CONTRACEPTIVE CONTINUATION IN KENYA

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ABSTRACT HOLLY MCCLAIN BURKE: CONTRACEPTIVE CONTINUATION IN KENYA (Under the direction of Carolyn Tucker Halpern)

Contraceptive discontinuation is high in Kenya—a quarter of family planning (FP) users discontinue within 12 months, despite having FP needs. The purpose of this dissertation was to provide the foundation for interpretation of the findings of a four-year, quasi-experimental intervention study being conducted to encourage the continued use of contraceptives by developing, implementing and evaluating a communication campaign intended to increase continuation rates among contraceptive injectable users in Nyando District, Kenya. The pre-intervention research in this dissertation is presented in two papers.

For the first paper, fourteen focus group discussion (FGDs) were conducted in Nyando District among current contraceptive injectable users and their salient references, people who influence women's use and discontinuation of contraception. The purpose of the FGDs was to understand why women discontinue using contraceptives. For the second paper, continuation rates were measured in two districts in western Kenya before implementing a campaign to increase contraceptive continuation. Prospective data were collected over 9-months to: (a) describe factors which predict occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users, and (b) determine if rates and predictors of discontinuation differ between districts. The second study incorporated novel time-dependent attitudinal and motivational factors.

In the first paper, discontinuation occurred for logistical, social and medical reasons. Common reasons for discontinuation included side effects, husbands' opposition, provider and/or clinic restrictions, misconceptions about injectables, stock outs, and lack of cash to purchase contraceptives or pay for FP services.

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The following factors predicted discontinuation in the second paper: side effects or health concerns, nervousness about using contraception, no previous use of modern FP, unmarried at study enrollment, preferring more privacy during FP appointment, and paying more for FP services. Associations between predictors and discontinuation differed between the districts, as did rates of discontinuation.

The findings from both papers highlight the importance of side effects and health concerns on premature discontinuation of contraception suggesting that FP services more strongly address these topics. Both studies also indicate that interventions aimed at increasing continuation be tailored to address community-specific concerns. Results are used to suggest intervention points for increasing continuation of FP in western Kenya.

To the memory of my father

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CHAPTER 1. Introduction

Family planning campaigns have historically and successfully targeted women not using contraception with messages describing the advantages of preventing unwanted pregnancies and method-specific information. While these campaigns are warranted, we appear to have forgotten about women after they agree to adopt a method. For contraceptive methods to work effectively women must continue using the method over time. Four categories of method discontinuation are: method failure, switching, abandonment by users not in need (due to desire for pregnancy or reduced risk of pregnancy), and abandonment by users in need (i.e., those at risk of unintended pregnancy). It is this last type, abandonment of users in need, which is the focus of this dissertation.

Discontinuation may lead to unintended pregnancy and the multitude of health, economic and social consequences that it entails. The true public health impact of contraception (improved maternal and infant health, quality of life and economic well-being) will not be realized until all women who want to prevent pregnancies are using their method of choice continuously and effectively.

Despite increases in contraceptive prevalence over the past decades, discontinuation rates are high among women in the developing world. According to the 2003 Kenya Demographic and Health Survey (DHS), 33% of married women were using a modern method, but 25% of all contraception users discontinued within 12 months of beginning use, despite still being in need of family planning (*not* due to desire for pregnancy or reduced risk of pregnancy).

Interventions focused on increasing continuation rates are sparse. As a starting point, it is logical to look at interventions that have increased contraception adoption.

Communication campaigns have been successful in increasing contraceptive adoption around the world, including Kenya. A campaign to increase contraceptive continuation in Kenya may serve as a model for other African countries. In response to the need for effective interventions to increase continuation, a four-year prospective, quasi-experimental study is being conducted that is developing, implementing and evaluating a communication campaign intended to increase continuation rates among contraceptive injectable users in Nyando District, Kenya. This dissertation focuses on the developmental work and baseline information that is needed to interpret the findings from the evaluation of the intervention study (expected in 2010).

This dissertation uses data from the pre-intervention study to address the following specific aims:

 Using qualitative methods, to identify reasons why women in Nyando District Kenya discontinue using contraceptive injectables as seen from the perspectives of current users and their salient referents;

(2) To describe the factors which predict the occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users still in need of family planning in the treatment (Nyando District) and comparison (Mumias District) sites before implementation of the communication campaign; and

(3) To determine if the rates and predictors of discontinuation differ between the study districts before implementation of the communication campaign.

The achievement of these aims will advance our understanding of contraceptive continuation behavior in western Kenya, which can be used to inform interventions designed to increase continuation rates in the region. This dissertation will also contribute valuable information to guide interpretation and recommendations generated from evaluation of the intervention.

Background

Discontinuation may lead to unintended pregnancy

Unintended pregnancy is defined as a pregnancy that is unwanted (occurred when no children or no more children were desired) or mistimed (occurred earlier than desired).[1] Women who have unintended pregnancies and their resulting children are more likely to encounter negative health, social, and economic outcomes.[1] Women who have unintended pregnancies are more likely to be physically abused during the pregnancy [2], and experience lower levels of psychological well-being [3], lower educational attainment, increased poverty, and increased welfare dependency.[1, 4] Infants born to women who report the pregnancy was unwanted are more likely to die during the first year of life and be abused, and less likely to receive resources required for healthy development.[1] Another consequence of unintended pregnancy is abortion. In the US, data from the National Survey of Family Growth demonstrated over half of unintended pregnancies in 1994 ended in abortion.[5] Despite being safe in the US, in settings were abortion is illegal women face greater risk of morbidity and mortality from incomplete or septic abortions, as well as legal ramifications and stigma associated with the procedure.[1]

Unintended pregnancy may occur for a number of reasons, including nonuse of contraceptives, failure to use contraceptives consistently and correctly, and method failure among those using a method correctly.[4] Discontinuation may explain why women in countries with relatively high contraceptive prevalence are experiencing unintended pregnancies, [4, 6] given that the level of current use and demographic impact of contraception becomes increasingly more dependent on continuation as contraceptive adoption increases.[6-9]

Hormonal contraceptives, including contraceptive injectables, are the most popular reversible methods of family planning in the world and in Kenya. [10] However, these methods do not approach their theoretical effectiveness due to their relatively high

discontinuation rates. For example, a study using data from Demographic and Health Surveys (DHS) from 15 developing countries found that 10-34% of users became pregnant within three months of discontinuing a modern method.[6] The authors concluded (p 138), "...as fertility declines, family planning programs would profit from a shift in emphasis from providing methods to new clients towards providing services, such as counseling, that may help reduce discontinuation rates."[6] Discontinuation is a common problem.[11, 12] In a six-country study, conducted in Morocco, Tunisia, Egypt, Ecuador, Indonesia, and Thailand, over one-fifth of couples who had not intended to become pregnant or were pregnant due to method failure had discontinued their method within one year of acceptance.[11]

Contraceptive use and discontinuation in Kenya

In the late 1970s Kenya had the highest fertility rate in the world.[13] Through public health efforts the country has since experienced one of the most dramatic fertility declines. The decrease in the fertility rate has been attributed to the increase in contraceptive prevalence. Indeed, contraceptive use of any method among married women has increased from 17% in 1984 to 33% in 1993 to 39% in 1998 and 41% in 2003.[14] The predominant method used in 2003 was injectables (15% of currently married women), followed by the pill (8%). Other methods used among currently married women included periodic abstinence (7%), female sterilization (5%), IUD (3%), implants (2%), male condom (1%), folk methods (<1%) and withdrawal (<1%). Changes in the method mix demonstrate that the prevalence of injectable use has increased while the use of the pill has decreased. In relation to other countries in east and southern Africa, Kenya has the third highest level of contraceptive use, exceeded only by Zimbabwe and South Africa.

Despite the fact that 33% of currently married women in Kenya reported using a modern method in 2003, 20% of births were reported as unwanted and 25% were reported as mistimed that year among this group.[14] Although, the overall proportion of births reported mistimed or unwanted has not changed since 1998, the proportion reported

unwanted has increased from 1998 to 2003 with a comparable reduction in the proportion reported mistimed.

Contraceptive discontinuation in Kenya has increased since the 1998 DHS and the increase has been attributed to the relatively high discontinuation rates for pills and injectables. [14,15] Despite the popularity of the method, 21% of injectable users in Kenya discontinue use of the method within 12 months of starting, despite still having family planning needs (i.e., discontinuation is *not* due to desire for pregancy or reduced risk to pregnancy). [14]

Contraceptive injectables

Contraceptive injectables are highly effective, reversible methods of pregnancy prevention and are in the first tier of contraceptive effectiveness.[16, 17] Two types of injectables are progestin-only and combination injectables, which include progestin and estrogen. The most common type of injectable is the progestin-only formulation called depot medroxyprogestrone acetate (DMPA), and it is the focus of this dissertation.[18] DMPA is given by an intramuscular injection every three months and works primarily by stopping ovulation.[18] Another type of progestin-only injectable is norethindrone enanthate (NET-EN), which is administered every two months. Both DMPA and NET-EN have failure rates in the range of 0.4 per 100 woman-years according to a multicenter trial conducted by the World Health Organization (WHO).[19] Other sources cite a first year, perfect use failure rate of 0.3%.[16] Actual use of these methods yields a failure rate of around 3% over the first 12 months of use.[16, 20] A new formulation of DMPA for subcutaneous injection has been approved for use in the United States and United Kingdom, but is currently not available in developing countries.[18]

Injectables are characterized by active use and passive discontinuation. In other words, women have to do something for the method to be effective, i.e., return to the clinic

every three months for an injection. Discontinuation of injectables is passive, meaning all women have to do to discontinue is not return for their next injection. This is in contrast to methods which require passive use, active discontinuation like implants and IUDs—once inserted women do not have to do anything for the method to be effective. However, if they want to discontinue using implants or IUDs women must actively seek out a provider who can remove it. This distinction has implications for studying and influencing discontinuation behavior.

