopia," *Cost Effectiveness and Resource Allocation : C/E*, vol. 7, no. Journal Article, pp. 6–6, 2009.
[234] A. Dutta, C. Barker, and A. Kallarakal, "The HIV Treatment Gap: Estimates of the Financial Resources Needed versus Available for Scale-Up of Antiretroviral Therapy in 97 Countries from 2015 to 2020," *PLoS Med*, vol. 12, no. 11, p. e1001907, 2015.
[235] N. Ishikawa *et al.*, "Health outcomes and cost impact of the new WHO 2013 guidelines on prevention of mother-to-child transmission of HIV in Zambia," *PloS one*, vol. 9, no. 3, p. e90991, 2014.
[236] J. H. Perriëns, V. Habiyambere, B. Dongmo-Nguimfack, and G. Hirnschall, "Prices paid for adult and paediatric antiretroviral treatment by low-and middle-income countries in 2012: high, low or just right," *Antivir.Ther.(Lond.)*, vol. 19, no. suppl 3, pp. 39–47, 2014.
[237] C. C. Maclean and J. S. Stringer, "Potential cost-effectiveness of maternal and infant antiretroviral interventions to prevent mother-to-child transmission during breast-feeding," *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 38, no. 5, pp. 570–577, 2005.
[238] A. L. Ciaranello *et al.*, "Cost-effectiveness of World Health Organization 2010 guidelines for prevention of mother-to-child HIV transmission in Zimbabwe," *Clin.Infect.Dis.*, vol. 56, no. 3, pp. 430–446, 2013.
[239] B. M. Chitah, "Costing of Paediatric Treatment alongside Clinical Trials under Low Resource Constraint Environments: Cotrimoxazole and Antiretroviral Medications in Children Living with HIV/AIDS," *AIDS Research and Treatment*, vol. 2016, no. Journal Article, 2016.
[240] The World Bank, "Democratic Republic of Congo Health, Nutrition and Population Country: Status Report," 2005.
[241] L. Gibbons, J. M. Belizán, J. A. Lauer, A. P. Betrán, M. Merialdi, and F. Althabe, "The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage," *World health report*, vol. 30, no. Journal Article, pp. 1–31, 2010.
[242] O. Galárraga *et al.*, "Unit Costs for Delivery of Antiretroviral Treatment and Prevention of Mother-to-Child Transmission of HIV," *Pharmacoeconomics*, vol. 29, no. 7, pp. 579–99, 2011.
[243] Cordaid, "Annual Report," 2016.
[244] P. Musgrove and J. Fox-Rushby, "Cost-effectiveness analysis for priority setting," *Disease control priorities in developing countries*, vol. 2, no. Journal Article, 2006.
[245] The World Bank, "Efficiency or cost-effectiveness."
[246] B. R. Luce, "Estimating costs in cost-effectiveness analysis," *Cost-effectiveness in health and medicine*, no. Journal Article, 1996.
[247] R. H. Lee, "Future costs in cost effectiveness analysis," *J.Health Econ.*, vol. 27, no. 4, pp. 809–818, 2008.

[248] M. Kruse, J. Sørensen, and D. Gyrd-Hansen, "Future costs in cost-effectiveness analysis: an empirical assessment," *The European Journal of Health Economics*, vol. 13, no. 1, pp. 63–70, 2012.
[249] M. R. Gold, *Cost-effectiveness in health and medicine*. Oxford university press, 1996.
[250] S. E. Casey *et al.*, "Use of facility assessment data to improve reproductive health service delivery in the Democratic Republic of the Congo," *Conflict and health*, vol. 3, no. 1, p. 1, 2009.
[251] Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), "Review of the Democratic Republic of the Congo (DRC) by the Committee on the Elimination of Discrimination Against Women (CEDAW)," 2013.
[252] World Health Organization, "Cost effectiveness and strategic planning (WHO-CHOICE)," 2016.
