

Dynamic patterns of contraceptive use among Kenyan women

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Abstract

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INTRODUCTION: Access to voluntary family planning (FP) programs is essential to support women in achieving their reproductive goals, and has a myriad of benefits for maternal, newborn, and child health and women’s economic, social, and reproductive empowerment. Contraceptive discontinuation among women who wish to avoid pregnancy is common, but relationships between contraceptive experiences and discontinuation are unclear. This dissertation assesses prevalence and correlates of contraceptive side effects, method switching, and discontinuation in a cohort of Kenyan women.

METHODS: A prospective cohort study of women and adolescent girls using modern, reversible contraception was conducted among women attending FP clinics. Participants completed weekly short message service (SMS) surveys on contraceptive experiences over a 24-week period. We used the non-parametric Kaplan-Meier estimator to estimate incidence of method switch and modern method discontinuation and associated 95% confidence intervals (CI). Cox proportional hazards models were used to estimate adjusted hazards ratios (aHR) of 1) method

switch, and 2) modern method discontinuation associated with experience of specific contraceptive side effects. We aimed to develop and validate a screening tool to identify women at high risk of discontinuation using a stepwise model selection process. Predictive performance of the screening tool was assessed using time-dependent receiver operating characteristic (ROC) curves and area under the curve (AUC) in an internal validation cohort. Finally, we estimated adjusted prevalence ratios (aPR) of individual correlates of risk of specific contraceptive side effects using log-binomial generalized estimating equation models.

RESULTS: Among 825 women using injectables, implants, oral contraceptive pills (OCP) or intrauterine devices (IUD), incidence of method switch was 61.3 per 100 woman-years (95% CI 52.4-71.8) and incidence of discontinuation of modern contraception was 38.5 per 100 woman-years (95% CI 31.6-47.0). Reports of contraceptive side effects were common, with 24% (95% CI 22-26%) of woman reporting side effects weekly. Sexual side effects were the most prevalent side effect measured (weekly Pr 15%, 95% CI 13-16%). Lack of expected bleeding was associated with method switch (aHR 2.07, 95%CI 1.00-4.28). Irregular menstrual bleeding (aHR 2.62, 95%CI 1.35-5.07), weight changes (aHR 1.99, 95%CI 1.08-3.64), and sexual side effects (aHR 1.83, 95%CI 1.00-3.35) were associated with discontinuation. Considering only women's characteristics at enrollment, we found that a simplified risk score comprised of routinely captured information in FP clinics had moderate ability to predict contraceptive discontinuation in our validation cohort (AUC-ROC: 0.73, 95% CI 0.51-0.94). The tool identified a majority of women as high risk (61%), resulting in a low positive predictive value (28%). Prevalence of contraceptive side effects over study follow-up was associated with reporting prior experience of side effects (aPR 1.72, 95% CI 1.37-2.18) and having fears or concerns about side effects (aPR 1.36, 95% CI 1.12-1.65) at enrollment. Women who reported spending the "right amount of time" with their FP provider were less likely to report non-bleeding-related side effects during

follow-up (aPR 0.61 [95%CI 0.46-0.81] for cramping or abdominal/back pain; aPR 0.58 [95%CI 0.44-0.76] for sexual side effects; and aPR 0.66 [95%CI 0.60-0.88] for weight changes).

CONCLUSION: Contraceptive side effects, method switch, and discontinuation were common in a cohort of Kenyan women. The findings from this dissertation may help to inform design of interventions to more effectively target and tailor FP counseling and care to the individualized contraceptive needs and preferences of women who wish to use contraception but who experience method-related challenges.

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CHAPTER ONE – Introduction

Meeting women’s contraceptive needs is a critical priority for improving reproductive, maternal, and perinatal health outcomes worldwide (1, 2). Globally, 40% of pregnancies are unintended and 220 million women have an unmet need for family planning (FP) (3, 4). In sub-Saharan Africa, an estimated one-quarter of women of reproductive age who wish to avoid pregnancy are not using modern contraception (5). There is extensive evidence demonstrating positive outcomes of modern contraceptive use on the health of women, girls, and children (1, 2, 6-8). Contraception can support women and couples to effectively achieve their reproductive and fertility goals, thereby decreasing adverse maternal and newborn health outcomes associated with unsafe abortion (9), short birth intervals (10), and unintended high-risk pregnancies among adolescents and women of advanced maternal age (11). Women’s ability to achieve their reproductive goals – often through use of effective contraception – also leads to demonstrable benefits in female educational attainment and economic empowerment (12-14), and may increase women’s sexual and reproductive autonomy (15).

Given these wide-ranging positive impacts, it is hardly surprising that contraception is lauded as a key driver of global development (8). At the same time, the global FP community is increasingly grappling with its role in reproductive coercion and discrimination (16-18). In the context of FP programs, reproductive justice frameworks move beyond the recognition of contraceptive access as a human right, emphasizing the need for FP care that is responsive to individual women’s values and preferences and that addresses structural oppression and violence (16). FP programs grounded in a reproductive justice approach aim to provide high-quality, respectful care that supports all women to achieve their reproductive goals by prioritizing and respecting women’s values, preferences, and autonomy (19).

In order to design and implement just reproductive health programs, understanding barriers to contraceptive use among women who wish to use contraception is critical. Globally, FP programs and policies have primarily focused on addressing barriers to contraceptive uptake. This prioritization is evident in global targets, such as the FP2020 goal to increase the number of additional modern contraceptive users by 120 million by the year 2020 (20). Less attention has been paid to the contraceptive challenges faced by women who are currently using or who have used contraception in the past. Evidence from low- and middle-income countries suggests that early contraceptive discontinuation due to method-related challenges is common: over one-third of contraceptive users discontinue within 12 months of initiation and over half within 2 years (21, 22); among these women, the predominant reason cited for discontinuation is challenges using the method, including experience of side effects or concerns about adverse health effects (22). Women's ability to switch from one method to another that better fits her preferences may support contraceptive continuation, yet may be hampered by inadequate counseling or barriers to timely access to alternate methods (23-25). Understanding women's experiences using contraception and the role these experiences play in method-related switching and discontinuation is necessary for designing new contraceptive technologies and health service delivery models that support women who wish to use contraception do so.

Despite recent increased attention on contraceptive discontinuation, prospective research on factors that influence method-related discontinuation and method switch are scarce. Timely method switching – whereby women are able to minimize pregnancy risk while changing method types – may play a key role in contraceptive continuation, but this phenomenon is not well understood. Existing data sources measuring contraceptive use, such as the repeated cross-sectional Demographic and Health Surveys (DHS) collected in low-income countries, have found high discontinuation among adolescents and short-term method users (21, 26). However, existing

data sources typically rely on retrospective report of contraceptive use with long recall windows. To date, prospective studies of contraceptive experiences are limited, particularly in low-resource settings (27). As a result, there is a lack of evidence-based strategies to support women after contraception is initiated (28-31). Real-time assessment of user preferences and experiences could inform interventions to more effectively support women in making decisions both at the time of contraceptive selection and during use (22). In this dissertation, we conducted a prospective cohort study among Kenyan women using modern, reversible contraception to examine relationships between women's individual-level characteristics, experiences using contraception, and subsequent contraceptive decision-making in order to understand potential drivers of method-related discontinuation.

Contraceptive side effects and method-related discontinuation

Contraceptive discontinuation among women who are not actively planning a pregnancy is common (21, 22, 32-34). Analyses of DHS data from 19 low- and middle-income countries find 38% 12-month and 65% 36-month discontinuation rates among users of reversible methods (21). Among injectable users, the median duration of use is less than one year (21). Furthermore, nearly 40% of women with an unmet need for contraception are previous users who have since discontinued (32). Reasons for discontinuation vary and include lack of need (either due to desire for pregnancy or lack of sexual activity), method failure, and method-related reasons (35). This final category comprises inconvenience using the method, partner opposition or lack of support, and side effects or health concerns. Discontinuation may be intentional or unintentional ("passive"), with barriers such as cost, difficulties with method re-supply, distance to facility-based FP services, and other access issues contributing to inadvertent discontinuation in the latter case (23, 36-39).

“Method-related” discontinuation, defined as discontinuation for reasons related to challenges using a method including side effects or health concerns, points towards a “mismatch” between current offerings of FP programs and women’s preferences for contraception. Evidence from low- and middle-income countries (LMICs) demonstrates that discontinuation specifically due to side effects and health concerns is the predominant driver of discontinuation among women who do not desire a pregnancy, with the highest rates of side effect-related discontinuation among users of hormonal contraception (21). Method-related problems are the main stated reason for discontinuation of all modern contraceptive methods (21). Side effects are central to women’s contraceptive decision-making, yet the epidemiology of contraceptive side effects in LMICs is not well characterized. The injectable contraceptive method depot medroxyprogesterone acetate (DMPA) is used by over one-third of modern contraceptive method users in sub-Saharan Africa (40); despite the method’s popularity, a recent systematic review concluded that there is a lack of high-quality evidence available on the side effects of DMPA (41).

This paucity of and inconsistent evidence on side effects, particularly with regards to “non-specific” side effects such as changes in mood and libido, may limit providers’ ability to provide evidence-based and person-centered counseling on aspects of contraceptive use that are critical to sustained and satisfied method use. While some researchers argue that side effect counseling should recognize both the limitations of current empirical evidence and the “value of women’s lived experiences” (41), this is often not the case in practice: qualitative research has revealed that there are frequent discrepancies between health providers’ and women’s views on the tolerability and severity of contraceptive side effects (42). As a result, providers may minimize or ignore women’s concerns about side effects (43, 44). Alternatively, some researchers have suggested that healthcare providers should not discuss contraceptive side effects proactively, for fear of women experiencing “nocebo” effects (45).

These views fail to recognize that unanticipated side effects viewed as “minor” by providers may nevertheless cause significant worry, as well as physical discomfort and inconvenience among users (43, 46, 47). Concerns about adverse health impacts may be particularly prominent among those who wish to have children in the future and are unsure of the effect of side effects on fertility (42, 48). Beyond health concerns, side effects may have significant and/or long-lasting negative consequences in specific interpersonal, sociocultural, or religious contexts. For example, studies have found that changes in menstrual patterns were cited as a reason for divorce in Mali (46); in Uganda, contraceptive side effects are blamed for fatigue, inability to perform manual labor, and resulting economic hardship (49).

Recent scholarship emphasizes the need to contextualize women’s experience of contraceptive side effects in the sociocultural and economic implications of specific side effects (47). The complex and contextual meanings of side effects deeply impact how women experience and respond to side effects in different settings, as well as their preferences for specific side effects (26). Viewing side effects through a contextual lens also sheds light on the persistence of what FP providers have long called “myths and misconceptions” (22, 50, 51). For example, numerous studies among women in sub-Saharan Africa have found that beliefs that contraception can cause long-term health problems such as harm to the “womb” and infertility are prevalent and negatively associated with modern contraceptive use (51-53). While such beliefs lack a biological basis – leading to their labeling as “myths” – they may also reflect women’s lived experiences in communities where side effects may have significant social and socioeconomic ramifications: in some settings, heavy bleeding is reported to cause conflicts with male partners, while amenorrhea is interpreted as a sign of infertility and overall poor health leading to extramarital affairs or marital dissolution (44, 47). As such, addressing “myths and misconceptions” may require side effects counseling that goes beyond clinical explanations to acknowledge contextual meanings and provide culturally-tailored guidance.

Contraceptive method switching

Method-related discontinuation is often explicitly interpreted as discontinuation for reasons that “imply dissatisfaction with the method or associated services” (35). However, it is important to distinguish between two distinct contraceptive use outcomes: method-related discontinuation of all contraceptive methods, and method-specific discontinuation (discontinuation of a specific method type) to switch to another method type. “Method-specific” discontinuation followed by switch to another method type either immediately or after a short interval of non-use is increasingly viewed as a programmatic success, indicating women’s ability to “update” her contraceptive method type to better meet her preferences (22). Evidence suggests that increasing the number of contraceptive method types available reduces overall contraceptive discontinuation, in part because women who have difficulty using one method have other options available to them (22). However, in the absence of resources to support timely switching from one method type to another, switching may increase the risk of unintended pregnancy, unsafe abortion, and other adverse health outcomes for mother and newborn (22). This is particularly true when method switching occurs with a relatively long interruption in contraceptive use.

Patterns of contraceptive switching have not been well described; however, existing studies suggest that the rate of method switch within 12 months may vary considerably between settings and populations (22). A study of 479 postpartum women in Malawi found that 45% switched methods in the first year after delivery, with the majority (82%) switching to a method of equal or higher efficacy (54). A study conducted in urban Senegal among a general population of women of reproductive age found that 38% of women discontinued a method within 12 months; of these, only 17% subsequently switched to use a new method (25). Switching (compared to discontinuation) has been found to be more common among formally educated (23, 35), wealthier, and urban women (35). A study conducted in Honduras found that women who switched, rather

than discontinued, contraception were more likely to have sought follow-up health care or support from a partner. Switching was also more common among women who had recently started a new method and among women who experienced side effects (23). Method-specific patterns of switching vary widely by country, which may reflect regional differences in method or service availability (22). However, comparisons of switching across different settings and studies are limited by the lack of a single, standard definition for contraceptive switching, may conflate timely switching (low pregnancy risk) with switches that occur with a long lapse in contraceptive use (higher pregnancy risk), and often only make comparisons between women who switch and those who discontinue methods without considering women who continue method use.

Numerous studies suggest that improvements in FP infrastructure, counseling, and patient experience may promote contraceptive continuation by increasing women's knowledge and access to timely method switching (55-59). High-quality counseling may promote continuation by supporting clients in selecting a method that fits their preferences, preparing them for potential side effects and problems, and informing them about actions to take if problems occur (22). As a result, effective counseling may in fact increase method switching, as women are increasingly able to discontinue methods that do not match their preferences (22, 60), although the mechanisms by which counseling influences women's contraceptive experiences and satisfaction remain unclear. Receipt of counseling about the range of methods, side effects, and the possibility of switch to an alternative method has been shown to be prospectively associated with lower risk of discontinuation at 3-months in some settings, but evidence is mixed (61).

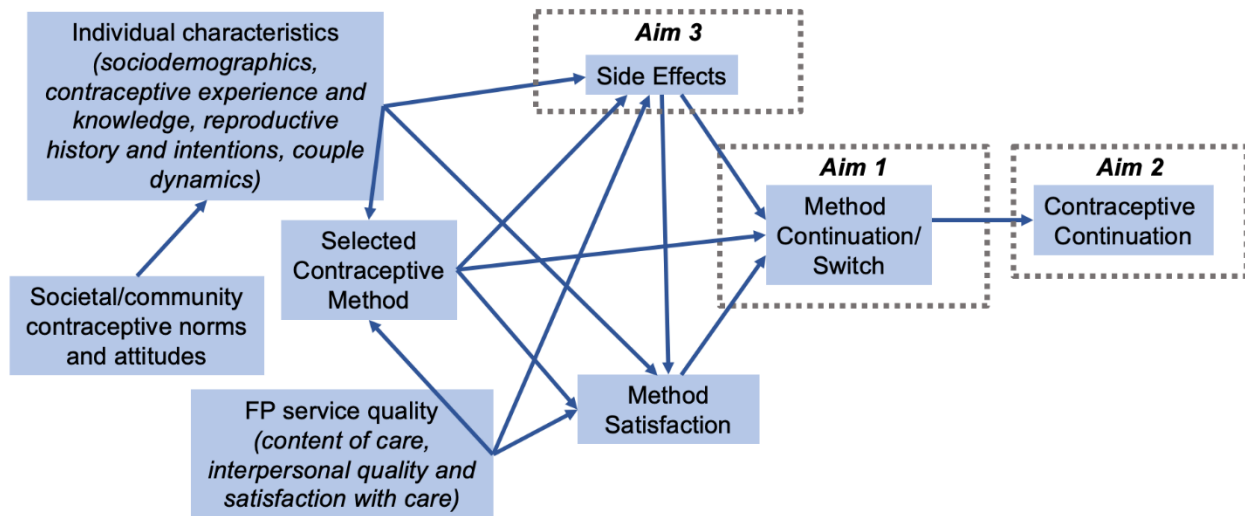
Limitations of existing data on contraceptive decision-making

The DHS and other widescale demographic surveys capture retrospective histories of contraceptive use at the month-level, reasons for method discontinuation, and quality of FP services received at method initiation. These methods may suffer from recall bias due to the

relatively long recall period (typically the preceding 5 years) and reclassification of method failure as a desire for pregnancy, a phenomenon that underestimates failure and unintended pregnancy rates (62). Shorter intervals of time (<4 weeks) may be characteristic of passive discontinuation, but such intervals are not currently captured through large-scale contraceptive surveys. Thus, women cannot report contraceptive switching that occurs within a single month in traditional demographic surveys. This may lead to misclassification of switching as dual method use or prevent capture of short-term switching events entirely.

DHS data have several other limitations regarding collection of important contextual factors and outcomes. For example, only women who have recently discontinued contraceptive use are asked about their experience of side effects; current question wording also fails to differentiate between fears or concerns about side effects versus actual experience of side effects, two distinct phenomena. Information on experiences of specific types of side effects is also not systematically captured, preventing examination of varying tolerability of different types of side effects. This prevents a comprehensive comparison of side effect experiences between women who do and do not choose to continue contraceptive use, limiting inferences into factors affecting tolerability and acceptability of contraceptive side effects. In contrast, only current contraceptive users are asked about quality of FP services received; as a result, validity of such estimates may be threatened by selection bias (27). FP service quality, patient experiences of FP care, and women's satisfaction with their current contraceptive method are rarely captured and linked with prospective contraceptive outcomes.

Figure 1.1 Conceptual framework of factors associated with contraceptive method switch and discontinuation



There is a paucity of prospectively collected data among contraceptive users on the timing and tolerability of side effects experienced by women in LMICs (26, 63), and their impact on overall method satisfaction and continuation. As a result, little is known about the specific decision-making processes of how, when, and which side effects influence dissatisfaction and discontinuation (22, 64), or why some women experiencing side effects choose to continue method use while others switch or discontinue contraception altogether. Figure 1 presents an adapted conceptual model from the framework proposed by Jain (65), illustrating the complex relationships between individual and contextual factors and method switching and contraceptive discontinuation.

In this dissertation, **Chapter 2** estimates incidence of method switch and discontinuation and aims to understand how individual factors, experience with the FP care received, as well as experiences with contraceptive side effects are associated with subsequent risk of switching and discontinuation. **Chapter 3** assesses characteristics of women who discontinue contraceptive use, creating a risk score to identify women who are not planning a pregnancy who have a high likelihood of stopping contraceptive use. **Chapter 4** focuses on understanding women's

experience of side effects, including prevalence overall and by specific side effect type, as well as individual-level correlates of side effects. Taken together, this dissertation addresses key gaps in the published literature by exploring complex patterns of contraceptive use, including dynamic experiences of specific side effects and their relationships to method discontinuation and switching, and using novel data captured prospectively and at high-frequency. The overarching goal of this dissertation is to generate insights into women's contraceptive decision-making processes to effectively inform the design of evidence-based FP interventions that are responsive to women's reproductive and contraceptive values, preferences, and needs.

CHAPTER TWO – Contributions of side effects to contraceptive discontinuation and method switch among Kenyan women: a cohort study

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**Contributions of side effects to contraceptive discontinuation and method switch among
Kenyan women: a prospective cohort study**

Short Title: Side Effects, Contraceptive Method Switch, and Discontinuation

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ABSTRACT

Objective: To determine the contribution of specific contraceptive side effects to method switch and modern-method discontinuation among Kenyan women.

Design: A prospective cohort study

Setting: Five counties in Western Kenya

Participants: Women aged ≥ 18 years old and emancipated female minors ≥ 14 years old using modern, reversible contraception were recruited while attending 10 public health facilities.

Methods: Patient-reported side effect symptoms, method switch, and discontinuation were reported through weekly text message-based surveys for 24 weeks.

Main outcome measurements: Prevalence, hazards ratio (HR)

Results: Among 825 women, 44% were using implants, 43% injectables, 7% intrauterine device, and 6% oral contraceptive pills at enrollment. During the 24-week follow-up, incidence of contraceptive switch was 61.3 per 100 person-years (95% confidence interval [CI] 52.4-71.8) and incidence of discontinuation was 38.5 per 100 person-years (95%CI 31.6-47.0). On average, one-quarter (prevalence [Pr] 0.24, 95%CI 0.22-0.26) of participants reported side effects or method problems weekly, with sexual side effects the most prevalent symptom (Pr 0.15, 95%CI 0.13-0.16). Lack of expected bleeding was associated with higher risk of method switch (adjusted hazard ratio [aHR] 2.07, 95%CI 1.00-4.28). Risk of all-modern method discontinuation was higher among women experiencing irregular bleeding (adjusted hazard ratio [aHR] 2.62, 95%CI 1.35-5.07), weight changes (aHR 1.99, 95%CI 1.08-3.64), and sexual side effects (aHR 1.83, 95%CI 1.00-3.35).

Conclusions: Side effects, method switch, and discontinuation were frequent among Kenyan women using modern contraception. Irregular bleeding, weight changes, and sexual side effects increased risk of contraceptive discontinuation. Addressing these side effects is critical in the upstream development of new contraceptive methods and for counseling on current methods.

Tweetable abstract:

Spotting, weight changes, sexual problems increase discontinuation of #contraception, but many continue despite side effects

INTRODUCTION

Understanding women's contraceptive experiences is essential to develop and deliver family planning (FP) methods that match women's needs and preferences. Side effects are a central aspect of women's contraceptive decision-making, contributing not only to physical discomfort and fear, but in some settings to significant sociocultural and economic hardships (22, 26, 44, 66-68). Despite recognition of the importance of side effects in contraceptive use, there are few longitudinal studies assessing side effects in low- and middle-income countries (LMIC). Prospective data on the relationships between specific contraceptive side effects and subsequent method switching or contraceptive discontinuation is critical for understanding the impacts of specific side effects and for developing contraceptive technology and programs that are responsive to women's preferences.

Worldwide, fear of side effects is the most common reason given for contraceptive non-use among women who do not wish to become pregnant (42, 44, 69, 70). Less is known about determinants of method continuation, switch, or discontinuation among women who experience side effects. Evidence suggests these relationships may be context specific (22). At the country-level, data from the DHS reveal high between-country variability in user-reported discontinuation or non-use due to side effects – from 9% in Mozambique to nearly 50% in Tanzania (68, 69, 71). Evidence from qualitative research emphasizes that tolerability of side effects is influenced by a number of factors, including the severity and presentation of symptoms, individual preferences, desire for fertility control, as well as biological and contextual understanding of side effects (47, 72). For example, amenorrhea may be viewed as an anticipated benefit of contraceptive use, or as an accumulation of “dirt” in the body (47). Women with strong desire to avoid pregnancy may be more likely to tolerate contraceptive side effects, particularly if they lack information or access to alternative methods (73). There is growing recognition of such tradeoffs between need for pregnancy prevention and contraceptive preferences, which may result in continued use despite method dissatisfaction (19, 47, 74). Understanding the contribution of side effects to contraceptive

use behaviors in priority geographic regions is critical for honing global priorities for contraceptive method development and services.

We conducted a prospective cohort study among Kenyan women who were using modern, reversible contraceptive methods to measure real-time incidence of method switch and modern-method discontinuation over 24 weeks and assess relationships between side effects and contraceptive switch or discontinuation.

METHODS

Study population

Between February and May 2018, we enrolled women using modern, reversible contraception who were attending one of ten public FP or maternal and child health (MCH) clinics located in the Homa Bay, Kakamega, Kisumu, Nyamira, and Bungoma counties of Kenya. Adult women (≥ 18 years old) and emancipated female minors (≥ 14 years old with a prior pregnancy) were eligible to participate if they were currently using a modern, reversible contraceptive method (75), had daily access to a mobile phone with a Safaricom SIM card, and were able to read and respond to SMS messages in their preferred language (English, Swahili, Luo, or Kisii) by themselves or with assistance. Women who were initiating, continuing, or switching a modern contraceptive method were eligible. Study methods have been previously described (76). We restricted our analysis to participants using injectables, implants, intrauterine devices or systems (IUD/IUS), and daily oral contraceptive pills (OCP). Women with missing (or not adequately specified) baseline contraceptive methods or who were lost to follow-up after enrollment were excluded from the analysis. We also excluded women who at enrollment stated a desire for pregnancy within 1 year.

Data collection

Participants completed a short message system (SMS) survey administered at enrollment and weekly for 24 weeks. The enrollment survey captured sociodemographic characteristics and reproductive and contraceptive history, while follow-up surveys collected data on weekly method use, reasons for method switch and discontinuation, and side effect experiences. Participants received a single SMS reminder after 24 hours for incomplete surveys and were sent a 25 Kenyan Shilling (~\$0.25 USD) airtime credit upon completion of each survey.

Ethical considerations and public involvement

The study was approved by the Ethical Review Committee of Maseno University, Kenya (MSU/DRPI/MUERC/00462/17). While the study did not require approval from University of Washington's (UW) Human Subjects Division (HSD) due to its "not engaged" determination (STUDY00002934), this analysis was approved by UW's HSD (STUDY00008142). Participants provided written consent prior to study enrollment. Local and national stakeholders from Kenya's Ministry of Health and national reproductive health non-governmental service provider organizations convened for a regional dissemination meeting of preliminary study findings held in March 2019.

Ascertainment and definitions of key variables

Contraceptive side effects. Participants who reported experiencing any side effects or problems with their current contraceptive method in the past week (or were unsure) were asked a series of method-specific questions about symptoms. We measured the following specific side effects: heavy or prolonged bleeding, irregular bleeding, lack of expected bleeding, abdominal or back pain (including painful menses and cramping), changes in weight (either gain or loss), and sexual side effects, including problems related to sexual pleasure, libido, or discomfort during intercourse. Participants were asked to report if specific side effects occurred in the past week, except weight changes, for which occurrence was reported in the past month. Side effects were

defined based on the most recent survey from either the current or prior 3 weekly surveys and coded as missing if all surveys in this interval were incomplete or “not sure”/refused responses. Additional details are provided in the S2 Supplementary Material and S2.1 Table.

Discontinuation and method switch. We defined all-modern method discontinuation as a period of at least 2 consecutive weeks when the participant reported not using any modern contraceptive method. Modern methods were defined to include injectables, implant, IUD/IUS, OCP, the emergency contraceptive pill, condoms (male and female), diaphragm, sterilization, lactational amenorrhea, Standard Days Method, and the Two Day Method (75). The 2-week period required for discontinuation was selected to minimize outcome misclassification based on single-week entry errors and to allow single weeks of method interruption (such as during method resupply), while maintaining sensitivity to detect short intervals of non-use. Method switch was defined as using a different modern method type than reported at enrollment for a period of at least 4 consecutive weeks in order to minimize misclassification due to entry errors (S2 Supplementary Material).

Other covariates of interest. Strength of desire to avoid pregnancy was defined based on a single question captured at enrollment that asked how much of a problem it would be if they were to become pregnant in the next few weeks (big, small, or no problem). Participants were considered contraceptive naïve if they reported no prior FP use at enrollment. Method satisfaction was defined based on a 5-point Likert scale of overall satisfaction with the current method (very dissatisfied, dissatisfied, neutral, satisfied, or very satisfied).

Statistical analysis

We estimated incidence and adjusted hazard ratios (aHR) of method switch and discontinuation by each side effect using cause-specific Cox proportional hazard models (77). Adjusted models included *a priori* potential confounders (marital status, contraceptive method at enrollment, age, FP user type [initiator, switcher, or continuer at enrollment], and postpartum

status [end of last pregnancy <6 months ago]) and were stratified by enrollment facility (78). We used Cox proportional hazards models to account for competing risks by censoring women at the time of first switch in discontinuation models, or time of first discontinuation in switch models. We assessed robustness of the cause-specific modeling approach in sensitivity analyses using Fine-Gray competing risks models (79).

We combined last observation carried forward with next observation carried backwards to fill to the mid-point of the missing intervals of contraceptive use or method type, but did not impute monotonic right censoring (80); imputed data was used to define discontinuation and switch. We used a complete case approach to missing side effects and baseline covariates in primary models, but conducted a sensitivity analysis using multiple imputation with chained equations (MICE) (81) to impute missing side effects. In all models, we used MICE to impute side effects for 26 participants who reported a switch in the first week of follow-up and were not asked about side effects of their original method.

We calculated attributable risk and population attributable risk percentages with 95% confidence intervals (CI). We estimated mean weekly prevalence of side effects by contraceptive use outcome (continuation, switch, or discontinuation) using log-binomial generalized estimating equations with an independent correlation structure, robust standard errors, and indicator variables for week of follow-up and contraceptive use outcome.

In exploratory analyses, we assessed effect modification of the relationship between side effects and discontinuation and switch by the following potential effect modifiers: youth, gravidity, contraceptive naivety, and strength of desire to avoid pregnancy. We also estimated the relationship of method dissatisfaction on method switch and discontinuation using cause-specific Cox models analogous to the primary side effects models. We conceptualized side effects as a confounder of the relationship between dissatisfaction and switch (and discontinuation), so additionally adjusted for experience of any side effects.

RESULTS

Of 1212 women enrolled, we included 825 (68%) in our analysis (S2.1 Fig). The most common reasons for exclusion were completely missing follow-up (14%, n=171) or a missing/refused response to fertility intentions at enrollment (11%, n=138). Approximately half (48%) of participants were between age 25-34 years, with 39% <25 years (Table 2.1). Most (82%) were married and had at least one prior pregnancy (94%), with 29% reporting the end of their most recent pregnancy within 6 months of enrollment. At enrollment, implants (44%) and injectables (43%) were the most common methods used. The majority (61%) of women were continuing method users. Half (52%) of women reported having ever experienced contraceptive side effects in their lifetime. The majority (56%) reported becoming pregnant in the next few weeks would be a “big problem.” Over 70% (488/684) of participants reported experiencing side effects or method problems at least once over follow-up; ever experience of specific side effects ranged from 35% for heavy/prolonged bleeding to 51% for sexual side effects (S2.2 Table).

Method switching

We observed 254.3 woman-years of follow-up and 156 method switches, for an overall incidence rate of 61.3 per 100 woman-years (95%CI 52.4-71.8) (S2.2 Fig and S2.3 Table). Descriptive patterns of contraceptive method use are presented in (Figure 2.1). Switches occurred equally from LARC to non-LARC methods (40%) and vice versa (38%). We did not detect differences in the unadjusted risk of switch between women using IUDs (HR 1.13, 95%CI 0.60-2.12) or injectables (HR 1.18, 95%CI 0.80-1.75) compared to women using implants; however, risk of switch was 2-fold higher among OCP than implant users (HR 2.12, 95%CI 1.18-3.81) (S2.4-S2.5 Tables). Among women who provided a reason for switching methods (49%, 77/156), the most frequently reported reason was side effects (61%, 47/77), followed by desire for a more effective method (19%, 15/77).

Point estimates of weekly prevalence of side effects were higher among women who eventually switched methods than those who continued using their initial method (Table 2.2). However, only lack of expected bleeding was significantly associated with switch in adjusted analyses (aHR 2.07, 95%CI 1.00-4.28) (Fig 2.2). Sensitivity analyses produced similar results (S2.3-S2.4 Figs).

We detected evidence of age as an effect modifier of the relationship between sexual problems and risk of method switch: among young women <25 years old, sexual side effects were not significantly associated with method switch (aHR 0.41, 95%CI 0.11-1.56) (S2.6 Table and S2.5 Fig). However, among older women (age ≥25), sexual side effects were associated with a 2.8-fold risk of switch (aHR 2.81, 95%CI 1.51-5.22). We find a similar trend age as an effect modification of the association between any side effects or method problems and switch, although the interaction term was not statistically significant at conventional levels (p=0.058). Point estimates suggest similar effect modification by gravidity, although our ability to detect statistically significant interactions was limited by the small number of nulligravid participants (n=50, 6%). We did not find evidence of effect modification by first-time contraceptive use or strength of desire to avoid pregnancy. We detect higher hazard of switched among women were “dissatisfied” with their current method (aHR 2.55, 95%CI 1.03-6.30), relative to those who were “very satisfied” (S2.7 Table).

Discontinuation

There were 98 discontinuation events, for an overall incidence of 38.5 per 100 woman-years (95% CI 31.6-47.0). Among 38 (39%) women who discontinued and provided a reason, desire for pregnancy (34%) was the most frequently cited reason, despite excluding women who stated at enrollment that they were planning to become pregnant in the next year. Side effects (24%) were the next most common reason. Risk of discontinuation was 2.5-fold as high among

OCP (HR 2.46, 95%CI 1.30-4.65) compared to implant users. We did not detect differences in risk of discontinuation between IUD or injectable users compared to implant users.

We detected higher risk of discontinuation among women with irregular bleeding (aHR 2.62, 95%CI 1.35-5.07), weight changes (aHR 1.99, 95%CI 1.08-3.64), and sexual side effects (aHR 1.83, 95%CI 1.00-3.35) compared to women who did not report these side effects. Results from sensitivity results were similar; however, associations were not statistically significant at the $\alpha=0.05$ when multiple imputation was used, while only irregular bleeding and weight changes significantly increased risk of discontinuation in Fine-Grey competing risks models.

Nearly three-fourths (71%) of women reported experiencing side effects or method problems at least once over follow-up. Sexual problems were the most prevalent side effects reported (Pr 0.15, 95%CI 0.13-0.16), followed by weight changes (Pr 0.13, 95%CI 0.11-0.15), cramping or abdominal/back pain (Pr 0.12, 95% CI 0.11-0.14), and irregular bleeding (aPr 0.08, 95%CI 0.07-0.10). In this population, eliminating all contraceptive side effects experienced in the past month would be expected to reduce overall discontinuation by 16% (95%CI 2-27%) (S2.8 Table). Irregular bleeding (population attributable fraction [PAF] 12%, 95%CI 7-17%), weight changes (PAF 12%, 95%CI 4-19%), and sexual problems (PAF 11%, 95%CI 3-19%) make the largest contributions to discontinuation and explain approximately one- to two-thirds (38-62%) of discontinuation among women who experience these side effects.

Strength of desire to avoid pregnancy modified the relationship between side effects and discontinuation for both sexual side effects ($p=0.030$) and cramping ($p=0.046$), with a trend for irregular bleeding ($p=0.056$). Among women with weak desire to avoid pregnancy, we observe increased risks of discontinuation by 5.7-fold associated with irregular bleeding ($p=0.0009$), 4.4-fold for cramping or abdominal/back pain ($p=0.0007$), and 3.4-fold for sexual side effects ($p=0.008$). Among women with strong desire to avoid pregnancy, side effects were not associated with discontinuation. We did not find evidence of effect modification of the relationships between side effects and discontinuation by age, FP history, or gravidity. Relative to women who were

“very satisfied” with their method, we found that being only “very dissatisfied” was associated with increased risk of discontinuation (aHR 6.85, 95%CI 1.84-25.48).

DISCUSSION

Contraceptive side effects, method switch, and discontinuation were common in a cohort of women using modern, reversible contraception in Western Kenya who did not want to become pregnant within the next year. Method switching has often been estimated in combination with all-method discontinuation or defined to allow long gaps in method use that may correspond with substantial risk of unintended pregnancy. Here, we leveraged novel prospective data collected weekly to highlight modern method switching occurring within short time intervals, an outcome which can be viewed as a positive indication of women’s knowledge of and ability to tailor methods to preferences (24). By this definition, we find that one quarter (25%) of women switched contraceptive methods by 24 weeks after FP/MCH clinic attendance. An additional 16% discontinued all modern contraception during this period. Rates of switch and discontinuation were lowest among implant users and highest among OCP users, consistent with other studies (25, 67, 68, 82, 83). In other studies from Kenya, method discontinuation was ~30% 6-12 months after contraceptive initiation (84, 85). In the multi-country HIV-1 prevention ASPIRE trial, cumulative one-year discontinuation was 38% among DMPA users and 48% among OCP users (82), comparable to the 24-week cumulative incidence in our study of 17% and 36%, respectively. Implant users in our study reported higher rates of method switching (21%) and discontinuation (12%) than the combined rate of 11% for method switch and discontinuation in ASPIRE by 6 months. ASPIRE participants received ongoing contraceptive counseling to promote continuation, which may explain lower rates of switch and discontinuation.