Side effects are the predominant determinant of discontinuation of injectables

Family planning service-related factors, including quality of care, have been thought to be associated with contraceptive discontinuation.[8] However, studies of quality of care have not been able to show large effects on discontinuation rates.[21-24] Consistent determinants of discontinuation include: type of method used, side effects, age (younger women are more likely to discontinue than older women), fewer number of living children, fertility intentions (women wanting to increase space between their children are more likely to discontinue the object of care between their children are more likely to discontinue a change in marital status (women who experience a change in marital status are more likely to discontinuation appears to be less consistently associated with the number of methods available [21], socio-economic factors including education [7, 11, 12], urban-rural residence [11], husband's disapproval [25], or cost or lack of access to the method [7, 21].

According to the 2003 DHS conducted in Kenya, side effects are the most common reason reported for discontinuation. [14] This finding is predominantly due to side effects associated with pills and injectables, the most commonly used methods. Among the discontinuations reported in the five years before the 2003 DHS, the percentage that were attributed to side effects increased from 20% in 1998 to 25% in 2003. Furthermore, in 2003 13% of currently married women who were not currently using a method reported that they

did not intend to use a method in the future because of fear of side effects. The proportion climbs to 20% for those women under 30 years of age.

The study of 15 developing countries discussed above found that hormonal methods, including injectables, were more likely to be discontinued due to side effects or health concerns.[21] Excluding Zimbabwe, which has a relatively low discontinuation rate for this method, discontinuation of injectables due to side effects ranged from 15% to 37% among the fourteen other countries surveyed.

The term "side effects" may be thought to encompass the following: clinical side effects, clinical health concerns, and fears about contraceptive injectables. Clinical side effects and health concerns are those which have been evaluated through research studies and are found in the medical literature on injectables. The last category, fears about injectables, includes those side effects or health concerns women fear or worry about, yet are not founded in the medical literature. Some may call these fears "myths," however this label should not minimize the enormous influence they may have on discontinuation. Given the important role side effects, health concerns, and fears play in discontinuation they are examined more closely in the following sections.

Clinical side effects of DMPA injectables

The clinical side effects of DMPA include:

- Changes in menstrual bleeding (light spotting at first, amenorrhea especially after the first year of use, or rarely, heavy bleeding);[18, 26, 27]
- Weight gain; [18, 26, 27]
- Delayed return to fertility (about four months longer than women using combined oral contraceptives); [18, 26, 27]
- Headaches[18, 26, 27]
- Dizziness[18, 27]
- Mood changes[18, 26, 27]
- Abdominal bloating and discomfort[18]
- Reduced libido[18, 26, 27]
- Breast tenderness[26]
- Nausea[26, 27]
- Hair loss[26]
- Acne[26]

Menstrual changes

The most common reason for discontinuation of hormonal methods is disruption of the menstrual cycle.[19] Menstrual irregularity (increased number of days of light bleeding or amenorrhea) is very common among injectable users.[16] Amenorrhea increases over time among DMPA users. Only 30% of DMPA users have regular cycles in the first year and this decreases to 17% of users at five years.

A study in South Africa found that some of the discontinuers were "taking a break" from injectables.[28] The majority of these women stated bleeding problems as the reason for the break and reported they intended to return for another injection when their normal menstrual cycle returned. In a study in the Philippines, DMPA users also reported waiting until their menstrual cycle returned to receive their next injection.[29] Clearly, this improper use of DMPA may lead to unintended pregnancies.

Several studies of hormonal methods have found an association between menstrual side effects and discontinuation.[30, 31] A study of injectables in Kenya found that menstrual changes were the main reasons for discontinuation.[32] Using menstrual diaries, Tolley et al. found in Egypt that increases in duration of bleeding predicted discontinuation even when women did not perceive their menstrual length had changed.[33]

Weight changes

DMPA users may experience weight gain or feel bloated.[16] The gain in weight is probably due to increased appetite (an effect caused by progestin) and not fluid retention. The DMPA inserts says users may gain 5.4 pounds (average) during the first year, 8.1 pounds after 2 years, and 13.8 pounds after four years of use.

Mood changes, depression

While overall depression levels among DMPA users do not increase, individual women may respond to the medication with increases in depression.[16] Given the longevity

of DMPA and the inability to discontinue immediately, service providers are cautioned about the use of DMPA with women who have a history of severe postpartum depression. *Reduced libido*

A qualitative study of DMPA users in Quirino Province of the Philippines found that women experienced decreased interest in sex and vaginal dryness during intercourse, which may lead to marital problems.[29] These side effects were also mentioned among injectable and pill users in a qualitative study in Kenya.[34] The loss of sexual desire due to hormonal contraceptive use may cause some husbands to think their wives are having sexual relations with other men.[34]

Recent studies among South African progestin-only injectable users highlight an opposite effect of this method on vaginal secretions—vaginal wetness.[35] While not described in the published medical literature, this side effect was the second most common side effect mentioned (after amenorrhea) by injectable users in a community-based cross-sectional household survey in a rural district of KwaZulu-Natal in South Africa.[36] In several parts of central and southern Africa "dry sex" is practiced and the side effect of vaginal wetness is perceived as undesirable.[37-40] In the study in KwaZulu-Natal, for example, almost 18% of injectable users reported this is what they liked least about the method.[36]

Clinical health concerns of DMPA injectables

The previous section described short term side effects that, while certainly important for discontinuation and method satisfaction, generally do not cause serious morbidity or mortality. This section reviews the latest research on health concerns of injectables which may cause fear among users and thus influence discontinuation of these methods. *Cardiovascular disease*

Progestin-only injectables do not contain estrogen and therefore do not appear to cause any of the cardiovascular complications associated with pill use.[16] However, some

studies have found decreases in high density lipoprotein (HDL) and increases in total and low density lipoprotein (LDL) cholesterol levels associated with injectables.

Sexually transmitted infections (STIs)

Baeten and colleagues examined the relationship between hormonal contraception use and the risk of STIs in a prospective cohort of HIV negative sex workers in Mombasa, Kenya.[41] Compared to those using no contraception, DMPA users were at increased risk of chlamydia infection and decreased risk of bacteria vaginosis, trichomoniasis, and pelvic inflammatory disease after controlling for sexual behavior and demographic factors. There were no associations detected between DMPA and gonorrhea, vaginal candidiasis, syphilis, and genital ulcer disease. The authors credit the biological plausibility of these findings to animal studies which suggest a link between the progesterone hormone and growth of Chlamydia trachomatis genital infections.[41]

Human immunodeficiency virus (HIV)

Women with genital tract infections, including chlamydia, have increased susceptibility to HIV infection.[42] DMPA does not provide protection against HIV and may be associated with chlamydia infection as described above; therefore, it is logical to investigate the relationship between use of these hormonal methods and HIV infection. Seven studies have investigated the relationship between DMPA and HIV and have yielded mixed findings.[43-50] Two of the studies found an increased risk of HIV among DMPA users[44, 48] and five found no association.[43, 45, 46, 49, 50] The studies which found an increased risk have focused on high risk populations such as sex workers, limiting generalizability to the general population.[51] Moreover, several studies have methodological shortcomings which undermine the findings.[49, 51, 52]

A recent prospective study of a South African cohort of women aged 35-49 years found no association between HIV risk and DMPA or NET-EN use.[53] However studies in Uganda and Zimbabwe suggest that age may have a modifying effect on the relationship

between hormonal contraceptive use and HIV acquisition.[49, 51] While this study found no overall increase risk of HIV acquisition, it found an increased risk among women 18-24 years for DMPA users, but a decreased risk of HIV acquisition for users 25-35 years. *Cervical and breast cancers*

Cervical cancer is caused by certain types of the human papilloma virus (HPV).[54] Not all women with HPV develop cancer; therefore other factors must be influencing the progression to cancer in HPV infected women. It has been hypothesized that hormonal contraceptive use, including progestin-only injectables, may increase the risk of cancer of the cervix. However, a case-control study conducted in South Africa did not find a relationship between injectable use and risk of invasive cancer of the cervix.[55] Similarly, no relation was found between DMPA use and increased risk of cervical cancer in a WHO Collaborative Study.[56]

Interest in whether DMPA use increases the risk of breast cancer stems from animal studies which found that DMPA induces mammary tumors in dogs.[57] Indeed, this was the reason for the delay in licensing the contraceptive in the United States.[58] Three studies, including one case-control study in South Africa, did not find an association between DMPA use and the risk of breast cancer.[59-61] A New Zealand study found an overall relative risk (RR) of breast cancer to be 1.0 for DMPA users (no association).[59] When subgroups were analyzed, however, a RR of 2.0 was found among users 25 to 34 years and the risk was the greatest among women who used DMPA for six or more years. These finds suggest that DMPA may accelerate the presentation of breast cancer in young women.

Bone density

DMPA prevents ovulation and strongly inhibits estrogen production from ovaries.[62] Estrogen deficiency among DMPA users adversely affects bone mineral density.[62-64] A decrease in bone density may increase the risk for osteoporosis later in life.[64] The effects may be especially detrimental before achievement of peak bone mass, as is the case for

adolescent DMPA users.[63] A population-based prospective cohort study, however, found substantial post-discontinuation recovery of bone.[64] This finding indicates that the effects on bone density may be reversible after cessation of DMPA. The WHO medical eligibility criteria currently state that the advantages of DMPA generally outweigh the theoretical or proven risk of bone density loss for women under age 18.[65]

Fears about DMPA injectables

Women may also discontinue injectables if they believe continued use of the method will lead to health problems. While not founded in medical literature, such fears may be just as important as those discussed above for those interested in decreasing contraceptive discontinuation. Some documented fears about injectables, many of which stem from menstrual changes associated with hormonal methods, include the fear of infertility, an accumulation of blood in the body, loss of balance, and fear of delivering deformed children. *Infertility*

A qualitative study of young men and women in Mali highlights the important social consequences of menstrual disruption that hormonal contraceptive users may face. Amenorrhea or prolonged bleeding induces fears of sterility among young women, a dire consequence in a culture which places a woman's value on her ability to produce children.[66]

Injectables do not cause infertility, but the longevity of DMPA in women's bodies may delay the return of fertility up to a year, which may cause some women to fear infertility.[16, 27] While the median time to conception following the expiration of the last dose is six months, studies have shown that it could take up to 9-10 months for ovulation to return.[16] A cross-sectional clinic-based survey in two regions of the Western Cape of South Africa assessed women's preferences for DMPA compared to the other common injectable, NET-EN.[67] Among women who preferred NET-EN over DMPA the most common reason for their preference was that NET-EN was thought to better preserve future fertility.