[253] C. Ma, "Account for sector heterogeneity in China's energy consumption: Sector price indices vs. GDP deflator," *Energy Econ*, vol. 32, no. 1, pp. 24–29, 2010.
[254] J. Fox-Rushby and J. Cairns, *Economic evaluation*. McGraw-Hill Education (UK), 2005.
[255] Centers for Disease Control and Prevention, "Morbidity and mortality weekly report (MMWR), Appendix A: AIDS-defining conditions," 2008.
[256] M. S. Shiels *et al.*, "Cancer burden in the HIV-infected population in the United States," *J.Natl.Cancer Inst.*, vol. 103, no. 9, pp. 753–762, 2011.
[257] E. Y. Chiao, S. E. Krown, E. A. Stier, and D. Schrag, "A population-based analysis of temporal trends in the incidence of squamous anal canal cancer in relation to the HIV epidemic," *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 40, no. 4, pp. 451–455, 2005.
[258] S. Mitra and L. Crane, "Diagnosis, treatment, and prevention of anal cancer," *Curr.Infect.Dis.Rep.*, vol. 14, no. 1, pp. 61–66, 2012.
[259] L. G. Johnson, M. M. Madeleine, L. M. Newcomer, S. M. Schwartz, and J. R. Daling, "Anal cancer incidence and survival: the surveillance, epidemiology, and end results experience, 1973–2000," *Cancer*, vol. 101, no. 2, pp. 281–288, 2004.
[260] "Anal Cancer - Cancer Stat Facts." [Online]. Available: https://seer.cancer.gov/statfacts/html/anus.html#incidence-mortality. [Accessed: 09-Sep-2018].
[261] F. Nakagawa, M. May, and A. Phillips, "Life expectancy living with HIV: recent estimates and future implications," *Curr.Opin.Infect.Dis.*, vol. 26, no. 1, pp. 17–25, 2013.
[262] A. Trickey *et al.*, "Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies," *The Lancet HIV*, vol. 4, no. 8, pp. e349–e356, 2017.
[263] H. Samji *et al.*, "Closing the gap: increases in life expectancy among treated HIV-positive individuals in the United States and Canada," *PloS one*, vol. 8, no. 12, p. e81355, 2013.
[264] M. J. Silverberg *et al.*, "Risk of anal cancer in HIV-infected and HIV-uninfected individuals in North America," *Clin.Infect.Dis.*, vol. 54, no. 7, pp. 1026–1034, 2012.
[265] D. Solomon *et al.*, "The 2001 Bethesda System: terminology for reporting results of cervical cytology," *JAMA*, vol. 287, no. 16, pp. 2114–2119, 2002.
[266] B. S. Apgar, L. Zoschnick, and T. C. Wright Jr, "The 2001 Bethesda System terminology," *Am.Fam.Physician*, vol. 68, no. 10, pp. 1992–1998, 2003.
[267] J. M. Palefsky *et al.*, "Virologic, immunologic, and clinical parameters in the incidence and progression of anal squamous intraepithelial lesions in HIV-positive and HIV-

negative homosexual men," *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 17, no. 4, pp. 314–319, 1998.
[268] A. Kreuter *et al.*, "Anal carcinoma in human immunodeficiency virus-positive men: results of a prospective study from Germany," *Br.J.Dermatol.*, vol. 162, no. 6, pp. 1269–1277, 2010.
[269] E. A. Holly, M. L. Ralston, T. M. Darragh, R. M. Greenblatt, N. Jay, and J. M. Palefsky, "Prevalence and risk factors for anal squamous intraepithelial lesions in women," *J.Natl.Cancer Inst.*, vol. 93, no. 11, pp. 843–849, 2001.
[270] A. J. Durante, A. B. Williams, M. Da Costa, T. M. Darragh, K. Khoshnood, and J. M. Palefsky, "Incidence of anal cytological abnormalities in a cohort of human immunodeficiency virus-infected women," *Cancer Epidemiol.Biomarkers Prev.*, vol. 12, no. 7, pp. 638–642, 2003.