Amongst all contraceptive side effects, changes in menstrual bleeding have received the most attention by researchers and healthcare providers (26). While bleeding side effects have been associated with discontinuation (26, 48), several studies among IUD and OCP users have

found that bleeding side effects did not influence discontinuation (86, 87). We found irregular bleeding increased risk of discontinuation, but not method switch. Conversely, lack of expected bleeding was associated with switch, but not discontinuation. Weight changes and sexual side effects were each associated with discontinuation and were as important contributors to discontinuation as irregular bleeding. In particular, contraceptive research has paid little attention to the impacts of contraception on women's sexual pleasure and experiences, particularly in LMICs (63, 88, 89). Our findings build upon previous findings that highlight the importance of sexual experience in contraceptive acceptability and sustained use, and the need to both prioritize sexual pleasure and functioning in new contraceptive technology development and to improve counseling along the care continuum for affected women (89).

The prevalence of side effects reported in our study population was high, with nearly 30% of women experiencing at least one side effect or method-related problem weekly. Despite the high burden of side effects, many women continued using their initial contraceptive method. Our findings are consistent with recent evidence from a cohort study in India, which found that half of women who experienced side effects were still using their initial method at 6 months (90). Adjusting for side effects, risk of discontinuation was higher among women who felt "very dissatisfied" with their method, but not among those who were less than fully satisfied with their method. Our findings suggest that women's needs for pregnancy prevention often outweigh the physical, psychological, and other costs of contraceptive use. There are several explanations for continued method use among women experiencing side effects: supply-side factors such as limited range of available methods, time and monetary costs, and provider coercion may all limit women's ability to switch or discontinue methods (17, 19, 91). On the demand-side, continuation may be driven by perceptions of side effects as tolerable, inconsequential, or even beneficial (26), gaps in contraceptive knowledge, specific contraceptive needs (such as concealability), perceived risk of pregnancy with method switch, or previous poor experiences with other methods.

Notably, we found stark differences in women's responses to side effects based on the strength of their desire to avoid pregnancy, even among those who expressed no short-term intention to become pregnant. In exploratory analyses, we found 3- to 6-fold risk of discontinuation associated with side effects among women who expressed weak desire to avoid pregnancy, but no association among women with a strong desire to avoid pregnancy. These findings highlight the shortcomings of conceptualizing continued use as method acceptability, and the need for continued outreach to address contraceptive users' dynamic needs and experiences over time.

Individual characteristics may also prevent women from effectively switching methods despite experiencing side effects. We found that method switch was more common among older women who experienced sexual side effects, but not among young women. Young women who reported heavy/prolonged bleeding or any side effects also switched methods less frequently than older women, although these differences were not statistically significant. While these exploratory analyses should be interpreted with caution, our findings suggest that young women experiencing side effects may face unique barriers to timely and effective method switching. Young women may also perceive specific side effects to be less "bothersome" than do older women. Future research is needed to further elucidate the main factors, including those at the health systems-level, driving continued method use among women experiencing side effects.

Our study has several strengths. We utilized a unique, prospective design with high-frequency capture of side effects among all contraceptive users, providing important insight into a complex phenomenon. The prospective design and weekly surveying tempo give us unique ability to detect dynamic experiences of contraceptive use. We were able to explore heterogeneity in the relationship between side effects, switch, and discontinuation by specific types of side effects. While much of the published literature defines discontinuation at the month level (68, 85), weekly surveys permitted focus on definitions of method switching and discontinuation that identify short-term gaps in method use that may represent important pregnancy risks in a cohort of women who wish to delay pregnancy for at least one year.

Our study is also subject to limitations. Method misclassification is possible due to entry errors using the SMS survey for data collection and inability to correct inconsistent responses. However, we expect misclassification to be non-differential, biasing findings towards the null. This may have limited our ability to detect true associations. In addition, our study is limited by the short duration of follow-up (24 weeks) and limited number of IUD and OCP users. Failure to ascertain changes in fertility preferences, partner status, and sexual activity over time may also have resulted in residual confounding. Finally, reliance on brief but high-frequency surveys also prevented capture of perceptions of the severity of side effects or the degree to which women perceived side effects as bothersome, both of which may be important explanatory factors in switch and discontinuation (90, 92).

CONCLUSION

Contraceptive acceptability has previously been conceptualized as sustained use of a contraceptive method (73). However, this definition fails to recognize that women continue using methods that poorly align with their contraceptive preferences. Our findings suggest that specific contraceptive user groups, including women who are young and have strong desire to avoid pregnancy, often continue using methods despite experiencing side effects. As a result, FP providers and policymakers should not equate contraceptive continuation with method acceptability or satisfaction when tracking program successes. Global FP initiatives must recenter their objectives to focus on meeting women's contraceptive preferences, in addition to their needs for pregnancy prevention. This requires a critical examination of how current metrics, programs, and policies may fail to identify contraceptive dissatisfaction and barriers to method switch and discontinuation among women who experience method-related challenges.

COMPETING INTERESTS

The authors declare no competing interests.

CONTRIBUTION TO AUTHORSHIP

CWR and ALD secured funding for the study and were involved in study design, coordinated data collection and validation of the data, participated in the analysis, and contributed to writing the article. PK coordinated data collection. JUG contributed to designing the study, validation of the data, data analysis, and writing the article. BAR, BLG, and ELL participated in the analysis and contributed to writing the article. JM and TO contributed to study design and data collection. GJS and JK contributed to study design and to writing the article. All authors reviewed and approved the final manuscript.

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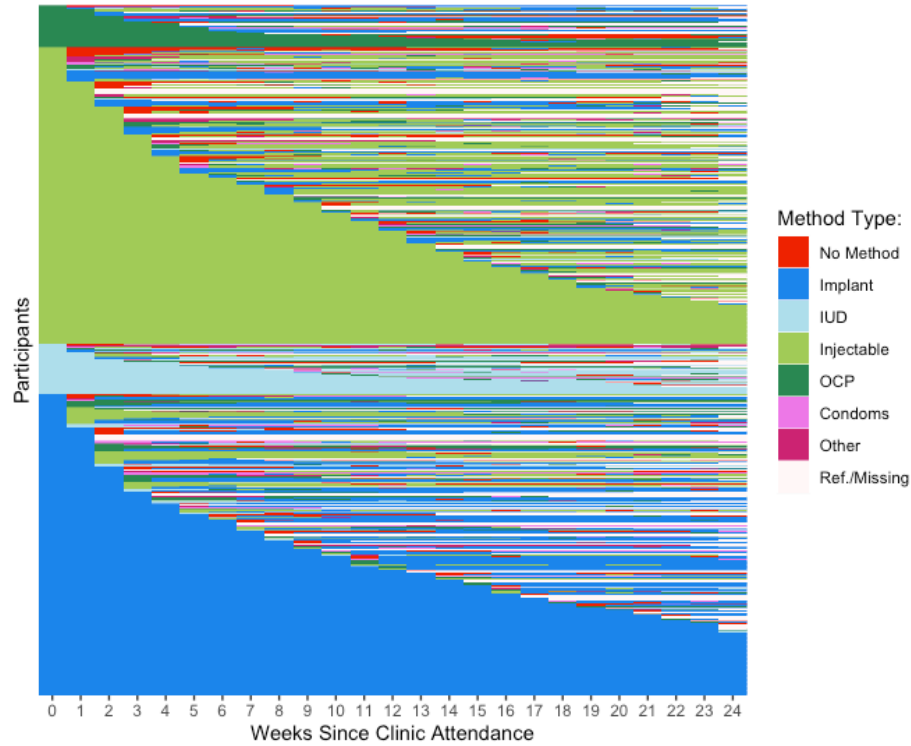
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TABLES & FIGURES

Figure 2.1 Patterns of participant-reported contraceptive method use over 24 weeks

Panel A. Imputed data



Panel B. Complete case data

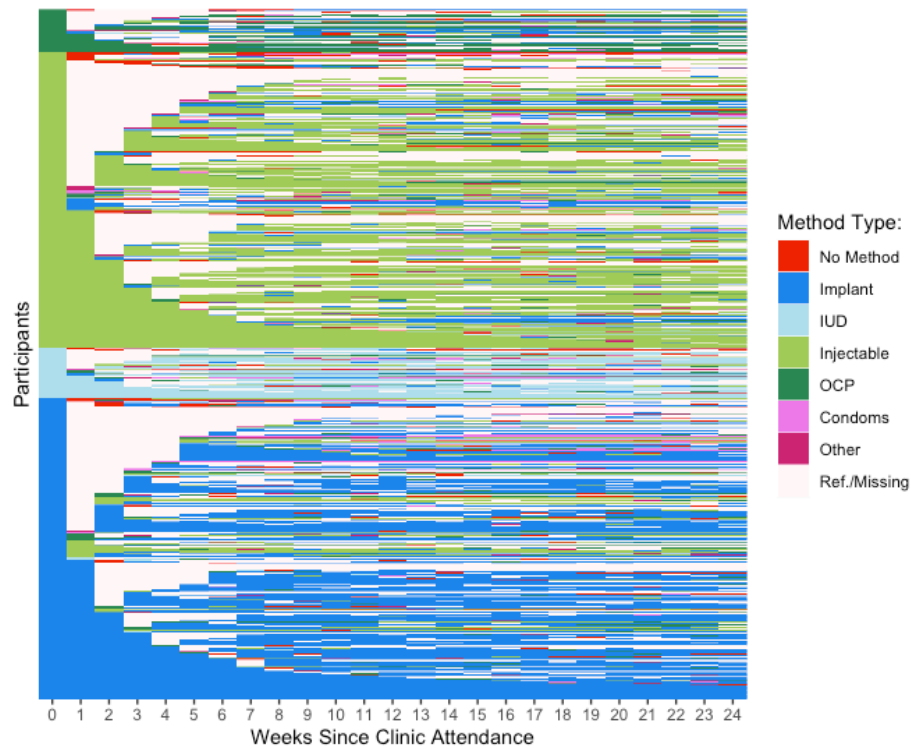
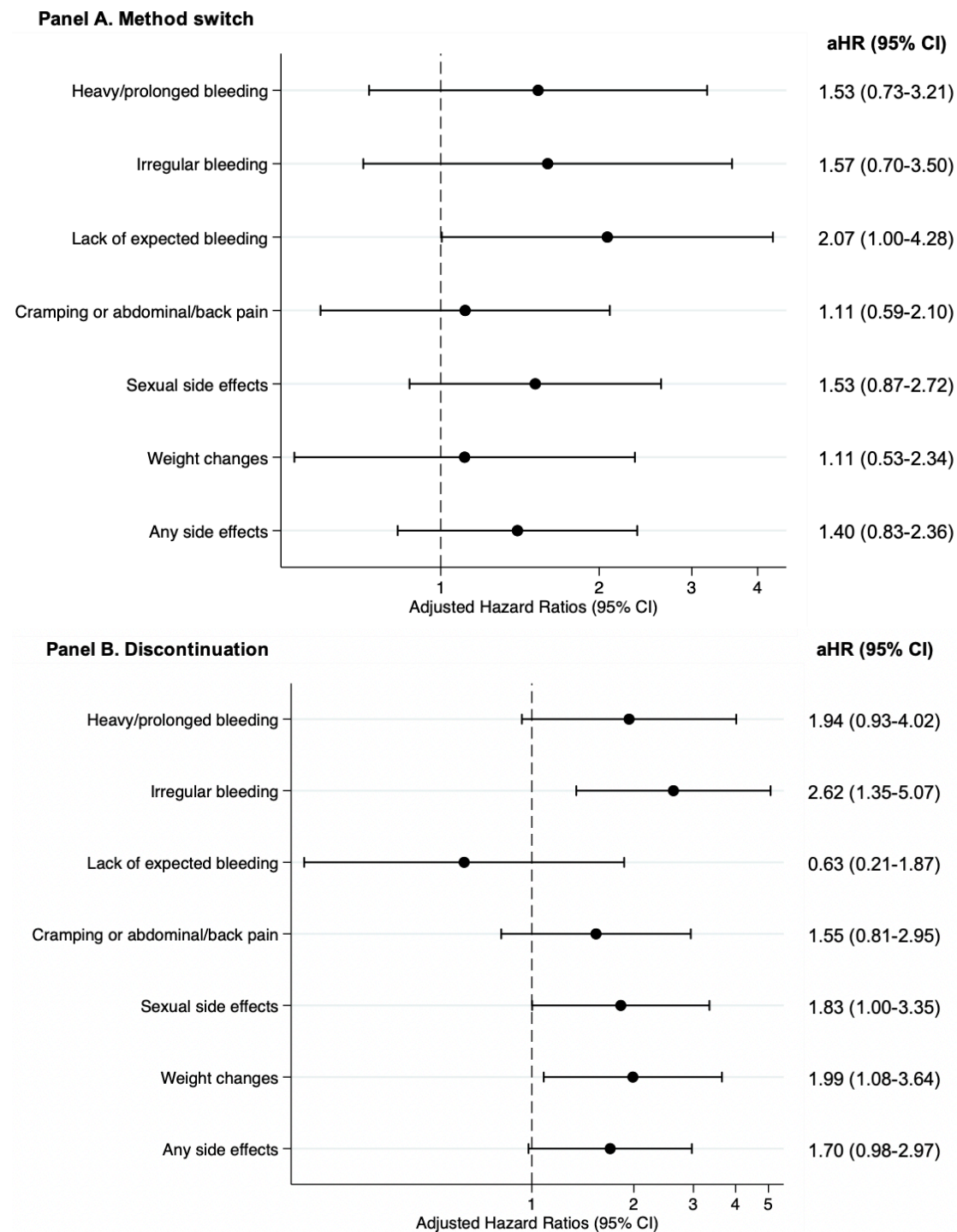


Figure 2.2 Adjusted hazard ratios of method switch and discontinuation by side effects experience



Notes: Cause-specific hazard ratios estimated using Cox proportional hazards models stratified by enrollment facility. All models are adjusted for the following baseline covariates: marital status, contraceptive method type, age (in years), years of completed education, FP user type (initiator, continuer, switcher at baseline), postpartum status (end of pregnancy within 1 year of study enrollment), and current breastfeeding. Adjusted models comprise 676-682 participants due to missing values in the side effects exposures and covariates

Table 2.1 Characteristics of female contraceptive users at study enrollment

	<i>N</i>	Overall n (%) or median (IQR)
Panel A. Baseline characteristics		
Age (years)		26 (23, 31)
Age category		
<25		313 (39)
25-34	810	391 (48)
>34		106 (13)
Married (legal or presumed)	822	671 (82)
Completed education (years)	823	8 (4, 13)
Nulligravid	817	50 (6)
<6 months since most recent pregnancy	817	237 (29)
Currently breastfeeding	809	381 (47)
<i>Method type</i>		
Implant		360 (44)
IUD	825	60 (7)
Injectable		354 (43)
OCP		51 (6)
<i>FP user type</i>		
Initiating contraception		212 (26)
Switching method	819	105 (13)
Continuing method used in past month		502 (61)
<i>History of contraceptive side effects or method problems^a</i>		
No	756	241 (32)
Yes		392 (52)
Contraceptive naïve		123 (16)
<i>Fertility intentions</i>		
Wants no children in the future		184 (22)
Not sure if wants children in the future		68 (8)
Yes, not sure of preferred timing of next pregnancy	825	100 (12)
Yes, next pregnancy in 1-2 years		77 (9)
Yes, next pregnancy in >2 years		396 (48)
<i>Becoming pregnant in the next few weeks would be a:</i>		
Big problem		453 (56)
Small problem	815	67 (8)
No problem		186 (23)

Not sure		109 (13)
Received all 3 components of Method Information Index (MII) ^b (ref: <3)	794	455 (57)

IUD = intrauterine device; OCP = oral contraceptive pills

^aAt enrollment, women were asked if they had ever used family planning before the current day in their lifetime. Women were then asked about use of specific modern, reversible methods (injectables, implants, IUD, OCP, and condoms). For each method for which they reported lifetime use, they were asked about experience of any side effects or problems with the method. History of contraceptive side effects is coded as “yes” if women reporting experiencing side effects with any of the individual methods. FP naivety was defined as reporting no history of FP use prior to the date of enrollment and initiating a method on that day. Women reporting no prior FP use but continuing/switching a method on the date on enrollment were coded as missing, since they were not administered questions on method-specific side effects history.

^bThe MII is coded as a binary variable equal to 1 if women reported received all 3 of the following counseling components during the FP visit on the date of study enrollment (or at her most recent visit, if she did not receive FP services on the date of enrollment): information on other methods, side effects of selected method, and what to do if side effects occur; the variables is coded as 0 if <3 counseling items were reported.

Notes: The analysis is restricted to women who did not report desiring their next pregnancy within 1 year and who were using implants, injectables, IUD or OCP at baseline. For the 59/818 (7%) of participants who reported using a second method of family planning, their primary method was used to define method switch in this analysis. Of participants using a dual method at study enrollment, 33/53 (63%) were using condoms, 17/53 (32%) fertility-awareness based methods, and 3/53 (6%) other methods.

Table 2.2 Weekly probability of side effects, by contraceptive use outcome

	Continued	Switched	Discontinued	Full Sample
	Prevalence (95% CI)	Prevalence (95% CI)	Prevalence (95% CI)	Prevalence (95% CI)
Heavy/prolonged bleeding	0.07 (0.06-0.08)	0.11 (0.07-0.17)	0.11 (0.07-0.18)	0.07 (0.06-0.09)
Irregular bleeding	0.08 (0.06-0.09)	0.14 (0.09-0.22)	0.16 (0.10-0.24)	0.08 (0.07-0.09)
Lack of expected bleeding	0.07 (0.06-0.08)	0.12 (0.08-0.19)	0.07 (0.04-0.13)	0.07 (0.06-0.08)
Cramping or abdominal/back pain	0.11 (0.10-0.13)	0.24 (0.17-0.33)	0.20 (0.14-0.30)	0.12 (0.11-0.14)
Sexual side effects	0.14 (0.12-0.16)	0.25 (0.18-0.35)	0.22 (0.15-0.32)	0.15 (0.13-0.16)
Weight changes*	0.12 (0.11-0.14)	0.18 (0.12-0.28)	0.20 (0.13-0.30)	0.13 (0.11-0.15)
Any side effects or method problems	0.23 (0.21-0.25)	0.36 (0.28-0.47)	0.35 (0.26-0.47)	0.24 (0.22-0.26)

* All side effects were reported as occurring in the past 1 week with the exception of weight changes, which were reported as occurring in the past month

Notes: Participants are defined based on their contraceptive use outcome (method switch, discontinuation, or censoring, whichever occurred first). Side effects are defined using the participant's weekly report. Reported side effects for the week of method switch are excluded (as these capture side effects of the new method) with the exception to women switching in week 1, for whom we use imputed values for side effects of the initial method. Mean weekly prevalence and corresponding 95% confidence intervals were estimated using log-binomial generalized estimating equations adjusted for contraceptive use outcome (continued, switched, discontinued). Note that participants were censored due to switch, discontinuation, non-response or loss-to-follow-up. Analyses comprise 704-710 participants due to missing values in side effects.

CHAPTER THREE – A risk scoring tool for predicting Kenyan women at high risk of contraceptive discontinuation

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A Risk Scoring Tool for Predicting Kenyan Women at High Risk of Contraceptive Discontinuation

Running Title: Risk Score to Predict Contraceptive Discontinuation

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Abstract

Objective: We developed and validated a pragmatic risk assessment tool for identifying contraceptive discontinuation among Kenyan women who do not desire pregnancy.

Study design: Within a prospective cohort of contraceptive users, participants were randomly allocated to derivation (N=558) and validation (N=186) cohorts. Risk scores were developed by selecting the Cox Proportional Hazards model with the minimum Akaike information criterion. Predictive performance was evaluated using time-dependent receiver operating characteristic curves and area under the curve (AUC).

Results: The overall contraceptive discontinuation rate was 36.9 per 100 woman-years (95% confidence interval [CI] 30.3-44.9). The predictors of discontinuation selected for the risk score included: use of a short-term method or copper intrauterine device (vs. injectable or implant), method continuation or switch (vs. initiation), <9 years completed education, not having a child aged <6 months, and having no partner or a partner supportive of family planning (vs. being unmarried or having uncertain partner support). AUC at 24 weeks was 0.76 (95%CI 0.64-0.87) with 70.0% sensitivity and 78.6% specificity at the optimal cut-point in the derivation cohort. Discontinuation was 3.8-fold higher among high- vs. low-risk women (95%CI 2.33-6.30). AUC was 0.68 (95%CI 0.47-0.90) in the validation cohort. A simplified score comprising routinely-collected variables demonstrated similar performance (derivation-AUC: 0.73 [95%CI 0.60-0.85]; validation-AUC: 0.73 [95%CI 0.51-0.94]). Positive predictive value was 36.6% for the full and 26.1% for the simplified score.

Conclusions: The risk scores demonstrated moderate predictive ability but identified large proportions of women as high-risk. Future research is needed to improve sensitivity and specificity of a clinical tool to identify women at high risk for experiencing method-related challenges.

Implications

Contraceptive discontinuation is a major driver of unmet contraceptive need globally. Few tools exist for identifying women who may benefit most from additional support in order to meet their contraceptive needs and preferences. This study developed and assessed the validity of a provider-focused risk prediction tool for contraceptive discontinuation among Kenyan women using modern contraception. High rates of early discontinuation observed in this study emphasize the necessity of investing in efforts to develop new contraceptive technologies and stronger delivery systems to better align with women's needs and preferences for voluntary family planning.

1. Introduction

Globally, an estimated 220 million women at risk for an unplanned pregnancy are not using contraception (4, 5, 93). Meeting women's contraceptive needs is a priority for reproductive justice (94) and for improving maternal and newborn health (1, 2). Increasingly, discontinuation is recognized as a key driver of unmet contraceptive need (22, 32-34). By one year, over one-third of women using modern, reversible contraceptive methods discontinue contraception in low- and middle-income countries (68). Method-related problems, such as side effects and difficulty using methods, are the most common reasons given for discontinuation (67, 68). Helping women who wish to avoid pregnancy, but who experience contraceptive method-related challenges, achieve their reproductive goals is critical for preventing unintended and mistimed pregnancy.

Current family planning (FP) guidelines emphasize tailoring counseling to individual needs and focusing on essential information, with the goal of helping women identify the contraceptive method that will best meet their personal needs (95). Recent studies suggest that quality of FP counseling, including provision of method information and counseling on options for switching methods if dissatisfied, is protective against early discontinuation (24, 96-99). Several randomized trials have also found low-intensity interventions such as SMS reminders result in improved continuation rates (60, 100, 101). However, current counseling guidelines do not aid providers in identifying women at highest risk of method-related discontinuation who could benefit from FP counseling or support specifically focused on meeting contraceptive needs and preferences. Intensive counseling may be burdensome or irrelevant to many women seeking FP services. Given the reality of time-constrained FP visits, tools that can support providers to more effectively tailor their counseling messages are needed.

Risk scoring systems have been developed for a variety of adverse health outcomes in sub-Saharan Africa (102-104). However, tools to identify women who may benefit most from additional

counseling and support to ensure their contraceptive needs and preferences are met have not been constructed. We developed an empiric prediction tool that could be used by FP providers to identify women at highest risk for contraceptive discontinuation.

2. Methods

2.1 Study population

We used data from the Mobile Data Collection for Contraceptive Use, Behaviors, and Experience (mCUBE) study, a prospective cohort study of women's contraceptive experiences. Study participants were enrolled February-May 2018 while attending FP or maternal and child health clinics within ten public health facilities in five counties of Western Kenya (Bungoma, Homa Bay, Kakamega, Kisumu, and Nyamira). Women were eligible if they were ≥ 18 years (or an emancipated minor ≥ 14 years with a previous pregnancy); had daily access to a mobile phone with a Safaricom SIM card; were able to read and respond to SMS in English, Swahili, or one of two local languages (Luo or Kisii) either alone or with the help of a trusted person; and were currently initiating, continuing, or switching a modern, reversible contraceptive method. Modern methods included injectables, implants, intrauterine devices or systems (IUD), oral contraceptive pills (OCPs), emergency contraceptive pills, condoms, diaphragms, lactational amenorrhea, Standard Days Method, and Two Day Method (75).

2.2 Data collection

Data were collected through structured SMS surveys operated by the Kenya-based company mSurvey (Nairobi, Kenya). Study staff administered an enrollment SMS survey, capturing information on sociodemographic characteristics, reproductive and contraceptive history, contraceptive use, fertility goals, and perceived quality and satisfaction with FP services. Participants received weekly follow-up SMS surveys for 24 weeks that captured information on contraceptive use, method type, reasons for switch or discontinuation (if applicable), side effects,

and healthcare utilization. Details on contraceptive method and discontinuation ascertainment are provided in the Online Appendix (Appendix: Chapter 3 Supporting Information).

2.3 Ethical considerations

All study procedures were approved by the Maseno University Ethical Review Committee. Participants signed a written consent form prior to any study procedures. The University of Washington's (UW) Human Subjects Division (HSD) determined ethical approval from UW was not required as the UW research team was not considered engaged in human subjects research; however, this specific analysis was approved by UW HSD.

2.4 Risk score development and validation

Contraceptive discontinuation was defined as a period of ≥ 2 consecutive weeks during which women self-reported they were not currently using any modern contraceptive method. We defined discontinuation based on a ≥ 2 -week period in order to capture short-term discontinuation episodes that have not been widely explored in the published literature. Method switches were considered as continuation unless a ≥ 2 -week period elapsed with no modern method use. Our analytic sample comprised participants with complete baseline data for all risk factors considered and at least 1 complete observation during follow-up. Women who desired a pregnancy in the next year were excluded, as they were expected to be more likely to discontinue to become pregnant rather than for method-related reasons (105). Potential predictors considered for the risk score included sociodemographic and clinical characteristics routinely collected in Kenyan FP clinics. Additional potential predictors not routinely collected (education, whether her partner supported her contraceptive use, feelings about a hypothetical near-term pregnancy, side effects history, and perceived quality of FP care) were also evaluated.

For score development and validation, 75% were randomly assigned to a derivation cohort to select the prediction model and the remaining 25% to a validation cohort. Due to the relatively high level of interval censoring (3,194/15,266, or 21% of weekly observations), we imputed weekly self-reported method use by carrying forward the last observation and carrying backward the next observation; we did not impute after a participant's final complete weekly report (S3 Supplementary Material). In the derivation sample, stepwise selection was used to identify the Cox proportional hazards model with the minimum Akaike information criterion (106). If potential predictors were collinear in the full sample, the variable with a greater scientific basis for inclusion based on the published literature was included prior to model selection. Covariates considered in model selection are in Table 1. A full risk score model using all variables selected in the stepwise model as well as a simplified model comprising variables routinely collected in FP clinics were created.

To construct risk scores, points were assigned to each variable by taking the ratio of its coefficient to the minimum coefficient in the multivariable Cox model rounded to the nearest integer (102, 103). We assessed predictive value of the risk score using receiver operating characteristic (ROC) curves and area under the curve (AUC) estimates at 12 and 24 weeks using an inverse-probability-of-censoring-weighting approach for right-censored data (S3 Supplementary Material).(107) The 12- and 24-week timepoints were selected to assess rapid discontinuation after uptake and the maximum follow-up time, respectively. Time-dependent sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were estimated, with optimal cut points defined by Youden's J statistic. Risk score performance was evaluated in the validation and full cohorts using time-dependent AUC-ROC analysis.

Several sensitivity analyses were conducted. First, in addition to excluding women desiring pregnancy in the next year, the primary risk score was reconstructed additionally excluding

women who desired a future pregnancy but were unsure when. Second, the full risk score was fit using a subdistribution hazard model (79), with discontinuation for pregnancy desire as a competing risk. We modeled missing reason for discontinuation using multiple imputation with chained equations (81). Third, we explored an alternative methodology for variable selection using the Cox extension of the least absolute shrinkage and selection operator (LASSO) with a grouped penalty for categorical covariates (S3 Supplementary Material). Comparative performance of the stepwise- and LASSO-Cox risk scores is of interest, as LASSO may reduce overfitting compared to standard stepwise approaches (108). Finally, we rederived the risk score using an alternative definition of discontinuation that required 4, rather than 2, weeks of method non-use to assess robustness of our findings to selection of the discontinuation interval. Additional sensitivity analyses to assess the potential impact of measurement error in self-reported method use are presented in the S3 Supplementary Material. All analyses were conducted in Stata v15.1 (StataCorp, College Station, TX) and R v3.6.2 (The R Project for Statistical Computing).

3. Results

Of 1212 mCUBE study participants, 744 (61%) were included in this analysis; 255 (21%) were excluded due to missing enrollment characteristics, 91 (8%) due to missing follow-up, 68 (6%) due to missing both enrollment and follow-up data, and 54 (4%) due to reported desire to become pregnant within 1 year. Among participants with complete enrollment data, we observed no differences in having any completed follow-up (defined as response to at least one weekly survey) or duration of completed follow-up by method type. Additional details on characteristics of the analytic sample are provided in the S3 Supplementary Material. Median age was 26 years (interquartile range [IQR] 23-31) and half (51%) reported completing <9 years of education (Table 3.1). Most (94%) women had at least one prior pregnancy, with 30% having a child <6 months old. Three-quarters of participants reported having a partner who supported her FP use. Implants (43%) and injectables (42%) were the most prevalent contraceptive methods at enrollment. The

full cohort contributed 268.2 woman-years of follow-up with 99 incident contraceptive discontinuation events, for an overall incidence of 36.9 per 100 woman-years (95%CI 30.3-44.9) (Figure 3.1). Overall, 38% of women were initiating contraception or switching to a new contraceptive method at enrollment. Among these women, we observed a discontinuation rate of 25.7 per 100 woman-years (95%CI 17.6-37.5 per 100 woman-years), corresponding to a 12-month cumulative incidence of 22.7% (Figure 1). Discontinuation rates by user and method type are provided in the S3 Supplementary Material. Most (119/194, 61%) women newly initiating contraception were motivated by a change in their perceived risk of unintended pregnancy, while 15% (30/194) cited birth spacing and 9% (17/194) a recent increase in sexual activity. Among method switchers, 60% (55/91) switched due to side effects or health concerns with their prior method. There were few differences between the derivation and validation cohorts. Compared to participants included in the analysis, excluded participants had lower education attainment and were more likely to desire no future children, use other modern methods (condoms or fertility-awareness methods), and report fears about using FP (S3 Supplementary Material).

3.1 Risk Score Development

Incidence of discontinuation in the derivation cohort was 37.3 per 100 woman-years (95%CI 29.7-46.7) (Figure 3.1). The full risk score included the following variables: method type, continuing or switching methods, vs. contraceptive initiation, <9 years of completed education, not having a child aged <6 months, being unmarried, and having a partner supportive of FP (Table 3.2). Injectables and implants were combined into a single reference category for method type; this post-hoc decision was based on the similar risk of discontinuation observed among women using these methods (aHR: <1.01). Due to the small number of women using emergency contraceptive pills, fertility-based methods, and condoms in our sample, these methods were also grouped in a single category in the analysis. Reporting an unsupportive partner or being uncertain of partner's support for FP was associated with contraceptive continuation. The median score in the derivation

cohort was 6 (IQR 5-7; range 0-12) (Table 3.2). The AUC was 0.76 at 24 weeks (95%CI 0.64-0.87) and 0.70 at 12 weeks (95%CI 0.63, 0.78) (Figure 3.2A). At the optimal cut-point of 6, 41.8% (n=233) were identified as high-risk, with 70.9% sensitivity, 78.6% specificity, and 36.6% PPV at 24 weeks (Table 3.3). Discontinuation risk was 3.8-fold higher among women with risk scores >6 vs. ≤6 (95%CI 2.33-6.30) (Figure 3.3A).

A simplified risk score that excluded variables not routinely collected (partner support for FP and educational attainment) had a median value of 3 points in the derivation cohort (IQR 2-3; range: 0-8) (Table 3.2). Performance of the simplified score was similar to the full score, with a 24-week AUC of 0.73 (95%CI 0.60-0.85) and 12-week AUC of 0.67 (95%CI 0.59-0.75) (Figure 3.2A). The score demonstrated 80.6% sensitivity, 57.1% specificity, and 24.7% PPV at the optimal cut-point of 2, with 63.4% (n=354) defined as high-risk (Table 3.3). Discontinuation risk was significantly higher among women with scores of >2 (vs. ≤2) (hazard ratio [HR]: 2.46, 95%CI 1.40-4.34) (Figure 3.3A). Both risk scores demonstrated improved predictive ability over any single score component (S3 Supplementary Material).

3.2 Risk Score Validation

In the validation cohort, incidence of discontinuation was 35.9 per 100 woman-years (95%CI 24.0-53.5) (Figure 3.1). 24-week AUC was 0.68 (95%CI 0.47-0.90) for the full and 0.73 (95%CI 0.51-0.94) for the simplified risk score (Figure 3.2B). The full risk score demonstrated 58.6% sensitivity and 77.8% specificity at the cut-point defined in the derivation cohort, while the simplified score had 74.9% sensitivity and 66.7% specificity (Table 3.3). The risk scores demonstrated similar predictive ability in the full cohort (Table 3.3B, S3 Supplementary Material).

3.3 Sensitivity Analyses and Alternative Methodological Approaches

Overall, 60% (n=45/75) of women reporting method discontinuation in the derivation cohort were missing reason for discontinuation (S3 Supplementary Material). To assess the possible impact of including discontinuation in our analyses due to desire for pregnancy, we conducted two sensitivity analyses: first, treating discontinuation for pregnancy desire as a competing risk; and second, additionally excluding women unsure of the preferred timing of next pregnancy. Both analyses yielded similar estimates as the primary model (S3 Supplementary Material). Alternative model selection using the LASSO-Cox approach resulted in a similar prediction model, selecting all variables from the full risk score and several additional variables (fertility intentions and perceived accuracy of information provided during FP visit), and predictive performance (S3 Supplementary Material). Our results were also robust to an alternative definition of discontinuation that required at least 4 weeks of non-use and to a number of additional sensitivity analyses that assessed potential measurement error in self-reported method use (S3 Supplementary Material).

4. Discussion

All women seeking contraception would benefit from receiving accurate, culturally-relevant, and personalized counseling. However, a simple algorithm could be used to identify women seeking FP care who may benefit most from tailored counseling on strategies for method-related challenges to ensure their contraceptive needs and preferences are met. We developed and assessed the validity of a pragmatic risk assessment tool in a cohort of Kenyan women seeking FP services to predict contraceptive discontinuation among women who do not wish to become pregnant. Using a Cu-IUD or short-term modern method, switching or continuing a specific method type (relative to newly initiating contraception), having <9 years completed education, not having a child <6 months old, and being unmarried or having a partner with supportive attitudes towards FP (versus a partner who is unsupportive or whose attitudes are unknown) were selected as predictors in the full risk score. Both the full and simplified risk scores demonstrated moderate

predictive ability to identify contraceptive discontinuation in the 24 weeks after receiving FP services, but identified high proportions of women as high-risk (>40% and 60% for the full and simplified score, respectively). While targeting “false positives” for additional counseling or support may not present additional risks to the patient, development of a score with improved positive predictive value is necessary to address pragmatic considerations regarding additional demands on provider time.