A qualitative study of sexually active and virgin US adolescents suggests further global evidence surrounding fears of menstrual disruptions. This study, which asked minority women aged 12-18 years what they have "heard" about hormonal methods, found concerns about menstrual side effects emerge as a frequent theme.[68] Specifically, the authors identified the following four themes: (1) menstruation is natural and should not be altered; (2) menstruation is necessary for cleansing the body; (3) intermenstrual bleeding and amenorrhea may indicate the method is not working; and (4) menstrual irregularity may affect fertility and physical health. The population in this US study obviously differs substantially from Kenyan women, however, without a comparable study in Kenya to compare, these themes provide insight into some of the possible concerns women may have regarding hormonal methods.

Accumulation of blood in the body

A qualitative study of the contraceptive practices and understanding of Filipino women found they believe that menstruation keeps women healthy and would prefer an increase in menstruation over a decrease or amenorrhea.[29] In particular, the women view menstrual blood as dirty and therefore believe blood needs to come out for a woman to be clean. According to the women, the lack of menstruation associated with hormonal contraceptive use results in an accumulation of dirty blood in the body which can lead to side effects such as headache, dizziness, blurry vision, hotheadedness, and even bleeding from the nose and mouth.

Loss of balance

The women in the Filipino study described above feel the experience of side effects during contraceptive use is an indication that the contraceptive method is not suitable for their body.[29] For most of the women in this study, weight loss during contraceptive use is a sign that the method is not suitable for that particular woman. A study among women in the Nyanza Province, Kenya also found that women believe side effects are a signal to the

woman that (p 301) "a particular contraceptive does not 'rhyme' with her body." [34] This belief has important implications for discontinuation of hormonal methods since many methods, including injectables, have minor side effects.

Deformed children

In the qualitative study in Kenya discussed above, women feared that pills may cause birth defects, such as children born with multiple heads, lameness, missing or extra eyes, or no skin.[34] Severe side effects are believed to be the result of improper use of pills such as missing pills or receiving the pills from an untrained provider. Unusual side effects like these, however, were only discussed in about one-third of the conversations in the in-depth interviews conducted by the researchers during this study. No similar data could be located about injectable use, but findings from this pill study may provide insight into women's fears about other hormonal methods like injectables.

Multiple side effects

While the side effects have been presented one-by-one above, injectable users may experience multiple side effects sequentially or simultaneously. Multiple side effects increase the likelihood of discontinuation.[30] A study of Canadian DMPA users found that menstrual changes combined with depression and/or weight gain are primary reasons for discontinuation after the first injection.[69]

Interventions aimed at increasing continuation rates are sparse

Given its prevalence and direct impact on the rate of unintended pregnancies, discontinuation of hormonal methods should be a top priority of family planning programs worldwide. Unfortunately, interventions aimed at reducing discontinuation are sparse. Recently, an evaluation was conducted in Nicaragua of the Decision-Making Tool for Family Planning Clients and Providers developed by the WHO's Department of Reproductive Health and Research and the Johns Hopkins University Center for Communication Program.[27, 70] The evaluation found no differences in continuation rates among clients

attending experimental clinics who used this counseling tool compared to clients from control clinics, despite the experimental group reporting significantly better counseling experiences than the control.[70]

Several other studies have demonstrated that intensive counseling about side effects increases continuation rates of injectables.[71-73] However, adequate counseling does not appear common in Kenya.[14] Indeed, less than half of modern contraceptive users reported that they were informed of other methods available or about side effects of the method they were provided. No other types of interventions aimed at increasing continuation rates could be located in the peer review literature.

In a Cochrane systematic review, only one out of six randomized control trials (RCTs) of enhanced counseling studied showed improved continuation of hormonal methods.[10] The RCTs were conducted in Slovenia (former Yugoslavia), Mexico and four US cities, limiting the generalizability of this study to the Kenyan context. The authors of this review recommended that interventions to improve continuation of hormonal methods focus on pre-emptive intensive counseling about side effects coupled with multiple contacts. Communication campaigns—which deliver messages repetitively—may be a viable solution to improve continuation.

A communication campaign is a promising strategy for delivering information about side effects, with the goal of increasing continuation rates

Communication campaigns have been associated with increased adoption of contraception around the world.[74-78] A study conducted in Tanzania found a positive association between recall of a family planning message from a national mass media campaign that included family planning radio dramas, and use of a modern contraceptive method.[79] The authors consider radio as one of the best methods for disseminating family planning messages in this setting. An analysis of DHS data from six African countries found that exposure to media in general was associated with higher contraceptive use in all countries

examined.[74] In three of the countries—Kenya, Madagascar and Ghana—exposure to family planning messages on the radio was associated with higher contraceptive use after controlling for a host of socio-demographic factors and general media exposure.

In addition to mass media, communication campaigns can employ lay health advisors to disseminate family planning information or reinforce mass media messages in a community. A longitudinal study in Bangladesh found a five times greater rate of increase in modern contraceptive use among women who participated in a series of group discussions in their community organized by trained family planning field workers compared to women who were visited by a family planning field worker in their home.[80]

As demonstrated above, research to-date remains inconclusive with regards to the effectiveness of interventions which aim to improve quality of services and counseling on continuation rates. Communication campaigns using mass media have not been fully examined for their potential to increase continuation of hormonal methods.

In Kenya exposure to family planning messages in the media is high.[14] Seventy five percent of women heard or saw a message about condoms on the radio, television or in a newspaper/magazine in the past few months. Radio is the most common source (73%), followed by television (37%) and newspaper/magazine (35%). Moreover, the majority of women (68%) surveyed found it acceptable to air condom messages in the media. Given its ability to influence contraceptive adoption and the potential reach to millions of Kenyan women, a communication campaign may serve as a promising method for delivering information about and management of side effects. This hypothesis will be assessed in the intervention study (expected 2010). The purpose of this dissertation is to provide the crucial foundation for interpretation of the findings of the intervention study.

The previous sections presented the public health implications of contraceptive discontinuation, the contraceptive use and discontinuation context in Kenya, the determinants of premature discontinuation of contraceptive injectables, and intervention

strategies to increase continuation. In the next section the theoretical model for this dissertation is discussed.

Theoretical Model

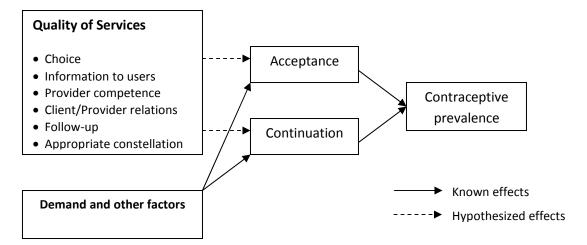
Expansion of the Bruce-Jain framework with components from the Theory of Reasoned Action provides a model for predicting continuation

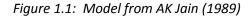
In 1989 Jain proposed an analytical model linking quality of family planning services to fertility through contraceptive prevalence, acceptance and continuation of contraceptive methods.[8] Jain's model, illustrated to the step of contraceptive prevalence, is depicted in Figure 1. The definition of quality of services in this model is based on the concept of quality of care proposed by Bruce in 1988. [81]

Under the heading of quality of services, Jain hypothesized the following to be predictors of continuation: choice of contraceptive methods, information given to users, provider competence, client/provider relations, re-contact and follow-up mechanisms, and appropriate constellation of services. Choice refers to both the number of methods consistently available and variability among the different methods offered. Jain suggests users be informed about (1) contraindications, risk and benefits of the method, (2) how to use the method, potential side effects, and how to manage side effects, and (3) what users can expect from providers in terms of support, supply and referrals. Provider competence is the skill level and experience of the service provider. Client/provider relations describe the quality of the contact and communication between clients or potential clients and the provider. Follow-up mechanisms are the efforts employed to promote the continued use of family planning methods. Appropriate constellation of services entails positioning services so they are acceptable and convenient to couples.

Quality of services are primarily considered supply factors in this model. Demand factors, including fertility motivations, influence continuation as well. Jain considers the couples' desire or motivation to regulate their fertility to be the most important factor

affecting demand for contraception. These factors are encompassed in the box labeled "Demand and other factors" in Jain's model.





This dissertation does not test all of Jain's model, but uses elements of the model as a foundation and then expands the model using constructs from the Theory of Reasoned Action (TRA). TRA was developed to understand the relationship between attitudes and behaviors.[82-84] TRA is founded on the premise that the most important predictor of behavior is an individual's behavioral intention. Behavioral intention is influenced by an individual's attitude toward performing the behavior and their subjective norm associated with the behavior.

Attitudes toward performing the behavior are dependent upon beliefs about outcomes of performing the behavior weighted by the individual's evaluation (or value placed) of those outcomes. In the context of this dissertation, potential users' salient beliefs about continuing to use a contraceptive method need to be determined and addressed for behavior change to occur. Specifically, beliefs that inhibit the desired behavior should be countered and those that encourage the behavior should be supported. Subjective norm is influenced by perceived attitude of important referents (i.e., family members, friends, health care provider) towards the behavior the individual is considering, weighted by the individual's motivation to comply with those referents (or the value they place on the referents' opinion). With regards to this dissertation, the salient referents are important groups of people who influence the contraceptive behavior of the users.

The TRA components of behavioral and normative beliefs can be used to expand Jain's framework to include *perceived* side effects and health concerns held by contraceptive users and their salient reference groups. While Jain acknowledges that users need to be informed about potential side effects of methods, the provision of such information during a brief counseling session with a medical professional may not change users' beliefs, which are often deeply entrenched in and reinforced by cultural norms. Moreover, Jain's concept of "information to users" only includes those side effects which were demonstrated in clinical studies of specific contraceptive methods and not the *actual* beliefs or fears users may hold about use of contraceptives. This is an important distinction because, as previous research demonstrates, the side effects reported in medical publications may be different from the concerns of potential users. According to TRA, failure to address users' perceived side effects and health concerns, even if these concerns would be considered myths by medical professionals, will thwart behavior change.