[271] A.-B. Moscicki *et al.*, "Human papillomavirus infection and abnormal cytology of the anus in HIV-infected and uninfected adolescents," *AIDS*, vol. 17, no. 3, pp. 311–320, 2003.
[272] N. A. Hessol *et al.*, "Anal intraepithelial neoplasia in a multisite study of HIV-infected and high-risk HIV-uninfected women," *AIDS*, vol. 23, no. 1, pp. 59–70, 2009.
[273] A. S. Baranoski, R. Tandon, J. Weinberg, F. F. Huang, and E. A. Stier, "Risk factors for abnormal anal cytology over time in HIV-infected women," *Obstet.Gynecol.*, vol. 207, no. 2, pp. 107. e1-107. e8, 2012.
[274] M. Gaisa, K. Sigel, J. Hand, and S. Goldstone, "High rates of anal dysplasia in HIV-infected men who have sex with men, women, and heterosexual men," *AIDS*, vol. 28, no. 2, pp. 215–222, 2014.
[275] M. Gaisa *et al.*, "High Rates of Anal High-Grade Squamous Intraepithelial Lesions in HIV-Infected Women Who Do Not Meet Screening Guidelines," *Clin.Infect.Dis.*, vol. 64, no. 3, pp. 289–294, 2017.
[276] A. Wexler *et al.*, "Invasive anal squamous-cell carcinoma in the HIV-positive patient: outcome in the era of highly active antiretroviral therapy," *Diseases of the colon & rectum*, vol. 51, no. 1, pp. 73–81, 2008.
[277] J. A. Aberg *et al.*, "Primary care guidelines for the management of persons infected with human immunodeficiency virus: 2009 update by the HIV medicine Association of the Infectious Diseases Society of America," *Clinical infectious diseases*, vol. 49, no. 5, pp. 651–681, 2009.
[278] New York State Department of Health AIDS Institute. HIV Clinical Resource, "Anal dysplasia and cancer guideline," 2007.
[279] USPSTF/Veterans Administration, "Anal dysplasia," 2016.
[280] R. D. Cranston, S. Hart, J. Gornbein, S. Hirschowitz, G. Cortina, and A. Moe, "The prevalence, and predictive value, of abnormal anal cytology to diagnose anal dysplasia in a population of HIV-positive men who have sex with men," *Int.J.STD AIDS*, vol. 18, no. 2, pp. 77–80, 2007.
[281] J. M. Berry, J. M. Palefsky, N. Jay, S. C. Cheng, T. M. Darragh, and P. V. Chin-Hong, "Performance characteristics of anal cytology and human papillomavirus testing in patients with high-resolution anoscopy-guided biopsy of high-grade anal intraepithelial neoplasia," *Dis.Colon Rectum*, vol. 52, no. 2, pp. 239–247, 2009.

[282] J. J. Kwong, P. Cook, and L. Bradley-Springer, “Improving anal cancer screening in an ambulatory HIV clinic: experience from a quality improvement initiative,” *AIDS Patient Care STDS*, vol. 25, no. 2, pp. 73–78, 2011.
[283] H. Scott, J. Khoury, B. A. Moore, and S. Weissman, “Routine anal cytology screening for anal squamous intraepithelial lesions in an urban HIV clinic,” *Sex.Transm.Dis.*, vol. 35, no. 2, pp. 197–202, 2008.
[284] J. M. Palefsky, E. A. Holly, C. J. Hogeboom, J. M. Berry, N. Jay, and T. M. Darragh, “Anal cytology as a screening tool for anal squamous intraepithelial lesions,” *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 14, no. 5, pp. 415–422, 1997.