Among the variables selected for inclusion in our risk score, several are established risk factors for contraceptive discontinuation, including short-term method use, being unmarried, and low educational attainment (22, 68). Relatively high discontinuation among Cu-IUD users was unexpected, and may be explained in part by the small sample size. In a sensitivity analysis treating discontinuation for pregnancy desire as a competing risk, we observed a lower adjusted hazard of discontinuation among IUD users, relative to implant and injectable users; this finding suggests that Cu-IUD users may be more likely to discontinue due to pregnancy desire. Further research in a larger sample that explores possible interactions between method type and future pregnancy intentions, planning, and ambivalence is warranted. Surprisingly, we found contraceptive discontinuation was higher among women who reported partner support for FP. Perceived partner attitudes may serve as a proxy measure for fertility intentions and attitudes towards a mistimed pregnancy (109, 110). In this study, we captured a single-item measure for pregnancy ambivalence which may have inadequately captured complex feelings towards pregnancy and parenthood (111). Higher risk of discontinuation among method continuers, compared to switchers or initiators, may also be explained by unmeasured differences in the level and intensity of motivations to prevent pregnancy. Future studies may benefit from finer measurement of fertility intentions, pregnancy ambivalence, and relationship dynamics (105).

Indicators of perceived quality of care and satisfaction were not selected for inclusion in the full risk score. Several recent studies have found that method information counseling reduced risk of discontinuation by 64%-80% (24, 98). However, these studies included women newly initiating or switching contraceptive methods; in contrast, 62% of our study participants were “continuers” at enrollment, and it is plausible that experienced contraceptive users may be less receptive to, or in need of, introductory information on topics such as alternative contraceptive method types and potential side effects.

A strength of this study is its prospective design and high-frequency data collection. The remote nature of data collection reduced participant burden, permitting weekly assessment of short-term and unintentional discontinuation events that may be missed in less frequent, retrospective contraceptive history-taking. Remote data collection may also reduce social desirability bias (23). Women were recruited while seeking FP services in public facilities, and our estimates of discontinuation among women newly initiating a contraceptive method were similar to national data (25.8%) (85). Facility-based recruitment also allowed for evaluation of indicators of perceived quality and satisfaction with FP services. Finally, we defined discontinuation based on 2 or more consecutive weeks of reported non-use, rather than a single week, to reduce sensitivity to data entry errors.

Our study has several limitations. Measurement error may be higher in self-administered surveys, given the absence of a trained enumerator to probe inconsistent responses, ensure comprehension, and correct entry errors. While we did not validate self-reported contraceptive use using medical records or clinical assessment, future research would benefit from using supplementary data sources to validate self-reports. The SMS format encourages short survey instruments; we may therefore have failed to measure specific drivers of discontinuation including lack of sexual activity and experience of side effects at enrollment among continuers. Over half

of all women who discontinued did not provide a reason, which limited our ability to differentiate method-related discontinuation from discontinuation for pregnancy desire. While censoring was not associated with method-type, relatively high loss to follow-up may introduce selection bias. In addition, the number of IUD, pill and other modern method users was small, which limited our ability to explore predictors of discontinuation by method type and develop method-specific risk scores. The short duration of follow-up also makes our results generalizable only to early discontinuation events.

We developed and assessed validity of a pragmatic risk assessment tool to identify women at high risk of contraceptive discontinuation after utilization of FP services. The tool demonstrated moderate predictive ability but low positive predictive value. Future research is needed to develop provider-focused tools that can support women with contraceptive methods and care that are better aligned with their needs and preferences.

Competing Interests

The authors declare no competing interests.

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Table 3.1 Sociodemographic, reproductive, and family planning characteristics of the derivation and validation cohorts at study enrollment

	Derivation Cohort (n=558) n (%)	Validation Cohort (n=186) n (%)	p-value
Sociodemographic characteristics			
Age category (years)			
≤20	43 (8)	16 (9)	0.66
21-25	211 (38)	77 (41)	
26-30	153 (27)	53 (28)	
31-35	87 (16)	24 (13)	
>35	64 (11)	16 (9)	
Completed education <9 years	283 (51)	93 (50)	0.87
<i>Relationship status</i>			
Not married (legal or presumed)	103 (18)	36 (19)	0.96
Partner supportive of FP	422 (76)	139 (75)	
Partner not supportive of FP or unsure of partner support	33 (6)	11 (6)	
Reproductive characteristics			
Number of living children [median (IQR)]	2 (1, 3)	2 (1, 3)	0.43
Does not have a child aged <6 months	392 (70)	132 (71)	0.85
<i>Fertility intentions</i>			
Unsure intention to have children or unsure of preferred timing	116 (21)	31 (17)	0.55
Desires no future children	121 (22)	38 (20)	
Desires next pregnancy in 1-2 years	48 (9)	19 (10)	
Desires next pregnancy in >2 years	273 (49)	98 (53)	
<i>Pregnancy in the short-term future would be a:</i>			
Not sure	72 (13)	27 (15)	0.77
Big problem	315 (56)	98 (53)	
Small problem	48 (9)	15 (8)	
No problem	123 (22)	46 (25)	
Characteristics of FP services received			
Contraceptive method type			
Injectables	226 (41)	84 (45)	0.50
Implant	241 (43)	79 (42)	
Intrauterine device (Cu-IUD/IUS)	376 (6)	10 (5)	
Pills ^a	31 (6)	5 (3)	
Other modern ^b	24 (4)	8 (4)	
FP user type			

Initiating contraception	146 (26)	48 (26)	0.89
Switching from one method type to another	70 (13)	21 (11)	
Continuing method used in past month	342 (61)	117 (63)	
History of contraceptive side effects			
No	289 (52)	95 (51)	0.14
Yes	258 (46)	91 (49)	
Unsure	11 (2)	0 (0)	
Traveled less than 30 minutes to reach health facility	351 (63)	118 (63)	0.90
Quality of care and satisfaction			
"Very satisfied" with services received	267 (48)	86 (46)	0.70
Felt that her privacy was not protected during the visit	33 (6)	14 (8)	0.43
Felt provider gave:			
Accurate information	50 (9)	15 (8)	0.71
Inaccurate information or unsure of accuracy	508 (91)	171 (92)	
Felt provider's treatment was "very respectful"	493 (88)	160 (86)	0.40
Number of items in Method Information Index received [median (IQR)] ^c	3 (1, 3)	3 (1, 3)	0.81
Feelings about using FP:			
No fears or concerns	353 (63)	127 (68)	0.35
Reported having fears or concerns	184 (33)	55 (30)	
Unsure of having fears or concerns	21 (4)	4 (2)	

^aPills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

^c The Method Information Index is calculated based on 3 questions: "during your visit: 1) were you informed about other methods?, 2) were you informed about side effects or problems with the method?, 3) were you told what to do if you had side effects or problems with the method?". Responses were summed to provide a count of the number of counseling items received, from 0 (received none of these counseling items) to 3 (received all items).

Notes: p-values obtained using χ^2 test for proportion or Wilcoxon rank-sum test of medians for continuous measures.

Table 3.2 Adjusted hazard ratios of multivariable risk score models on contraceptive discontinuation in the derivation cohort

	Full Risk Score		Simplified Risk Score	
	HR (95% CI)	Points	HR (95% CI)	Points
Contraceptive method type				
Cu-IUD/IUS	1.58 (0.67, 3.72)	1	1.56 (0.66, 3.66)	1
Pills ^a	3.16 (1.59, 6.26)	3	3.32 (1.68, 6.57)	3
Other modern ^b	5.32 (2.46, 11.42)	4	4.95 (2.32, 10.59)	4
<i>Reference: Injectables, implants</i>	<i>Ref.</i>	0	<i>Ref.</i>	0
FP user type				
Continuing method used in past month	2.25 (1.14, 4.23)	2	2.41 (1.23, 4.73)	2
Switching from one method type to another	2.10 (0.88, 5.06)	2	2.07 (0.87, 4.97)	2
<i>Reference: Initiating contraception</i>	<i>Ref.</i>	0	<i>Ref.</i>	0
<9 years completed education	1.62 (1.01, 2.60)	1	--	--
Does not have child aged <6 months	1.60 (0.89, 2.86)	1	1.57 (0.88, 2.82)	1
Relationship status				
Spouse supportive of FP	4.58 (0.63, 33.24)	3	--	--
Not married (legal or presumed)	7.34 (0.97, 55.21)	4	1.70 (0.98, 2.93)	1
<i>Reference: Spouse unsupportive/unsure of spousal support</i>	<i>Ref.</i>	0	--	--
Maximum score		12		8

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Notes: Full risk score selected using stepwise forwards and backwards select to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified risk score was developed by removing features in the full risk score that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities. β is the Cox proportional hazards model coefficients (non-exponentiated).

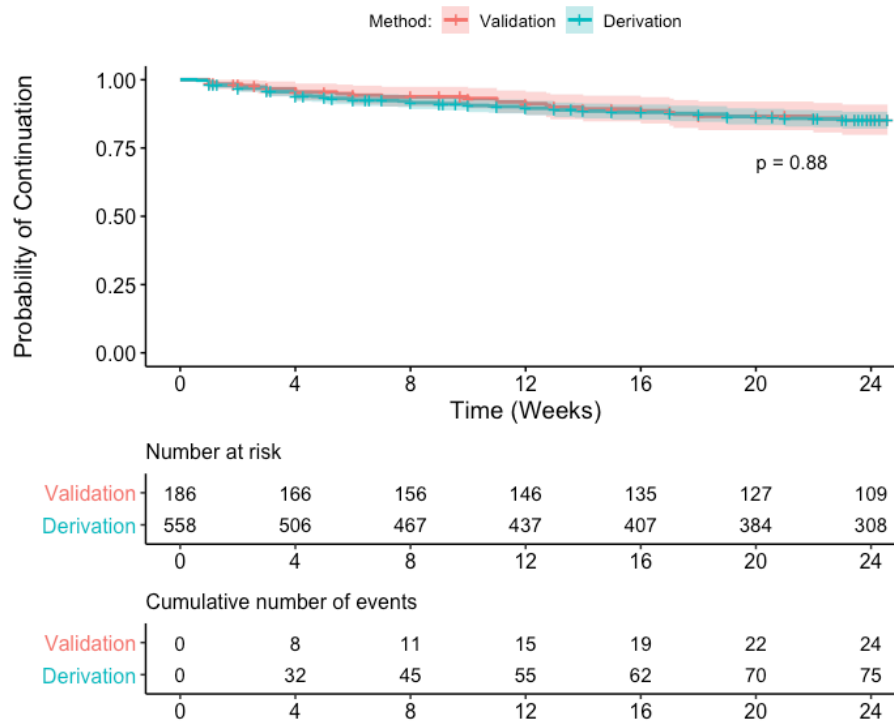
Table 3.3 Predictive performance of full and simplified risk scores on contraceptive discontinuation at 24 weeks, by cohort

Panel A. Full risk score	Cohort		
	Derivation	Validation	Full
Proportion defined as "high risk"	41.8%	40.3%	41.4%
Sensitivity	70.9%	58.6%	67.9%
Specificity	78.6%	77.8%	78.3%
Positive predictive value	36.6%	31.4%	35.3%
Negative predictive value	93.9%	91.5%	93.3%
Panel B. Simplified risk score			
Proportion defined as "high risk"	63.4%	61.3%	62.9%
Sensitivity	80.6%	74.9%	79.2%
Specificity	57.1%	66.7%	60.9%
Positive predictive value	24.7%	28.1%	26.1%
Negative predictive value	94.4%	93.9%	94.4%

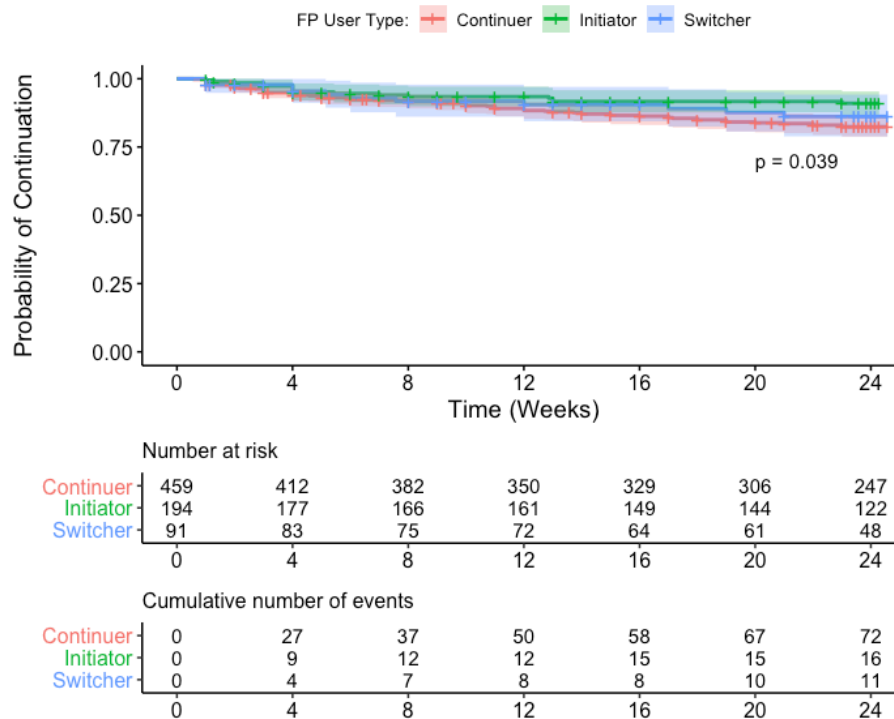
Notes: The full risk score includes the following variables: use of Cu-IUD, pills or other modern method (condoms or fertility-awareness based methods) (vs. injectables or implants), switching methods or continuing a contraceptive method at clinic attendance (vs. newly initiating contraception), <9 years completed education, not having a child <6 months of age, being unmarried or having a partner who is supportive of the participant's contraceptive use. The simplified risk includes only the following subset of variables: use of Cu-IUD, pills or other modern method (condoms or fertility-awareness based methods) (vs. injectables or implants), switching methods or continuing a contraceptive method at clinic attendance (vs. newly initiating contraception), not having a child <6 months of age, and being unmarried. All estimates calculated for score cut-point, defined as optimal based on maximizing Youden's J statistic. This corresponds to a score of >6 for the full risk score and >2 for the simplified risk score. All values calculated at 24 weeks.

Figure 3.1 Contraceptive discontinuation by 24 weeks

A. Contraceptive discontinuation by cohort



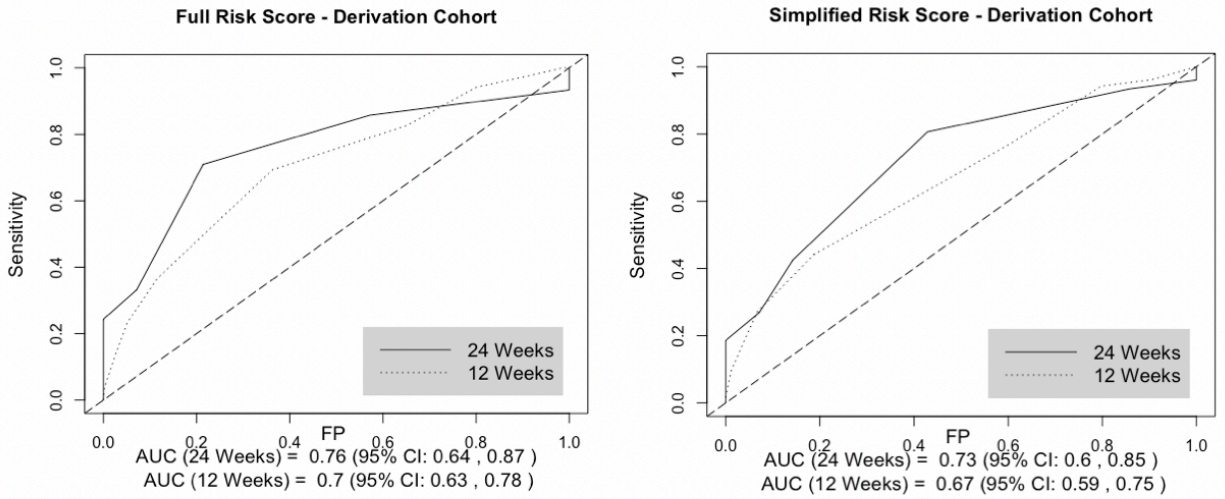
B. Contraceptive discontinuation by FP user type (method Initiator, switcher, or continuer)



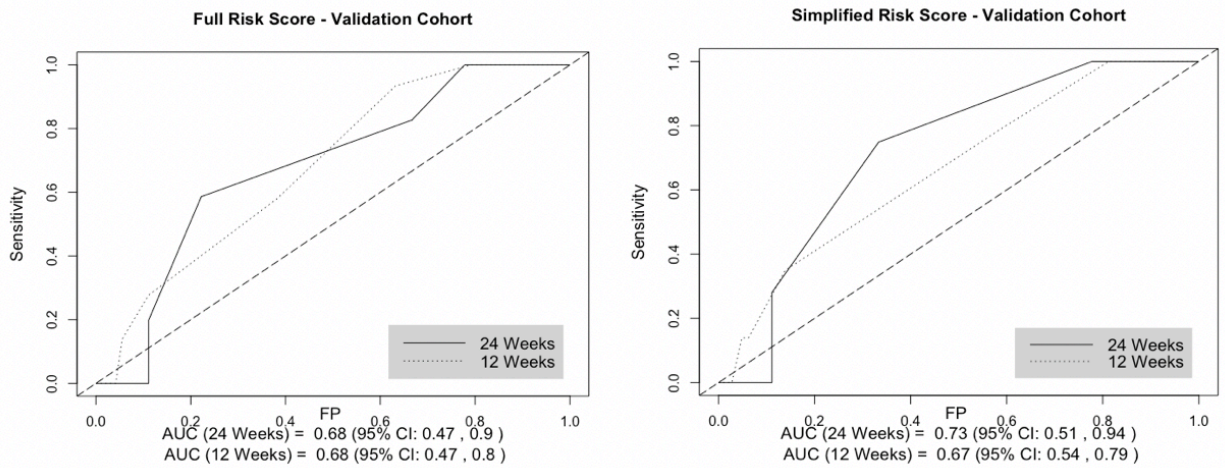
Notes: p-values calculated using the regular log-rank test with weights equal to 1.

Figure 3.2 Receiver operating characteristic curve and optimal cut-points of risk scores

A. Derivation cohort



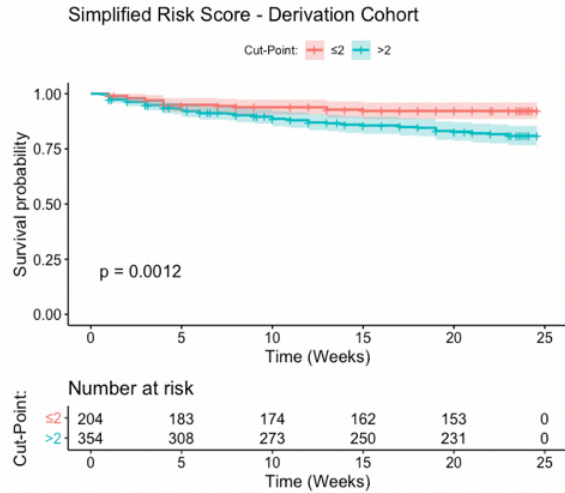
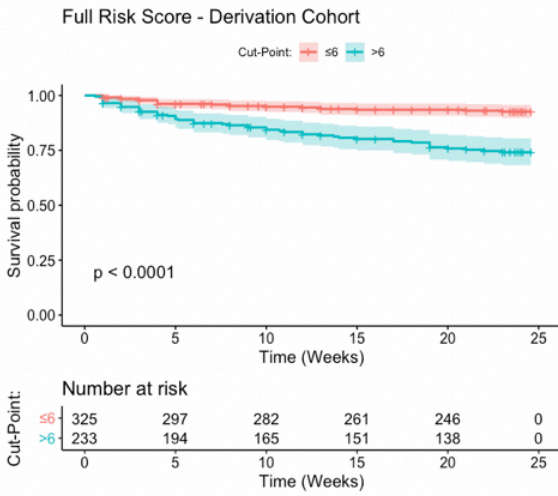
B. Validation cohort



Notes: ROC = receiver operating characteristic curves; AUC = area under the ROC curve (AUC)

Figure 3.3 Survival probabilities by optimal cut-points of risk scores

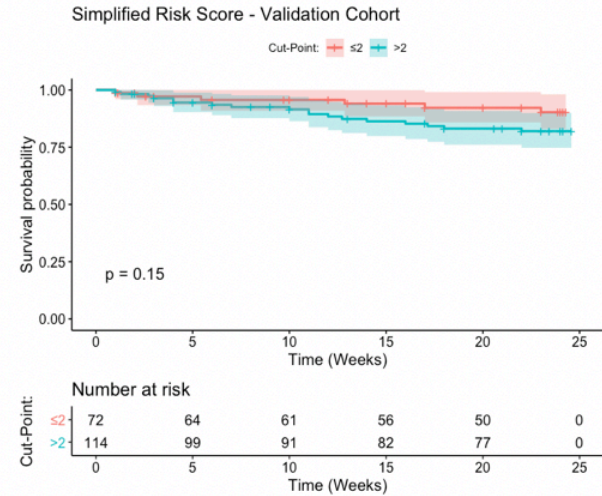
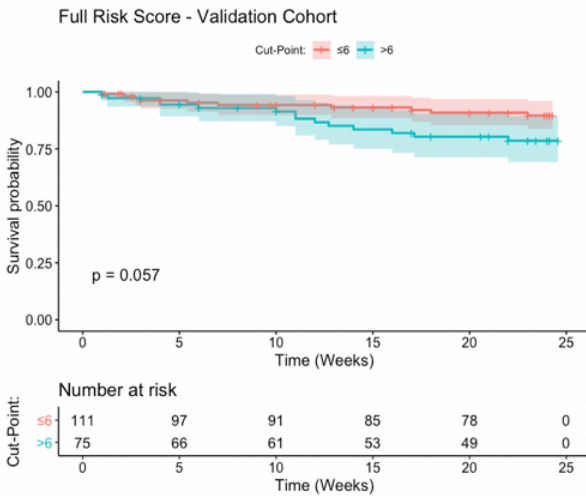
Panel A. Derivation cohort



HR (95% CI)
Risk score > 6 (ref: ≤ 6) 3.83 (2.33, 6.30)

HR (95% CI)
Risk score > 2 (ref: ≤ 2) 2.46 (1.40, 4.34)

Panel B. Validation cohort



HR (95% CI)
Risk score > 6 (ref: ≤ 6) 2.16 (0.96, 4.86)

HR (95% CI)
Risk score > 2 (ref: ≤ 2) 1.96 (0.78, 4.93)

Notes: p-values calculated using the regular log-rank test with weights equal to 1.

CHAPTER FOUR – Patterns and correlates of contraceptive side effects among Kenyan women: A prospective cohort analysis

Patterns and correlates of contraceptive side effects among Kenyan women: A prospective cohort analysis

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Abstract

Background: Contraceptive side effects and health concerns are the predominant reason for contraceptive non-use and discontinuation among women who wish to avoid pregnancy, yet the prevalence of specific contraceptive side effects in low- and middle-income countries is unclear.

Methods: In a prospective cohort study of Kenyan women using modern, reversible contraceptive methods, we used SMS surveys to measure mean weekly prevalence of side effects over a 24-week follow-up period among women using injectables, implants, oral contraceptive pills, or intrauterine contraceptive devices at study enrollment. Side effects were assessed overall and by specific type (bleeding- and non-bleeding-related). We identified individual-level correlates of weekly prevalence of side effects using log-binomial generalized estimating equations. Correlates were considered significant at the $p < 0.05$ level after Benjamini-Hochberg adjustment for multiple hypothesis testing.

Results: Among 731 participants, mean weekly prevalence of any side effects was 24% (95% confidence interval [CI] 22-26%). Non-bleeding-related side effects were more common than disruptions to menstrual bleeding patterns, with sexual side effects the most prevalent of the side effects measured (mean weekly prevalence [Pr] 15%, 95%CI 13-16%). We detected small but statistically significant temporal declines in prevalence of side effects at the population-level over the 24-week period. History of side effects and fears or concerns about side effects reported at enrollment were associated with higher prevalence of side effects (adjusted prevalence ratio [aPR] 1.72, 95%CI 1.37-2.18, and aPR 1.36, 95%CI 1.12-1.65; respectively). Receiving family planning care perceived to be high quality was associated with lower prevalence of non-bleeding-related side effects.

Conclusions: Contraceptive side effects were common in a cohort of Kenyan women using modern, reversible contraceptive methods. Experience of side effects was associated with side effects history as well as fears of side effects, while higher perceived quality of care was associated with lower prevalence of several specific side effects. Our findings suggest that interventions tailored to address women's specific side effects history and concerns could improve women's experiences using contraception.

Background

Side effects are the predominant reason for contraceptive discontinuation and non-use among women who do not desire pregnancy, yet there is a lack of prospective data describing women's experiences of side effects in low- and middle-income countries (LMICs) (22, 66, 68, 71). Side effects or health concerns are the most common reason given for non-use among women in LMICs, with 26% of married women citing side effects as a reason for not using contraception despite wishing to avoid pregnancy (66). Women are also more likely to state side effects as a reason for contraceptive non-use if they have used contraception in the past,(66) suggesting that experience of side effects is an important factor influencing both current and future contraceptive use. Improved understanding of the epidemiology of contraceptive side effects in LMICs, including specific symptoms, incidence over time, and individual-level risk factors, is critical for designing evidence-based interventions to address a major barrier to contraceptive use globally.

Current clinical counseling regarding contraceptive side effects is primarily based on evidence from efficacy trials or comparative studies of specific method types conducted in high-resource settings. Prospective evidence from LMIC populations is relatively scarce (26, 63). Other approaches to monitoring and evaluating family planning (FP) in demographic surveys conducted in LMICs fail to capture comprehensive information on side effects: the Demographic and Health Surveys (DHS), for example, collect side effects experience retrospectively only among women not currently using contraception. This measurement approach is subject to recall bias and precludes comparison of women who do and do not choose to continue contraceptive use. Largescale demographic surveys also do not collect information on specific side effects types or symptoms, preventing examination of differences in manifestations or relative frequency of specific side effects across individuals or settings. The Performance Monitoring for Action (PMA) surveys now captures side effects experience in its longitudinal cohorts; however, the annual

frequency of data collection limits detection of dynamic temporal patterns of side effects over shorter time intervals.

This lack of comprehensive data on side effects is problematic for two reasons: first, prior studies suggest that tolerability (26, 47) and even incidence (42) of specific types of contraceptive side effects may vary widely across populations. Evidence drawn from high-income settings may therefore result in counseling that is less accurate or relevant for LMIC populations (112). Second, few studies have examined predictors of contraceptive side effects (113). As a result, counseling on side effects is rarely tailored to individual user characteristics (112). Ability to identify women at high risk of experiencing future side effects, beyond their selected method type, could be useful for designing counseling or follow-up care interventions that are tailored to the preferences and experiences of specific groups.

We use data from a prospective cohort study among women using modern, reversible contraception in Western Kenya to measure the frequency of specific types of contraceptive side effects and to identify characteristics of women who are more likely to experience side effects over a 24-week-long period.

2. Methods

2.1 Study population

We conducted a prospective cohort study conducted in Western Kenya in 2018, as previously described (76). Briefly, women were recruited and enrolled at 10 public FP or maternal and child health clinics in 5 counties in Western Kenya. Women were eligible to participate in the study if they were ≥ 18 years old or emancipated minors (≥ 14 with a prior pregnancy), currently using a form of modern, reversible contraception (75), had daily access to a mobile phone with a

Safaricom SIM card and either had the phone in possession or could provide the phone number, and were able to read and respond to short message service (SMS) messages in English, Swahili, or a local language (Luo or Kisii) themselves or with the assistance of a trusted person. For this analysis, we excluded women without at least one complete response on side effects experience over the follow-up period or who were using methods not designed for long-term continuous use (emergency contraceptive pills) or not associated with substantial side effects (modern fertility awareness-based methods and condoms).

2.1 Data collection

Study staff administered an SMS-based enrollment survey to capture baseline characteristics. The survey captured sociodemographic characteristics, reproductive and contraceptive use history, attitudes and preferences about future pregnancies, and experiences of care received during the most recent FP visit. Indicators related to the most recent FP visit were captured, including elements of counseling quality, satisfaction, and access (travel time to the health facility). Participants received brief weekly SMS surveys for 24 weeks, which included questions on current method use, reasons for switch or discontinuation, experience of side effects, and method dissatisfaction. Participants received a small airtime incentive (~\$0.25 USD) for each completed survey.

2.2 Ascertainment and definitions of key variables

Contraceptive side effects

The primary outcomes of interest were weekly report of any contraceptive side effect and weekly report of symptom-specific contraceptive side effects. Women reporting current method use or discontinuation in the past week were asked whether they experienced any “side effects or problems” with the method in the past week. Participants who affirmed experience of side effects

or problems or stated they were “not sure” were then asked about specific types of side effects. Side effects were defined in non-mutually exclusive categories as any, and by the following specific symptom categories: heavy or prolonged bleeding, irregular bleeding (spotting, breakthrough bleeding, and bleeding after sexual intercourse), lack of expected bleeding, cramping or abdominal/back pain (including painful menses), sexual problems (loss of libido or sensation or painful intercourse), and weight changes. Additional details on ascertainment of specific side effects can be found in Table S4.1.

Baseline characteristics assessed as correlates of side effects

We captured information on women’s sociodemographic, reproductive, and contraceptive history characteristics at baseline. Women were defined as early postpartum if they reported the end of their most recent pregnancy (whether a livebirth or otherwise) within 6 months of enrollment. FP user type was defined as either initiating contraception (“initiator”), switching method types (“switcher”), or continuing a method used in the past month (“continuer”) at study enrollment. History of side effects was coded as a categorical variable equal to “yes” if the participant reported ever experiencing side effects or problems while using injectables, implants, intrauterine device (IUD), oral contraceptive pills (OCP), or condoms, “no” if she reported past contraceptive use but no experience of side effects with any of these methods, or “FP naïve” if she was initiating contraception for the first time in her life at study enrollment. Women were defined as having fears of side effects if they reported having “fears or concerns about using family planning” and selected side effects as their primary concern. Attitudes towards pregnancy were assessed by asking women how much of a “problem” it would be were they to become pregnant in the next few weeks (big, small, no problem, or unsure).⁽¹¹⁴⁾ Perceived quality of care received at the most recent FP visit (as reported at baseline) was assessed using several variables. Two questions measured overall satisfaction: women were asked to what extent they agreed with the statement that their FP needs were met (“strongly agree” to “strongly disagree”) and their overall satisfaction with FP

care received (“very satisfied” to “very dissatisfied”). To assess interpersonal care, we asked participants how they were treated (“very respectfully” to “very disrespectfully”), about their perception of the amount of time spent with the health provider (“right amount of time”, “too short”, or “too long”), and about their privacy (“protected”, “somewhat protected”, or “not protected”). We assessed quality of counseling using a modified version of the Method Information Index (MII), which assesses whether women received three key counseling messages (information on other method types, possible side effects of selected method, and actions to take if side effects occur) (24, 98); we specifically asked whether these components of counseling were delivered in the participant’s most recent FP visit (Table S4.2).

2.3 Ethical considerations

Study procedures were approved by the Ethics Review Committee of Maseno University, Kenya. The study received a “Not Engaged” determination by the University of Washington Human Subjects Division (UW HSD); however, this analysis was approved by the UW HSD. Participants provided written informed consent.

2.4 Statistical analysis

We estimated prevalence of contraceptive side effects overall and by method type using log-binomial generalized estimating equations (GEE). Participants were censored due to missingness (which occurred due to errors in the survey platform, non-response, or participant opt-out) or at the first report of method switch or discontinuation of all modern contraception for at least 2 consecutive weeks. Models were specified with indicators for method type, time in 4-week intervals, an interaction term between method type and time, an independent working correlation structure with clustering at the individual-level, and robust standard errors. We also estimated time trends in side effect prevalence using a linear term for weeks since enrollment.

Correlates of weekly side effects were assessed using analogous log-binomial GEE models, fitting separate models for each potential correlate of interest. All potential correlates were measured at study enrollment. Prevalence estimates are based on weekly report of side effects, and therefore represent the mean weekly prevalence over the 24-week follow-up period. Models were adjusted for suspected confounders selected *a priori* based on causal diagrams (Figure S4.1, Table S4.3). Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status, age category, early postpartum status, and number of living children. Remaining models were adjusted by age category, marital and early postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type. We report conventional 95% confidence intervals (CI), but determined statistical significance based on the p-value adjustment approach proposed by Benjamini-Hochberg to address multiple hypothesis testing (115). We specify a false discovery rate of 0.05 for correlates tested within each of the side effects outcomes separately, as well as for each of the sensitivity analyses. We used a complete case approach, with no imputation of missing values in potential correlates or side effects outcomes.

Sensitivity analyses

We conducted several sensitivity analyses. We conducted subgroup analyses by FP user type in order to assess robustness of our results to inclusion of initiators, switchers, and continuers at enrollment. We also fit the primary log-binomial models with dummy variables for week of follow-up, as well as analogous Poisson models including an offset equal to the log number of weeks in which the participant reported side effects in order to assess selection effects due to participants being censored at method switch or discontinuation. Finally, we fit a model for fear of side effects

that included history of side effects as an additional adjustment variable in order to explore whether there is an independent relationship between fear and side effects.

Results

Overall, we included data from 731 of 1,212 participants enrolled in the cohort. The most common reasons for exclusion were absence of follow-up data (N=171/481, 36%) and/or missing contraceptive method type at enrollment (N=130/481, 27%). The median age was 26 years old (interquartile range [IQR] 23, 30), with 38% (n=273) <25 (Table 4.1). Most (82%) women were married, had at least one living child (92%), and expressed an intention to delay their next pregnancy for at least 2 years (46%) or to have no more children (21%). The distribution of modern, reversible contraceptive methods used in the cohort was split between hormonal implant (44%) and injectable (43%) use, with only 5% and 8% using copper intrauterine devices (Cu-IUD) or oral contraceptive pills (OCP), respectively. Over half (53%) reported previously having contraceptive side effects, and 29% reported having fears or concerns about side effects. The majority of women reported that their privacy was protected (93%) during their most recent FP care visit, and 87% said they were treated very respectfully by the FP provider. Half of women strongly agreed that all of their needs were met by their FP visit at enrollment (50%), while 46% said that they were very satisfied overall with the care they received and 57% reported that they had received all three standard components of the MII.

Contraceptive side effects

Weekly prevalence of any side effects was 24% (95%CI 22-26%), with sexual side effects (15% [95% Confidence Interval [CI] 13-16%) and weight changes (13% [95%CI 12-15%]) being the most common specific side effects reported (Figure 4.1, Table S4.4). Weekly prevalence of heavier/prolonged and irregular bleeding was 7% (95%CI 6-9%) and 8% (95%CI 7-10%), respectively. Contraceptive side effects were most prevalent in the first 4 weeks following

enrollment, with a mean prevalence of 29% (95%CI 26-33%) compared to 18% (95%CI 16-21%) at weeks 21-24 (Figure 4.2, Table 4.2). Side effects for more specific types were higher at 0-4 weeks than at 21-24 weeks, with decreases in prevalence of sexual side effects from 18% (95%CI 15-20%) to 10% (95%CI 8-13%) and of cramping or abdominal/back pain from 15% (95%CI 13-18%) to 8% (95%CI 6-10%). Heavier/prolonged and irregular bleeding patterns were each reported by 10% (95%CI 8-12%) of participants in the first 4 weeks of follow-up, with only 5% (95%CI 4-7%) and 6% [95%CI 4-7%] reporting these bleeding problems, respectively, by 21-24 weeks. Significant linear declines in side effects overall, and for all specific side effect categories, were detected with the exception of lack of expected bleeding. Population-level temporal decreases in prevalence of side effects were found in subgroup analyses of women who switched methods or continued a method used in month prior to enrollment, but not among women who initiated contraception at enrollment (Table S4.5, Figure S4.2).