Jain's model ignores the influence of salient referents or important groups of people who influence the contraceptive behavior of the users. According to TRA, salient referents and their beliefs about potential users continuing to use a contraceptive method need to be identified and incorporated into interventions aimed at changing behavior. Evidence from a previous qualitative study in four developing countries suggests that interventions focusing on contraception should involve husbands, friends, and family members of the users.[85] Women reported that these referents influence their decision to use, continue using and remove a subdermal contraceptive implant. In two of the countries studied, Egypt and the

Dominican Republic, mothers and mothers-in-law were especially influential in decisions affecting fertility and expressed the most resistance towards the method and the most worry about side effects. This dissertation includes the perspectives of salient referents that were omitted in Jain's model.

Significance

The research in this dissertation lays the ground work for the evaluation of the intervention study (expected 2010). As discussed above, communication campaigns may be a viable solution to increase continuation of hormonal methods; however their potential has not been fully examined. The intervention study is the first of its kind to utilize a communication campaign to increase contraceptive continuation rates. If proven effective, this intervention strategy may serve as a model for other African countries experiencing high discontinuation rates and thereby have significant public health impact.

This dissertation is structured as two related papers followed by overall conclusions. The methods are described in detail in each paper. The **first paper** addresses the first aim, to identify reasons why women in Nyando District Kenya discontinue using contraceptive injectables from the perspectives of current users and their salient referents. Findings from this qualitative study are used to suggest points of intervention for future efforts at increasing continuation of family planning methods among injectable users in Nyando District. Additionally, the achievement of this aim will provide contextual information for interpretation of the evaluation findings from the intervention study.

The **second paper** addresses the second and third aims using prospective longitudinal data measuring pre-intervention continuation rates from two districts in Kenya. The goals of this paper are to describe the factors which predict the occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users still in need of family planning in the two study districts before implementation of the communication

campaign, and to determine if the rates and predictors of discontinuation differ between the districts before implementing the communication campaign.

Building on the literature, the factors hypothesized in the second aim to predict discontinuation in the two study districts are those found in previous studies of contraceptive discontinuation in other locations around the world. This dissertation also extends existing literature by measuring several factors which have not been explored in previous studies of contraceptive continuation, but that health behavior theories such as the Health Belief Model, Theory of Planned Behavior, and Social Cognitive Theory suggest may be important determinants of continuation behavior. These theories have been shown to predict numerous other health behaviors and therefore should be explored for their potential effect on contraceptive continuation behavior. [86]

It is important to determine if similar factors influence discontinuation in the study districts because this finding would provide support for universal (versus local) reasons for discontinuation. It is important to note that finding that a particular factor is "significant" at one site but not at the other does not imply that the association of that factor with the outcome differs between the two sites. However, if similar reasons for contraceptive discontinuation are found in diverse samples, public health practitioners could develop and recommend universal or template intervention(s) for increasing continuation. However, if a set of different predictors is found in diverse samples then a more tailored approach is indicated.

In addition, the findings from the second aim are used to suggest characteristics that predict discontinuation of family planning methods while still in need among women in this population. Given limited funds for family planning, public health practitioners could use this information to target women most at-risk for premature discontinuation with efforts to increase contraceptive continuation and reduce unintended pregnancies.

The results of the third aim are vital to the interpretation, and ultimately utilization, of the findings from the evaluation of the intervention study. The third aim, to determine if the rates and predictors of discontinuation differ between the study districts before implementation of the communication campaign, is necessary because the evaluation relies on quasi-experimental methods.

Communication campaigns are designed to reach the masses and therefore, the products developed for campaigns (radio spots, posters, etc) are widely distributed. Even if a particular media product is targeted to one particular group it is difficult to prevent people outside this target group from accessing the products. The very nature of a campaign, therefore, makes it impractical to conduct a randomized experiment to evaluate the effectiveness of a campaign. Quasi-experimental designs test descriptive causal hypotheses about manipulable causes without random assignment of subject to treatment and control conditions.[87] Instead, assignment to treatment conditions occurs by self-selection, which may result in systematic differences between the treatment and control groups other than the presence of the treatment. Self-selection may lead to selection bias, which is a threat to the internal validity of the study. Since quasi-experimental designs create less compelling support for counterfactual inferences, alternative explanations for the study findings must be ruled out to get a more valid estimate of the treatment effect.

For the intervention study the lack of randomization means that we cannot be sure that the new contraceptive injectable users in the treatment and comparison districts do not differ in systematic ways other than being exposed to the intervention (the communication campaign). While the two study districts in the study have been carefully selected to be as equivalent as possible on the factors thought to influence the outcome (i.e., urbanization, sexual practices, and fertility desires), in the absence of randomly assigning new injectable users into treatment (receive the campaign) and control (do not receive the campaign) conditions, selection bias may be an alternative explanation for the evaluation findings.

Moreover, even a rough estimate of the degree of equivalence between the pre-intervention (baseline) discontinuation rates of the two districts is unavailable because discontinuation rates are lacking for many smaller geographic units, such as the two districts in this study. Given these deficiencies, the evaluation for the intervention study uses an untreated comparison group design with independent pretest and posttest samples. Selection bias is assumed to be present because the two groups (districts) are nonequivalent. The pre-intervention study allows for the measurement and comparison of baseline discontinuation rates (the outcome) between the two districts.[87] The assumption is the smaller the difference in pre-intervention discontinuation rates among the two districts is, the lower the likelihood of initial selection bias and the more confidence we can place in the evaluation findings.

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CHAPTER 2. Reasons for discontinuation of contraceptive injectables: A qualitative assessment of contraceptive utilization among current users and their salient references in Nyando District, Kenya

Abstract

Discontinuation of contraception is a major problem in Kenya. A quarter of women abandon their contraceptives within 12 months of beginning use, despite still being in need. Focus group discussion (FGDs) were conducted in Nyando District, in western Kenya, to identify target groups and appropriate messages for a communication campaign to increase contraceptive continuation.

Fourteen FGDs were conducted among current contraceptive injectable users and salient references, people who influence women's use and discontinuation of contraception. Four were with current users and two with each of five salient reference groups: husbands, mothers-in-law, community leaders, service providers and long-term contraceptive injectable users. The purpose of the FGDs was to understand why women discontinue using contraceptives (with a focus on injectables). Thematic analysis was performed using NVivo 8 software.

Discontinuation of contraceptives in Nyando District occurs for logistical, social and medical reasons. Women do not always have control over continued use of contraception. Common reasons for discontinuation include side effects, husbands' opposition, provider and/or clinic restrictions, misconceptions about injectables, stock outs, and lack of cash to purchase contraceptives or pay for family planning (FP) services. Current users and reference groups have low knowledge of side effects of contraceptives, especially injectables, and lack of adequate knowledge about injectables was a key factor in discontinuation.

This research expands the literature by examining social influences on discontinuation by incorporating the perspectives of salient reference groups. The results suggest points of intervention for increasing continuation in this community and similar resource-poor settings.

Introduction

In the late 1970s, Kenya had the highest fertility rate in the world.[1] Through public health efforts, the country has since experienced one of the most dramatic fertility declines. The decrease in the fertility rate has been attributed to the increase in contraceptive prevalence.[1] According to the 2003 Kenya Demographic and Health Survey (KDHS), 33% of married women were using a modern method, but 25% of all contraception users discontinued within 12 months of beginning use, despite still being in need of family planning (*not* due to desire for pregancy or reduced risk to pregnancy). [2] One-fifth of the pregnancies in 2003 and the births in the five years preceding the 2003 KDHS were reported as unwanted and a quarter were reported as mistimed. Contraceptive discontinuation in Kenya has increased since the 1998 KDHS and the increase has been attributed to the relatively high discontinuation rates for pills and injectables. [2,3] The predominant method used in 2003 was injectables (14% of currently married women), followed by the pill (8%). Despite its popularity, 21% of injectable users discontinue use of the method within 12 months of starting, despite still having family planning (FP) needs.[2]

FP service-related factors, including quality of care, have been thought to be associated with contraceptive discontinuation.[4] However, studies of quality of care have not been able to show large effects on discontinuation rates.[5-8] Consistent determinants of discontinuation include: type of method used, side effects, age (younger women are more likely to discontinue than older women), fewer number of living children, fertility intentions (women wanting to increase space between their children are more likely to discontinue compared with women who have completed childbearing), and a change in marital status.[9] Discontinuation appears to be less consistently associated with the number of methods available [5], socio-economic factors including education [9-11], urbanrural residence [11], husband's disapproval [12], cost or lack of access to the method [5,10].

In Kenya, side effects are the most common reason for discontinuation, predominantly due to side effects associated with pills and injectables.[2] Among the discontinuations reported in the five years before the KDHS, the percentages that were attributed to side effects increased from 20% in 1998 to 25% in 2003. In 2003, 13% of currently married women not currently using a method reported that they do not intend to use a method in the future because of fear of side effects. The proportion increases to 20% for women under 30 years of age.