[285] A. P. Chung and D. B. Rosenfeld, “Intraoperative high-resolution anoscopy: a minimally invasive approach in the treatment of patients with Bowen’s disease and results in a private practice setting,” *Am.Surg.*, vol. 73, no. 12, pp. 1279–1283, 2007.
[286] W. G. Willeford, L. Barroso, J. Keller, N. Fino, and L. H. Bachmann, “Anal Dysplasia Screening and Treatment in a Southern Human Immunodeficiency Virus Clinic,” *Sex.Transm.Dis.*, vol. 43, no. 8, pp. 479–482, 2016.
[287] W. C. Mathews, A. Sitapati, J. C. Caperna, R. E. Barber, A. Tugend, and U. Go, “Measurement characteristics of anal cytology, histopathology, and high-resolution anoscopic visual impression in an anal dysplasia screening program,” *JAIDS J.Acquired Immune Defic.Syndromes*, vol. 37, no. 5, pp. 1610–1615, 2004.
[288] S. E. Weis *et al.*, “Prevalence of anal intraepithelial neoplasia defined by anal cytology screening and high-resolution anoscopy in a primary care population of HIV-infected men and women,” *Diseases of the Colon & Rectum*, vol. 54, no. 4, pp. 433–441, 2011.
[289] R. M. Andersen, “Revisiting the behavioral model and access to medical care: does it matter?,” *J.Health Soc.Behav.*, no. Journal Article, pp. 1–10, 1995.
[290] R. Andersen and J. F. Newman, “Societal and individual determinants of medical care utilization in the United States,” *Milbank Q.*, vol. 83, no. 4, p. Online-only-Online-only, 2005.
[291] R. M. Andersen, P. L. Davidson, and S. E. Baumeister, “Improving access to care,” *Changing the US health care system: Key issues in health services policy and management*, no. Journal Article, pp. 33–69, 2013.
[292] G. M. Clifford *et al.*, “Cancer risk in the Swiss HIV Cohort Study: associations with immunodeficiency, smoking, and highly active antiretroviral therapy,” *J.Natl.Cancer Inst.*, vol. 97, no. 6, pp. 425–432, 2005.
[293] E. A. Engels *et al.*, “Cancer risk in people infected with human immunodeficiency virus in the United States,” *International journal of cancer*, vol. 123, no. 1, pp. 187–194, 2008.
[294] P. Patel *et al.*, “Incidence of types of cancer among HIV-infected persons compared with the general population in the United States, 1992–2003,” *Ann.Intern.Med.*, vol. 148, no. 10, pp. 728–736, 2008.
[295] M. J. Silverberg *et al.*, “HIV infection, immunodeficiency, viral replication, and the risk of cancer,” *Cancer Epidemiol.Biomarkers Prev.*, vol. 20, no. 12, pp. 2551–2559, 2011.
[296] E. L. Yanik, K. Tamburro, J. J. Eron, B. Damania, S. Napravnik, and D. P. Dittmer, “Recent cancer incidence trends in an observational clinical cohort of HIV-infected patients in the US, 2000 to 2011,” *Infectious agents and cancer*, vol. 8, no. 1, p. 18, 2013.
[297] Centers for Medicare and Medicaid Services, “Medicaid Analytic eXtract (MAX) general Information,” 2017.

[298] S. Crystal, A. Akincigil, S. Bilder, and J. T. Walkup, "Studying prescription drug use and outcomes with medicaid claims data: strengths, limitations, and strategies," *Med.Care*, vol. 45, no. 10 Supl 2, pp. S58-65, 2007.
[299] M. A. Ford and C. M. Spicer, "Sources of Data on HIV Care to Assess Indicators of HIV Care and Access to Supportive Services," no. Journal Article, 2012.
[300] Centers for Medicare & Medicaid Services, "Medicaid Analytic eXtract (MAX) validation," 2013.
[301] US Department of Health and Human Services, "Area Health Resources File," 2013.