Correlates of side effects

History of contraceptive side effects and fear of side effects were significantly associated with reported experiences of any side effects (Table 4.3). Women with a history of side effects were 73% more likely to experience any side effects or method problems (95%CI 1.37-2.18) compared to prior contraceptive users who did not report ever having side effects. Similarly, women who reported having fears or concerns about side effects were 36% more likely to report any side effects or method problems (95% CI 1.12-1.65) than women who did not express fears or concerns. This association persisted after adjusting for history of side effects (aPR 1.34 [95%CI 1.09-1.65; p=0.006]).

In sensitivity analyses stratified by FP user type, history of contraceptive side effects was significantly associated with any side effects only among “continuers” (aPR 2.03; p<0.001) (Table S4.6). Fear of side effects was associated with a higher prevalence of side effects among initiators

and switchers (aPR 1.58; p=0.004) and continuers (aPR=1.25; p=0.070), although neither association was statistically significant after Benjamini-Hochberg adjustment. Results were robust to inclusion of dummy variables for weeks since enrollment and use of a Poisson rather than log-binomial distribution (Tables S4.7-S4.8).

Correlates of specific side effects were similar to those of any side effects; history of contraceptive side effects was significantly associated with all specific side effects, with effect sizes ranging from 1.8- to 2.3-fold (Figure 4.3). Fear of side effects was associated with specific side effects with adjusted prevalence ratios ranging from 1.32 to 1.49, although these associations were not statistically significant after adjustment for multiple comparisons. As for any side effects, we did not detect a relationship between sociodemographic characteristics or reproductive history and experience of specific side effects (Table S4.9).

We did, however, detect several differences in correlates for specific side effects. Women who reported a desire to have children in the future but who were unsure of when they would like to become pregnant were less likely to report any side effects (aPR 0.54 [95%CI 0.38-0.77]) or cramping or abdominal/back pain (aPR 0.49 [95%CI 0.30-0.79]), compared to women who did not want to have any children in the future but who were otherwise similar with respect to age, marital status, number of living children, and postpartum status. We did not find evidence of associations between fertility intentions and any other specific side effects.

We did not detect a relationship between measured aspects of perceived quality of care and prevalence of bleeding-related side effects during follow-up. However, women who reported a higher quality of FP care had a lower prevalence of non-bleeding related side effects. Women who reported receiving the “right amount of time” with the FP provider had a lower prevalence of cramping or abdominal/back pain (aPR 0.61 [95%CI 0.46-0.81]), sexual side effects (aPR 0.58

[95%CI 0.44-0.76]), and weight changes (aPR 0.66 [95%CI 0.60-0.88]) (Figure 4), relative to women who did not. Strongly agreeing that all needs were met during the FP visit was associated with a 32% (aPR 0.68 [95%CI 0.53-0.88]) lower prevalence of cramping or abdominal/back pain, while being “very satisfied” overall with care received was associated with a 30% (aPR 0.70 [95%CI 0.55-0.89]) and 32% (aPR 0.68 [95%CI 0.52-0.88]) lower prevalence of sexual side effects and weight changes, respectively. While we did not detect associations between quality and satisfaction indicators and prevalence of any side effects, we found that spending the “right amount of time” with a provider was associated with a lower prevalence of any side effects among method “continuers” at enrollment (aPR 0.70; p=0.003).

Discussion

Contraceptive side effects were common in a cohort of Kenyan women using modern, reversible forms of contraception. Weekly prevalence of side effects was highest in the first month of follow-up, with nearly one-third of participants reporting side effects weekly in this period followed by declines in all side effects except lack of expected bleeding by 24 weeks. However, absolute decreases in the prevalence of side effects were small, with nearly 20% of women reporting side effects in the final month of follow-up. This suggests that the burden of contraceptive side effects – as perceived and reported by women using contraception – may be higher than acknowledged in standard contraceptive counseling messaging (112).

Our findings also describe the relative burden of specific side effects. Contraceptive-induced disruptions to menstrual bleeding patterns have received the most attention from both a clinical and research perspective (26). This is in part due to mixed evidence linking hormonal methods to “non-specific” (non-bleeding-related) side effects (41), as well as a lack of research focused on specific categories of side effects such as those related to sexual function and pleasure (63, 89, 116). In our study, we found that non-bleeding-related side effects were the most prevalent of

specific side effects measured, with nearly one in five participants reporting sexual side effects and 15% reporting cramping, abdominal pain, or backaches in the first month of follow up, compared to <10% for each of the bleeding-related side effects. Qualitative research suggests that the relationships between contraception and sexual pleasure are complex and multidimensional, and that contraception may influence sexual pleasure in both positive and negative ways (89, 109). Future research is needed to elucidate women's experiences of non-bleeding-related side effects in LMICs, including effects on couple dynamics and partner support for contraception.

Prior experience with contraceptive side effects was associated with subsequent side effects in our study after adjustment for method type, age, and marital and postpartum status, with increased risks ranging from 72% for any side effects or method problems to 2.3-fold for irregular bleeding. This finding is consistent with several proposed mechanisms. Several studies demonstrate possible biologic factors that may increase women's susceptibility to contraceptive side effects (42, 113). Prior experience of side effects may also affect the salience or perceived severity of future side effects. For example, women who have previously experienced mild side effects could be less likely to note similar symptoms if they arise; conversely, women who have experienced severe side effects in the past may be highly sensitized to any sign of similar symptoms in the future. Other women may perceive past side effects – such as amenorrhea – as tolerable or even beneficial (26), leading to continued method use and probable future side effects. Regardless, a simple screening question about history of side effects could be useful for providers to target counseling based on women's past experiences and any remaining concerns about side effects.

Concerns or fears about side effects were common in our study population, expressed by nearly 30% of participants. Reported fear of or concerns about side effects at study enrollment was

significantly associated with a higher prevalence of reporting any side effects over follow-up; this association persisted after adjustment for history of side effects, suggesting that fear of side effects is not (solely) driven by prior adverse experiences. Conversely, we found that women who perceived care as high quality were less likely to report non-bleeding-related side effects, although we found no association with changes in bleeding patterns. Our findings align with prior studies that find that high-quality anticipatory side effects counseling may improve women's experiences with the selected method (96, 101, 117-120). Anticipatory counseling may act on experience of side effects through a number of possible pathways, including supporting selection of a method that better aligns with women's side effects preferences (117). In addition, improved knowledge of the method's mechanism of action and documented side effects could reduce attribution of non-specific symptoms to the contraceptive method, which may explain the presence of associations with non-specific, but not bleeding-related, side effects (118).

We also found significant differences in risk of side effects by fertility intentions, with higher prevalence of side effects among women who expressed a desire for future children but who were uncertain about their preferred pregnancy timing, relative to women who reported wanting no more children. These findings suggest that women's reproductive goals and intentions may affect aspects of contraceptive experiences, with uncertain intentions possibly influencing recognition and salience of side effects, as well as the extent to which they are viewed as bothersome.

Our study has several strengths. We measured contraceptive side effects in real-time among women using a range of contraceptive methods. Use of SMS for remote capture of side effects over time provides unique insights into diverse side effect experiences. The weekly surveying schedule allowed for prospective collection of side effects data with high-frequency, minimizing misclassification of temporal patterns in side effects as well as risk of recall bias by subsequent side effects or contraceptive use outcomes. Notably, recall bias could be present even in studies

that use prospective designs but that employ less frequent surveying, for example if women are more likely to remember side effects considered to be severe or adverse.

There are also a number of limitations. The brevity required for SMS-based data collection precluded capturing information on the extent to which women perceived side effects to be severe or bothersome. Women may be more likely report side effects perceived to be severe or adverse, which may have limited our ability to capture mild side effects. Additionally, since participants were asked about their experiences of multiple different symptoms after indicating they had a side effect or problem with their method, we may have captured data on physiologic effects of contraceptive methods that were experienced but considered non-bothersome. Remote SMS surveys are also susceptible to entry errors (121), as participants were not able to modify incorrect entries after they were sent. However, we expect that any misclassification in side effects would be non-differential with respect to the correlates of interest, which would be expected to bias results towards the null. Given the observational design, our results are also subject to unmeasured and residual confounding.

Conclusion

History of and concerns about contraceptive side effects, as well as less than full satisfaction with care received, were associated with future risk of side effects over a 24-week period. Our findings suggest that interventions that fully address women's questions and concerns about side effects, that are tailored to women's individual side effects history, and that increase women's satisfaction with FP care may improve women's contraceptive experiences.

Tables and Figures

Table 4.1 Participant characteristics at study enrollment (N=731)

	n	N (%) or median (IQR)
Sociodemographic and health characteristics		
Age (median [IQR])	719	26 (23, 30)
<i>Age category</i>		
<25		273 (38)
25-34	719	357 (50)
>34		89 (12)
Married (legal or presumed)	728	597 (82)
Household income (Kenyan Shillings/month)	731	1500 (500, 5000)
No living children	716	59 (8)
<6 months since most recent pregnancy	722	215 (30)
Currently breastfeeding	714	341 (48)
Contraceptive characteristics and fertility intentions		
<i>Contraceptive method*</i>		
Implant		322 (44)
Cu-IUD	731	57 (8)
Injectable		317 (43)
OCP		35 (5)
<i>FP user type</i>		
Initiating		180 (25)
Switching	725	92 (13)
Continuing		453 (62)
Using a second method of contraception	722	52 (7)
<i>History of contraceptive side effects</i>		
No		207 (31)
Yes	670	354 (53)
FP naïve		109 (16)
Fear of contraceptive side effects	700	200 (29)
<i>Fertility intentions</i>		
Wants no future children		148 (21)
Not sure if wants future children		61 (8)
Desires pregnancy, unsure when	721	85 (12)
Desires pregnancy in <1 year		32 (4)
Desires pregnancy in 1-2 years		60 (8)
Desires pregnancy in >2 years		335 (46)
<i>Becoming pregnant in the near future would be a:</i>		
Big problem	721	399 (55)
Small problem		62 (9)

No problem		168 (23)
Not sure		92 (13)
Spousal support for contraceptive use [†]	597	550 (92)

Quality and satisfaction with most recent facility-based FP services

"Strongly agree" that all FP needs were met	713	353 (50)
"Right amount of time" spent with provider	715	546 (76)
Privacy protected	716	667 (93)
Very satisfied	717	332 (46)
Treated "very respectfully" by provider	716	625 (87)
Received all components of Method Information Index [‡]	706	400 (57)

Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

* For the 50/731 (7%) of participants who reported using a second method of family planning, their primary method was used to define method switch in this analysis.

† Among married (legal or presumed) women only

‡ We used a modified version Method Information Index (MII), a binary indicator that the participant reported receiving the following 3 health information topics at her most recent FP visit (not necessarily the visit in which she first obtained her current method): 1) information on other method types, 2) information on side effects of the selected method, and 3) information on what to do if side effects occur.

Table 4.2 Prevalence of side effects, by contraceptive method type

	Mean Prevalence (95% CI)		Linear time trend	
	Weeks 1-4 of follow-up	Weeks 21-24 of follow-up	PR (95% CI)	p-value
Any side effects or method problems	0.29 (0.26-0.33)	0.18 (0.16-0.21)	0.98	<0.001
Heavy/prolonged bleeding	0.10 (0.08-0.12)	0.05 (0.04-0.07)	0.97	<0.001
Irregular bleeding	0.10 (0.08-0.12)	0.06 (0.04-0.07)	0.97	<0.001
Lack of expected bleeding	0.07 (0.06-0.09)	0.06 (0.05-0.08)	0.99	0.168
Cramping, abdominal/back pain	0.15 (0.13-0.18)	0.08 (0.06-0.10)	0.97	<0.001
Sexual side effects	0.18 (0.15-0.20)	0.10 (0.08-0.13)	0.97	<0.001
Weight changes*	0.14 (0.12-0.17)	0.10 (0.08-0.12)	0.98	0.002

PR = prevalence ratio

* Reported occurrence in the past month, rather than the past week (as for all other side effects)

Notes: Weekly prevalences and 95% confidence intervals calculated using log-binomial GEE models adjusted for month of follow-up with an independent working correlation structure and robust standard errors. Linear time trends were assessed using analogous models but with time modeled as a linear term equal to the number of weeks since study enrollment (1-24).

Table 4.3 Correlates of contraceptive side effects or method-related problems

		Any Side Effects or Problems with Contraceptive Method	
	N§	aRR (95% CI)	p-value
<i>Sociodemographic and health characteristics</i>			
<i>Age</i>			
<25		<i>Ref.</i>	
25-34	713	1.10 (0.91, 1.32)	0.320
>34		0.74 (0.54, 1.02)	0.065
Married (legal or presumed)	710	1.17 (0.92, 1.48)	0.196
<i>Household income quartile</i>			
Fourth		<i>Ref.</i>	
Third	710	1.06 (0.83, 1.36)	0.633
Second		1.10 (0.88, 1.37)	0.411
First		1.03 (0.80, 1.33)	0.821
No living children	695	1.38 (1.02, 1.87)	0.039
<6 months since most recent pregnancy	701	0.98 (0.80, 1.19)	0.837
Currently breastfeeding	693	0.97 (0.80, 1.17)	0.729
<i>Contraceptive characteristics and fertility intentions</i>			
<i>Method type†</i>			
Implant		<i>Ref.</i>	
Cu-IUD	696	1.05 (0.76, 1.45)	0.771
Injectable		1.09 (0.90, 1.32)	0.395
OCP		0.75 (0.46, 1.21)	0.236
<i>FP user type</i>			
Initiating		<i>Ref.</i>	
Switching	696	1.11 (0.82, 1.51)	0.502
Continuing		0.98 (0.78, 1.23)	0.845
<i>History of contraceptive side effects</i>			
No		<i>Ref.</i>	
Yes	644	1.72 (1.37, 2.18)	<0.001*
FP naïve		1.40 (1.02, 1.91)	0.038
Fear of contraceptive side effects	668	1.36 (1.12, 1.65)	0.002*
<i>Fertility intentions</i>			
Wants no children in future		<i>Ref.</i>	
Not sure if wants children in future		1.05 (0.72, 1.54)	0.794
Desires pregnancy, unsure when	687	0.54 (0.38, 0.77)	<0.001*
Desires pregnancy in <1 year		0.93 (0.61, 1.43)	0.750
Desires pregnancy in 1-2 years		1.02 (0.72, 1.44)	0.928
Desires pregnancy in >2 years		0.88 (0.68, 1.15)	0.323
<i>Becoming pregnant in the near future would be a:</i>			
Big problem	687	<i>Ref.</i>	

Small problem		1.04 (0.74, 1.47)	0.815
No problem		0.89 (0.71, 1.11)	0.300
Not sure		1.03 (0.78, 1.36)	0.822
Spousal support for contraceptive use‡	569	0.90 (0.65, 1.24)	0.532
Perceived quality of most recent FP care			
"Strongly agree" that all FP needs were met	680	0.87 (0.73, 1.05)	0.147
"Right amount of time" spent with provider	682	0.75 (0.61, 0.93)	0.007
Privacy protected	683	1.04 (0.74, 1.46)	0.836
Very satisfied	684	0.86 (0.72, 1.02)	0.091
Treated "very respectfully"	682	0.90 (0.68, 1.18)	0.434
Received all components of the Method Information Index	673	0.91 (0.75, 1.10)	0.307

Cu-IUD = intrauterine device; OCP = oral contraceptive pills

* indicates statistical significance based on threshold values using the Benjamini-Hochberg method and a false discovery rate of 0.05

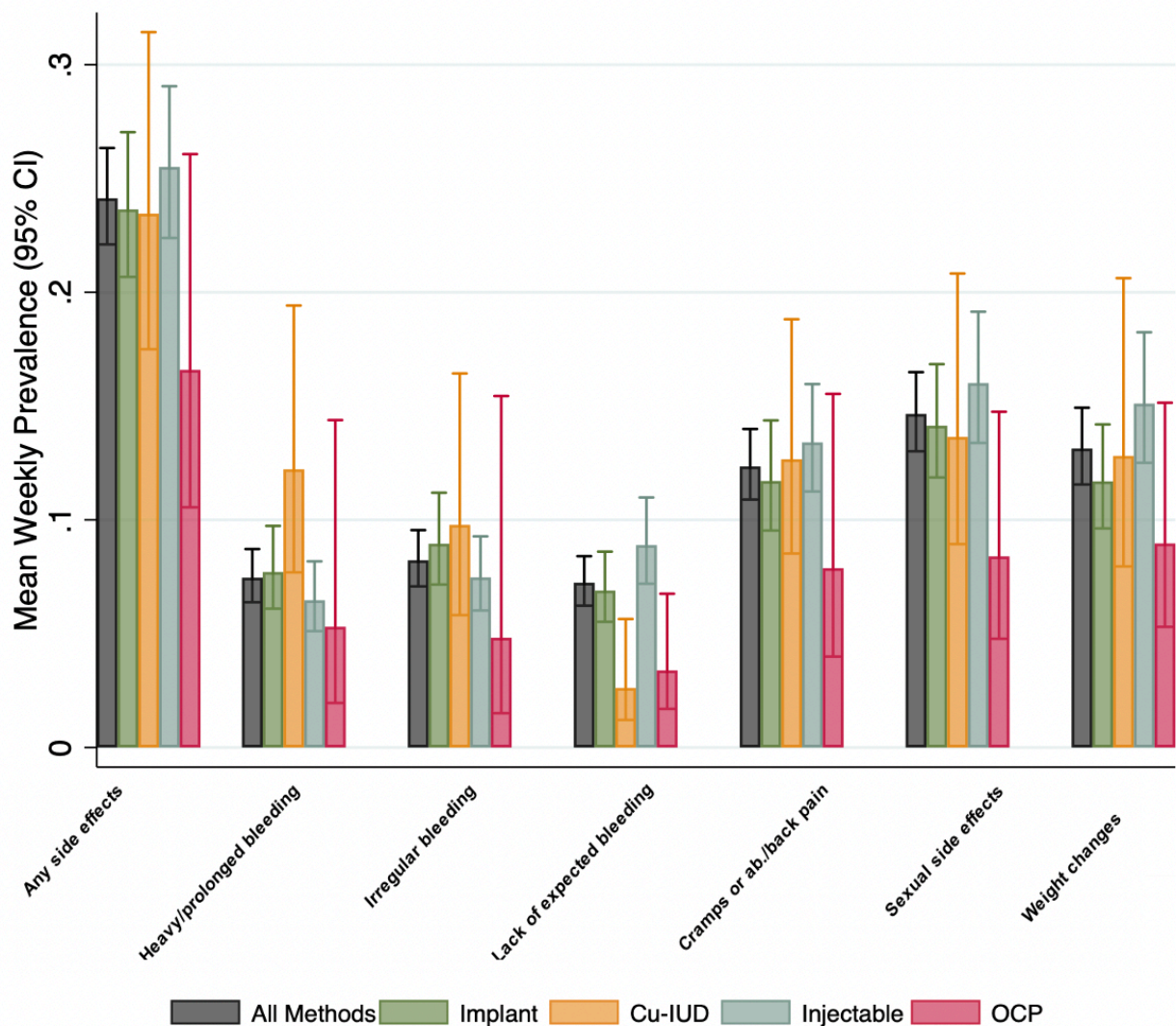
§ Sample size indicates number of distinct participants included in analysis, rather than number of weekly observations

† Method type indicates primary method used at study enrollment.

‡ Among married (legal or presumed) women only

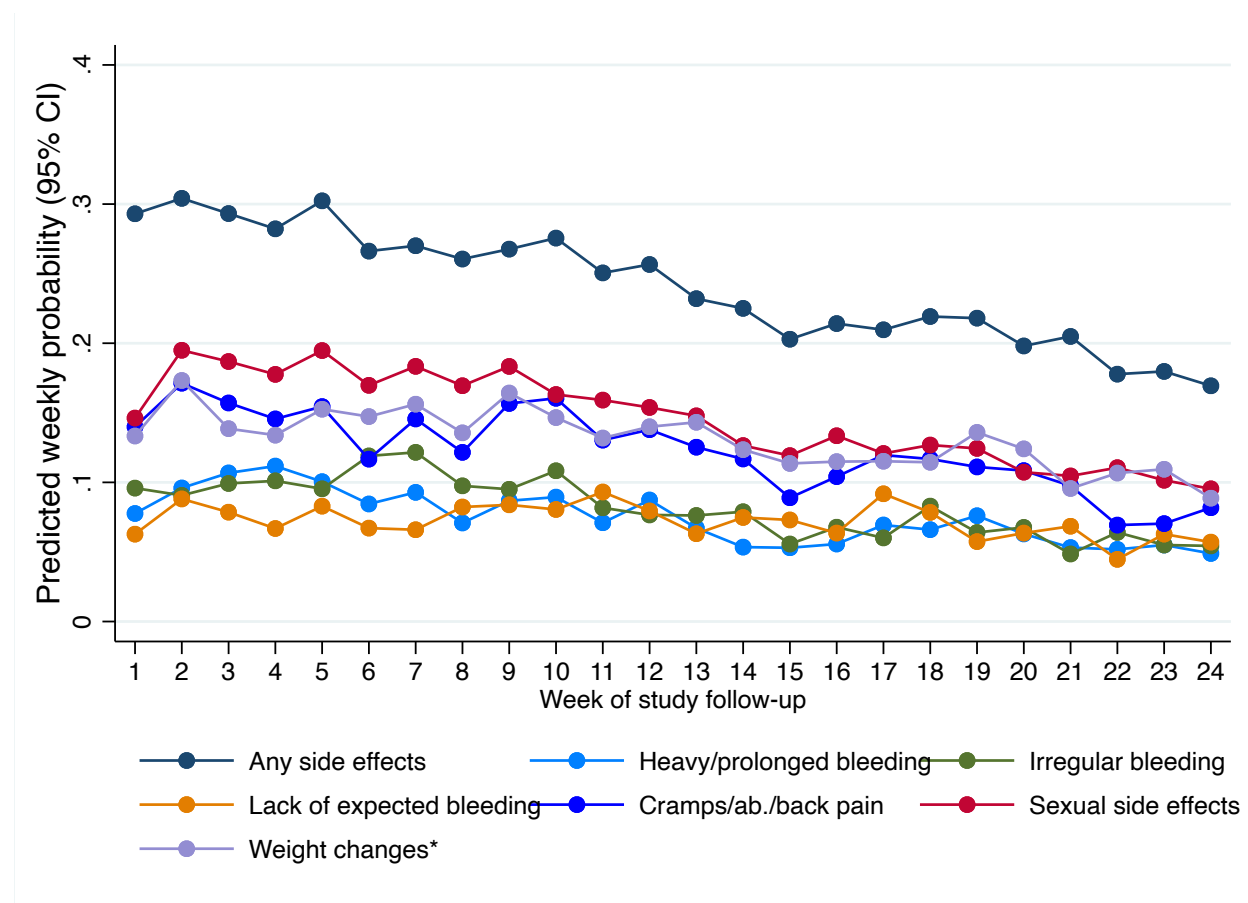
Notes: Adjusted prevalence ratios (aPr) and 95% confidence intervals estimated using separate log-binomial GEE models for each independent variable of interest. GEE models were fit with an independent working correlation structure that accounts for clustering at the individual-level and robust standard errors. All models are restricted to women using implants, injectables, IUD or OCP at baseline. We report conventional p-values, but asterisks indicate Benjamini-Hochberg adjusted p-values accounting for a false discovery rate of 0.05. Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status (with the exception of spousal support, which was estimated among married women only), age category, early postpartum status, and number of living children. The model for method type was adjusted by age category, marital status, and early postpartum status. Remaining models (of contraceptive history and quality and satisfaction indicators) were adjusted by age category, marital and postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type.

Figure 4.1 Mean prevalence of side effects, by contraceptive method type



Notes: Unadjusted weekly prevalences represent mean prevalence over the follow-up period. Estimated prevalences and 95% confidence intervals calculated within subgroups of users of each method type using log-binomial GEE models with an independent working correlation structure and robust standard errors.

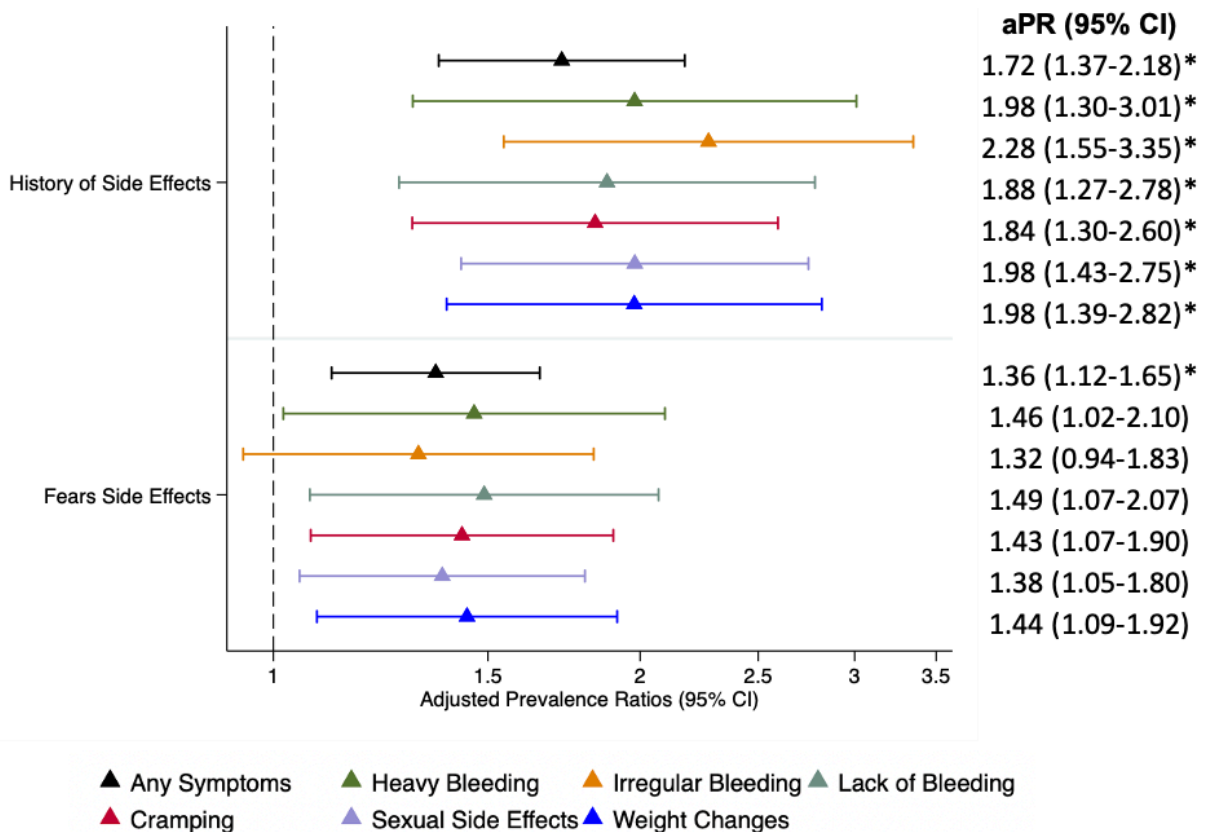
Figure 4.2 Probability of experiencing side effects by weeks since study enrollment



*Weight changes were reported as occurring in the past month; all other side effects were reported for the past week.

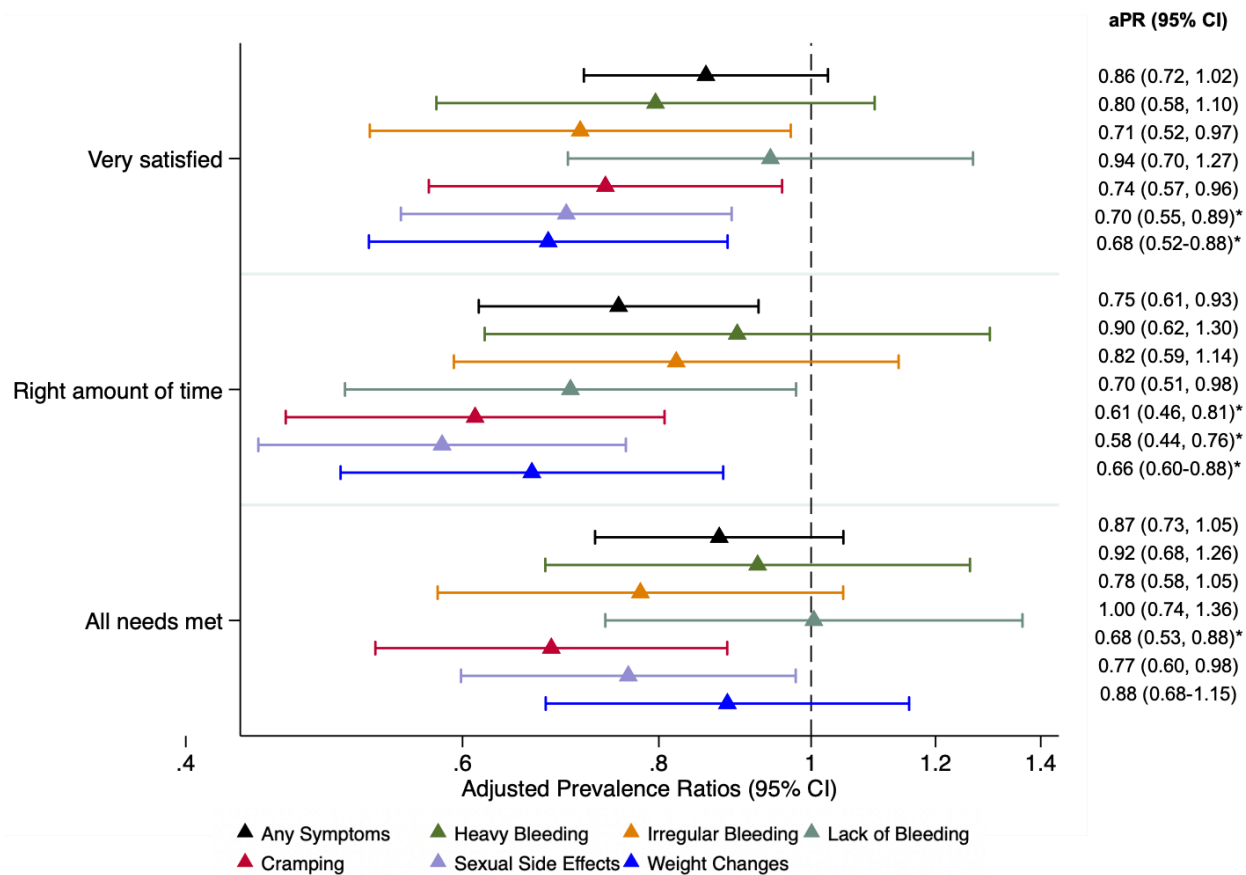
Notes: Mean weekly prevalence (or probability) of any side effects or method problems was estimated at time (in weeks) since study enrollment. Prevalence estimates were generated using separate log-binomial GEE models for each outcome of interest (any side effects/method problems, and specific side effects), with an independent correlation structure and robust standard error and dummy variables for week of study follow-up. The models were otherwise unadjusted.

Figure 4.3 Relative weekly prevalence of side effects, by history and fear of contraceptive side effects at study enrollment



* Statistically significant after Benjamini-Hochberg adjustment with a false discovery rate of 0.05
 Notes: Adjusted prevalence ratios (aPR) estimated using separate log-binomial GEE models with an independent working correlation structure and robust standard errors. Error bars indicate conventional 95% confidence intervals, while asterisks indicate statistical significance using the Benjamini-Hochberg method with a false discovery rate of 0.05. Estimated risk ratios for history of side effects compare risk of any side effects or method problems among participants who reported experiencing in their lifetime side effects or problems using at least one of the following methods: pills, injectables, implants, IUD, or condoms, relative to women who reported using family planning in their lifetime but no experience of side effects. (Estimates for women who were FP naive at study enrollment are omitted from this figure.) Adjustment variables were selected a priori. Models assessing fear of side effects (assessed once at study enrollment) the independent variable were adjusted by method type, early postpartum status, FP user type (initiating, switching, or continuing), marital status, and age category. Due to collinearity, we did not adjust the model for prior side effects by FP user type.

Figure 4.4 Relative weekly prevalence of side effects, by satisfaction with FP care received



* Statistically significant after Benjamini-Hochberg adjustment with a false discovery rate of 0.05
 Notes: Adjusted prevalence ratios (aPR) estimated using separate log-binomial GEE models with an independent working correlation structure and robust standard errors. Error bars indicate conventional 95% confidence intervals, while asterisks indicate statistical significance using the Benjamini-Hochberg method with a false discovery rate of 0.05. Models adjusted by method type, early postpartum status, FP user type (initiating, switching, or continuing), marital status, and age category. Due to collinearity, we did not adjust the model for prior side effects by FP user type. Adjustment variables were selected *a priori* based on causal diagrams.

CHAPTER FIVE – Conclusions

Supporting women to achieve their goals for spacing or limiting pregnancies is critical for advancing the health and wellbeing of women and their families globally (6, 13). The Sustainable Development Goals (SDG) aim to achieve universal coverage of voluntary sexual and reproductive health care, including FP, by 2030 (8). FP programs have been recognized as a lever to drive broader progress towards the SDGs due to their demonstrated impacts on women's empowerment and autonomy, educational and economic participation, and maternal and child health (8). Despite declining fertility rates in many regions of the world (122), contraceptive prevalence among women who wish to avoid pregnancy remains low in many LMICs. In Africa, nearly one in four women of reproductive age are estimated to have an unmet need for contraception (123) and 39% of all pregnancies are unintended (124).

FP initiatives and programs have largely focused on expanding access to FP services in order to reach women and girls who were previously excluded (20). While these efforts remain crucial, relatively few resources focus on supporting sustained contraceptive use among women who wish to use contraception but who face adverse experiences using contraception; as a result, contraceptive discontinuation among women who are not planning a pregnancy is common (22, 67, 68, 125-127). Women's personal experiences and concerns about contraceptive side effects or adverse health outcomes have emerged as a clear barrier to uptake and consistent use of contraception (22, 67, 68). Nevertheless, few studies have prospectively examined incidence of specific side effects or relationships between women's experiences of side effects and their decisions to switch methods or discontinue contraception altogether in LMICs. As a result, there is a lack of evidence-based strategies to support women who wish to continue using contraception but who face challenges in doing so (29).

This dissertation addressed this gap through the use of novel data captured through short message service (SMS) questionnaires sent directly to a cohort of women using modern, reversible contraception in Western Kenya. Women's contraceptive experiences – including self-report of specific contraceptive side effects, method switching, and contraceptive non-use – were captured weekly, allowing assessment of prevalence, temporal trends, and correlates in specific types of contraceptive side effects (**Chapter 4**) and associations of side effects and other contraceptive user characteristics with subsequent method switching and discontinuation (**Chapters 2 and 3**).

In **Chapter 2**, we estimated that both contraceptive method switch and discontinuation of all modern contraceptive methods were common over a 24-week follow-up period. Among women using implants, injectables, oral contraceptive pills (OCP), and intrauterine devices (IUD), one quarter switched from one modern method type to another and another 16% discontinued all modern methods over this period. These findings are in line with previous studies of contraceptive use dynamics in Kenya (84, 85), which have found high rates of discontinuation among modern, reversible method users.