The term "side effects" encompasses the following two categories: clinical side effects and health concerns, and health-related fears. Clinical side effects and health concerns are those which have been evaluated through research studies and are found in published medical literature. The most common reason for discontinuation of hormonal methods is disruption of the menstrual cycle.[13] Menstrual irregularity (increased number of days of light bleeding or amenorrhea) is very common among injectable users.[14] Other clinical side effects and health concerns associated with injectable use include: weight gain, mood changes, reduced libido, headaches, dizziness, abdominal bloating/discomfort, nausea and reduced bone density. [15-20]

The second category includes health concerns that women fear or worry about, yet which have no basis in the medical literature. Some call these fears myths; however, as a cause of discontinuation, these fears are as important as documented clinical side effects. Women may stop using injectables if they believe continued use of the method will lead to health problems. Some documented fears about injectables, many of which stem from menstrual changes associated with hormonal methods, include the fear of infertility, an accumulation of blood in the body, loss of balance, and fear of delivering deformed children. [14,17, 21, 22]

While previous research has primarily focused on user and methodrelated characteristics associated with discontinuation, little attention has been paid to the

influence of other people on discontinuation. This is a significant omission because women do not make family planning decisions in isolation, but rather their contraceptive behavior is influenced by their social enviroment, including cultural norms. In an effort to identify target groups and appropriate messages for a communication campaign to increase contraceptive continuation among contraceptive injectable users, focus group discussions (FGDs) were conducted in Nyando District, Kenya in 2007. This research expands our understanding of discontinuation by examining social influences on discontinuation by incorporating the perspectives of salient reference groups. The results of this analysis are used to suggest points of intervention for increasing continuation of FP in this community and similar resource-poor settings.

Methods

Fourteen FGDs were conducted among current contraceptive injectable users and their salient references, which are groups of people who influence women's use and discontinuation of contraception. First, four FGDs were conducted with current contraceptive injectable users recruited from Ministry of Health Family Planning clinics in Nyando District, Kenya to determine why women discontinue using contraceptives (with a focus on injectables) and identify their salient references. FGD data from current users were analyzed and five salient reference groups identified for a second round of FGDs. Then two FGDs were conducted with each of the groups: husbands, mothers-in-law, community leaders, service providers and long-term contraceptive injectable users. Table 2.1 shows the number of participants in each FGD.

A local research company experienced in conducting social science research in the study area recruited participants and conducted the FGDs. The FGDs were led by experienced, trained interviewers, fluent in the local language, Dholuo. Due to the sensitivity of the study topic, interviewers were the same gender and roughly the same age as focus group participants. We used a semi-structured open-ended FGD guide. The same

questions were asked in the same order of all participants and responses were inductively probed. Discussions were tape recorded and transcribed verbatim and then translated to English. The FGDs consisted of 8-12 participants and were homogenous with respect to gender and respondent type (i.e., current user, service provider, community leader). The discussions averaged 1.5 hours.

A detailed codebook was developed by both authors where themes (reasons for discontinuation) were identified and defined. Several codes were predetermined based on FP literature, but the majority of codes were created inductively, and therefore, generated from reading the transcripts.[23,24] This inductive thematic approach allows themes to emerge from the data.[25]

Transcripts were coded by the first author using QSR's NVivo 8 software.[26] The cross tabulation reporting function ("matrix coding") was used to identify patterns in themes by respondent type. Based on these reports, both authors examined the evidence that supports each theme quantitatively (i.e., code application frequencies by type of participant generating the data) and qualitatively (i.e., context of code). To capitalize on the FGD enviroment, we looked for participant interactions (i.e., encouragement, disagreement) with groups.[27] The results section features quotations from FGD participants.

Results

A total of 65 themes were identified, of which 21 were predetermined based on the FP literature. We placed these themes into three higher- level conceptual constructs with regard to why women discontinue using contraceptive injectables in Nyando District: logistical, social, and medical reasons for discontinuation. Logistical reasons include clinic restrictions and service providers' lack of knowledge about injectables, which lead to premature discontinuation, difficulties getting to the clinic for injections, stock outs, and lack of cash to pay for clinic visits and/or injectables. Social reasons include salient reference group (i.e., husbands, mother-in-laws) oppositition to contraceptive use, and religious and

cultural beliefs that prohibit or thwart contraceptive use. Medical reasons encompassed clinical side effects and health concerns, and health-related fears about contraceptive injectables. Participants used various names to describe contraceptive injectables including: the jab, injectables, Depo, and Depo Provera. Some just referred to the method as family planning. Table 2.2 provides a summary of the 56 codes which were expressed in at least two FGDs.

Logistical reasons

Logistical reasons were mostly given by service providers, and current and long-term contraceptive injectable users. Clinic restrictions, lack of knowledge about injectables, stock outs, and lack of cash were the most common themes. Participants in both FGDs with husbands mentioned lack of cash and stock outs as a reasons for discontinuation. Common clinic restrictions include service providers only allowing women who already had multiple children to receive injections and requiring husbands' permission to receive an injection. One current injectable user explains who can use injectables in her community,

It depends on the number of children that you have. Maybe you sat down with your husband and you have agreed that you want to plan your family plan, so you can agree and go to the doctor. Doctors sometimes don't agree. Maybe if you have one child and you want to stop giving birth, he [the doctor] can't allow you because he knows that you will need another child. So in a house you can have three children. This one he [the doctor] can allow you to use injectable, especially if you have discussed with your husband because he will first ask you if you have discussed the issue with your husband. [CIU, FGD 1]

Some of the service providers agreed with a parity restriction, while others did not. When asked what types of women can receive FP injections in the clinics, three service providers [FGD 1] responded:

R2: All women of child bearing age but there seems to be contraindication for women who have not given birth because if you open the [injectables] pack, it says that it should be used with women who have at least one child because it delays fertility. So they have written it clearly.

R6: I would say the method would depend on the person who is to use it. Also as my colleagues have said, about the age and the parity of the user.

R4: I want to react to what [R2] said. To me it would appear misleading if we say women who have not given birth are contraindicated to injectables. What I say is that we give them information. They are the decision makers. Having let them know that it will delay the ovulation and they still want to use the method, you should just allow them to use.

A similar discussion emerged in the second FGD with service providers. When asked the same question about who receives injectables, a service provider responded, "Any mother who has started seeing her menses." Indeed, "mothers" was the most common answer in all FGDs to the question about who uses contraceptive injectables in this community indicating that this method is primarily used by women who already have children.

As aluded to in the above quotation, another common clinic restriction is that women have to be menstruating to receive the initial injection. Often, if women are not menstruating on the day they visit the clinic, they are sent home and asked to come back when they are mentruating. In some clinics, women are also required to present their FP card to receive their next injection. A current injectable user [FGD 3] explains how this restriction can prevent contraceptive continuation in her community, "Sometimes if the man [husband] sees

that the child has grown and the neighbor has a baby, he can even take your [family planning] card and hide it and that's your end with family planning."

Service providers identified several side effects of injectables which cause them to not re-inject clients. Many of these side effects are not supported by medical research, including hypertension, low body weight, and short menstrual cycles. When asked why women stop using injectables, a service provider [FGD 1] responded:

Due to side effects like hypertension, they come to the facility and after sometime, the [blood] pressure increases. Maybe she didn't have [high] blood pressure but after using it [injectables], she develops [it]. So you can advise her to stop.

Stock outs of injectables was a problem mentioned in over half of the FGDs. When a clinic runs out of injectables, they ask clients to buy the injectables at a pharamacy and return to the clinic for injection. In addition to the extra financial and time costs associated with traveling to the pharmacy, this solution poses an insurmountable financial constraint to many clients since the pharamacies charge a much higher price than FP clinics, which often provide methods free or at a nominal charge. According to the service providers in the FGDs, many clients who leave the clinic without receiving their injection do not return. One long-term user [FGD 2] describes how injectable users can become discouraged when the method is out of stock at the clinics and not affordable at pharmacies and private hospitals:

It can reach a time when the injectables are not there [in the family planning clinics]. Even if we go to the places where we get them from, you can be discouraged until you stop because you go and you find that they are not there. There are some people who offer the same service but their price is high and sometimes you don't have the money.

Another long-term user [FGD 1] describes community health workers (CHWs) as a convenient source of injectables in her community when the clinic runs out of stock:

The hospital these days has no injectables for family planning, so you are sent to the clinic. Then you buy the drug. Then you can be injected because even if you go to the sub district or health centre, it's expensive. But the CHW will only charge you ten shillings [approximately 0.12 USD]. And even the distance to Pap Onditi [clinic] is too much and when you reach, there you find a very long line. But the CHWs are just around so you can go back and perform your duties.

Some of the service providers [FGD 1] suggest that the change in focus from FP to HIV/AIDS may be to blame for the stock outs as explained below.

... instead of concentrating on sustainability of supply of the same contraceptives, the idea [focus] is now based on HIV control and management. That now leads to the shortage of contraceptives and mothers stop using them because it is very expensive. Depo-Provera is about 80-90 shillings [approximately 1 USD] in some of the chemists which is of course if somebody is not having the money cannot purchase and in the end conceives.

Social reasons

Social reasons were mostly given by community leaders, husbands and current and long-term contraceptive injectable users. Husbands' opposition to contraceptive use was mentioned in all 14 FGDs. Specific reasons for husband opposition included (in decreasing frequency): decreased libido on the part of women (mentioned in all 14 FGDs), wants more children, preference for male children, changes in bleeding, and discovery of covert use. Participants explained that decreased libido may result in two situations. First, women are

suspected of taking on a new sexual partner, or second, husbands may take a new sexual partner or second wife. One husband [FGD 1] illustrates:

With me, the weakness that I see [in injectables] is that one for the bedroom. It removes appetite [libido] from women. They are not in the mood for sex. They are always tired. I also see that it can destroy one's marriage because if men are [sexually] active, men say that there is weakness for the garden and that one for bed. If the man is [sexually] active and the woman is not, it can lead the man to extramarital affairs. It can also make a man to marry another wife.

Covert use (women using contraception without their husband's knowledge) was described in all FGDs. However, in 11 FGDs participants also talked about both partners making contraceptive decisions together. Mother-in-law opposition was mentioned in five FGDs.

Religious opposition was mentioned in roughly half of the FGDs. Participants specifically cite the Catholic church as being opposed to contraceptive use. Participants in both FGDs with husbands and one with long-term users stated concern about FP reducing the population of the community. A long-term injectable user [FGD 1] explains,

There was a member of parliament who was complaining that Luos [the name of the predominate tribe residing in Nyando District] are practicing family planning and that is why the population of Luos has gone down while the Kalenjins [another tribe] are giving birth and don't even want to hear about family planning. So we should reflect back and go to our tradition. Before it us who were many and now we are few. So we should stop family planning and conceive and raise our population.