[302] W. E. Cunningham *et al.*, "The effect of socioeconomic status on the survival of people receiving care for HIV infection in the United States," *J.Health Care Poor Underserved*, vol. 16, no. 4, pp. 655–676, 2005.
[303] H. A. Robbins *et al.*, "Patterns of repeated anal cytology results among HIV-positive and HIV-negative men who have sex with men," *Papillomavirus Research*, vol. 5, no. Journal Article, pp. 143–149, 2018.
[304] AIDSVu, "About AIDSVu," 2017.
[305] K. Baicker, A. Chandra, and J. Skinner, "Geographic variation in health care and the problem of measuring racial disparities," *Perspectives in biology and medicine*, vol. 48, no. 1, pp. 42-S53, 2005.
[306] P. Larie, "Official authorized addenda: Human immunodeficiency virus infection codes and official guidelines for coding and reporting ICD-9-CM," *Morbidity and Mortality Weekly Report: Recommendations and Reports*, pp. 11–19, 1994.
[307] Family Planning National Training Center, "Commonly used ICD-9 codes in reproductive healthcare," 2013.
[308] "Free HCPCS Code List." [Online]. Available: http://www.icd9data.com/HCPCS/. [Accessed: 13-Sep-2018].
[309] L. L. Siekas and D. M. Aboulafia, "Establishing an anal dysplasia clinic for HIV-infected men: initial experience," *AIDS Read*, vol. 19, no. 5, pp. 178–86, 2009.
[310] T. Darragh and B. Winkler, "The ABCs of anal-rectal cytology," *CAP Today. May*, pp. 42–50, 2004.
[311] K. Lindsey, C. DeCristofaro, and J. James, "Anal Pap smears: should we be doing them?," *Journal of the American Academy of Nurse Practitioners*, vol. 21, no. 8, pp. 437–443, 2009.
[312] M. L. Welton, B. Winkler, and T. M. Darragh, "Anal-rectal cytology and anal cancer screening," presented at the Seminars in Colon and Rectal Surgery, 2004, vol. 15, pp. 196–200.
[313] J. M. Bland and D. G. Altman, "Survival probabilities (the Kaplan-Meier method)," *BMJ*, vol. 317, no. 7172, p. 1572, 1998.
[314] M. Goel, P. Khanna, and J. Kishore, "Understanding survival analysis: Kaplan-Meier estimate," *International journal of Ayurveda research*, vol. 1, no. 4, p. 274, 2010.
[315] M. Cleves, *An introduction to survival analysis using Stata*, Revised third. Stata Press, 2016.
[316] "Lesson 3 Logistic Regression Diagnostics." [Online]. Available: https://stats.idre.ucla.edu/stata/webbooks/logistic/chapter3/lesson-3-logistic-regression-diagnostics/. [Accessed: 14-Sep-2018].
[317] R. M. O'brien, "A caution regarding rules of thumb for variance inflation factors," *Quality & quantity*, vol. 41, no. 5, pp. 673–690, 2007.

[318] I. L. Leeds and S. H. Fang, “Anal cancer and intraepithelial neoplasia screening: A review,” *World journal of gastrointestinal surgery*, vol. 8, no. 1, p. 41, 2016.
[319] P. V. Chin-Hong and J. M. Palefsky, “Natural history and clinical management of anal human papillomavirus disease in men and women infected with human immunodeficiency virus,” *Clin.Infect.Dis.*, vol. 35, no. 9, pp. 1127–1134, 2002.
[320] University of California, San Frascisco, “DARE and HRA | Anal Cancer Information,” *Anal Cancer Information*, 2014. [Online]. Available: https://analcancerinfo.ucsf.edu/dare-and-hra. [Accessed: 28-Oct-2018].
[321] R. A. Ortoski and C. S. Kell, “Anal cancer and screening guidelines for human papillomavirus in men,” *J.Am.Osteopath.Assoc.*, vol. 111, no. 3_suppl_2, pp. S35–S43, 2011.