We also found a high prevalence of contraceptive side effects experienced prior to method switch or discontinuation, with an average of 24% (95% CI 22-26%) of women reporting side effects or method problems weekly and 71% reporting side effects at least once over the follow-up period. Of several specific bleeding- and non-bleeding-related side effects measured, sexual side effects, weight changes, and cramping or abdominal/back pain were the most commonly reported, affecting 12-15% of women weekly on average. Analysis of temporal trends in side effects experienced prior to method switch or discontinuation (**Chapter 4**) suggests that side effects remain common at the population-level over the nearly 6-month follow-up period, with a mean

prevalence of 18% (95% CI 16-21%) among women who continued method use at 21-24 weeks after enrollment.

While we did find evidence of population-level waning in side effects, which is consistent with standard contraceptive counseling messages given by FP providers (112, 128), decreases in side effect prevalence were small in absolute terms. The high burden of side effects experienced by women who were continuing to use their original method at enrollment at the end of study follow-up is at odds with standard contraceptive counseling practice, in which women are reassured that most side effects should resolve over a 3-5 month period (112). Counseling messages are based largely on evidence generated from clinical trials conducted in high-income settings, which may fail to capture mild symptoms (43) or variability in side effects incidence or manifestations of specific symptoms across populations (42). Discrepancies between the information that women receive during counseling and their own experiences may lead to increased health concerns and dissatisfaction, which in turn may increase method-related discontinuation. As a result, context-specific counseling that reflects experiences and preferences of local populations is essential for providing person-centered and culturally-relevant contraceptive counseling (129).

In the primary analyses (**Chapter 2**), we found that side effects were the most common reason given for method switch (61%, 47/77) among women who provided a reason for switch. However, reason for switching may be biased by the high level of missingness (as reason was available for only 51% [n=77/156] of switching events). Of the specific side effects measured, only lack of expected bleeding was associated with method switch (aHR 2.07, 95%CI 1.00-4.28). Experience of several specific side effects increased risk of discontinuation of all modern contraceptive methods (aHR 2.62, 95%CI 1.35-5.07 for irregular bleeding; aHR 1.99, 95%CI 1.08-3.64 for weight changes; and aHR 1.83, 95%CI 1.00-3.35 for sexual side effects).

These primary analyses may obscure important differences in the relationships between side effects, switch, and discontinuation within subgroups. In exploratory analyses, we found that sexual side effects increased risk of method switching among older women (age ≥ 25), but not among young women and adolescent girls. With regards to discontinuation, women who expressed a strong desire to avoid pregnancy had no increased risk of discontinuation if they experienced side effects relative to those who did not. However, among women who were not actively planning a pregnancy but who expressed a weak desire to avoid pregnancy, side effects increased risk of discontinuation by 3- to 6-fold. Pregnancy ambivalence and positive “affective attitudes” towards pregnancy have been found to be associated with discontinuation, holding stated fertility intentions constant (130, 131). These findings shed light on the role of contraceptive side effects as a mediator of the relationship between attitudes toward pregnancy and contraceptive continuation.

Taken together, these exploratory analyses support existing evidence that women’s experience of, and responses to, contraceptive side effects are both complex and heterogeneous (26, 47, 89). They also point to the complicated tradeoffs that women may face between need for effective pregnancy prevention and the potential physical, interpersonal, and economic costs of experiencing adverse side effects. Such tradeoffs result in method continuation among a group of women who are nevertheless dissatisfied with their current contraceptive method. In **Chapter 2**, for example, we find differences in risk of discontinuation only when comparing women who were “very dissatisfied” versus “very satisfied” with their current contraceptive method (aHR 6.85, 95% CI 1.84, 25.48). Interestingly, there was no evidence of increased risk of discontinuation comparing women who were only “dissatisfied”, relative to “very satisfied”. In future planned analyses, we intend to examine trajectories and correlates of method dissatisfaction in order to identify factors that influence continuation, switch, and discontinuation among dissatisfied users.

Recognizing substantial heterogeneity in women's responses to contraceptive side effects, the results from this dissertation suggest that early identification of women who are at risk of experiencing side effects (**Chapter 4**) and method-related discontinuation (**Chapter 3**) is possible. In **Chapter 3**, we aimed to develop and validate a pragmatic screening tool that could be used by FP providers in low-resource settings to identify women at highest risk of contraceptive discontinuation. We found that a simplified risk score comprised of information routinely captured within FP clinics in Kenya's public sector had moderate predictive performance in our validation cohort (AUC-ROC at 24 weeks: 0.73, 95% CI 0.51-0.94), with a sensitivity of 75% and a specificity of 67%. The score is based on only four pieces of information, making it relatively simple to implement within public health clinics with sparse resources for routine data collection. Feasibility of the simplified score is limited however by the high proportion (61%) of women identified as high-risk for discontinuation in the derivation cohort, which results in a low positive predictive value (28%). This limits utility for routine in-person implementation, particularly if screening a high proportion of women as high-risk results in overwhelming demands to resource-constrained health systems.

We also identify several individual-level characteristics that are associated with future risk of experiencing side effects (**Chapter 4**). Namely, prior experience of contraceptive side effects (adjusted prevalence ratio [aPR] 1.72, 95% CI 1.37, 2.18) and expressing fears or concerns about side effects at the time of study enrollment (aPR 1.36, 95% CI 1.12, 1.65) were associated with increased weekly prevalence of side effects over study follow-up. Conversely, women who were fully satisfied with the FP care they received at their most recent FP visit across several dimensions (perceptions of time spent with provider, needs being met by care received, and overall satisfaction) were less likely to report non-bleeding side effects (cramping or abdominal/back pain, sexual side effects, and weight changes) over follow-up.

Findings from **Chapters 3 and 4** could be useful for informing development of new strategies to support women who experience method-related challenges. To date, little evidence exists on predictors or correlates of contraceptive side effects (113). Similarly, most evidence on method-related discontinuation focuses on differences in risk by method type, with less focus on other individual-level predictors (22). Our findings suggest that it may be possible to identify specific groups of women who are at highest risk of experiencing method-related challenges and discontinuation. New strategies to support these women could act through two main mechanisms: first, screening tools (such as that developed in **Chapter 3**) could be used to target high-risk women to receive specialized care or follow-up support. By focusing on a high-risk subset of all contraceptive users, such targeting strategies may be highly feasible in resource-constrained settings. Second, deeper understanding of individual-level characteristics that are associated with risk of method-related challenges could improve tailored contraceptive counseling that better addresses women's prior contraceptive experience, preferences and needs. Our findings in **Chapter 4** suggest that a high proportion of women have persistent concerns or fears about side effects even after receiving FP counseling. Interventions specifically designed to identify women's specific concerns about side effects and provide tailored counseling to fully address these worries may be warranted.

Anticipatory counseling on contraceptive side effects, as well as information on strategies to deal with side effects should they arise, has been found to promote contraceptive continuation in some settings (132), but not others (98). Prior evidence points to the importance of interpersonal aspects of care, such as rapport and established trust between a woman and the FP provider (96, 117, 118); these "non-technical" aspects of quality care may be as (if not more) important than so-called "task-oriented" aspects of care, such as provision of specific counseling messages. Digital interventions may be a feasible mode for providing person-centered that is both "targeted" and "tailored" (133-138), particularly in low-resource settings. The flexibility of digital platforms to

provide both automated as well as customizable content allows for delivery of high-quality counseling while maintaining low costs (135). Digital interventions may be an effective means of strengthening continuity of care, an aspect of quality care that has long been recognized as fundamental (139-141) but that has received relatively little attention in FP programs. Task-shifting of contraceptive counseling and care from routine, in-person care to remote delivery using digital platforms may lower burden on health care systems and has the potential of improving client experiences. For these reasons, digital and other “self-care” interventions have been lauded by the World Health Organization as a strategy for achieving universal coverage of sexual and reproductive health care (142). Future research should assess the feasibility and efficacy of digital interventions for providing counseling that is not only accurate and relevant, but that also delivers high interpersonal quality of care, facilitates ongoing support and dialogue with users, and strengthens linkages between the community and the health system.

A key component of future formative research should also be examination of method-specific interactions between potential explanatory factors (e.g. side effects experience, counseling interventions) and subsequent switch and method-related discontinuation. Analyses presented in this dissertation were limited by the predominance of injectable and implant users and the modest sample size, which did not allow for assessment of effect modification by method type. Future work to develop a pragmatic screening tool for method-related discontinuation may benefit from considering such interactions, with the aim of developing method-specific interventions for “targeting” and “tailoring” FP care.

The analyses presented in this dissertation emphasize the complex and dynamic nature of women’s contraceptive experiences. The SMS-based surveying platform used to collect the data used in these analyses has a number of unique advantages relative to traditional forms of data collection (121). Notably, it enabled nearly “real-time” capture of experiences of side effects and

contraceptive use, allowing us to identify detailed trajectories of contraceptive use experiences that are not captured through standard surveying formats such as the widely-used month-based contraceptive calendar (143). Examples of this include our ability to capture information on specific types of side effects and to detect short-term interruptions in contraceptive use. However, the SMS-based data collection mode has several limitations. Misclassification due to entry errors may be higher than in traditional surveying formats, due to the absence of a trained enumerator and the inability to correct SMS responses once sent. Future studies using SMS as a primary or supplemental source of participant-generated data would benefit from including additional validation measures for key outcomes, such as asking participants to confirm their responses to specific questions. In addition, formative and interventional research is needed to codify best practices in participant-generated data – including question and response formats, validation, length, frequency, and reimbursement – that maximize validity and response.

The SMS data collection mode required brevity: in order to maximize response, we designed follow-up surveys to take approximately 5 minutes to complete. The use of brief questionnaires may present a more person-centered approach to research by minimizing opportunity costs of research participation and reducing survey fatigue. However, it also presents challenges from a measurement perspective: for example, we were unable to capture important aspects of women's experiences that may further elucidate relationships between side effects, method switch, and discontinuation. These include perceived tolerability and severity of side effects, as well as the extent to which side effects negatively impacted aspects of women's life. Measurement of these aspects of side effects may improve the sensitivity of future studies to detect relationships between specific adverse side effects and subsequent switch and discontinuation.

We also did not capture information on changes in women's fertility intentions during follow-up, which may have reduced our ability to distinguish between method-related discontinuation and

planned discontinuation among women not actively planning pregnancy at study enrollment. Our findings emphasize the dynamic nature of fertility intentions over relatively short periods of time (144-146): while we excluded women who were actively planning pregnancies at enrollment from our primary analysis of the association between side effects and discontinuation (Chapter 2), we nevertheless found that desire for pregnancy was the most common reason provided by women who discontinued over the study period. Measurement of method-related discontinuation would benefit from frequent data capture on fertility intentions to measure changes in women's goals over time.

Finally, prior research on quality of FP care has shown that contextual characteristics of the health system and community may be important explanatory factors in women's responses to experience of contraceptive side effects or method-related challenges. Women's ability to promptly switch from one modern method to another, for example, is predicated on their knowledge of a range of method types, as well as their ability to access these methods. Ultimately, women's contraceptive decision-making is modified by their environment, including community and social norms, couple and peer dynamics, and attitudes towards contraceptive use and readiness of the health system to provide quality FP services. To date, the majority of evaluations of FP interventions measure program impacts at the individual level, which obscures complex multilevel relationships between individuals and their environments (147).

In summary, deeper understanding of women's perceptions and responses to contraceptive method-related challenges is critical for designing effective interventions to support women who wish to use contraception. Evidence from this dissertation suggests that women's responses to specific side effects vary. Among women using modern, reversible contraception, menstrual disruptions resulting in unpredictable or irregular bleeding patterns, weight changes, and sexual side effects were the least well tolerated side effects in terms of contraceptive continuation.

Conversely, we found little evidence of elevated risk of discontinuation among women experiencing amenorrhea or a lack of expected bleeding, although these were associated with increased risk of method switching. These findings provide insight into the relative tolerability of specific side effect profiles among Kenyan women, evidence which is important for the design and delivery of an expanded range of contraceptive technologies in specific geographies.

Our findings also point towards differential responses to side effects by individual-level factors such as age and strength of desire to avoid pregnancy, suggesting specific barriers to contraceptive satisfaction in these groups that could be addressed through targeted and tailored programs. Overall, the high burden of side effects in this population, coupled with the high prevalence of stated fears and concerns about side effects, indicate that novel interventions are needed to support women to improve their contraceptive experiences and satisfaction. In particular, interventions designed to reach women during their contraceptive use journeys – and not just at the point of method initiation – could address a major gap in current FP programming. Above all, it is critical that such interventions provide counseling and care that respects women's autonomous contraceptive decision-making as a positive outcome (19), regardless of women's fertility intentions and including decisions to discontinue contraception. Centering women's voices and respecting women's contraceptive choices is a key step towards decolonizing global reproductive health programs and research and designing improved strategies to deliver person-centered care.

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APPENDIX

CHAPTER TWO - Contributions of side effects to contraceptive discontinuation and method switch among Kenyan women: a prospective cohort study

S2 Supplementary Material

Study enrollment

After screening for eligibility, eligible participants completed a written informed consent. Women who completed informed consent were defined as enrolled in the study based on successful completion of two SMS-based survey items on their own mobile phones: 1) an opt-in screening question, which asked the participant to select 1 to continue with the survey, and 2) by selecting her preferred language (English, Swahili, Luo, or Kisii). Completion of these two questions was required to trigger the automated weekly SMS follow-up surveying. As a result, participants who failed to complete these questions on their own mobile phone (either intentionally or due to survey timeout, which was noted by study staff in instances of mobile network issues) did not receive follow-up messaging and so were not considered enrolled in the study despite having completed informed consent.

Definition of method switch and discontinuation

To reduce measurement error in ascertainment of method switching, method switch was defined based on the following requirements: 1) apparent switches (weeks in which a method type that differed from that used at enrollment was reported) were recoded as “0” (non-switches) if the participant reported that she did not switch methods in the past week and did not report switching methods at any time in the following 4 weeks; and 2) the participant was required to report use of the new method type for at least four consecutive weeks. In addition, apparent switches were recoded as “0” (non-switch) if the participant reported using a method other than the enrollment method that was previously determined to be a “non-switch.” The purpose of these requirements

was to limit misclassification due to participant entry error, which is possible given the remote, self-questionnaire mode of data collection.

Contraceptive discontinuation is defined as a period of 2 or more consecutive weeks in which the participant reports use of either no contraceptive method or a traditional contraceptive method. It is therefore a measure of discontinuation of all modern methods of contraception. To operationalize this definition, we made several assumptions about method use reported over weekly surveys: 1) weekly surveys in which the participant reported using contraceptive but for which the method type is missing or refused (comprising 0.20% [27/13,229] weekly observations using the LOCF/NOCB singly imputed dataset) were considered to represent continued use of the initial method; such instances were not considered method switches or discontinuation if occurring in consecutive weeks; 2) fertility-awareness based (FAB) methods (included lactational amenorrhea) were reporting using the common terms “counting days” or “breastfeeding method (before return of menses after childbirth)”; since use of a modern method was required for study enrollment, we assume that women reporting “counting days” as their contraceptive method during follow-up (n=20/13,229, 0.15%) were using a modern FAB method.

Ascertainment of contraceptive side effects

Each week, study participants who reported current method use or discontinuation in the past 7 days were asked if they had experienced any side effects or problems using that method in the past week using the question text, “In the past week, have you had any side effects or problems using [method type]?” We defined overall experience of any side effects or method problems in the past week and month as a binary variable equal to 1 if the participant reported “yes,” 0 if the participant reported “no”, and missing in the case of “not sure,” declined, or incomplete responses.

We ascertained experience of specific side effects using a series of follow-up questions tailored to contraceptive method type. Relevant questions used to ascertain specific side effects are provided in S1 Table, and were asked only of women reporting “yes” or “not sure” to the question about experiencing any side effects or problems with their method in the past week. These women were also asked a final question about other symptoms experienced (“Have you had any other side effects or problems using family planning in the past week?”), which allowed women to write in symptoms in a free text response. These responses were then translated as needed and categorized within the symptom categories where relevant by the U.S.- and Kenya-based study coordinators. In some cases, frequent free text responses were incorporated into a larger category: for example, while there was no specific question for abdominal or back pain, free-text responses about these symptoms were grouped into the “cramping” symptom category.

Specific side effects were each coded as a binary variable equal to 1 if the woman reported experiencing the symptom, or 0 if either 1) the woman reported no experiencing any side effects or method problems in the past week, or 2) she reported experiencing side effects but not that specific symptoms. Women were coded as missing in the case of “not sure”, missing, or declined responses to the specific symptom, or if her response to the overall question about any side effects was missing or refused.

Ascertainment of sociodemographics and reproductive health characteristics

Sociodemographic characteristics and reproductive and contraceptive history were assessed at the time of study enrollment. Baseline fertility intentions were defined categorically as desiring no future children, unsure about future children, desiring future children but unsure of preferred timing, or desiring a pregnancy in 1-2 years or in >2 years. Women stating a desired pregnancy within 1 year were excluded from analyses, in order to focus on method-related rather than planned discontinuation.

Sensitivity analyses

Treatment of competing risks

We assessed the robustness of our primary cause-specific model to treatment of competing risks by estimated adjusted subdistribution hazards ratios using the Fine-Grey technique (S1 Fig).(79) Estimates generated from Fine-Grey models were qualitatively similar to those of the primary cause-specific models. For method switch, we estimated increased but not statistically significant risks of method switch associated with any side effects as well as with each specific side effect. For discontinuation, we estimate increased risk of discontinuation associated with all but lack of expected bleeding. In these models, only irregular bleeding was associated with a significantly increased risk of discontinuation.

Sensitivity analysis of imputation method

We also assessed robustness of our primary models to choice of imputation method, with estimated associations using multiple imputation with chained equations (MICE) to address missingness in side effects presented in S2 Fig. Our results appear to be relatively robust to choice of imputation method, with imputed models showing similar but less precise point estimates for specific side effects.

Exclusion of participants not initiating a new method type at study enrollment

Participants were recruited and enrolled into the study during attendance at a public FP or MCH clinic, and were eligible if they were currently using a modern, reversible contraceptive method. As a result, study enrollment does not represent the point of method initiative. Women who reported continuing a method used in the past month were enrolled mid-way through a contraceptive use episode. As a result, there is some concern of selection effects, in which the enrollment method may be less likely to capture women who initiated contraception and

immediately switched or discontinued methods. We conduct a sensitivity analysis in which we re-estimate the primary models in a sample that includes only women initiating a new contraceptive method at enrollment (which includes those newly initiating contraception as well as those switching from one method to another method) (S9 Table). Our results again appear relatively robust to this exclusion. While point estimates of risk of method switch associated with side effects are closer to the null value relative to primary models, they remain not statistically significant. For discontinuation, we estimate a significantly increased risk associated with irregular bleeding (aHR 4.36, $p=0.003$), with trends towards increased risk for any side effects (aHR 2.84, $p=0.075$) and heavy/prolonged bleeding (aHR 3.32, $p=0.080$). These findings are consistent with the hypothesis that continuing users may represent a group who were better able to tolerate heavy/prolonged and irregular bleeding, as we estimate larger (but imprecise) estimates associated with these symptoms among women initiated new contraceptive methods. As such, our primary models would be expected to underestimate risks associated with bleeding side effects. We find no evidence of increased risk of discontinuation associated with sexual side effects in this sample (aHR 1.23, $p=0.801$), a finding which warrants future research.

S2. Tables & Figures

S2.1 Table. Side effects symptom ascertainment

Side effects symptom category	Relevant question text
Any side effects	<p>“In the past week, have you had any side effects or problems using ([CURRENT METHOD] if current user or “family planning” if reported stopping FP use in past week)?”</p> <p><i>Note: Participants who responded yes or not sure to this question were asked about specific symptoms using the questions below.</i></p>
Heavy/prolonged bleeding	<p>“Did you get your monthly periods in the past week?” If YES:</p> <p>“Were your monthly periods heavier than usual in the past week?”</p>
Irregular bleeding	<p>“Did you get your monthly periods in the past week?” If YES:</p> <p>“Have you had more irregular bleeding or spotting than usual the past week?”</p>
Lack of expected bleeding	<p>“Did you get your monthly periods in the past week?” If NO:</p> <p>Were you expecting your monthly periods in the past week?</p>
Cramping or abdominal/back pain	Have you had more cramping than usual in the past week?
Weight changes	Have you had weight changes in the past month?
Sexual side effects	<p>Have you had problems with sexual pleasure or desire in the past week?</p> <p>OR</p> <p>Have you had pain during intercourse in the past week?</p>
Other side effects (hand coded free text)	<p>“Have you had any other side effects or problems using family planning in the past week?” If YES:</p> <p>“What other side effects or problems have you had in the past week?” [Free text response]</p>

S2.2 Table. Percent of weeks prior to method switch or discontinuation in which participants reported side effects

Percent of weeks participant reported side effect:	Any side effects or method problems n (%)	Heavy/prolonged bleeding n (%)	Irregular bleeding n (%)	Lack of expected bleeding n (%)	Cramps or abdominal/back pain n (%)	Sexual side effects n (%)	Weight changes* n (%)
0% (never)	197 (29)	442 (65)	419 (61)	429 (63)	345 (50)	337 (49)	344 (51)
>0-25%	235 (34)	161 (24)	171 (25)	191 (29)	198 (29)	190 (28)	194 (29)
>25-50%	100 (15)	47 (7)	53 (8)	38 (6)	81 (12)	73 (11)	71 (10)
>50-75%	51 (7)	17 (2)	19 (3)	10 (1)	19 (3)	29 (4)	21 (3)
>75%	101 (15)	15 (2)	21 (3)	17 (2)	41 (6)	54 (8)	49 (7)
No. participants	684	682	683	685	684	683	679

* All side effects were reported as occurring in the past week with the exception of weight changes, which were reported as having occurred in the past month.

Notes: Row categories are defined as the percent of weeks an individual participant reported experiencing the side effects (calculated out of weeks with completed surveys). Column percentages represent the percent of women in each category (never reported the side effect to "reported the side effect in >75% of weeks). Participants were censored at the week of all-method discontinuation or the week prior to method switch. As such, side effects reflect those experienced using the initial method type used at study enrollment. Participants who switched methods in the first week of follow-up are excluded from these descriptive summaries, as they were not asked about experience of side effects with their initial method.

S2.3 Table: Contraceptive use dynamics over 24 weeks

	n	Overall n (%) or IR (95% CI)
Panel A. Method switch		
Incidence of method switch (per 100 woman-years)*	825	61.3 (52.4-71.8)
Incidence of method switch by method type(per 100 woman-years)*		
Implant	825	52.1 (39.6-65.9)
IUD		63.9 (36.3-112.5)
Injectable		64.1 (50.6-81.1)
OCP		130.5 (80.0-213.1)
<i>Among switchers:</i>		
Switched from LARC to another LARC	157	9 (6)
Switched from LARC to non-LARC		62 (40)
Switched from non-LARC to LARC		59 (38)
Switched from non-LARC to another non-LARC		26 (17)
<i>Stated reason for switch</i>		
Side effects	157	47 (30)
More convenient method		10 (6)
More effective method		15 (10)
Other reason		5 (3)
Missing/refused		79 (51)
Panel B. Contraceptive discontinuation		
Incidence of discontinuation (per 100 woman-years)*	825	38.5 (31.6-47.0)
Incidence of discontinuation by method type (per 100 woman-years)*		
Implant	825	28.6 (20.3-40.2)
IUD		42.6 (21.3-85.2)
Injectable		41.8 (31.2-56.0)
OCP		97.9 (55.6-172.4)
<i>Stated reason for discontinuation</i>		
Pregnancy desire	98	13 (13)
Side effects		9 (9)
Forgot		7 (7)
Partner away		3 (3)
Other reason		6 (6)
Missing/refused		60 (61)

Notes: Analytic sample is restricted to women who did not report desiring their next pregnancy within 1 year and who were using implants, injectables, IUD or OCP at baseline; LARC = long-acting reversible contraceptive, which in our sample comprises IUD and implants. *Case-specific incidence rates (IR) are completely unadjusted; parentheses indicate 95% CI.

S2.4 Table. Discontinuation and method switch by baseline characteristics

	Discontinuation		Method Switch	
	HR (95% CI)	aHR (95% CI)	HR (95% CI)	aHR (95% CI)
<i>Method type</i>				
Implant	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
IUD	1.42 (0.65-3.10)	1.64 (0.72-3.74)	1.13 (0.60-2.12)	1.13 (0.59-2.16)
Injectable	1.42 (0.87-2.32)	1.43 (0.84-2.43)	1.18 (0.80-1.75)	1.14 (0.75-1.71)
OCP	2.46 (1.30-4.65)	2.93 (1.51-5.67)	2.12 (1.18-3.81)	1.84 (0.97-3.50)
<i>Desire for pregnancy in the future</i>				
None	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
Not sure	0.39 (0.13-1.14)	0.46 (0.15-1.34)	0.78 (0.40-1.53)	0.79 (0.40-1.54)
Yes, but unsure when	0.95 (0.47-1.91)	0.81 (0.34-1.92)	0.85 (0.46-1.56)	0.68 (0.35-1.32)
Yes, in 1-2 years	1.45 (0.77-2.75)	1.40 (0.66-2.94)	1.19 (0.66-2.15)	1.01 (0.55-1.86)
Yes, in >2 years	0.70 (0.43-1.14)	0.79 (0.42-1.47)	1.04 (0.70-1.56)	0.86 (0.54-1.36)
<i>FP user type at baseline</i>				
Initiator	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>	<i>Ref.</i>
Switcher	1.47 (0.67-3.21)	1.18 (0.50-2.78)	0.74 (0.42-1.32)	0.72 (0.40-1.30)
Continuer	1.34 (0.79-2.25)	1.25 (0.71-2.21)	0.76 (0.53, 1.09)	0.76 (0.52-1.13)
Received all 3 components of method information index (MII) ^a (<i>ref:</i> <3)	1.12 (0.69-1.80)	1.34 (0.80-2.27)	1.32 (0.91-1.92)	1.34 (0.88-2.05)

IUD = intrauterine device, OCP = daily oral contraceptive pills

^aThe MII is coded as a binary variable equal to 1 if women reported received all 3 of the following counseling components during the FP visit on the date of study enrollment (or at her most recent visit, if she did not receive FP services on the date of enrollment): information on other methods, side effects of selected method, and what to do if side effects occur; the variables is coded as 0 if <3 counseling items were reported.

Notes: adjusted cause-specific Cox proportional hazards models include the following covariates: method type at enrollment, marital status, age (years), completed education (years), FP user type, and postpartum status at enrollment (end of last pregnancy <6 months ago). All models (unadjusted and adjusted) stratified by enrollment facility.

S2.5 Table. Incidence of modern-method discontinuation and switch

	Modern-Method Discontinuation			Method Switch		
	Number of events	Person-time observed (years)	Incidence rate* (95% CI)	Number of events	Person-time observed (years)	Incidence rate* (95% CI)
Overall	98	254.3	38.5 (31.6, 47.0)	156	254.3	61.3 (52.4, 71.8)
<i>Method used at enrollment:</i>						
Implant	33	115.5	28.6 (20.3, 40.2)	59	115.5	51.1 (39.6, 65.9)
IUD	8	18.8	42.6 (21.3, 85.2)	12	18.8	63.9 (36.3, 112.5)
Injectable	45	107.8	41.8 (31.2, 56.0)	69	107.8	64.1 (50.6, 81.1)
OCP	12	12.3	97.9 (55.6, 172.4)	16	12.3	130.5 (80.0, 213.1)

* per 100 woman-years

S2.6 Table. Effect modification of associations between specific side effects and switch, discontinuation

	Discontinuation		Switch	
	aHR	p-value	aHR	p-value
Panel A. Strength of desire to avoid pregnancy				
<i>Heavy bleeding</i>				
Strong desire	0.90	0.794	1.03	0.921
Heavy bleeding	4.22	0.012	0.99	0.995
Heavy bleeding*Strong desire	0.26	0.135	1.90	0.559
<i>Irregular bleeding</i>				
Strong desire	1.09	0.838	1.14	0.698
Irregular bleeding	5.70	0.001	2.46	0.205
Irregular bleeding*Strong desire	0.21	0.056	1.00	0.997
<i>Lack of expected bleeding</i>				
Strong desire	0.64	0.230	0.96	0.902
Lack of expected bleeding	4.87x10 ⁻¹⁰	<0.001	1.97	0.323
Lack of expected bleeding*Strong desire	2.45x10 ⁹	--	1.05	0.948
<i>Cramping or abdominal/back pain</i>				
Strong desire	0.99	0.988	0.93	0.817
Cramping or abdominal/back pain	4.38	0.001	0.73	0.656
Cramping or abdominal/back pain*Strong desire	0.28	0.046	1.97	0.406
<i>Sexual side effects</i>				
Strong desire	0.95	0.901	0.94	0.871
Sexual side effects	3.43	0.008	1.90	0.165
Sexual side effects*Strong desire	0.21	0.030	1.06	0.924
<i>Weight changes</i>				
Strong desire	0.81	0.618	1.00	0.996
Weight changes	2.82	0.044	1.49	0.478
Weight changes*Strong desire	0.50	0.333	0.98	0.970
<i>Any side effects</i>				
Strong desire	0.92	0.849	1.01	0.987
Any side effects	2.58	0.046	1.67	0.319
Any side effects*Strong desire	0.50	0.260	0.92	0.878
Panel B. Young adulthood (<25 years old)				
<i>Heavy bleeding</i>				
Young adult	0.75	0.392	1.49	0.091
Heavy bleeding	1.85	0.202	2.83	0.006
Heavy bleeding*young adult	1.23	0.799	0.13	0.088
<i>Irregular bleeding</i>				

Young adult	0.74	0.382	1.42	0.148
Irregular bleeding	2.44	0.034	2.30	0.084
Irregular bleeding*young adult	1.34	0.667	0.33	0.235
Lack of expected bleeding				
Young adult	0.86	0.617	1.37	0.200
Lack of expected bleeding	0.83	0.739	2.68	0.015
Lack of expected bleeding*young adult	0.00	--	0.48	0.393
Cramping or abdominal/back pain				
Young adult	0.64	0.208	1.75	0.025
Cramping, abdominal/back pain	1.15	0.725	2.18	0.028
Cramping or abdominal/back pain*young adult	2.55	0.159	0.00	0.615
Sexual side effects				
Young adult	0.70	0.332	1.83	0.001
Sexual side effects	1.66	0.173	2.81	0.018
Sexual side effects*young adult	1.47	0.545	0.14	0.011
Weight changes				
Young adult	0.76	0.431	1.50	0.114
Weight changes	1.78	0.115	1.48	0.384
Weight changes*young adult	1.44	0.582	0.42	0.290
Any side effects				
Young adult	0.70	0.370	1.87	0.029
Any side effects	1.51	0.219	2.15	0.029
Any side effects*young adult	1.52	0.482	0.33	0.058

Notes: Cause-specific hazard ratios of discontinuation and method switch estimated using separate Cox proportional hazards models stratified by enrollment facility, with switch or discontinuation defined as the competing risk. All models are stratified by enrollment facility and adjusted for the following covariates: marital status, contraceptive method at enrollment, years of completed education, and FP user type (initiator, continuer, switcher at baseline) and early postpartum status (end of most recent pregnancy <6 months ago). Models except in which young adulthood is the exposure of interest adjust for age in years. Models of strength of desire to avoid pregnancy exclude participants who reported uncertainty in fertility intentions at baseline (unsure if want future pregnancy, unsure of ideal timing of next pregnancy, or not sure how big of a problem a near-term pregnancy would be). Desire to avoid pregnancy is defined as "strong" if the participant reported that becoming pregnant in the near future would be a "big problem" or weak if a "small problem" or "no problem." * symbol denotes coefficient on the interaction term for side effect and potential effect modifier.

S2.7 Table. Adjusted hazard ratios of switch and discontinuation by method satisfaction**Panel A. Method Switch**

	aHR (95% CI)	p-value
<i>Method satisfaction</i>		
Very satisfied	<i>Ref.</i>	
Satisfied	0.84 (0.46-1.52)	0.556
Neutral	1.58 (0.69-3.60)	0.267
Dissatisfied	2.55 (1.03-6.30)	0.044
Very dissatisfied	1.58 (0.31-8.19)	0.578
Any side effects	1.04 (0.58-1.86)	0.599

Panel B. Discontinuation

	Model 2	
	aHR (95% CI)	p-value
<i>Method satisfaction</i>		
Very satisfied	<i>Ref.</i>	
Satisfied	0.86 (0.44-1.68)	0.656
Neutral	1.55 (0.72-3.33)	0.260
Dissatisfied	1.14 (0.33-3.95)	0.833
Very dissatisfied	6.85 (1.84-25.48)	0.004
Any side effects	1.59 (0.90-2.79)	0.111

Notes: In addition to the categorical method satisfaction variable and an indicator of any side effects experienced based on the most recent available report in the current or prior 3 weeks, Cox PH models additionally include *a priori* adjustment variables: married (legal or presumed), method type, age (in years), years of education, FP user type at enrollment (initiator, switcher or continuer), and <6 months since end of last pregnancy.

S2.8 Table. Contributions of contraceptive side effects to discontinuation

	Population Attributable Fraction (95% CI)	Attributable Fraction, Among Exposed (95% CI)
Contraceptive side effects in past month:		
Any side effects	0.16 (0.02-0.27)	0.41 (-0.02-0.66)
Heavy/prolonged bleeding	0.07 (0.01-0.12)	0.48 (-0.07-0.75)
Irregular bleeding	0.12 (0.07-0.17)	0.62 (0.26-0.80)
Lack of expected bleeding	-0.03 (-0.13-0.06)	-0.58 (-3.69-0.47)
Cramping, abdominal/back pain	0.07 (-0.02-0.16)	0.35 (-0.23-0.66)
Sexual side effects	0.11 (0.03-0.19)	0.46 (0.01-0.70)
Weight changes	0.12 (0.04-0.19)	0.38 (0.10-0.58)

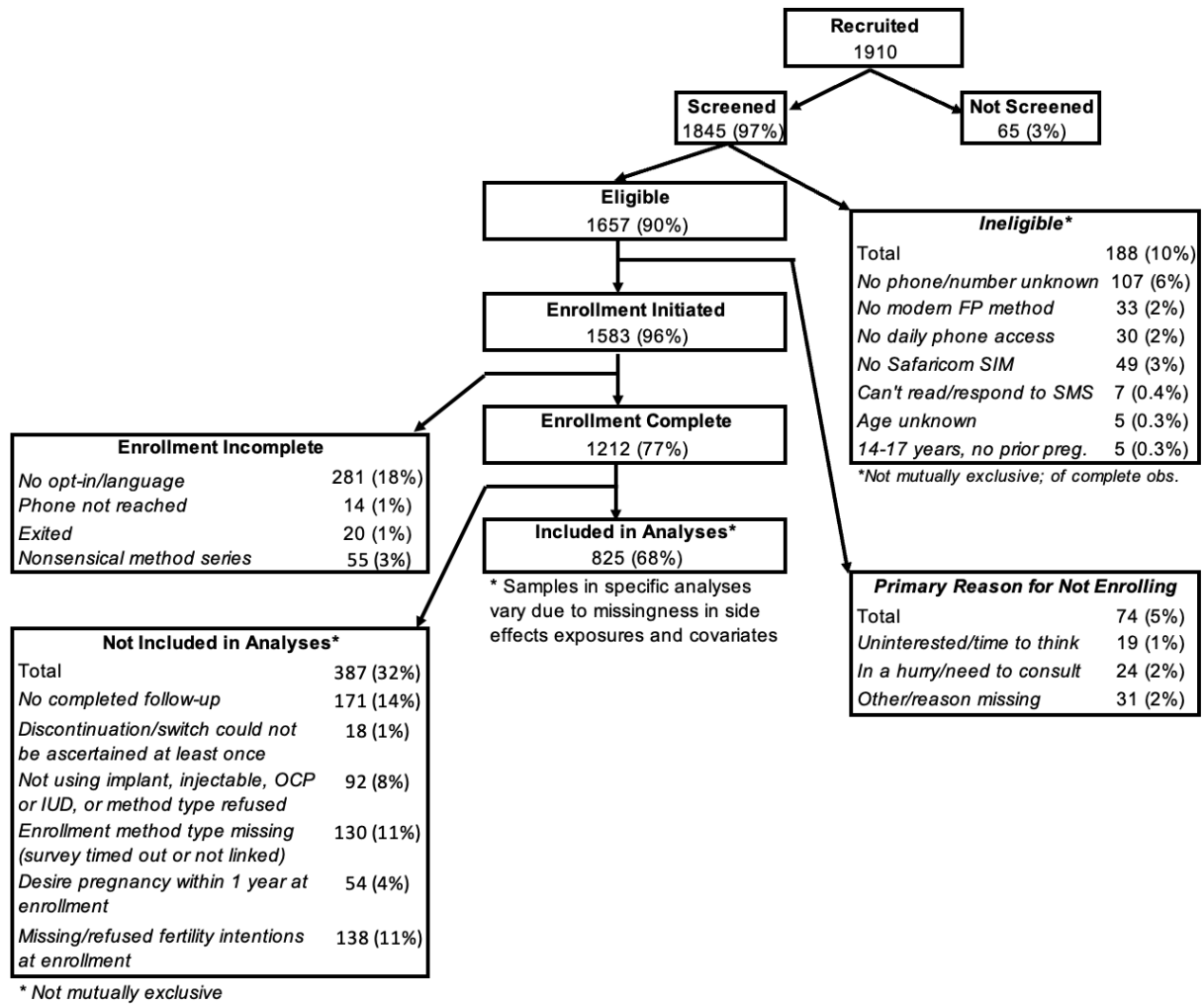
Notes: Cause-specific hazard ratios estimated using Cox proportional hazards models stratified by enrollment facility, with censoring due to method switch or loss to follow-up. All models are adjusted for the following covariates: marital status, contraceptive method at enrollment, age group, years of completed education, FP user type (initiator, continuer, switcher at baseline), and postpartum status, with estimated attributable fractions estimated with all covariates set to those observed in the study cohort.