A belief that emerged in half of the FGDs and was distributed across all respondent types except mothers-in-law, was that contraceptive injectable use is associated with prositution. When asked what category or type of women use injectables, community leaders [FGD 1] responded:

R5: Most of them that we see, you find that they are women who had separated from their partners. Maybe she stays in Ahero [a nearby town] doing a business [prostitution]. She left her house. Most of those women use injectables. Young women who are widows at an early age also tend to use injectables.

R1: Back when the idea of family planning came, we were being taught that if you are below thirty years, you can't be injected with injectable. But nowadays even school- going children from 18 years, 20 years and so on use injectable. That's why you hear people say that young girls use injectables. Even those who have not known whether they will one day become pregnant use injectable. And also that has made prostitution increase.

R6: According to what was earlier said, I just want to say that they are business ladies [prostitutes].

R8: You see family planning started early, nowadays even children of 18 years or 16 years do it. But it's not good. So it's mostly from 18 to 45 [years]. Most of them are business ladies [prostitutes].

R2: ... another thing may be one was selling her 'tomatoes' [meaning selling her body or engaging in prostitution] and now she has got someone who has married her. She can decide to stop using injectables so that she can conceive because she has a husband.

Medical reasons

Medical reasons for discontinuing injectables—both clinical side effects and healthrelated fears of injectables—were common across all groups. Beginning with clinical side effects, increased weight was mentioned in almost all of the FGDs. This side effect was primarlily viewed negatively although participants in five FGDs expressed favorable opinions about increased weight. Decreased bleeding or amennorhea was also mentioned in almost

all of the FGDs, although similar to increased weight, a few injectable users in four different FGDs expressed happiness with this side effect. Below are perspectives from three current users:

There is something that I have observed about injection, I don't know if it is me alone? [Asking question of the group] Sometimes I take long before I attend [menstruate], until I worry that I am pregnant. I don't see any sign showing that I am pregnant. Do you know that has made me to worry so much! Because me "I am just seated that I am seated" [meaning that I am just there helpless], I do not see, sometimes it [period] comes a little and then disappears again. [Current user, FGD 2]

You know that when you are seeing blood then sex is back, or how is it? [seeks opinion of other participants] Secondly, if you are seeing blood then you still feel that you are in the league of younger women because those who don't have menses we call them 'bim' [translates to 'Chimpanzee'] in 'Dholuo', So if you are still seeing your menses, then that means that you are still young. [Long-term user, FGD 1]

I like it [amenorrhea] because the war with my husband during my periods is no more. [Current user, FGD 1]

Injectable users also talk about waiting for their menses to return before getting their next injection even if their current injection expires. A long-term user [FGD 2] describes her re-injection patterns to the moderator:

- M: You were supposed to go back on 7th. Why didn't you go back?
- R4: I wanted to see my periods because since I started using [injectables], I have not received them.

M: You're waiting for periods?

R4: Yes

Another long-term user [FGD 2] describes how her concerns about amenorrhea led her to discontinue using injectables while she waited for her period to return:

R7: I had a break for one whole year without using it.

M: Without using any [contraceptive method] and you did not conceive as well?

R7: I did not use anything and after that whole year, I started using it again

M: Why did you take a break?

R7: I thought that since I was not seeing blood maybe they were getting collected somewhere in my body because since I began using the injectables, I had never seen blood.

M: You thought the blood was being collected somewhere?

R7: I thought they were being collected somewhere and when I asked the sister [nurse], she told me that there is nothing like that. But according to me, they were somewhere.

M: Mmm.

R7: Mmm. So I said that I want to have a break and see if the blood will come out after some time without the use of the injectables. Then use it again.

Increased bleeding or spotting was mentioned in almost all the FGDs. Husbands did not comment on bleeding increases or spotting; however both FGDs with husbands expressed dislike of amenorrhea. One husband [FGD 1] recounts:

Injectables are good but its also not very good. For example a woman always goes for her periods monthly. When she is using injectables, then they can inject her for one that lasts for three months, I can't talk about someone's wife. For those three months, a woman can miss her periods, after that she menstruates naturally... That makes them lack good health, even if she becomes fat, she is not very strong. Injectables make women unable to do other chores like going to the garden because they have no energy. They can only do office jobs. [Laughter] So you find that the woman cannot go to the garden. You know us --we go to the garden. You know the woman misses her periods but God put it that they should menstruate monthly. So that is where we don't understand. It [injectables] makes them tired; it doesn't want one to do heavy chores like going to the garden.

As indicated above, amenorrhea was associated with weakness and fatigue by some participants. Some associated amenorrhea with reduced libido. Backache was another common complaint. Backaches were mentioned in 10 out the 14 FGDs. In three FGDs, participants speculated that bleeding changes due to injectable use caused backaches among users. One husband [FGD 2] commented:

They [injectable users] mostly complain about backache, which is as a result of lack of periods. Somebody stays [without periods] for quite a long time, even for three years consecutively without periods. This causes the back pain.

As mentioned under the social reasons for discontinuation, lower libido was a common theme in all FGDs. One mother-in-law [FGD 2] explained:

It [injectables] can sometimes bring problems in the house when it reduces your sexual libido, then when the husbands want their conjugal rights and you are not in a mood to respond. Now at that time, you know it is war. He will say that you have some people outside where you satisfy your sexual desires such that when he proposes to you, you do not accept him.

Interestingly, in two FGDs participants mentioned that reduced libidbo was a desirable side effect. Two service providers [FGD 1] recount:

- R2: Ok, I wouldn't said it's for the majority. But ... for almost half of the women who use it, the libido is reduced. I can also say that there are women who come specifically for the injectables (e.g. the widows). ... they don't want to conceive and also they don't want to get involved with other people, so if they use it their libido will be reduced.
- R7: I agree with her, some women say that if they are using the injectables, their libido is reduced, especially widows. They liked Depo.

Other common clinical side effects mentioned during the FGDs included: abdominal discomfort, headaches, and delayed return to fertility. Mood changes and nausea were mentioned in three FGDs. Changes in vaginal lubrication were mentioned in only two FGDs and was not a major theme. Injection site pain was mentioned by only one participant and concern about loss of bone density was not mentioned at all.

Health-related fears of contraceptive injectables were common in all FGDs. The most common fears were infertility, delivering a deformed baby, and high blood pressure. Infertility was mentioned in 13 of the 14 FGDs. Many of the participants recounted stories of people in their community who had used injectables in the past and as a result of this use, could no longer conceive. One community leader [FGD 2] declares, "Another major problem is that the use of injectables can cause permanent sterility." A belief in this community is if a person uses injectables for five or more years, they will become infertile and this belief leads to discontinuation as one current user [FGD 1] describes, "Me, I discontinued using injectables because I could hear people say that if you use injectable for five years, you wouldn't be able to give birth. Then I decided to discontinue and it is during that time that I conceived again." A mother-in-law [FGD 1] recounts:

R2: Some people stop using injectables depending with how she has used it so that she can get another baby. She may wait hoping to get another baby but she fails to conceive. This sometimes happen to people.

M: That means that she stops [giving birth] permanently

R2: Yes

A mother-in-law in another FGD echos this belief, "On the use of injectable, they [current users] think that if they use injectables, then they won't give birth again in their lives, so they develop some fear." Service providers [FGD 1] provide further explanation of this belief:

R3: They [family planning clients] have a belief that if you use Depo, you become infertile. So they fear using it.

M: Is it a belief or is it the truth? In chorus: It's a belief.

R2: It can delay fertility but it can not make you infertile.

R1: You know what they always expect that if they stop using Depo, then they want to see their menses immediately. So if they fail to see their menses, they relate it to infertility

In the second FGD with service providers, infertility was only mentioned once by one provider who stated that a side effect of injectables was "secondary infertility." This same provider also said that injectables can lead to hypertension and varicose veins. None of the other service providers in that FGD spoke up to refute these claims. High blood pressure was considered a side effect of injectables by service providers in both FGDs.

Discussions about the fear of delivering a deformed baby as a result of using contraceptive injectables was common. However, the types of deformities mentioned varied

and included: deformed, blind, one or no eyes; unproportionality, many or no legs; short or no limbs; small, big, malformed, multiple or no head; combined organs; facial deformity; paralysis; missing fingers; mark on skin; two babies joined together; weakness; and delivering an animal (mongoose, cow, chimpanzee, monkey). Some participants refute these claims explaining that deformities existed before injectables were invented and people are now just blaming deformities on injectables.

Other participants believe that harm to the baby only results if the woman uses contraceptive injectables when she conceives. A community leader [FGD 2] explains:

It is at times true that injectables can cause deformation, but only if the mother started using this method after she conceived and she did not inform the health provider about this. ... for us to know that one has conceived, it is only if she attends... or if a pregnancy test is done on her ... otherwise contraceptives with hormones can cause someone to give birth to a child with deformity such as one with a finger missing, one eye, [and] combined vital organs.

Other fears of injectables expressed in a little less half of the FGDs included: death, decreased weight, and drowsiness or laziness. Drowsiness or laziness which results in trouble performing physical work was a major complaint of husbands in both FGDs and some current users, long-term users and mothers-in-laws. One husband laments, "What I dislike about it [injectables] is that it makes women lazy. Because they take something that does not suit their bodies from Depo-Provera injection. This is what it brings, and again she cannot do any difficult work." Another husband in that same FGD explains his view on the situation:

It looks like this people [who use injectables] sleep a lot because of their weight [gained by using injectables]. If there could be any way through which this weight could be reduced, then I think it would really help them [injectable users] because for

sure those who use Depo tend to add weight extremely making them very lazy. She cannot do anything, she can only sit and watch. So it's you the husband who will be working for her. And this is the reason they [injectable users] become weak.