[322] J. R. Roberts, L. L. Siekas, and A. M. Kaz, “Anal intraepithelial neoplasia: A review of diagnosis and management,” *World journal of gastrointestinal oncology*, vol. 9, no. 2, p. 50, 2017.
[323] J. M. Palefsky, “Practising high-resolution anoscopy,” *Sexual health*, vol. 9, no. 6, pp. 580–586, 2012.
[324] O. Richel, J. M. Prins, and H. J. de Vries, “Screening for anal cancer precursors: what is the learning curve for high-resolution anoscopy?,” *AIDS*, vol. 28, no. 9, pp. 1376–1377, 2014.
[325] G. Kaplan, M. H. Lopez, and J. M. McGinnis, “Transforming health care scheduling and access: Getting to now,” *Washington DC: Institute of Medicine*, 2015.
[326] I. B. T. LEE, “Reducing Waits and Delays in the Referral Process.”
[327] T. Parker-Pope, “Fear and Procrastination Delay Cancer Diagnoses,” *Well*, 14-May-2008. .
[328] J. A. Cook *et al.*, “Do HIV-positive women receive depression treatment that meets best practice guidelines?,” *AIDS and Behavior*, vol. 18, no. 6, pp. 1094–1102, 2014.
[329] A. Barnes *et al.*, “Cervical cancer screening among HIV-infected women in an urban, United States safety-net healthcare system,” *AIDS*, vol. 32, no. 13, pp. 1861–1870, 2018.
[330] J. R. Gaither *et al.*, “Guideline-concordant management of opioid therapy among human immunodeficiency virus (HIV)-infected and uninfected veterans,” *The Journal of Pain*, vol. 15, no. 11, pp. 1130–1140, 2014.
[331] A. M. Kilbourne *et al.*, “Development and application of a method to assess timeliness of medical care for HIV symptoms,” *Health Serv.Outcomes Res.*, vol. 2, no. 2, pp. 101–115, 2001.
[332] L. V. Torian and E. W. Wiewel, “Continuity of HIV-related medical care, New York City, 2005–2009: Do patients who initiate care stay in care?,” *AIDS patient care and STDs*, vol. 25, no. 2, pp. 79–88, 2011.
[333] P. M. Gorbach, L. E. Manhart, K. L. Hess, B. P. Stoner, D. H. Martin, and K. K. Holmes, “Anal intercourse among young heterosexuals in three sexually transmitted disease clinics in the United States,” *Sex.Transm.Dis.*, vol. 36, no. 4, pp. 193–198, 2009.
[334] B. D. Sommers, R. Gourevitch, B. Maylone, R. J. Blendon, and A. M. Epstein, “Insurance churning rates for low-income adults under health reform: lower than expected but still harmful for many,” *Health Aff.*, vol. 35, no. 10, pp. 1816–1824, 2016.
[335] L. Ku and E. Steinmetz, “Bridging the Gap: Continuity and Quality of Coverage in Medicaid,” *George Washington University.Published September*, no. Journal Article, 2013.

[336] T. M. Darragh and B. Winkler, "Anal cancer and cervical cancer screening: key differences," *Cancer cytopathology*, vol. 119, no. 1, pp. 5–19, 2011.
[337] J. S. Wells, M. M. Holstad, T. Thomas, and D. W. Bruner, "An integrative review of guidelines for anal cancer screening in HIV-infected persons," *AIDS patient care and STDs*, vol. 28, no. 7, pp. 350–357, 2014.
[338] The ANCHOR study, "About the Anal Cancer HSIL Outcomes Research (ANCHOR) study," 2017.
[339] Centers for Medicare and Medicaid Services, "Physician fee schedule search," 2017.
[340] Aetna, "High-resolution anoscopy," 2017.