S2.9 Table. Adjusted hazard ratios of side effects on switch and discontinuation among subset of participants initiating or switching methods at study enrollment

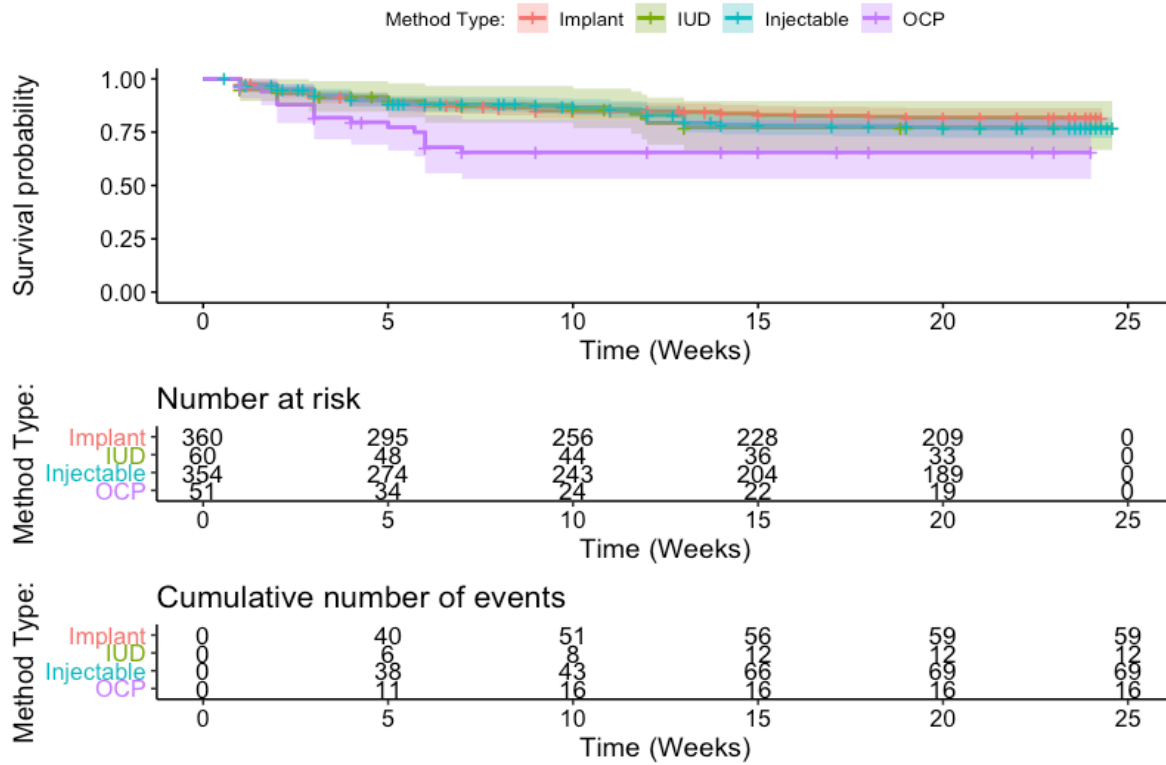
	Method Switch		Discontinuation	
	aHR	p-value	aHR	p-value
Any side effects	1.04	0.931	2.84	0.075
Heavy/prolonged bleeding	1.36	0.680	3.32	0.080
Irregular bleeding	0.99	0.993	4.36	0.003
Lack of expected bleeding	1.27	0.740	0.00	--
Cramps/abdominal or back pain	0.81	0.790	1.69	0.500
Sexual side effects	0.95	0.929	1.23	0.801
Weight changes	0.55	0.410	3.11	0.108

Notes: Cause-specific hazard ratios estimated using Cox proportional hazards models stratified by enrollment facility. Models include only participants who reported initiating contraception or switching from one method type to another at study enrollment. All models are adjusted for the following baseline covariates: marital status, contraceptive method type, age (in years), years of completed education, FP user type (initiator or switcher at baseline), and postpartum status (end of pregnancy within 6 months of study enrollment).

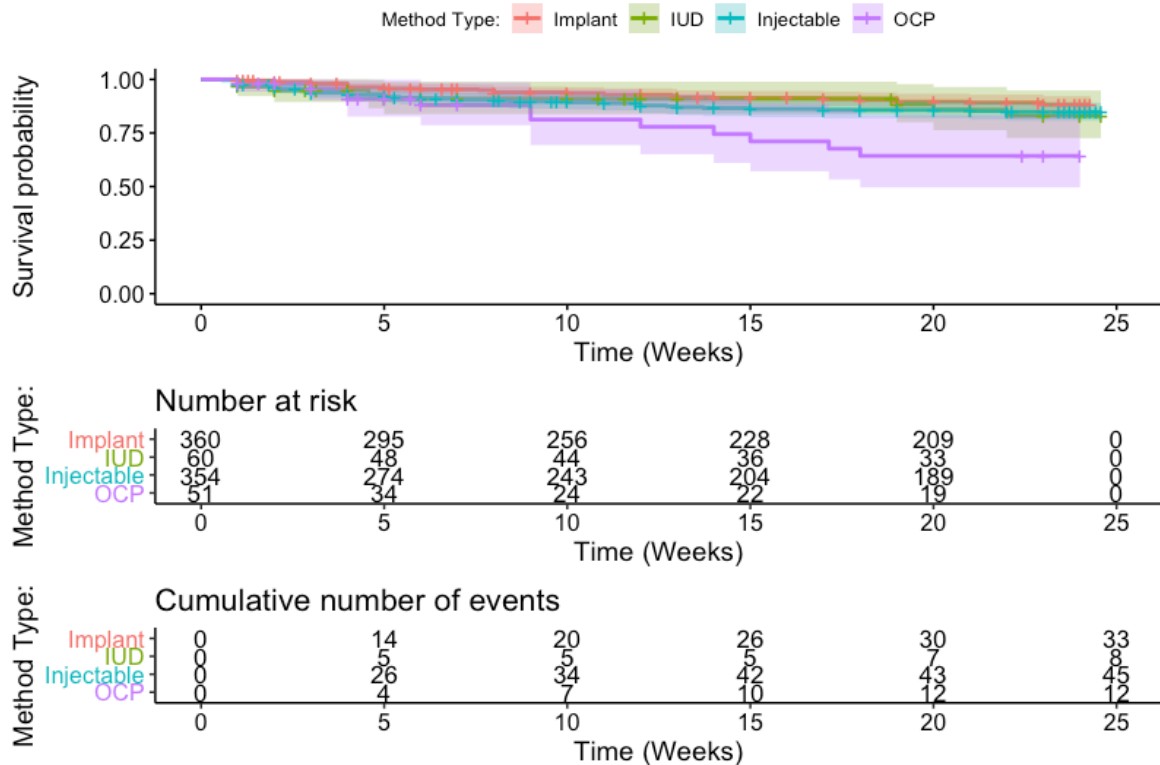
S2.1 Fig: Study Flow



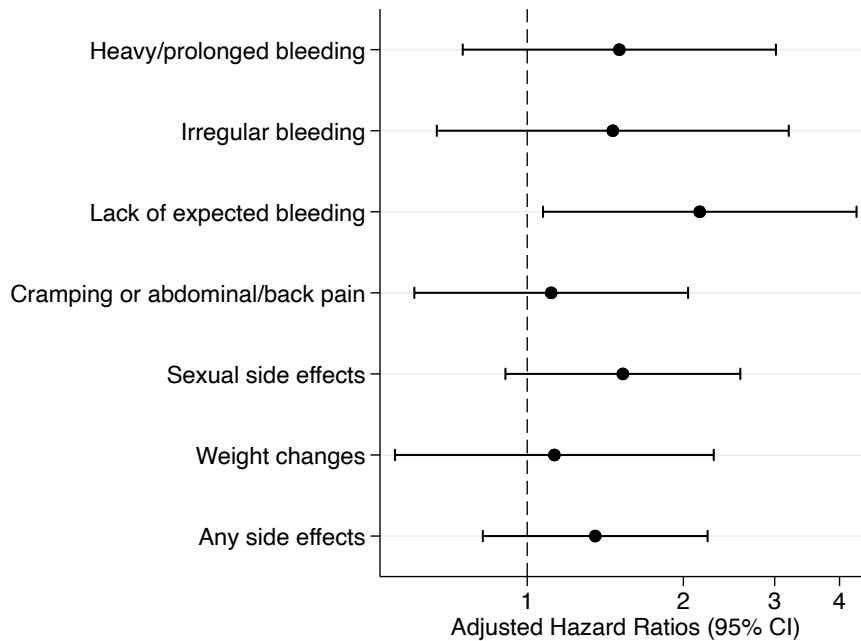
S2.2 Fig: Survival Probability of Method Switch and Discontinuation
 Panel A. Method switch



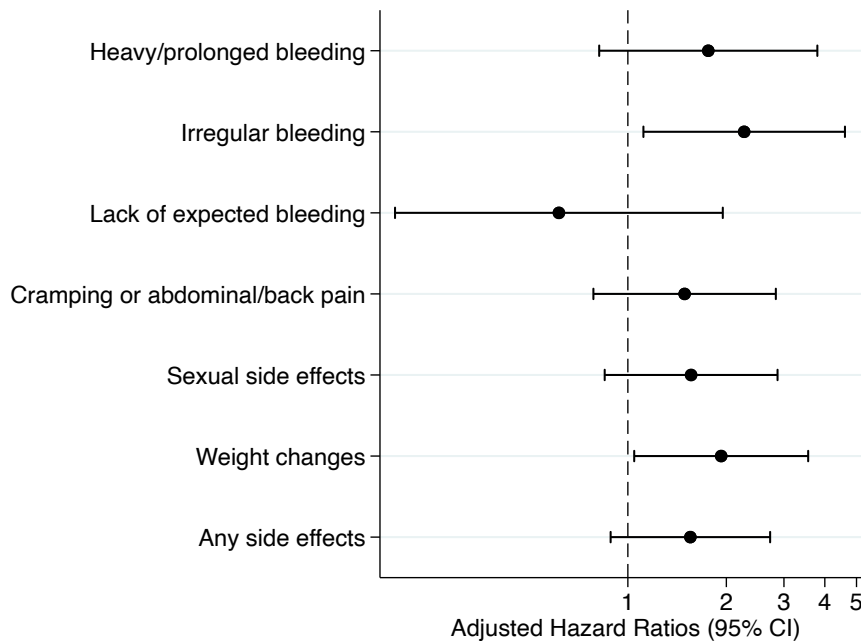
Panel B. Discontinuation



S2.3 Fig: Sensitivity Analysis: Fine-Grey competing risk survival models
Panel A. Adjusted subdistribution hazards ratios of method switch



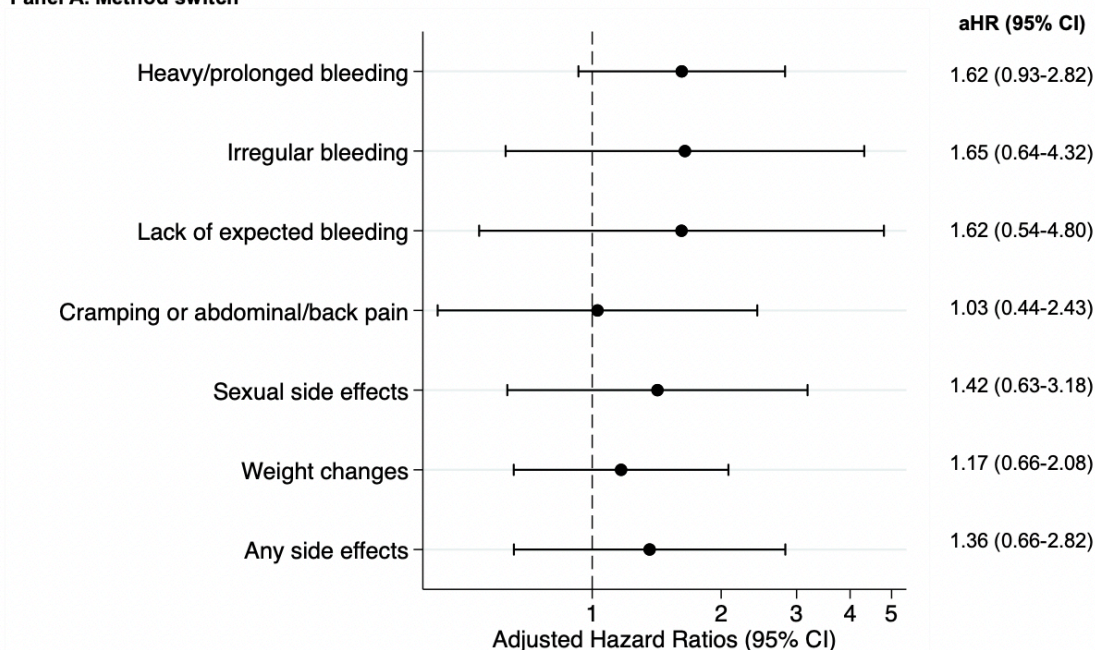
Panel B. Adjusted subdistribution hazards ratios of discontinuation



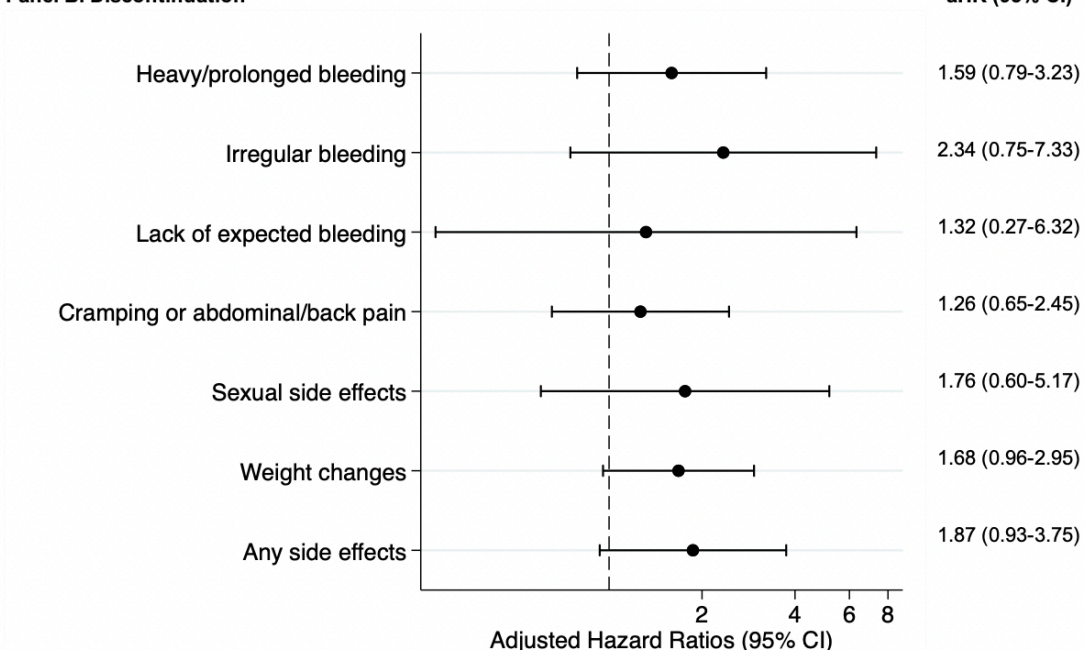
Notes: Adjusted subhazard ratios are estimated using Fine-Grey proportional hazards models for competing risks, with switch defined as the competing risk for discontinuation models and vice versa. Side effects are those reported in the past week for women discontinuing or continuing a method, and in the week prior to the past week (for women switching a method). All models are adjusted for the following covariates assessed at study enrollment: marital status, contraceptive method type, age (in years), years of completed education, FP user type (initiator, continuer, switcher at baseline), and postpartum status (end of pregnancy within 6 months of study enrollment).

S2.4 Fig: Sensitivity Analysis: Cause-specific hazard models using multiple imputation to address missing side effects exposure

Panel A. Method switch

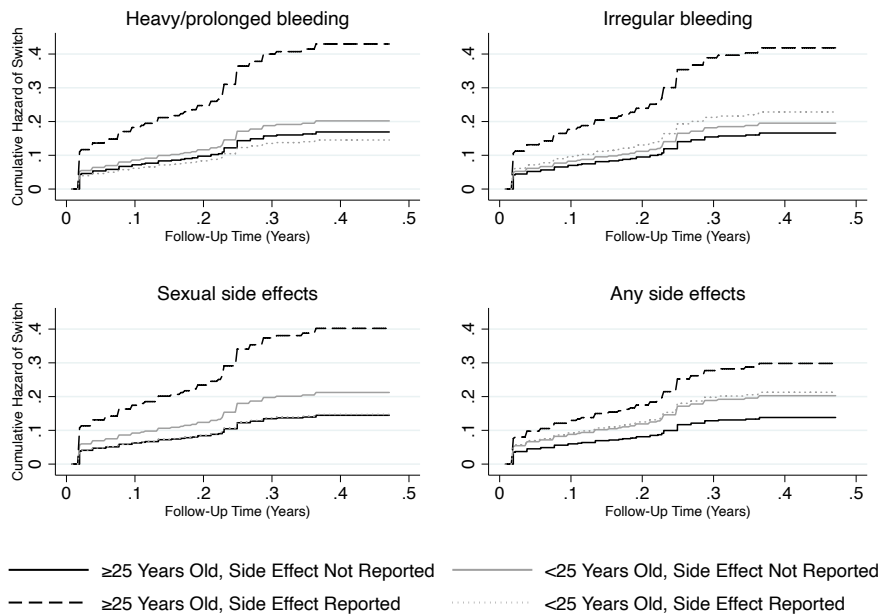


Panel B. Discontinuation

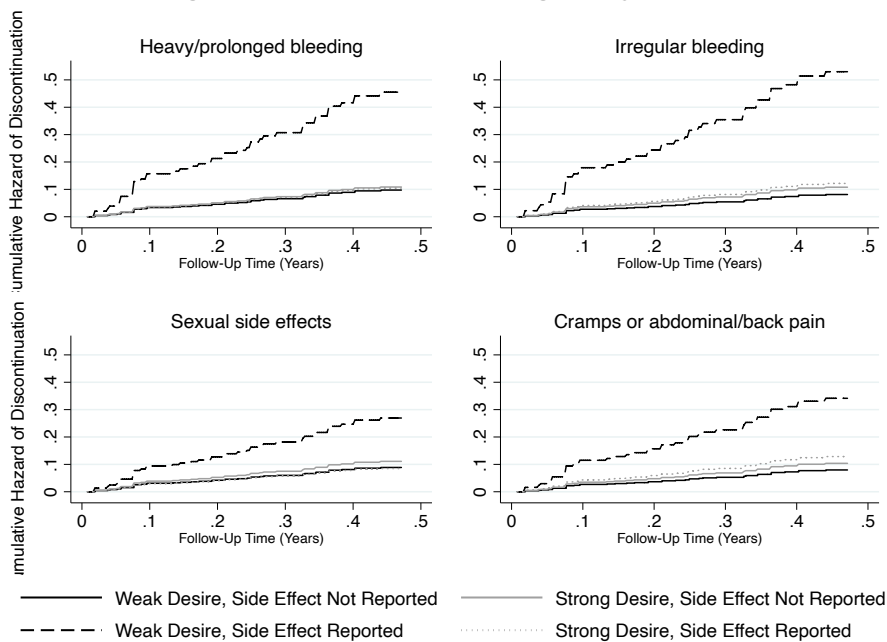


Notes: Cause-specific hazard ratios estimated using Cox proportional hazards models stratified by enrollment facility. Side effects are those reported in the past week for women discontinuing or continuing a method, and in the week prior to the past week (for women switching a method). All models are adjusted for the following covariates assessed at study enrollment: marital status, contraceptive method type, age (in years), years of completed education, FP user type (initiator, continuer, switcher at baseline), postpartum status (end of pregnancy within 6 months of study enrollment), and current breastfeeding. Multiple imputation was used to address missingness in report of side effects at any time in the prior 4 weeks (the primary exposure definition), with some missing values retained due to missingness in baseline covariates.

S2.5 Fig. Effect modification of side effects
Panel A. Youth as an effect modifier of switch



Panel B. Strength of desire to avoid pregnancy as an effect modifier of discontinuation



Notes: Panel A: Cause-specific Cox proportional hazards models include an indicator indicating report of the side effect, an indicator for age <25 years old, and an interaction term. Panel B: Cause-specific Cox proportional hazards models include an indicator indicating report of the side effect, an indicator for strength of desire to avoid pregnancy, and an interaction term. All models are additionally adjusted for the following baseline covariates: marital status, contraceptive method at enrollment, years of completed education, and FP user type (initiator, continuer, switcher at baseline), and postpartum status at enrollment (defined as end of last pregnancy within 6 year of study enrollment). For graphical presentation, these analyses are not stratified by enrollment facility and therefore do not correspond exactly to estimates reported in S6 Table.

CHAPTER THREE - A Risk Scoring Tool for Predicting Women at High Risk of Contraceptive Discontinuation:

S3 Supplementary Material

1. Method ascertainment over follow up

Contraceptive use was ascertained weekly via self-reported response to the question, “Are you currently using any method of family planning?” For affirmative responses, respondents were asked to provide the current method type. To assess use of fertility-based methods, women were given the option to select use of a “natural method,” terminology which was developed with the Kenya-based study team. Fertility awareness-based (FAB) method users were then asked to specify use of “counting days” or “breastfeeding method (before return of periods after childbirth)”. Because study eligibility required use of modern FAB methods, women reporting “natural method” use over follow-up were assumed to be using modern contraception in our primary analyses. To ascertain use of emergency contraceptive pills (ECP), women reported that they were currently using contraceptive pills and subsequently specified the type as “e-pill.” Women using coitus-dependent methods were not asked about contraceptive method use relative to sexual activity.

We assessed practice of the lactational amenorrhea method (LAM) through the following questions: "Which method are you currently using? Natural method. Which natural method are you currently using? Breastfeeding method (before return of periods after childbirth)." To be consistent with our treatment of use of other methods, which was only based on reported use rather than on specifics of adherence or method eligibility, we did not restrict reported LAM use only to those who meet the eligibility criteria.

2. Method-specific considerations for defining discontinuation

Depot medroxyprogesterone (DMPA)

While participants in our study did not specify type of injectable used, DMPA is the primary and typically only injectable method available in Kenya's public sector. DMPA has an established duration of efficacy of 13-17 weeks. In our primary analyses, we allow earlier instances of discontinuation among injectable users based on their self-reported use of no method. While this introduces probable measurement error among DMPA users in the discontinuation outcome, we selected this as our primary approach because no similar restrictions (such as a 17 week window of "immunity" from discontinuation) could be applied to users of other method types. We did not correct DMPA discontinuations based on scientific knowledge in the primary analysis, based on our expectation that this would introduce differential measurement error by method type (as similar corrections could not be made for other method users who likely also incorrectly reported non-use in some cases).

We assessed the robustness of our findings in a sensitivity analysis that prohibited DMPA discontinuation within 17 weeks of the most recent reported injection (Tables S7 and S8). Restricting discontinuation to at least 17 weeks after the most recent injection reduces the estimated incidence rate of discontinuation among baseline injectable users considerably, from 35.0 discontinuations per 100 woman-years (95% CI 25.6, 48.0) in the primary analysis to 11.7 per 100 woman-years (95% CI 6.9, 19.8). However, we found that the prediction model selected using data in which we restrict early DMPA discontinuation is very similar to that selected by our primary approach. Comparing the full risk score in Table 2 to Table S8, we find that all predictors from our primary model are selected using the alternative DMPA discontinuation definition and that estimated coefficients for these predictors are qualitatively and quantitatively similar across

specifications. These findings indicate that, while early discontinuations may artificially inflate estimated incidence of discontinuation among injectable users, predictors of discontinuation are relatively stable.

Coitus-dependent methods (ECP, condom, and FAB)

Due to the required brevity of the weekly surveys, we did not capture information on sexual activity over follow-up. By asking about women's "current method of family planning" each week, our intention was to capture use of coitus-dependent methods even in the absence of sexual activity. However, it is possible that coitus-dependent method users may be incorrectly categorized as discontinuers due to lack of sexual activity in the prior week.

We assess robustness of the risk score to this potential measurement error in several sensitivity analyses that exclude coitus-dependent and FAB methods (Table S9 and S10). In sub-groups excluding ECP and FAB method users (Table S9) and additionally excluding condom users (Table S10), we find that predictor models based on the primary stepwise AIC selection method are very similar to those developed in the full cohort (presented in Table 2). Predictors selected in both subgroups include all those selected in the primary model, with similar estimated coefficients.

Short-term gaps in method use

We deliberately selected a short (2-week) interval of method non-use to define our primary definition of contraceptive discontinuation. This decision was made in order to examine short-term or even unintentional lapses in method use that may nevertheless be meaningful discontinuation events in terms of increased risk of unintended pregnancy. However, we acknowledge that pregnancy risk during short-term gaps in method use differs by method type. We therefore conducted a sensitivity analysis in which we calculated incidence rates by FP method and user type at enrollment (Table S11) and rederived the risk score (Table S12) using an alternate

definition of discontinuation based on a 4- rather than 2-week gap in modern method use. We find that, while the alternate definition results in lower rates of discontinuation, the risk score development remains relatively robust to definition changes: IUD and short-term modern method use, <9 years completed education, not having a child aged <6 months, and either being unmarried or having a husband who is supportive of FP are selected as predictive factors in the risk score model with associations of similar magnitude as the primary model. One additional metric of patient satisfaction (being less than “very satisfied” with the FP services received) is also identified as a predictor of discontinuation.

3. Treatment of missing data

For observations missing data on method use or current method type over follow-up, we used a hybrid of last observation carried forward (LOCF) and next observation carried backward (NOCB) to singly impute method type (including use of no method) to the midpoint of the missing interval. Participants were censored at their latest observed follow-up time, with no attempt made to impute monotonic right censoring after the final complete follow-up observation. We made no attempt to impute missing baseline covariates.

Descriptive summary of missing data over follow-up, by FP user and method type

Among participants with complete baseline covariates of interest (n=835), we observe 744/835 (89%) had some follow-up and were included in the full analytic cohort. We compared differences in mean inclusion in the analysis by FP user type and method type used at study enrollment using Wald tests of means. We find no evidence of exclusion by method type. However, method switchers were slightly less likely to have any completed follow-up compared to initiators (90% vs. 84%, p=0.04).

The average completed follow-up in the full cohort included in the analysis (N=744) was 20.5 weeks. We observe no differences in righthand censoring by method or FP user type among those included in the full analytic cohort. Overall, 3,194/15,266 (21%) of weekly observations in the full cohort were imputed to account for interval censoring. Compared to injectable users, we observe no differences in the proportion of each participant's follow-up observations that were imputed by method category with the exception of Cu-IUD users, who had fewer censored observations (17% vs. 25%, $p=0.003$). Compared to initiators, method continuers had a higher proportion of imputed observations (24% vs. 19%, $p=0.004$), but no difference in interval censoring was found between initiators and switchers.

4. Time-dependent receiver operating curves (ROC) and area under the curve (AUC) analysis

We calculated time-dependent ROC-AUC, sensitivity, specificity, and positive and negative predictive values using the nonparametric inverse probability of censoring weighting (IPCW) estimator proposed by Blanche et al. and operationalized using the *timeROC* package for R, version 0.4 (<https://cran.r-project.org/web/packages/timeROC/timeROC.pdf>). ROC-AUC analyses were specified at 84 days (12 weeks) and 168 days (24 weeks). The Kaplan-Meier estimator was used to calculate censoring weights. Sensitivity and specificity were at the optimal cut-point for the full and simplified risk scores at time equal to 168 days.

5. Group LASSO-Cox model specification

Cox proportional hazards model

We used the Efron approach to handle ties in all Cox Proportional Hazards models.

Group LASSO-cox model

The group Cox-LASSO model with the smallest mean cross-validation error was selected using 100 repeated 10-fold cross-validations. Coefficients for variables selected using the group Cox-LASSO approach were estimated using a standard Cox model.

6. Cross-validation of ROC-AUC performance metrics

Cross-validation of the 24-week AUC and Brier scores were estimated using the “resample” function of the *MachineShop* package for R, version 2.1.0 (<https://cran.r-project.org/web/packages/MachineShop/MachineShop.pdf>). Performance metrics were calculated specifying a Cox model with the dependent variable equal to the continuous risk score (full, simplified and Cox LASSO), using the Efron method for ties.

7. Consideration of FP users who did not receive FP services on the date of study enrollment

Participants were recruited from FP and MCH clinics within public health facilities and were eligible if they were currently using a modern contraceptive method. Eligibility was not contingent on receipt of FP services on the date of enrollment. As a result, 12% (89/744) of the analytic cohort reported most recently receiving FP services more than 1 day +/- the recorded enrollment date. As a result, “continuers” may comprise two distinct profiles of contraceptive users: 1) women seeking FP services on the date of enrollment in order to obtain method resupply, for a method-related check-up, or to obtain counseling or care related to contraceptive use; and 2) women seeking other MCH services who also happened to be using a modern contraceptive method. We conducted a sensitivity analysis to assess robustness of our findings to exclusion of women who

reported that their most recent FP visit was not within 1 day of study enrollment (Table S13). Rederiving the prediction model in this restricted sample (N=449) resulted in similar predictor selection: IUD and short-term modern method use, <9 years completed education, not having a child aged <6 months, and either being unmarried or having a husband who is supportive of FP are selected as predictive factors in the risk score model with associations of similar magnitude as the primary model. Two additional predictors were also selected: a travel time of less than 30 minutes to the health facility and receiving more elements of method information counseling were both included as predictors based on the minimum AIC criterion, although neither of these predictors was associated with risk of discontinuation at the $p=0.05$ level. These findings indicate that our model is robust to inclusion of modern method users who were recruited for study participant while seeking health services other than FP care.

Tables

Table S3.1: Characteristics of the included and excluded sample

	Included in Analysis (n=744)	Excluded from Analysis* (n=468)		p
	n (%)	n	n (%)	
Sociodemographic characteristics				
Age (years) [median (IQR)]	26 (23, 31)	363	37 (23, 31)	0.54
Completed education <9 years	376 (51)	385	236 (61)	0.001
<i>Relationship status</i>				
Not married (legal or presumed)	139 (19)	363	67 (18)	0.89
Partner supportive of FP	561 (75)		277 (76)	
Partner not supportive of FP or unsure of partner support	44 (6)		19 (5)	
Reproductive characteristics				
Number of living children [median (IQR)]	2 (1, 3)	317	2 (1, 3)	0.29
Does not have a child aged <6 months	524 (70)	317	238 (75)	0.12
<i>Fertility intentions</i>				
Unsure intention to have children or unsure of preferred timing	147 (20)	322	77 (24)	0.001
Desires no future children	159 (21)		93 (29)	
Desires next pregnancy in 1-2 years	67 (9)		33 (10)	
Desires next pregnancy in >2 years	371 (50)		119 (37)	
<i>Pregnancy in the short-term future would be a:</i>				
Not sure	99 (13)	322	47 (15)	0.54
Big problem	413 (56)		163 (51)	
Small problem	63 (8)		30 (9)	
No problem	169 (23)		82 (25)	
Characteristics of FP services received				
<i>Contraceptive method type</i>				
Injectables	310 (42)	308	108 (35)	<0.001
Implant	320 (43)		122 (40)	
Intrauterine device (IUD)	46 (6)		21 (7)	
Pills ^a	36 (5)		23 (7)	
Other modern ^b	32 (4)		34 (11)	
<i>FP user type</i>				
Initiating contraception	194 (26)	304	88 (29)	0.24
Switching from one method type to another	91 (12)		27 (9)	

Continuing method used in past month	459 (62)		189 (62)	
History of contraceptive side effects				
No	384 (52)	282	132 (47)	0.06
Yes	349 (47)		140 (50)	
Unsure	11 (1)		10 (4)	
Traveled less than 30 minutes to reach health facility	469 (63)	286	183 (64)	0.78
Quality of care and satisfaction				
"Very satisfied" with services received	353 (47)	284	122 (43)	0.20
Felt that her privacy was not protected during the visit	47 (6)	283	14 (5)	0.41
Felt provider gave accurate information	679 (91)	278	247 (89)	0.24
Felt provider's treatment was "very respectful"	653 (88)	280	233 (83)	0.06
Number of items in Method Information Index received [median (IQR)] ^c	3 (1, 3)	261	3 (1, 3)	0.70
Feelings about using FP:				
No fears or concerns	48 (65)	320	181 (57)	0.007
Reported having fears or concerns	239 (32)		117 (37)	
Unsure of having fears or concerns	25 (3)		2 (7)	

Notes: p-values generated using Chi-squared tests for categorical variables and t-tests of means assuming unequal variance for continuous variables.

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

^c The Method Information Index is calculated based on 3 questions: "during your visit: 1) were you informed about other methods?, 2) were you informed about side effects or problems with the method?, 3) were you told what to do if you had side effects of problems with the method?". Responses were summed to provide a count of the number of counseling items received, from 0 (received none of these counseling items) to 3 (received all items).

* Women were excluded due to missing values in any baseline characteristics considered as risk factors or due to completely missing follow-up data. Reported characteristics are based on complete observations within each variable, with no imputation of missing values. Sample sizes for each variable are provided to show level of missingness within individual characteristics in the excluded sample.