Suggestions for improving continuation

Participants in all FGDs were asked for their advice to improve contraceptive continuation in their community. The groups containing male participants (husbands and community leaders) had many more suggestions than the groups containing female participants. Service providers had very few suggestions other than for the provision of a constant supply of injectables to the clinics and a reduction in the cost of injectables. The most common suggestion across all groups (13 out of the 14 FGDs) was to disseminate correct information about injectables or family planning in general to the community. Six groups specifically suggested that efforts focus on disseminating information about the advantages and disadvantages of injectables. Three groups suggested that only the advantages of injectables be discussed. And two groups suggested that efforts focus on dispeling myths about injectables. The following people or places were mentioned as ideal sources to disseminate this information: chief barazas (community-wide meetings), health providers and facilities, mass media channels (especially radio), community health workers, and other community gathering places (church, funerals). Participants from seven FGDs suggested that current injectable users could serve as role models to foster continuation in their community.

Male involvement was suggested to improve contraceptive continuation in five FGDs. Participants recommended that men be involved during the decision making process of starting FP and selecting a method so that they know about the advantages and potential side effects of injectables. A husband describes how men in this community can prevent women from continuing to use contraception:

...even if you stop or even if they are still using [injectables], it's the men who stop them [women] from using and also stopping them from going to the family planning. So expect that women have not refused to use family planning, they really want it. But it's their husbands that make them not to go for it. Husbands should be taught <u>more</u> than what should be taught to the women about family planning methods.

One community leader [FGD 2] advises:

Men also should be invited so that they are taught about the advantages of the injectables or family planning in general because in most cases women are taught about these things as men are left behind. This is also a problem. So those who have the ability to organize trainings should also invite men so that they also get the information required. Especially on the advantages of family planning or using the injectable, so that these men, who say there is a problem they can come and get to know the real advantages and disadvantages.

Governmental involvement in terms of disseminating family planning information, training providers, and maintaining a constant supply of injectables was suggested in four FGDs. Participants in four FGDs suggested that encouragement be provided to current users to help them continue using injectables. Some of the participants in the FGDs with husbands and mothers-in-laws recognized their influential role in contraceptive continuation, as well. One mother-in-law [FGD 1] noted, "Yes, we can educate them, we as parents who have given birth and we have experienced dificulties in this world we can encourage them to use injectables because of high economic standards which have increased rapidly."

Discussion

Numerous reasons influence whether women who want to space or limit births discontinue using injectables in Nyando District. These reasons are logistical, social,

medical or a combination of all three. A salient logistical reason uncovered in these data is the pervasive problem of commodity stock outs. If injectables are not available at the FP clinics, women in this community discontinue because they can not afford to purchase the product elsewhere. Other major logistical barriers lie within the clinics themselves. Unnecessary and sometimes incorrect provider and/or clinic restrictions inhibit women from receiving injections. Three clinic restrictions for injection and re-injection found in these FGD data are particularly worrisome and include parity, hypertension and menstruation requirements. The World Health Organization (WHO)'s medical eligibility criteria for contraceptive use do not restrict contraceptive injectables for nulliparious women, adolescents or those with hypertension.[28] Progestin-only injectables, which are the predominant injectables used in Kenya, do not contain estrogen and therefore do not cause any of the cardiovascular complications associated with pill use.[14] Women with adequately controlled hypertension or mild to moderately elevated blood pressure can continue using progestin-only injectables. [29] Finally, a simple checklist has been found to be effective at ruling out pregnancy and would allow nonmenstruating women immediate access to contraception. [30] This checklist has been endorsed by both the WHO and the Kenyan Ministry of Health Division of Reproductive Health.[31]

Social reasons also lead to premature discontinuation of injectables. Women in Nyando District do not always have control over the use and continued used of contraception because such decisions are often made by their husbands or other influential people in their community and household. Much of the opposition husbands hold towards the use of injectables or other methods stem from a low level of knowledge regarding side effects. Cultural beliefs about gender, sex and fertility also have an important role in discontinuation behavior. In this patriarchical society, polygamy and ritual sex surrounding social and agricultural events is practised.[32, 33] Fulfilling "conjugal duties" and bearing multiple children are critical parts of a married woman's duty. Contraception that reduces a

woman's libido and willingness to be an active sexual partner puts strain on marriages in the Luo community. Male and female FGD participants were well aware of this constraint of injectables, but offered numerous solutions to the problem, too. Participants suggest involving men in FP educational efforts might make them understand the advantages of FP, the potential side effects of injectables, and be more understanding if their wife experiences a side effect such as lowered libido.

Not surprisingly, medical reasons for discontinuation in this study were numerous. Similar to previous research, common side effects of injectables reported included weight gain and menstural changes. What is more interesting are the common side effects and health-related fears that the participants reported that are not found in medical literature on injectables like back aches, infertility, delivering a deformed baby, high blood pressure and drowziness. Educational and counseling efforts in this community should be tailored to address these community-specific concerns.

This study did not include discontinuers as a specific subgroup. This seeming oversight was actually by design since it is very diffult to identify and recruit discontinuers in the rural community in this study. Furthermore, it was expected and found to be true that many of the long-term users had discontinued using injectables in the past. However, the analysis would have been strengthened had we been able to include discontinuers as a separate group.

In the next phase of this research, we will distill and disseminate through local radio critical information on injectables to see whether this reduces discontinuation more in an experimental area than in a comparison area.

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Table 2.1: Number of FGD participants per group

Categories of participants	Number of participants
Current injectable users group 1	10
Current injectable users group 2	12
Current injectable users group 3	11
Current injectable users group 4	8
Husbands of injectable users group 1	11
Husbands of injectable users group 2	9
Mothers-in-law of injectable users group 1	8
Mothers-in-law of injectable users group 2	9
Service providers group 1	8
Service providers group 2	10
Community leaders group 1	8
Community leaders group 2	9
Long-term injectable users group 1	11
Long-term injectable users group 2	11
Total number of FGD participants	135

Code	Total frequency (range 2-14)	Frequency by respondent type	Emergent (e) versus
	(Talige 2-14)	(range 1-6)	Predetermined (p)
		(range r o)	code
Logistical reasons	-	_	ſ
Clinic restrictions	9	5	е
Stock outs of family planning (FP)			
method	8	5	р
Lack of knowledge	8	4	е
Lack of cash to purchase FP method			
or services	7	4	р
Other health issue leads to			
discontinuation	4	4	е
Problems getting to clinic	3	3	р
Social reasons			
Covert use of FP method	13	6	е
Cultural beliefs about gender roles	12	6	е
Husband (HUS) general opposition	12	6	р
Both partners decide to use FP			•
method together	11	5	е
HUS wants more children	10	4	e
Marital problems: Decreased libido	9	6	e
Decreased libido leads to suspicion	-	-	-
of women being unfaithful	8	5	е
Religious opposition	8	5	e
Cultural beliefs: general	7	5	e
Method use associated with	,	•	
prostitution	7	5	е
Decreased libido leads husband	,	•	U
seeking new sexual partner	5	4	е
Marital problems: Changes in	<u> </u>	Ŧ	
bleeding	5	4	е
HUS preference for male children	5	3	
Marital problems: Discovery of	5	3	e
	5	3	<u> </u>
covert use Cultural beliefs about sexual	5	3	е
	4	4	
Intercourse			e
Cultural beliefs about menstruation	4	3	е
Mothers-in-law (MIL) general	2	0	
opposition	3	3	е
Other (not HUS or MIL) general	•	0	_
opposition	3	3	е
Increase population in community	3	2	е
MIL wants more children	2	2	е
Other (not HUS or MIL) wants more	_	•	
children	2	2	е
Medical reasons	Γ		Ι
Sickness or poor health or side effect			
not specified	14	6	е
Infertility	13	6	р
Disliked decrease bleeding	12	6	р
Disliked weight gain	12	6	р
Deformed baby	11	6	р

Table 2.2: Codes expressed in two	o or	more	aroups
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Back aches	10	6	е
Increased bleeding	10	5	р
High blood pressure	9	5	е
Irregular bleeding or spotting	9	5	р
Disliked lower libido	8	6	р
Abdominal bloating/discomfort	8	5	р
Death to user	6	5	е
Headaches	6	5	р
Decrease in weight	6	4	е
Drowsy or laziness or trouble doing			
work	6	4	е
Delayed return to fertility	5	4	р
Liked weight gain	5	3	е
Dizziness or blurred vision	4	4	р
Increased appetite	4	3	р
Liked decrease bleeding	4	2	е
Decreased weight associated with			
HIV or AIDS	3	3	е
Mood changes	3	3	р
Nausea	3	3	р
Changes in vaginal secretions	2	2	р
Complications when giving birth	2	2	е
Fever	2	2	е
Liked lower libido	2	2	е
Varicose veins	2	2	е
Bleeding changes (not specified)	2	1	р

CHAPTER 3. Rates and predictors of contraceptive discontinuation in two districts in western Kenya

Abstract

Contraceptive discontinuation is high in Kenya—25% of family planning (FP) users discontinue within 12 months, despite having FP needs. Continuation rates were measured in two districts in Kenya before implementing a campaign to increase contraceptive continuation. Prospective data were collected over 9-months to: (a) describe factors which predict occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users, and (b) determine if rates and predictors of discontinuation differ between districts. This study incorporated novel time-dependent attitudinal and motivational factors.

The following predicted discontinuation: side effects or health concerns, nervousness about using contraception, no previous use of modern FP, unmarried at study enrollment, preferring more privacy during FP appointment, and paying more for FP services. Associations between predictors and discontinuation differed between the districts, as did rates of discontinuation. Findings suggest a tailored approach for interventions to increase continuation and that FP services address side effects and health concerns.

Background

Globally, contraceptive use is increasing. However, discontinuation rates are high, especially in the developing world. [1, 2] According to the 2003 Kenya Demographic and Health Survey (DHS), 33% of married women were using a modern method, but 25% of all contraception users discontinued within 12 months of beginning use, despite still being in need of family planning (*not* due to desire for pregancy or reduced risk to pregnancy). [3] Contraceptive discontinuation in Kenya has increased since the 1998 DHS and the increase has been attributed to the relatively high discontinuation rates for pills and injectables. [3,4] The predominant method used in 2003 was injectables (14% of currently married women), followed by the pill (8%). Despite its popularity, 21% of injectable users discontinue use of the method within 12 months of starting, despite still having family planning (FP) needs.