[341] A. C. Reed, P. L. Reiter, J. S. Smith, J. M. Palefsky, and N. T. Brewer, "Gay and bisexual men's willingness to receive anal Papanicolaou testing," *Am.J.Public Health*, vol. 100, no. 6, pp. 1123–1129, 2010.
[342] I. Rosa-Cunha *et al.*, "Description of a pilot anal pap smear screening program among individuals attending a Veteran's Affairs HIV clinic," *AIDS Patient Care STDS*, vol. 25, no. 4, pp. 213–219, 2011.
[343] G. D'souza *et al.*, "Uptake and predictors of anal cancer screening in men who have sex with men," *Am.J.Public Health*, vol. 103, no. 9, pp. e88–e95, 2013.
[344] K. Z. Apaydin, H. B. Fontenot, D. L. Shtasel, K. H. Mayer, and A. S. Keuroghlian, "Primary care provider practices and perceptions regarding HPV vaccination and anal cancer screening at a Boston community health center," *J.Community Health*, no. Journal Article, pp. 1–10, 2018.
[345] Mathematica Policy Research, "Medicaid Managed Care Enrollment and Program Characteristics, 2016," 2018.
[346] M. J. Mugavero *et al.*, "Racial disparities in HIV virologic failure: do missed visits matter?," *J.Acquir.Immune Defic.Syndr.*, vol. 50, no. 1, pp. 100–108, 2009.
[347] V. E. Stone, "Optimizing the care of minority patients with HIV/AIDS," *Clinical infectious diseases*, vol. 38, no. 3, pp. 400–404, 2004.
[348] L. E. Wilson *et al.*, "HIV-related medical service use by rural/urban residents: a multistate perspective," *AIDS Care*, vol. 23, no. 8, pp. 971–979, 2011.
[349] G. Suneja *et al.*, "Cancer treatment disparities in HIV-infected individuals in the United States," *J.Clin.Oncol.*, vol. 32, no. 22, pp. 2344–2350, 2014.
[350] J. F. Deeken *et al.*, "The rising challenge of non-AIDS-defining cancers in HIV-infected patients," *Clin.Infect.Dis.*, vol. 55, no. 9, pp. 1228–1235, 2012.
[351] M. Bower *et al.*, "British HIV Association guidelines for HIV-associated malignancies 2008," *HIV medicine*, vol. 9, no. 6, pp. 336–388, 2008.
[352] D. Mark Freedman MPH, M. John Weiser MPH, P. Linda R. Beer, and M. R. Luke Shouse MPH, "Anal Cancer Screening in Men who have sex with Men in Care for HIV infection, United States, 2009-2012," 2016.
[353] R. H. Miller and H. S. Luft, "Does managed care lead to better or worse quality of care?," *Health.Aff.(Millwood)*, vol. 16, no. 5, pp. 7–25, 1997.
[354] R. P. Insinga, E. J. Dasbach, and E. H. Elbasha, "Assessing the annual economic burden of preventing and treating anogenital human papillomavirus-related disease in the US," *Pharmacoeconomics*, vol. 23, no. 11, pp. 1107–1122, 2005.
[355] B. Sirovich, D. Gottlieb, and E. Fisher, "The burden of prevention: downstream consequences of Pap smear testing in the elderly," *Journal of Medical Screening*, vol. 10, no. 4, pp. 189–195, 2003.

[356] H. J. Henk, R. P. Insinga, P. K. Singhal, and T. Darkow, “Incidence and costs of cervical intraepithelial neoplasia in a US commercially insured population,” *Journal of lower genital tract disease*, vol. 14, no. 1, pp. 29–36, 2010.
[357] A. II, “MedStar Health, Inc.”
[358] R. P. Insinga, E. J. Dasbach, and E. R. Myers, “The health and economic burden of genital warts in a set of private health plans in the United States,” *Clinical Infectious Diseases*, vol. 36, no. 11, pp. 1397–1403, 2003.