Table S3.2: AUC Estimates for Individual Risk Score Components

	AUC (95% CI)	
	Derivation Cohort	Validation Cohort
Contraceptive method type		
IUD		
Pills ^a	0.59 (0.48, 0.70)	0.52 (0.40, 0.65)
Other modern ^b		
FP user type		
Continuing method used in past month	0.50 (0.40, 0.60)	0.51 (0.35, 0.67)
Switching from one method type to another		
<9 years completed education	0.62 (0.48, 0.76)	0.45 (0.26, 0.64)
Does not have child aged <6 months	0.61 (0.48, 0.75)	0.79 (0.63, 0.96)
Relationship status		
Partner supportive of FP	0.49 (0.48, 0.51)	0.50 (0.50, 0.50)
Not married (legal or presumed)		

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Notes: AUC-ROC at time equal to 24 weeks are presented for univariate Cox PH models. For categorical variables, levels within the categorical variable were modeled jointly.

Table S3: Sensitivity, specificity, and Youden's J statistic at selected cut point values

	Sensitivity	Specificity	Youden's J statistic
Full risk score			
5	0.857	0.429	0.286
6	0.709	0.786	0.495
7	0.332	0.929	0.261
Simplified risk score			
1	0.934	0.143	0.077
2	0.806	0.571	0.378
3	0.425	0.857	0.282
Group-LASSO risk score			
14	0.828	0.429	0.256
15	0.761	0.786	0.546
16	0.658	0.857	0.515

Notes: Time-dependent sensitivity and specificity estimates were calculated at 24 weeks. Youden's J statistic is defined as sensitivity

+ specificity - 1. The optimal cut point is selected as the value with the highest J statistic value.

Table S3.4: Cross-validated ROC-AUC and Brier scores at 24 weeks, by risk score
Full Cohort

<i>Risk Score</i>	<i>cvAUC</i>	<i>Brier Score</i>
Full	0.70 (0.58, 0.81)	0.14 (0.09, 0.19)
Simplified	0.67 (0.54, 0.78)	0.14 (0.09, 0.19)
Group-LASSO	0.71 (0.60, 0.83)	0.14 (0.09, 0.19)

Notes: 95% CI in parentheses. Cross-validated AUC and Brier Scores estimated using repeated 5-fold cross-validation with 100 repeats in the full cohort.

Table S3.5: Sensitivity analyses: Estimated coefficients and risk score calculations for restricted and competing-risk models

	Analysis 1*	Analysis 2†
	aSHR	aHR
Contraceptive method type		
IUD	0.77	1.43
Pills ^a	2.48	3.31
Other modern ^b	6.75	5.35
<i>Reference: Injectables, implants, or Cu-IUD/IUS</i>	<i>Ref.</i>	<i>Ref.</i>
FP user type		
Continuing method used in past month	2.27	2.29
Switching from one method type to another	2.34	1.72
<i>Ref: Initiating contraception</i>	<i>Ref.</i>	<i>Ref.</i>
<9 years completed education	2.01	1.68
Does not have child aged <6 months	1.64	1.37
Relationship status		
Partner supportive of FP	3.59	3.96
Not married (legal or presumed)	6.30	8.42
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	<i>Ref.</i>

* In sensitivity analyses 1, we estimate adjusted subhazards ratios for the components of the full risk score selected in the primary analysis but using a competing-risks survival model, with discontinuation due to desire to become pregnant considered a competing risk. We used multiple imputation with chained equations and 10 imputed datasets to model missing reasons for discontinuation.

† In sensitivity analysis 2, we exclude 68 women in the derivation cohort who reported a desire for a pregnancy in the future but who were unsure of their preferred timing (total sample in restricted derivation cohort of N=490). We report adjusted hazard ratios.

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Table S3.6: Sensitivity analyses: estimated Cox model coefficients and risk score calculations using alternate methodological approach

	Group LASSO Risk Score (n=558)	
	β	Points
Contraceptive method type		
Cu-IUD/IUS	0.40	2
Pills ^a	1.09	4
Other modern ^b	1.65	7
<i>Reference: implant, injectables</i>	<i>Ref.</i>	0
Reason for FP visit:		
Continuing method used in past month	0.75	3
Switching from one method type to another	0.79	3
<i>Ref: initiating contraception</i>	<i>Ref.</i>	0
Fertility intentions		
Does not desire future pregnancy	0.61	3
Desires next pregnancy in 1-2 years	0.44	2
Desires next pregnancy in >2 years	0.24	1
<i>Ref: Not sure if desires future pregnancy or unsure of preferred timing</i>	<i>Ref.</i>	0
Reported information provided was accurate	0.73	3
<9 years of completed education	0.56	2
Does not have child aged <6 months	0.44	2
Relationship status		
Partner supportive of FP	1.38	6
Not married (legal or presumed)	1.93	8
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	0

Maximum score

28

Notes: In the group LASSO model, variable selection was conducted using the group LASSO model to identify variables with non-zero coefficients; for the risk score point calculation, coefficients were estimated using a standard Cox PH model.

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Table S3.7: Sensitivity analysis: Incidence rate of discontinuation in the full cohort, comparing primary analysis to one that restricts DMPA discontinuation based on established duration of efficacy

	Primary analysis	DMPA sensitivity analysis^a
	IR (95% CI) per 100 woman-years	IR (95% CI) per 100 woman-years
<i>Contraceptive method type at enrollment</i>		
Injectables	35.0 (25.6, 48.0)	11.7 (6.9, 19.8)

^a In this sensitivity analysis, injectable users at enrollment could not experience a discontinuation event until at least 17 weeks since the last injection date reported. We assume that all injectable users were using DMPA, although injectable type was not captured in the surveys and it may be possible that other injectable contraceptives with shorter windows of efficacy were used. Most recent injection date was updated over time for individuals who continued injectable use or switched to injections over follow-up. If the most recent injection date was missing at baseline, we treated the most recent injection date as equal to the enrollment date.

Notes: IR indicates the incidence rate of method discontinuation in the full cohort (n=774). 95% confidence intervals were estimated using Stata's native "stptime" command.

Table S3.8: Sensitivity analysis: predictors of discontinuation in derivation cohort, restricting discontinuation among injectable users to ≥17 weeks since most recent injection

	Full List of Predictors HR (95% CI)	Simplified Predictors HR (95% CI)
Contraceptive method type		
Implant	1.65 (0.81, 3.34)	1.62 (0.81, 3.25)
Cu-IUD	2.99 (1.10, 8.11)	3.14 (1.18, 8.39)
Pills ^a	6.39 (2.74, 14.91)	7.11 (3.10, 16.36)
Other modern ^b	12.11 (4.49, 32.68)	9.39 (3.69, 23.92)
<i>Reference: Injectables</i>	<i>Ref.</i>	<i>Ref.</i>
FP user type		
Continuing method used in past month	3.70 (1.49, 9.22)	3.75 (1.55, 9.10)
Switching from one method type to another	3.14 (1.08, 9.13)	3.29 (1.15, 9.47)
<i>Reference: Initiating contraception</i>	<i>Ref.</i>	<i>Ref.</i>
Fertility intentions		
Desires no future children	3.54 (1.31, 9.59)	--
Desires next pregnancy in 1-2 years	1.92 (0.63, 5.87)	--
Desires next pregnancy in >2 years	1.72 (0.72, 4.13)	--
<i>Ref. Unsure intention to have children or unsure of preferred timing</i>	<i>Ref.</i>	--
<9 years completed education	1.73 (0.99, 3.03)	--
Does not have child aged <6 months	2.08 (0.98, 4.42)	1.94 (0.93, 4.02)
Number of living children	0.81 (0.63, 1.04)	--
Relationship status		
Partner supportive of FP	2.78 (0.38, 20.52)	--
Not married (legal or presumed)	5.51 (0.71, 42.77)	1.88 (1.00, 3.51)
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	--
Traveled less than 30 minutes to reach health facility	2.48 (1.33, 4.64)	--

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Notes: In this sensitivity analysis, injectable at enrollment could not experience a discontinuation event until at least 13 weeks since the last injection (assumed to be DMPA) reported at baseline. If the most recent injection date was missing, we treated the most recent injection date as equal to the enrollment date. Predictors selected using stepwise forwards and backwards to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified model was developed by removing predictors identified in the full model that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities.

Table S3.9: Sensitivity analysis: predictors of discontinuation in derivation cohort, excluding women using emergency contraceptive pills or fertility-based methods at enrollment (N=546)

	Full List of Predictors HR (95% CI)	Simplified Predictors HR (95% CI)
Contraceptive method type		
Cu-IUD/IUS	1.52 (0.65, 3.56)	1.55 (0.66, 3.65)
Pills ^a	3.09 (1.56, 6.12)	3.33 (1.68, 6.60)
Condoms ^b	5.03 (1.78, 14.26)	5.65 (1.98, 16.06)
<i>Reference: Injectables, implants</i>	<i>Ref.</i>	<i>Ref.</i>
FP user type		
Continuing method used in past month	2.11 (1.07, 4.18)	2.23 (1.13, 4.40)
Switching from one method type to another	2.01 (0.81, 4.96)	1.92 (0.78, 4.73)
<i>Reference: Initiating contraception</i>	<i>Ref.</i>	<i>Ref.</i>
<9 years completed education	1.63 (1.00, 2.66)	--
Does not have child aged <6 months	1.63 (0.89, 2.98)	1.59 (0.87, 2.92)
Relationship status		
Partner supportive of FP	3.91 (0.54, 28.47)	--
Not married (legal or presumed)	6.40 (0.85, 48.25)	1.70 (0.98, 3.00)
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	--
Felt provider gave accurate information	2.34 (0.72, 7.54)	--

^a Pills include daily combined and progestin-only oral contraceptives

^b In this analysis, all users of fertility-based or emergency contraception which are included in the "other modern methods" category in the primary analyses are excluded for total N=546 in the derivation cohort.

Notes: Predictors selected using stepwise forwards and backwards to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified model was developed by removing predictors that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities.

Table S3.10: Sensitivity analysis: predictors of discontinuation in derivation cohort, excluding women using condoms, emergency contraceptive pills, or fertility-based methods (N=534)

	Full List of Predictors HR (95% CI)	Simplified Predictors HR (95% CI)
Contraceptive method type		
Cu-IUD/IUS	1.55 (0.66, 3.63)	1.56 (0.66, 3.67)
Pills ^a	3.10 (1.56, 6.14)	3.34 (1.69, 6.62)
<i>Reference: Injectables, implants</i>	<i>Ref.</i>	<i>Ref.</i>
FP user type		
Continuing method used in past month	1.94 (0.96, 3.91)	2.10 (1.04, 4.22)
Switching from one method type to another	1.93 (0.78, 4.80)	1.81 (0.73, 4.49)
<i>Reference: Initiating contraception</i>	<i>Ref.</i>	<i>Ref.</i>
<9 years completed education	1.95 (1.17, 3.26)	--
Does not have child aged <6 months	1.54 (0.83, 2.86)	1.48 (0.79, 2.75)
Relationship status		
Partner supportive of FP	3.94 (0.54, 28.76)	--
Not married (legal or presumed)	6.52 (0.86, 49.25)	1.70 (0.97, 3.00)
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	--
Felt provider gave accurate information	2.44 (0.76, 7.87)	--

^a Pills include daily combined and progestin-only oral contraceptives

Notes: Restricted sample of derivation cohort excluded all users of condoms, emergency contraceptive pills, and fertility-based methods, for a total sample size of N=534. Predictors selected using stepwise forwards and backwards to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified model was developed by removing predictors that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities.

Table S3.11: Sensitivity analysis: Incidence rate of discontinuation in the full cohort (n=744), comparing 2 and 4 week intervals of method non-use to define discontinuation

Contraceptive method type	Discontinuation defined as:	
	≥2 weeks of no modern method use	≥4 weeks of no modern method use
	IR (95% CI) per 100 woman-years	IR (95% CI) per 100 woman-years
Contraceptive method type		
Injectables	35.0 (25.6, 48.0)	19.2 (12.6, 29.2)
Implants	26.8 (19.0, 37.9)	11.4 (6.7, 19.2)
Pills ^a	104.2 (59.2, 183.5)	56.5 (26.9, 118.4)
Cu-IUD	41.0 (19.6, 86.1)	22.4 (8.4, 59.6)
Other modern ^b	100.2 (52.1, 192.6)	60.5 (27.2, 134.8)
FP user and contraceptive method type		
<i>Initiating modern contraception</i>		
Injectables	22.0 (13.5, 35.9)	14.8 (8.2, 26.7)
Implants	32.9 (16.4, 65.7)	28.3 (13.5, 59.3)
Pills ^a	16.5 (7.4, 36.7)	5.4 (1.3, 21.4)
Cu-IUD	0.0 (--, --)±	0.0 (--, --)±
Other modern ^b	0.0 (--, --)±	0.0 (--, --)±
Other modern ^b	60.2 (15.1, 240.6)	56.6 (14.2, 226.3)
<i>Switching from one method type to another</i>	34.1 (18.9, 61.5)	14.9 (6.2, 35.8)
Injectables	35.1 (8.8, 140.3)	17.4 (2.4, 123.3)
Implants	30.4 (13.6, 67.6)	9.7 (2.4, 38.7)
Pills ^a	105.3 (26.3, 421.2)	105.3 (26.3, 421.2)
Cu-IUD	0 (--, --)±	0 (--, --)±
Other modern ^b	186.2 (26.2, 1322.0)	0 (--, --)±
<i>Continuing method used in past month</i>	44.1 (35.0, 55.6)	21.8 (15.8, 30.1)
Injectables	35.7 (24.8, 51.4)	16.7 (9.9, 28.1)
Implants	63.2 (20.4, 49.0)	15.4 (8.3, 28.6)
Pills ^a	145.0 (78.0, 269.5)	64.3 (26.8, 154.4)
Cu-IUD	104.2 (49.7, 218.6)	53.0 (19.9, 141.3)
Other modern ^b	117.2 (52.6, 260.8)	73.2 (27.5, 195.0)

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

± Confidence intervals not calculated, due to 0 observed failures in this group.

Notes: IR indicates the incidence rate of method discontinuation. 95% confidence intervals were estimated using Stata's native "stptime" command.

Table S3.12: Sensitivity analysis: predictors of discontinuation in derivation cohort, with discontinuation defined as at least 4 weeks of no method use

	Full List of Predictors HR (95% CI)	Simplified Predictors HR (95% CI)
Contraceptive method type		
Cu-IUD/IUS	1.87 (0.65, 5.38)	1.82 (0.64, 4.22)
Pills ^a	4.03 (1.74, 9.35)	4.25 (1.84, 9.81)
Other modern ^b	5.95 (2.22, 15.91)	4.86 (1.86, 12.70)
<i>Reference: Injectables, implants</i>	<i>Ref.</i>	<i>Ref.</i>
<9 years completed education	1.55 (0.82, 2.93)	--
Does not have child aged <6 months	2.19 (0.96, 4.99)	2.17 (0.96, 4.95)
Relationship status		
Partner supportive of FP	2.16 (0.29, 15.95)	--
Not married (legal or presumed)	4.80 (0.62, 36.91)	2.00 (1.04, 3.86)
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	--
Less than "very satisfied" with FP services received	1.80 (0.92, 3.51)	--

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

Notes: In this analysis, we use an alternative definition of the discontinuation outcome that requires 4 weeks of non-use of any modern method (rather than the 2 week period required in the primary definition). Predictors selected using stepwise forwards and backwards to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified model was developed by removing predictors identified in the full model that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities.

Table S3.13: Sensitivity analysis: predictors of discontinuation in derivation cohort, excluding women who did not receive FP services at enrollment (N=449)

	Full List of Predictors HR (95% CI)	Simplified Predictors HR (95% CI)
Contraceptive method type		
Cu-IUD/IUS	1.40 (0.50, 3.92)	1.39 (0.50, 3.92)
Pills ^a	3.08 (1.50, 6.34)	3.17 (1.54, 6.52)
Other modern ^b	4.89 (2.13, 11.21)	4.38 (1.95, 9.84)
<i>Reference: Injectables, implants</i>	<i>Ref.</i>	<i>Ref.</i>
FP user type		
Continuing method used in past month	2.36 (1.15, 4.87)	2.31 (1.13, 4.71)
Switching from one method type to another	1.78 (0.71, 4.48)	1.85 (0.74, 4.66)
<i>Reference: Initiating contraception</i>	<i>Ref.</i>	<i>Ref.</i>
<9 years completed education	1.74 (1.02, 2.99)	--
Does not have child aged <6 months	1.72 (0.91, 3.26)	1.67 (0.89, 3.13)
Relationship status		
Partner supportive of FP	4.57 (0.63, 33.21)	--
Not married (legal or presumed)	5.51 (0.72, 42.38)	1.30 (0.69, 2.43)
<i>Reference: partner unsupportive/unsure of partner support</i>	<i>Ref.</i>	--
Traveled less than 30 minutes to reach health facility	1.25 (0.74, 2.11)	--
Number of items in Method Information Index received^c	1.16 (0.92, 1.48)	--

^a Pills include daily combined and progestin-only oral contraceptives

^b Other modern methods include condoms, fertility-awareness based methods (LAM, Two Days Method, Standard Days Method), and emergency contraceptive pills

^c The Method Information Index is calculated based on 3 questions: "during your visit: 1) were you informed about other methods?, 2) were you informed about side effects or problems with the method?, 3) were you told what to do if you had side effects of problems with the method?". Responses were summed to provide a count of the number of counseling items received, from 0 (received none of these counseling items) to 3 (received all items).

Notes: In the full analytic cohort, 89/744 (12%) reported the most recent date that they received FP services as more than +/- 1 day of study enrollment. When we exclude these participants in this sensitivity analysis. In this sensitivity analysis, we excluded participants with a reported last FP visit greater than 1 day +/- of enrollment, for a total sample of N=449 in the derivation sample. Predictors selected using stepwise forwards and backwards to identify the Cox model with the minimum AIC value. The Efron approach was used to handle ties. The simplified model was developed by removing predictors identified in the full model that are not routinely collected (either verbally or in written documentation) in Kenyan public health facilities.

Figures

Figure S3.1: ROC curves for LASSO-Cox risk scores in the derivation and validation cohorts

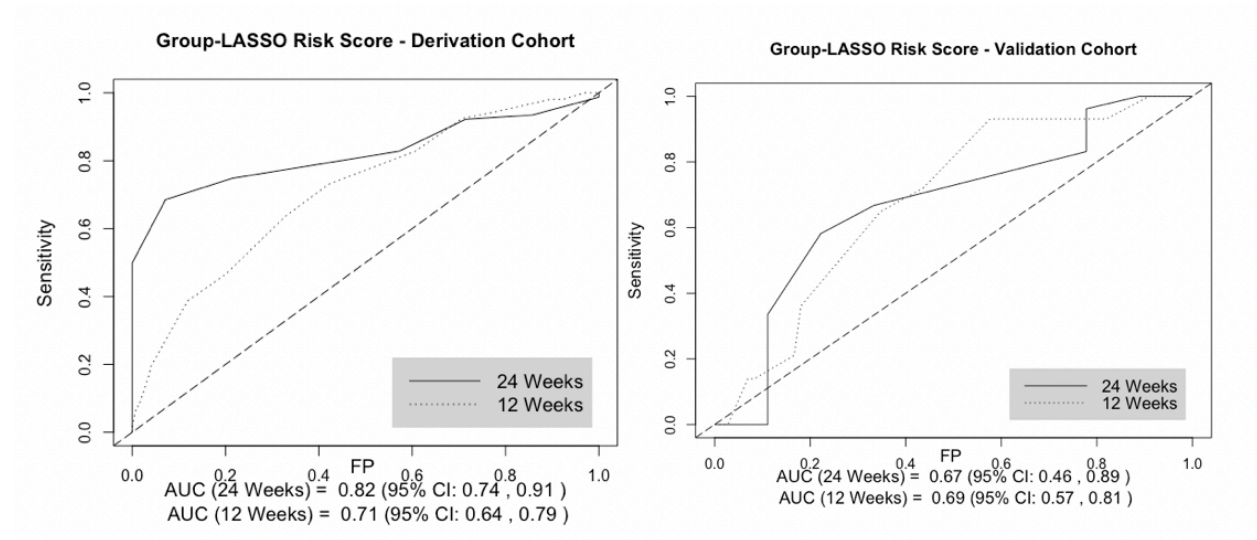


Figure S3.2: ROC curves for full, simplified, and group LASSO risk scores in full cohort

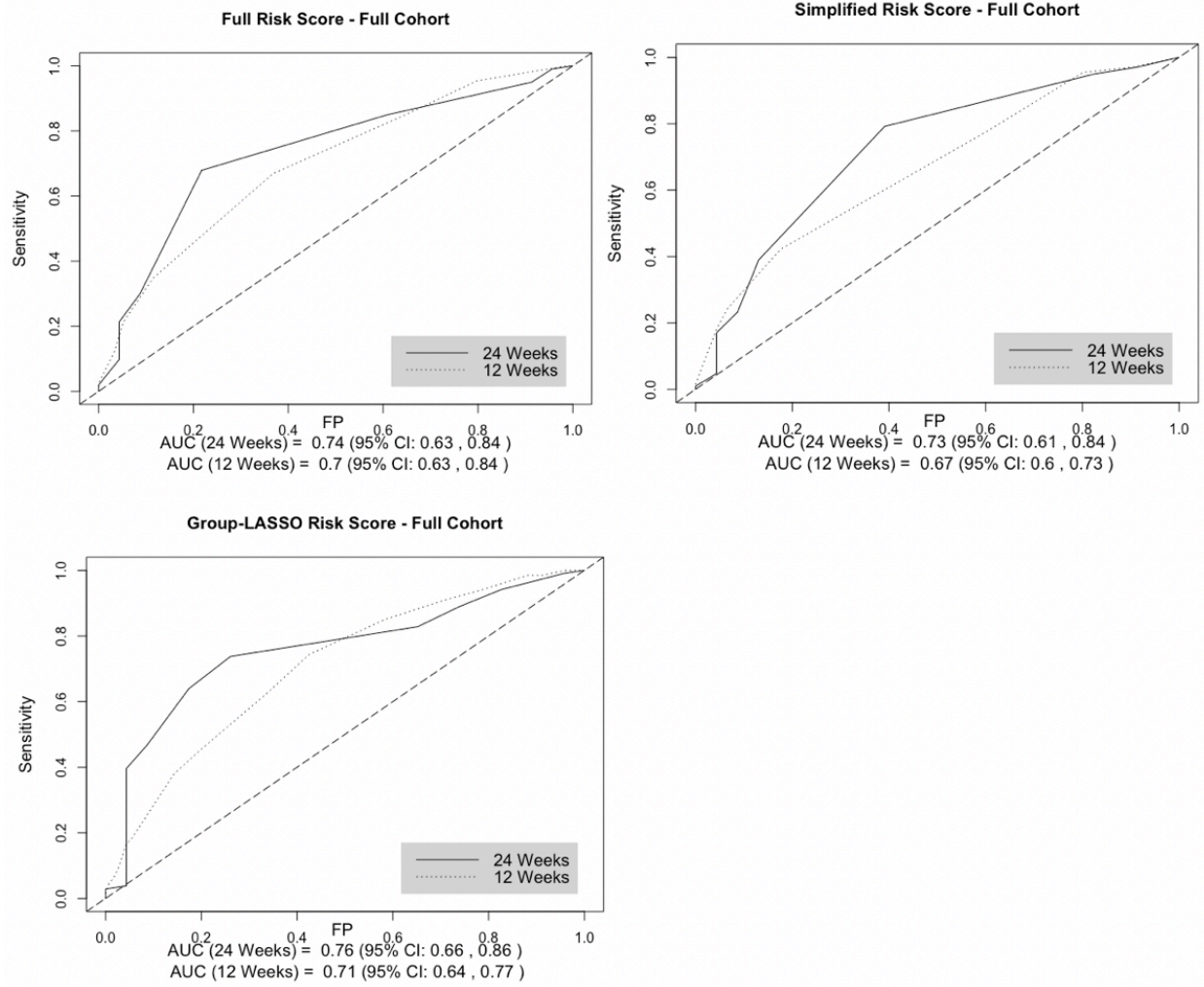


Figure S3.3: Survival probabilities by optimal cut-point of the group-LASSO risk score

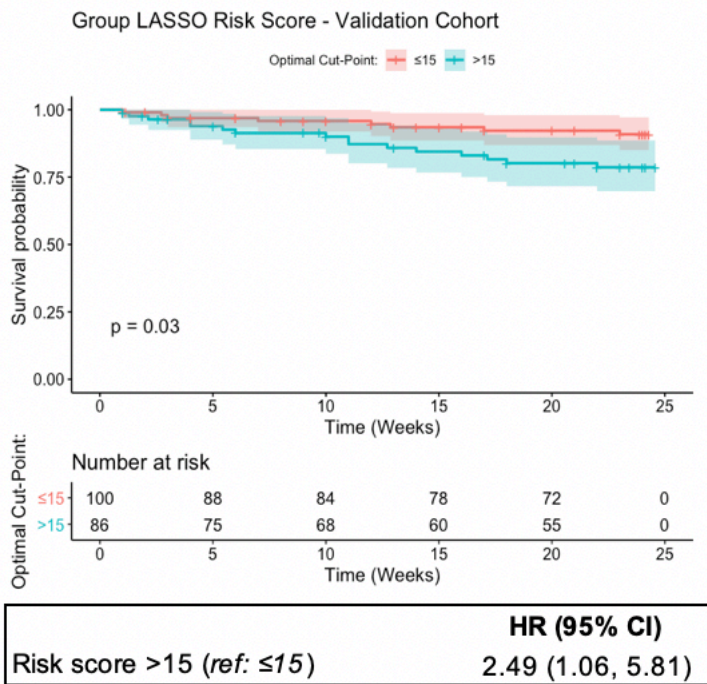
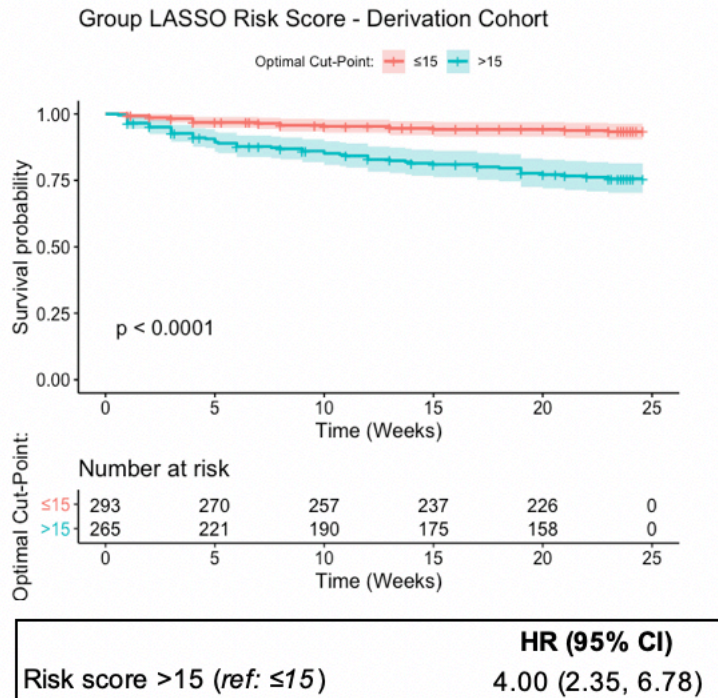
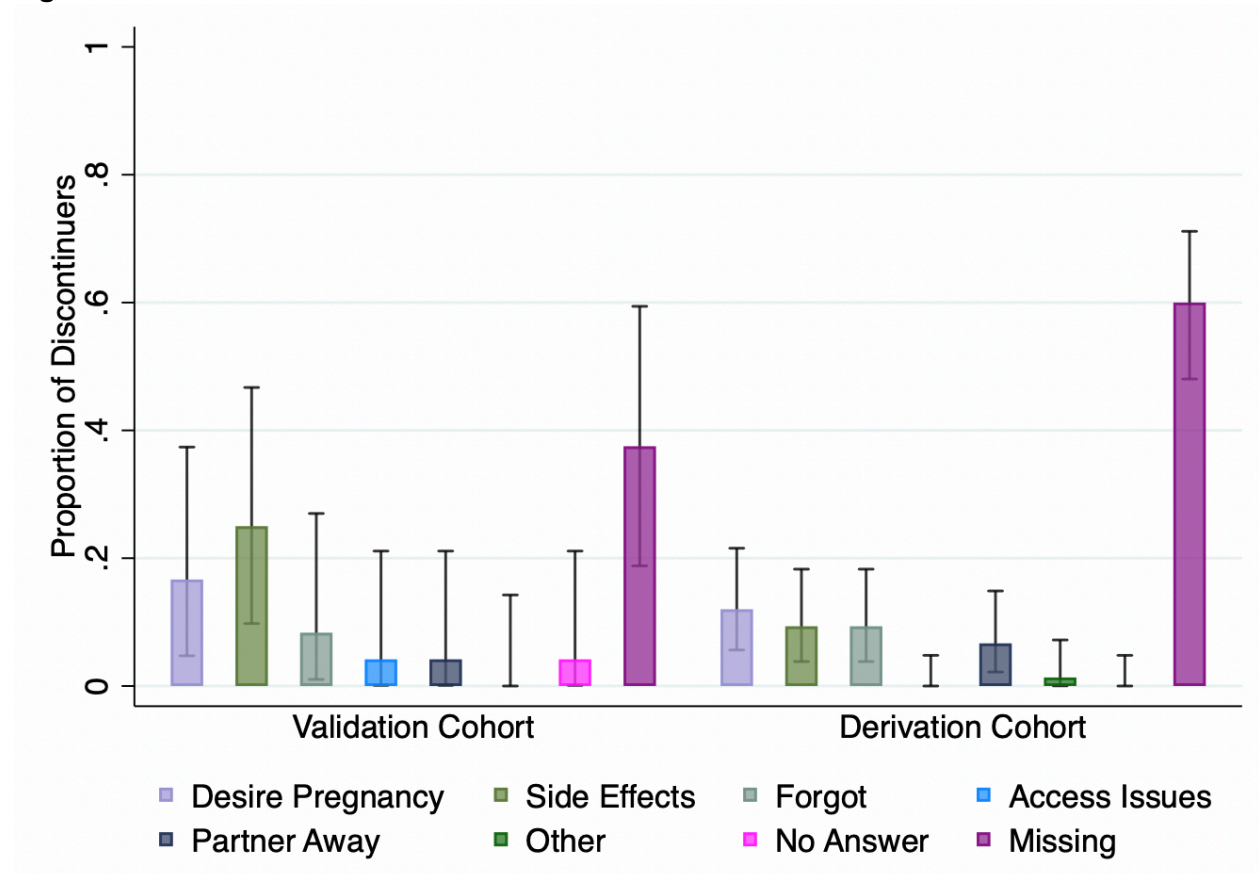


Figure S3.4: Stated reasons for discontinuation



CHAPTER FOUR - Patterns and correlates of contraceptive side effects among Kenyan women: A prospective cohort analysis

S4 Supplementary Material

Table S4.1. Ascertainment of side effects

Side effects symptom category	Relevant question text
Any side effects or problems with method	<p>“In the past week, have you had any side effects or problems using ([CURRENT METHOD] if current user or “family planning” if reported stopping FP use in past week)?”</p> <p><i>Note: Participants who responded yes or not sure to this question were asked about specific symptoms using the questions below.</i></p>
Heavy/prolonged bleeding	<p>“Did you get your monthly periods in the past week?” If YES:</p> <p>“Were your monthly periods heavier than usual in the past week?”</p>
Irregular bleeding	<p>“Did you get your monthly periods in the past week?” If YES:</p> <p>“Have you had more irregular bleeding or spotting than usual the past week?”</p>
Lack of expected bleeding	<p>“Did you get your monthly periods in the past week?” If NO:</p> <p>Were you expecting your monthly periods in the past week?</p>
Abdominal pain, back pain, cramping or painful menses	Have you had more cramping than usual in the past week?
Sexual side effects	<p>Have you had problems with sexual pleasure or desire in the past week?</p> <p>OR</p> <p>Have you had pain during intercourse in the past week?</p>
Weight changes	Have you had weight changes in the past month?
Other side effects (hand coded free text)	“What other side effects or problems have you had in the past week?” [Free text response]

Table S4.2. Survey questions used to construct the Method Information Index

Component	Survey Question Text:		
	Demographic and Health Survey (DHS) 7	Performance Monitoring & Accountability (PMA) Survey	mCUBE Enrollment Survey
1. Informed about other methods	<p>At that time (<i>when you first started using [CURRENT METHOD]</i>): Were you told about other methods of family planning that you could use?</p> <p>OR</p> <p>Were you ever told by a health or family planning worker about other methods of family planning that you could use?</p>	<p>At that time (<i>When you obtained your [CURRENT METHOD]</i>), were you told by the family planning provider about methods of family planning other than [CURRENT METHOD] that you could use?</p>	<p>During your visit (<i>family planning services you received today, or you most recent visit if you did not get family planning services today</i>), were you informed about other methods?</p>
2. Informed about side effects of current method	<p>At that time (<i>when you first started using [CURRENT METHOD]</i>): Were you told about side effects or problems you might have with the method?</p> <p>OR</p> <p>Were you ever told by a health or family planning worker about side effects or problems you might have with the method?</p>	<p>When you obtained your [CURRENT METHOD], were you told by the provider about side effects or problems you might have with a method to delay or avoid pregnancy?</p>	<p>During your visit (<i>family planning services you received today, or you most recent visit if you did not get family planning services today</i>), were you informed about side effects or problems with the method?</p>
3. Informed about what to do if side effects occur	<p>Were you told what to do if you experienced side effects?</p>	<p>Were you told what to do if you experienced side effects or problems?</p>	<p>During your visit (<i>family planning services you received today, or you most recent visit if you did not get family planning services today</i>), were you told what to do if you had side effects or problems with the method?</p>

Table S4.3. Adjustment variables included in correlates analyses

Independent variable	Adjustment variables
Age category	--
Marital status	Age category
Household income quartile, <6 months since most recent pregnancy Currently breastfeeding No living children	Age category, marital status
Fertility intentions Attitudes towards near-future pregnancy Spousal support for contraceptive use	Age category, marital status, <6 months since most recent pregnancy, number of living children
FP user type	Age category, marital status, <6 months since most recent pregnancy, method type*
Method type	Age category, marital status, <6 months since most recent pregnancy, FP user type
History of side effects§	Age category, marital status, <6 months since most recent pregnancy, method type
Fear of contraceptive side effects All needs were met Time spent with provider Privacy Satisfaction Respectful treatment by provider MII	Age category, marital status, <6 months since most recent pregnancy, method type, FP user type

* While contraceptive method type used at enrollment is hypothesized to be "downstream" or on the causal pathway from FP user type to contraceptive side effects, we are primarily interested in assessing an association that is not mediated by method type and therefore adjust for method type.

§ Although our causal diagram indicates adjustment for FP user type, we do not do so due to collinearity.

Table S4.4. Prevalence of side effects, by contraceptive method type

	Implant	Cu-IUD	Injectable	OCP	All Methods
	Mean Weekly Prevalence (95% CI)				
Any side effects or method problems	0.24 (0.21-0.27)	0.23 (0.17-0.31)	0.26 (0.22-0.29)	0.17 (0.11-0.26)	0.24 (0.22-0.26)
Heavy/prolonged bleeding	0.08 (0.06-0.10)	0.12 (0.08-0.19)	0.06 (0.05-0.08)	0.05 (0.02-0.14)	0.07 (0.06-0.09)
Irregular bleeding	0.09 (0.07-0.11)	0.10 (0.06-0.16)	0.07 (0.06-0.09)	0.05 (0.02-0.15)	0.08 (0.07-0.10)
Lack of expected bleeding	0.07 (0.06-0.09)	0.03 (0.01-0.06)	0.09 (0.07-0.11)	0.03 (0.02-0.07)	0.07 (0.06-0.08)
Cramping or abdominal/back pain	0.12 (0.10-0.14)	0.13 (0.09-0.19)	0.13 (0.11-0.16)	0.08 (0.04-0.16)	0.12 (0.11-0.14)
Sexual side effects	0.14 (0.12-0.17)	0.14 (0.09-0.21)	0.16 (0.13-0.19)	0.08 (0.05-0.15)	0.15 (0.13-0.16)
Weight changes*	0.12 (0.10-0.14)	0.13 (0.08-0.21)	0.15 (0.13-0.18)	0.09 (0.05-0.15)	0.13 (0.12-0.15)

Notes: Unadjusted weekly prevalences and 95% confidence intervals calculated within subgroups of users of each method type using log-binomial GEE models with an independent working correlation structure and robust standard errors.

Table S4.5. Temporal trends in prevalence of specific types of side effects, by contraceptive user type at study enrollment

	Linear time trend					
	Initiator		Switcher		Continuer	
	PR	p-value	PR	p-value	PR	p-value
Any side effects or method problems	0.99	0.11	0.98	0.03	0.97	<0.001
Heavy/prolonged bleeding	0.97	0.07	0.97	0.01	0.98	0.008
Irregular bleeding	0.98	0.25	0.97	0.02	0.97	<0.001
Lack of expected bleeding	1.01	0.50	1.01	0.46	0.98	0.03
Cramping, abdominal/back pain	0.98	0.14	0.98	0.12	0.97	<0.001
Sexual side effects	0.99	0.56	0.97	0.01	0.96	<0.001
Weight changes	1.00	0.75	0.99	0.47	0.98	0.001
Number of unique participants	177-180		90-91		448-451	

PR = prevalence ratio

Notes: Unadjusted weekly prevalences and 95% confidence intervals calculated within subgroups defined by FP user type (initiating contraception, switching from one modern method to another, or continuing use of a method at enrollment) using log-binomial GEE models with a linear term for time (weeks since enrollment in study [1-24]) with an independent working correlation structure and robust standard errors.

Table S4.6. Correlates of contraceptive side effects or method-related problems, stratified by FP user type

FP user type at study enrollment:	Initiating contraception or switching method type			Continuing method used in past month		
	N§	aPR	p-value	N§	aPR	p-value
<i>Sociodemographic and health characteristics</i>						
<i>Age</i>						
<25	267	<i>Ref.</i>		441	<i>Ref.</i>	
25-34		1.19	0.241		1.04	0.749
>34		0.89	0.694		0.69	0.056
Married (legal or presumed)	267	1.45	0.042	438	0.99	0.950
<i>Household income quartile</i>						
Fourth	267	<i>Ref.</i>		438	<i>Ref.</i>	
Third		1.04	0.835		1.06	0.721
Second		0.90	0.646		1.18	0.212
First		0.96	0.809		1.06	0.757
No living children	263	1.44	0.072	427	1.49	0.097
<6 months since most recent pregnancy	265	0.83	0.221	431	1.12	0.421
Currently breastfeeding	262	0.84	0.258	426	1.05	0.712
<i>Contraceptive characteristics and fertility intentions</i>						
<i>Method type†</i>						
Implant	265	<i>Ref.</i>		431	<i>Ref.</i>	
Cu-IUD		1.19	0.406		0.85	0.544
Injectable		1.10	0.553		1.08	0.552
OCP		0.68	0.228		0.78	0.423
<i>History of contraceptive side effects</i>						
No	254	<i>Ref.</i>		386	<i>Ref.</i>	
Yes		1.10	0.685		2.03	<0.001*
FP naïve		0.98	0.929		--	
Fear of contraceptive side effects	249	1.58	0.004	419	1.25	0.070
<i>Fertility intentions</i>						
Wants no children in future	259	<i>Ref.</i>		423	<i>Ref.</i>	
Not sure if wants children in future		0.96	0.903		1.09	0.699
Desires pregnancy, unsure when		0.42	0.009		0.63	0.033
Desires pregnancy in <1 year		1.26	0.520		0.66	0.109
Desires pregnancy in 1-2 years		0.71	0.322		1.20	0.357
Desires pregnancy in >2 years		0.89	0.673		0.88	0.434

Becoming pregnant in the near future would be a:

Big problem	259	Ref.		423	Ref.	
Small problem		0.90	0.692		1.26	0.311
No problem		0.65	0.051		1.01	0.933
Not sure		1.16	0.484		1.01	0.946
Spousal support for contraceptive use‡	204	0.88	0.581	363	0.96	0.854

Perceived quality of most recent FP care

"Strongly agree" that all FP needs were met	258	0.96	0.783	422	0.82	0.090
"Right amount of time" spent with provider	257	0.89	0.573	425	0.70	0.003*
Privacy protected	258	1.16	0.634	425	0.99	0.960
Very satisfied	259	0.94	0.693	425	0.79	0.048
Treated "very respectfully"	258	1.19	0.552	424	0.80	0.157
Received all components of the Method Information Index	256	0.79	0.118	417	1.00	0.999

Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

* indicates statistical significance based on threshold values using the Benjamini-Hochberg method and a false discovery rate of 0.05

§ Sample size indicates number of distinct participants included in analysis, rather than number of weekly observations

† Method type indicates primary method used at study enrollment.

‡ Among married (legal or presumed) women only

Notes: Adjusted prevalence ratios (aPR) and 95% confidence intervals estimated using separate log-binomial GEE models for each independent variable of interest within subgroups defined by FP user type (initiator/switcher or continuer). GEE models were fit with an independent working correlation structure that accounts for clustering at the individual-level and robust standard errors. All models are restricted to women using implants, injectables, IUD or OCP at baseline. We report conventional p-values, but asterisks indicate Benjamini-Hochberg adjusted p-values accounting for a false discovery rate of 0.05. Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status (with the exception of spousal support, which was estimated among married women only), age category, early postpartum status, and number of living children. The model for method type was adjusted by age category, marital status, and early postpartum status. Remaining models (of contraceptive history and quality and satisfaction indicators) were adjusted by age category, marital and postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type.

Table S4.7. Correlates of contraceptive side effects or method-related problems, with adjustment for enrollment facility

	N§	Any Side Effects or Problems with Contraceptive Method	
		aPR	p-value
<i>Sociodemographic and health characteristics</i>			
<i>Age</i>			
<25		<i>Ref.</i>	
25-34	713	1.08	0.408
>34		0.73	0.056
Married (legal or presumed)	710	1.14	0.278
<i>Household income quartile</i>			
Fourth		<i>Ref.</i>	
Third	710	1.06	0.679
Second		0.88	0.454
First		0.96	0.759
No living children	695	1.37	0.048
<6 months since most recent pregnancy	701	0.96	0.710
Currently breastfeeding	693	0.96	0.713
<i>Contraceptive characteristics and fertility intentions</i>			
<i>Method type†</i>			
Implant		<i>Ref.</i>	
Cu-IUD	696	1.03	0.869
Injectable		1.08	0.459
OCP		0.75	0.248
<i>FP user type</i>			
Initiating		<i>Ref.</i>	
Switching	696	1.11	0.530
Continuing		0.92	0.494
<i>History of contraceptive side effects</i>			
No		<i>Ref.</i>	
Yes	644	1.64	<0.001*
FP naïve		1.42	0.027
Fear of contraceptive side effects	668	1.29	0.029
<i>Fertility intentions</i>			
Wants no children in future		<i>Ref.</i>	
Not sure if wants children in future		1.01	0.967
Desires pregnancy, unsure when	687	0.53	<0.001*
Desires pregnancy in <1 year		0.90	0.628
Desires pregnancy in 1-2 years		0.96	0.795
Desires pregnancy in >2 years		0.86	0.248
<i>Becoming pregnant in the near future would be a:</i>			

Big problem		<i>Ref.</i>	
Small problem	687	1.00	0.991
No problem		0.74	0.020
Not sure		0.89	0.462
Spousal support for contraceptive use‡	569	0.90	0.510
Perceived quality of most recent FP care			
"Strongly agree" that all FP needs were met	680	0.86	0.175
"Right amount of time" spent with provider	682	0.76	0.086
Privacy protected	683	1.14	0.464
Very satisfied	684	0.85	0.153
Treated "very respectfully"	681	0.96	0.801
Received all components of the Method Information Index	672	0.98	0.883

Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

* indicates statistical significance based on threshold values using the Benjamini-Hochberg method and a false discovery rate of 0.05

§ Sample size indicates number of distinct participants included in analysis, rather than number of weekly observations

† Method type indicates primary method used at study enrollment.

‡ Among married (legal or presumed) women only

Notes: Adjusted prevalence ratios (aPR) and 95% confidence intervals estimated using separate log-binomial GEE models for each independent variable of interest. GEE models were fit with an independent working correlation structure that accounts for clustering at the individual-level and robust standard errors. All models are restricted to women using implants, injectables, IUD or OCP at baseline. We report conventional p-values, but asterisks indicate Benjamini-Hochberg adjusted p-values accounting for a false discovery rate of 0.05. Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status (with the exception of spousal support, which was estimated among married women only), age category, early postpartum status, and number of living children. The model for method type was adjusted by age category, marital status, and early postpartum status. Remaining models (of contraceptive history and quality and satisfaction indicators) were adjusted by age category, marital and postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type. All models additionally adjusted for enrollment facility (coded as dummy variables equal to the 10 health facility enrollment sites or using a dummy variable to indicate missing facility site).

Table S4.8. Sensitivity analysis: Correlates of any side effects or method problems using Poisson models

	Any Side Effects or Problems with Contraceptive Method	
	aPR	p-value
<i>Sociodemographic and health characteristics</i>		
<i>Age</i>		
<25	<i>Ref.</i>	
25-34	1.10	0.320
>34	0.74	0.065
Married (legal or presumed)	1.17	0.185
<i>Household income quartile</i>		
Fourth	<i>Ref.</i>	
Third	1.06	0.625
Second	1.10	0.407
First	1.03	0.801
No living children	1.36	0.046
<6 months since most recent pregnancy	0.98	0.826
Currently breastfeeding	0.97	0.744
<i>Contraceptive characteristics and fertility intentions</i>		
<i>Method type†</i>		
Implant	<i>Ref.</i>	
Cu-IUD	1.04	0.831
Injectable	1.08	0.417
OCP	0.74	0.215
<i>FP user type</i>		
Initiating	<i>Ref.</i>	
Switching	1.12	0.481
Continuing	0.97	0.779
<i>History of contraceptive side effects</i>		
No	<i>Ref.</i>	
Yes	1.72	<0.001*
FP naïve	1.38	0.043
Fear of contraceptive side effects	1.36	0.002*
<i>Fertility intentions</i>		
Wants no children in future	<i>Ref.</i>	
Not sure if wants children in future	1.03	0.888
Desires pregnancy, unsure when	0.53	0.001*
Desires pregnancy in <1 year	0.90	0.639
Desires pregnancy in 1-2 years	0.99	0.976
Desires pregnancy in >2 years	0.86	0.250
<i>Becoming pregnant in the near future would be a:</i>		
Big problem	<i>Ref.</i>	

Small problem	1.05	0.796
No problem	0.89	0.292
Not sure	1.03	0.827
Spousal support for contraceptive use‡	0.90	0.523
Perceived quality of most recent FP care		
"Strongly agree" that all FP needs were met	0.87	0.136
"Right amount of time" spent with provider	0.75	0.007
Privacy protected	1.04	0.826
Very satisfied	0.85	0.083
Treated "very respectfully" by provider	0.90	0.462
Received all components of the Method Information Index	0.91	0.330

Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

* indicates statistical significance based on threshold values using the Benjamini-Hochberg method and a false discovery rate of 0.05

§ Sample size indicates number of distinct participants included in analysis, rather than number of weekly observations

† Method type indicates primary method used at study enrollment.

‡ Among married (legal or presumed) women only

Notes: Adjusted prevalence ratios (aPR) and 95% confidence intervals estimated using separate Poisson models for each independent variable of interest. Poisson models were fit at the participant-level, with the outcome equal to the a count of the number of times side effects were reported over follow-up and an offset equal to the log number of follow-up surveys with a complete response (neither missing or "not sure") for side effects experience. All models are restricted to women using implants, injectables, IUD or OCP at baseline. We report conventional p-values, but asterisks indicate Benjamini-Hochberg adjusted p-values accounting for a false discovery rate of 0.05. Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status (with the exception of spousal support, which was estimated among married women only), age category, early postpartum status, and number of living children. The model for method type was adjusted by age category, marital status, and early postpartum status. Remaining models (of contraceptive history and quality and satisfaction indicators) were adjusted by age category, marital and postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type.

Table S4.9. Correlates of specific contraceptive side effects

	Heavy/ prolonged bleeding		Irregular bleeding		Lack of expected bleeding		Cramping or abdominal/ back pain		Sexual side effects		Weight changes	
	aRR	p-value	aRR	p-value	aRR	p-value	aRR	p-value	aRR	p-value	aRR	p-value
Sociodemographic and health characteristics												
<i>Age</i>												
<25	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
25-34	1.05	0.761	1.16	0.370	1.11	0.506	1.15	0.302	1.03	0.814	1.15	0.309
>34	0.67	0.121	0.69	0.183	0.64	0.157	0.82	0.337	0.54	0.009	0.70	0.077
Married (legal or presumed)	0.75	0.159	0.72	0.091	2.51	<0.001*	1.12	0.507	1.23	0.195	1.50	0.017
<i>Household income quartile</i>												
Fourth	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Third	1.56	0.068	1.63	0.016	0.90	0.639	1.26	0.190	1.16	0.404	1.19	0.358
Second	1.44	0.255	1.20	0.529	0.98	0.931	1.01	0.974	0.98	0.943	1.18	0.498
First	1.45	0.129	1.44	0.069	0.90	0.607	1.42	0.034	1.28	0.133	1.12	0.520
No living children	1.49	0.097	1.69	0.024	1.69	0.065	1.46	0.098	1.32	0.151	1.45	0.123
<6 months since most recent pregnancy	0.73	0.092	0.78	0.131	1.07	0.698	0.90	0.468	0.97	0.849	0.94	0.649
Currently breastfeeding	0.74	0.076	0.77	0.092	1.01	0.946	0.89	0.378	0.96	0.740	0.93	0.619
Contraceptive characteristics and fertility intentions												
<i>Method type†</i>												
Implant	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Cu-IUD	1.77	0.028	1.20	0.513	0.39	0.027	1.12	0.623	1.10	0.678	1.19	0.505
Injectable	0.80	0.221	0.85	0.335	1.34	0.071	1.11	0.461	1.11	0.419	1.28	0.079
OCP	0.71	0.525	0.53	0.332	0.59	0.157	0.72	0.353	0.69	0.188	0.84	0.531
<i>FP user type</i>												

Initiating	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Switching	1.51	0.128	1.29	0.333	0.90	0.657	1.25	0.351	1.16	0.465	0.93	0.754
Continuing	1.17	0.473	1.02	0.932	0.82	0.295	1.11	0.562	1.12	0.499	0.96	0.823
History of contraceptive side effects												
No	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Yes	1.98	0.001*	2.28	<0.001*	1.88	0.002*	1.84	0.001*	1.98	<0.001*	1.98	<0.001*
FP naïve	1.32	0.348	1.50	0.149	1.62	0.075	1.18	0.497	1.15	0.541	1.61	0.052
Fear of contraceptive side effects	1.46	0.039	1.32	0.105	1.49	0.018	1.43	0.015	1.38	0.020	1.44	0.011
<i>Fertility intentions</i>												
Wants no children in future	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Not sure if wants children in future	1.08	0.802	1.19	0.552	1.07	0.824	1.24	0.426	1.09	0.736	1.14	0.644
Desires pregnancy, unsure when	0.54	0.049	0.58	0.086	0.68	0.271	0.49	0.003*	0.57	0.035	0.65	0.118
Desires pregnancy in <1 year	1.16	0.713	1.21	0.652	0.88	0.708	1.15	0.673	1.12	0.713	1.34	0.325
Desires pregnancy in 1-2 years	0.80	0.433	1.07	0.784	1.29	0.420	1.16	0.543	1.36	0.176	1.34	0.252
Desires pregnancy in >2 years	0.67	0.043	0.86	0.464	1.03	0.914	0.86	0.442	0.97	0.869	1.07	0.735
<i>Becoming pregnant in the near future would be a:</i>												
Big problem	<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>		<i>Ref.</i>	
Small problem	1.03	0.910	0.99	0.961	1.36	0.319	1.10	0.676	1.09	0.711	0.95	0.852
No problem	0.62	0.018	0.75	0.123	1.04	0.858	1.00	0.997	1.06	0.691	0.94	0.741
Not sure	1.13	0.606	1.13	0.616	0.86	0.498	0.95	0.799	1.13	0.521	0.99	0.950
Spousal support for contraceptive use‡	0.58	0.022	0.57	0.028	1.10	0.743	0.79	0.288	0.84	0.388	0.93	0.753
Perceived quality of most recent FP care												
"Strongly agree" that all FP needs were met	0.92	0.622	0.78	0.099	1.00	0.979	0.68	0.004*	0.77	0.032	0.88	0.366

"Right amount of time" spent with provider	0.90	0.567	0.82	0.235	0.70	0.037	0.61	0.001*	0.58	<0.001*	0.66	0.004*
Privacy protected	1.91	0.059	1.61	0.167	0.98	0.937	1.16	0.547	0.95	0.821	1.04	0.877
Very satisfied	0.80	0.164	0.71	0.032	0.94	0.694	0.74	0.023	0.70	0.004*	0.68	0.004*
Treated "very respectfully"	1.22	0.391	1.03	0.890	0.82	0.380	0.88	0.529	0.76	0.139	0.99	0.956
Received all components of the Method Information Index	1.05	0.789	1.00	0.976	0.82	0.223	0.78	0.075	0.79	0.076	1.04	0.744

Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

* indicates statistical significance based on threshold values using the Benjamini-Hochberg method and a false discovery rate of 0.05

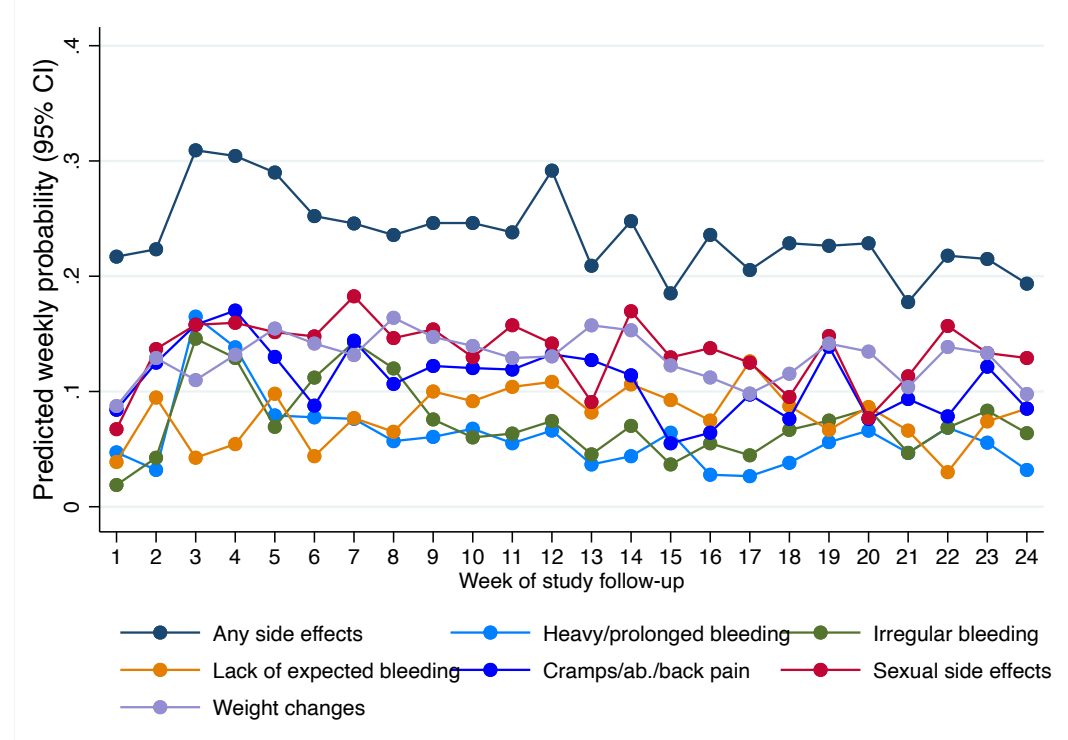
§ Sample size indicates number of distinct participants included in analysis, rather than number of weekly observations

† Method type indicates primary method used at study enrollment.

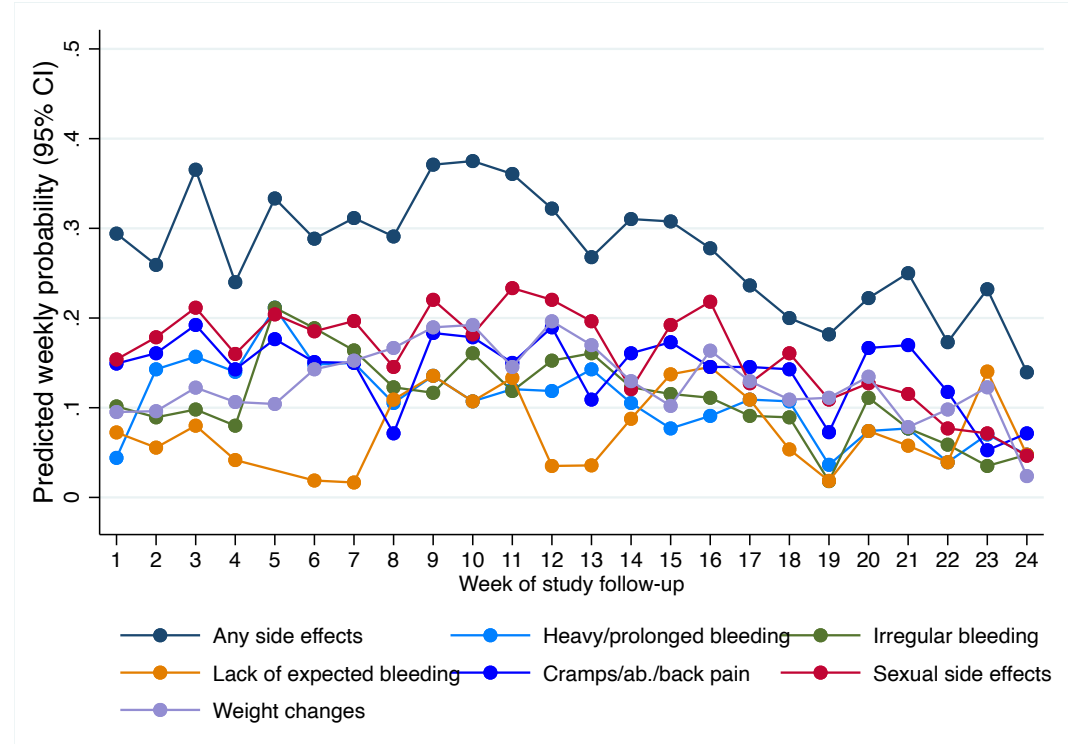
‡ Among married (legal or presumed) women only

Notes: Adjusted prevalence ratios (aPR) and 95% confidence intervals estimated using separate log-binomial GEE models for each independent variable and side effects outcome of interest. GEE models were fit with an independent working correlation structure that accounts for clustering at the individual-level and robust standard errors. All models are restricted to women using implants, injectables, IUD or OCP at baseline. We report conventional p-values, but asterisks indicate Benjamini-Hochberg adjusted p-values accounting for a false discovery rate of 0.05. Models of sociodemographic and health characteristics were adjusted by age category and marital status (with the exception of the model with age, which was otherwise unadjusted). Models of fertility preferences, strength of desire to avoid pregnancy and spousal support were adjusted by marital status (with the exception of spousal support, which was estimated among married women only), age category, early postpartum status, and number of living children. The model for method type was adjusted by age category, marital status, and early postpartum status. Remaining models (of contraceptive history and quality and satisfaction indicators) were adjusted by age category, marital and postpartum status, method type, and FP user type. Due to collinearity, we did not adjust the model for prior side effects by FP user type.

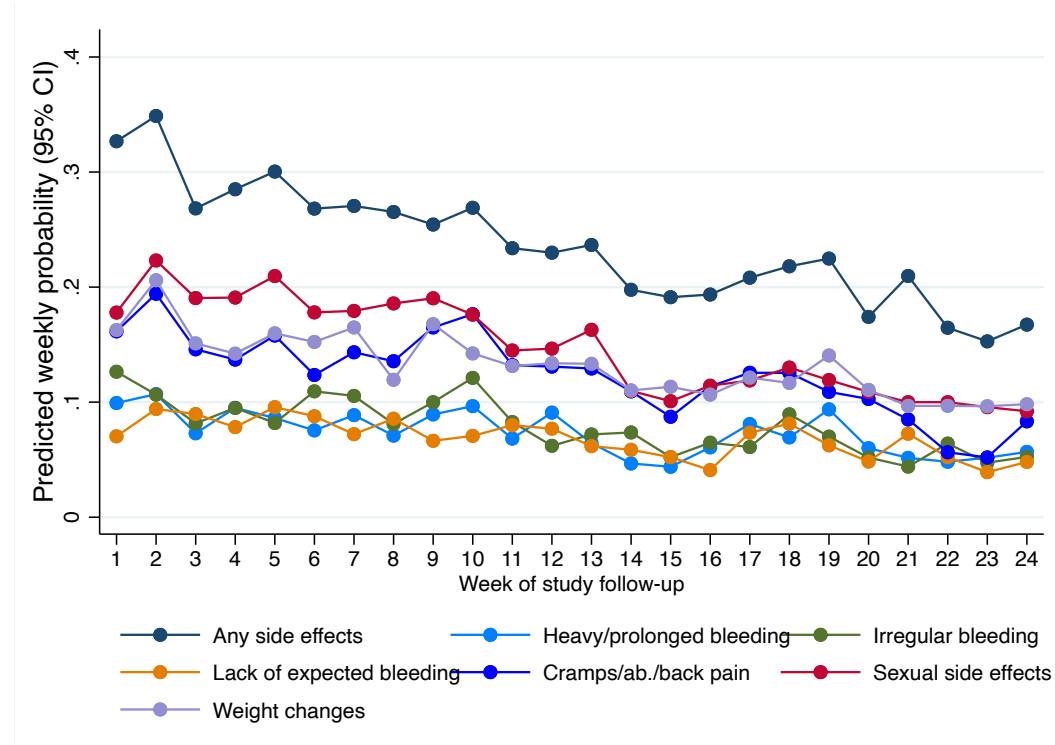
Figure S4.2. Weekly probability of side effects by FP user type at enrollment
 Panel A. Baseline "initiators"



Panel B. Baseline "switchers"



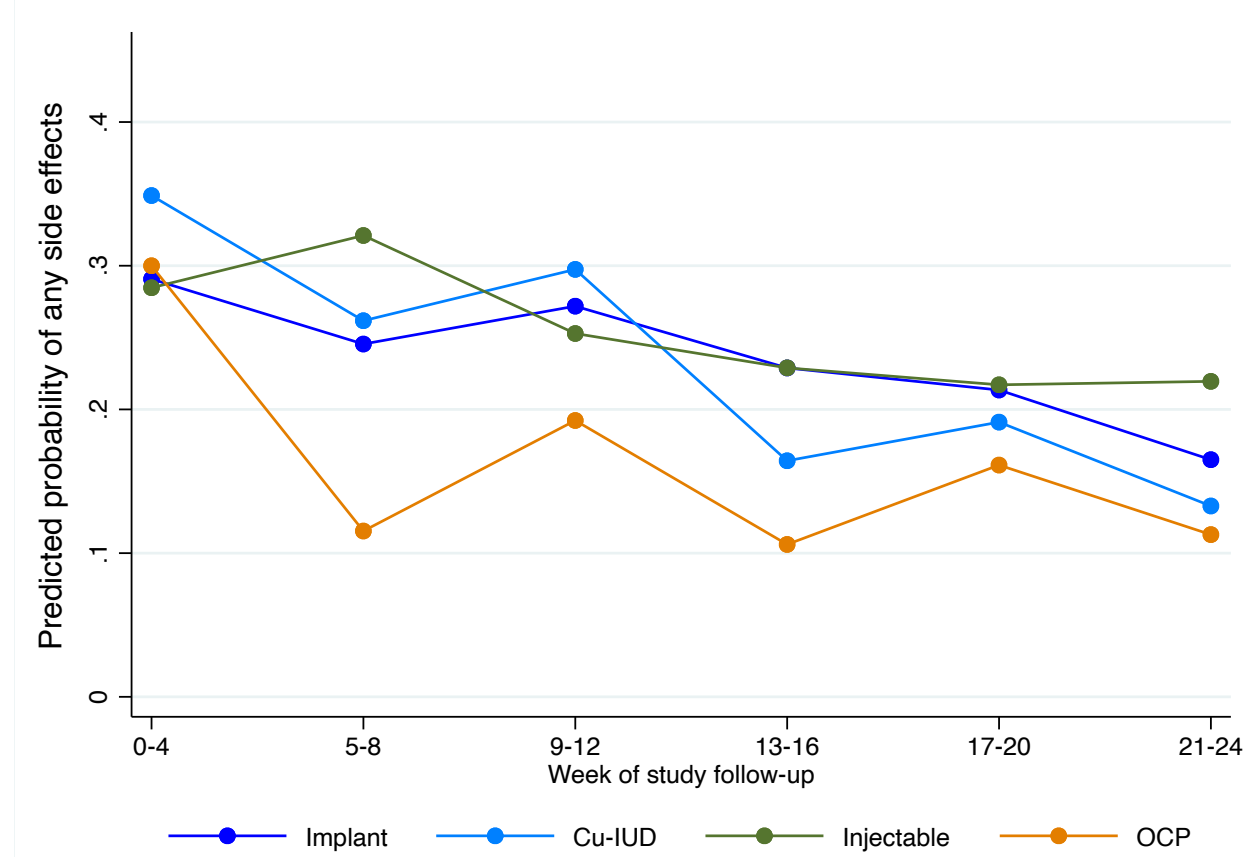
Panel C. Baseline “continuers”



*Weight changes were reported as occurring in the past month; all other side effects were reported for the past week.

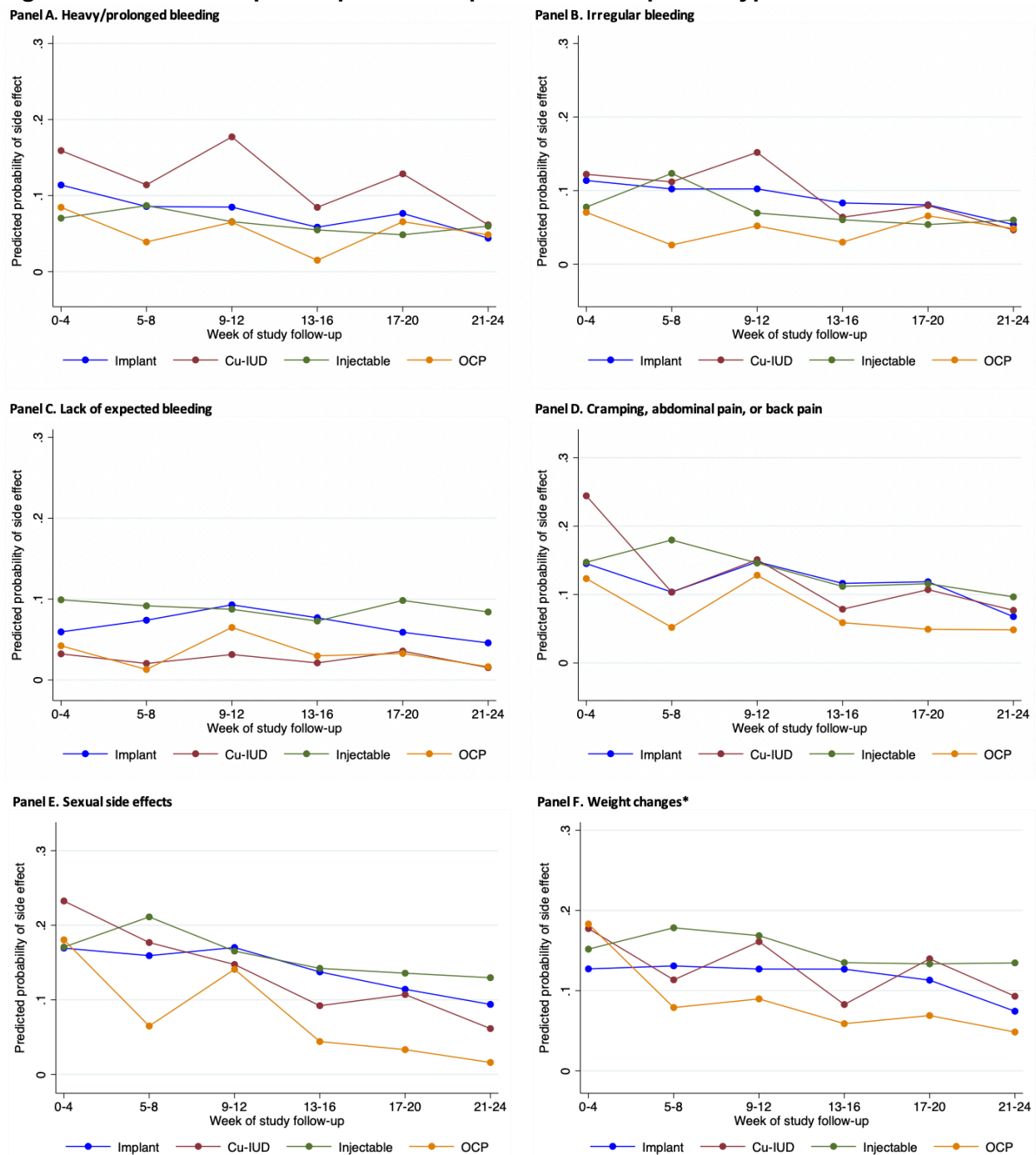
Notes: Mean prevalence (or probability) of any side effects or method problems was estimated in 4-week-long intervals of time since study enrollment. Prevalence estimates were generated using a log-binomial GEE model with an independent correlation structure and robust standard errors, with the dependent variable equal to weekly report of side effects (any or specific type) and dummy variables indicating week since study enrollment. The model was otherwise unadjusted.

Figure S4.3. Method-specific patterns in prevalence of any side effects or method problems



Notes: Mean prevalence (or probability) of any side effects or method problems was estimated in 4-week-long intervals of time since study enrollment. Prevalence estimates were generated using a log-binomial GEE model with an independent correlation structure and robust standard errors, with the dependent variable equal to weekly report of any side effects or method problems and the following independent variables: a dummy variable indicating the 4-week-period since study follow-up (1-6), an indicator for method type, and an interaction term between the time and method type variables. The model was otherwise unadjusted.

Figure S4.4. Method-specific patterns in prevalence of specific types of side effects



Cu-IUD = copper intrauterine device; OCP = oral contraceptive pills

Notes: Mean prevalence (or probability) of any side effects or method problems was estimated in 4-week-long intervals of time since study enrollment. Prevalence estimates were generated using separate log-binomial GEE models for each specific side effect with an independent correlation structure and robust standard errors and the following independent variables: a dummy variable indicating the 4-week-period since study follow-up (1-6), an indicator for method type, and an interaction term between the time and method type variables. Models were otherwise unadjusted.