FP service-related factors, including quality of care, are thought to be associated with contraceptive discontinuation.[6] However, studies of quality of care have not shown large effects on discontinuation rates.[7-10] Consistent determinants of discontinuation include: type of method used, side effects, age (younger women are more likely to discontinue than older women), fewer living children, fertility intentions (women wanting to increase space between their children are more likely to discontinue compared with women who have completed childbearing), and a change in marital status (women who experience a change in marital status are more likely to discontinue).[2] Discontinuation appears to be less consistently associated with the number of methods available [7], socio-economic factors including education [1,2,11], urban-rural residence [1], husband's disapproval [12], cost or lack of access to the method [7,11].

In Kenya, side effects are the most commonly stated reason for discontinuation, predominantly associated with pills and injectables.[3] Among the discontinuations reported in the five years before the 2003 DHS, the percentage that were attributed to side effects increased from 20% in 1998 to 25% in 2003. In 2003, 13% of currently married

women not currently using a method reported that they did not intend to use a method in the future because of fear of side effects. The proportion increased to 20% for women under 30 years of age.

A four-year prospective quasi-experimental study is currently being conducted to encourage contraceptive continuation by developing, implementing and evaluating a communication campaign intended to increase continuation rates among contraceptive injectable users in Nyando District, Kenya. This study is the first of its kind to utilize a communication campaign to increase contraceptive continuation rates. If proven effective, the intervention strategy could be applied in other settings around the world and could have significant public health impact.

The evaluation for the intervention study uses an untreated comparison group design with independent pretest and posttest samples. [5] Pre-intervention data on continuation rates in the treatment (Nyando District) and comparison (Mumias District) sites were collected before the campaign was introduced and are the focus of this paper. The goals of this paper are to: (a) describe the factors which predict the occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users still in need of FP in the two study districts before implementation of the communication campaign, and (b) determine if the rates and predictors of discontinuation differ between the districts before implementing the communication campaign.

Significance

Building on the literature discussed above, we hypothesize that predictors of discontinuation in the two districts in this pre-intervention study will be similar to those found in other locations around the world. This study extends existing literature by measuring several factors which have not been included in most previous studies of contraceptive continuation, but that health behavior theories such as the Health Belief Model, Theory of Planned Behavior, and Social Cognitive Theory suggest may be important determinants of

continuation behavior. These theories have been shown to predict numerous other health behaviors and therefore should be explored for their potential effect on contraceptive continuation behavior. [13] Some of these novel factors include motivations to avoid pregnancy, confidence in using contraception, and a woman's decision-making power within the sexual relationship. A study conducted in Honduras found contraceptive users' attitudes about childbearing vary over time, and also identified an association between fertility motivations and contraceptive discontinuation. [14] Unlike the Honduras study which measured attitudes at baseline and one-year later, the attitudinal factors in this current study were measured up to four times over the course of the study. The advantage of repeated measurements of a variable over time is the opportunity to include a more proximate measurement of the respondents' attitude/behavior/condition to the time of the event (i.e., discontinuation) and reduce potential recall bias.

In sum, this study offers the opportunity to investigate the effects of previously explored and novel factors on continuation behavior. Finding that the factors that influence discontinuation in the study districts are similar to those found in previous studies would provide support for universal (versus local) reasons for discontinuation. It is important to note that finding that a particular factor is "statically significant" at one site but not at the other is not the same as determining that the associations of that factor with the outcomes differ between the two sites. However, if similar reasons for contraceptive discontinuation are found in diverse samples, public health practitioners could develop and recommend universal or template intervention for increasing continuation.

The findings from this study may suggest characteristics of women in this population that predict discontinuation of FP methods while still in need. Given limited funds for FP, public health practitioners could use this information to target women likely to be most at-risk for premature discontinuation with efforts to increase contraceptive continuation and reduce unintended pregnancies.

Methods

Five hundred new injectable users from clinics in two districts in Kenya (1,000 participants in total) were enrolled in the pre-intervention study beginning April 2008. Participants were re-interviewed every three months over a nine-month period. We focused on injectables because they are the most popular contraceptive method in Kenya. Two comparable sites in the western region of Kenya were selected based on requirements for the intervention study as follows: Nyando District (treatment site) was selected because it is located in Nyanza Province, which has a high HIV prevalence rate (15%) compared to the national average (7%). [15] This situation has led to increased focus to improve reproductive health services in the region by both the government and non-governmental organizations. Mumias District (comparison site), located in Western Province, borders Nyanza to the north and does not share media channels which would be used for the intervention in Nyando. Mumias has an HIV prevalence rate of 6%. [15]

Sample selection

A list of Ministry of Health (MOH) clinics that provide contraceptive injectables to women was obtained for each study district. The number of clinics enrolled in each site depended on the number of new injectable users attending the clinics the previous year. Sample size for the pre-intervention study was based on the application of survival analysis for the intervention study¹. Given that 500 new injectable users needed to be recruited in each site during a three-month time period, clinics with the highest average number of

¹ A one-sided log rank test with an overall sample size of 912 participants (456 in the treatment group and 456 in the comparison group) achieves 90% power at a 0.05 significance level to detect a difference of 0.1 between 0.6 and 0.7--the proportions surviving in the comparison and treatment groups, respectively. Assuming exponential survival times, this corresponds to a constant hazard ratio of 0.7. The proportion of participants lost during follow-up was assumed to be 0.15. An effect size of 10% was assumed for the intervention study based on a review of previously evaluated reproductive health mass media and counseling interventions.

injectable clients (new and returning) were identified from the entire list of MOH clinics. A random sample of 10 clinics from each district was selected for inclusion in the study from the list of clinics with high injectable client flow.

All new injectable users who attended the study clinics during the three-month enrollment period were invited to join the pre-intervention study. The women were not required to be first time contraceptive users, but at enrollment, they had to be first time users of contraceptive injectables. Participants also had to be 18 years or older and residents of one of the two study districts.

Data collection

Baseline interviews for the pre-intervention study were conducted at the conclusion of participants' FP appointment in a location inside or just outside of the clinic. The three follow-up interviews were conducted at the participants' homes or another location designated by the participant every three months (a few days after the study participants would have received their next injection should they desire re-injection). Trained female research assistants administered quantitative questionnaires at each assessment period measuring demographic variables, time-invariant and time-dependent factors which may influence discontinuation, and the date of discontinuation of a modern FP method (after baseline).

Ethical considerations

Written informed consent was obtained from all study participants. Participants were given 200 Kenya Shillings (approximately \$3.00) for their time at each interview. The study was reviewed and approved by three ethical committees: Family Health International (FHI)'s Protection of Human Subjects Committee, the Kenyatta National Hospital Ethics Review Committee and the University of North Carolina at Chapel Hill Institutional Review Board.

Hypotheses

1. Based on existing literature the following factors are hypothesized to predict discontinuation while still in need of FP in the study districts:

- Experience of a side effect or report of a health concern
- Fear of side effects/health concerns
- Age (with younger women being more likely to discontinue than older women)
- Fewer living children
- Fertility intentions (with women who want to space their children being more likely to discontinue compared with women who have completed childbearing)
- Change in marital status (women who get married during the study are more likely to discontinue than women who do not change their marital status or get divorced)

2. The associations between predictors and contraceptive discontinuation will be the same in the two districts.

3. Survival curves for time to discontinuation of contraception while still in need will not be different in the two districts.

Dependent variable

First discontinuation of a modern contraceptive method while still in need of FP is the dependent variable and the "event" in the survival analysis models. This variable was constructed by asking participants about their continued FP use during the follow-up interviews. Participants who reported they continued using injectables or switched to any other modern FP method will be considered "continuers." Following the definition used by the DHS, the following contraceptive methods are considered modern methods: female sterilization, male sterilization, IUCD, implants, injectable contraceptives, oral contraceptives, male or female condom, diaphragm/spermicides, or lactational amenorrhea.

Participants who did not continue using injectables and did not switch to another modern method were asked why they discontinued. Reasons for discontinuation were used to group

women into one of two categories: "no longer in need" or "still in need" of FP. Based on standard DHS definitions, the following reasons were considered as "still in need:" discontinued because became pregnant while using method (method failure), husband/partner disapproved, health concerns, side effects, lack of access/too far, costs too much, inconvenient to use, or wanted a more effective method, but did not switch to another modern method. Participants who discontinued while still in need of FP were considered to have experienced an "event" in the survival models. Women were censored at the point at which they were lost, were no longer in need, or discontinued from the study.

At the time of the study, DMPA users were instructed to return to the clinic for reinjection every three months, and FP protocols in Kenya allowed repeat DMPA injections to be given as late as 14 weeks or 98 days after the previous injection. [16] The duration of modern method use in the study was calculated, using the smallest of the following values:

- Days that elapsed between date of last interview and enrollment date (Date of the last interview minus the enrollment date);
- Days covered by a modern contraceptive method: the later of the date of last injection plus 98 days or date when stopped using other modern methods, minus the enrollment date;
- c. 294 days (The maximum number of days covered by a modern contraceptive during the study, which is based on 98 days of protection from one DMPA injection multiplied by three follow-up interviews).

Independent variables

Descriptions of the independent variables considered in this study are found in the Appendix. Several of the independent variables are time-dependent, meaning that respondents provided answers to the same questions up to four different times (at baseline and three follow-up interviews). The variable items came from other questionnaires such as

the DHS or were created specifically to measure constructs suggested by health behavior theories. The data were structured using the counting process form of a Cox model [17].

Three separate exploratory factor analyses (EFA) were conducted in Mplus Version 5.2 to create several independent variables for use in the survival analysis models. [18] The purpose of EFA is to identify a more parsimonious conceptual understanding of a set of measured variables by determining the number and nature of common latent factors that account for the pattern of correlation among the variables.[19] The first EFA consisted of time-dependent variables intended to measure <u>motivations to avoid pregnancy</u>; the second was intended to measure the construct of <u>decision making power</u> regarding contraceptive use and health care; and the final was intended to measure <u>perceived quality of care</u> at the last FP appointment.

EFA is based on the common factor model which defines measured variables as linear functions of common factors. [20] Many of the variables included in the factor analyses for this study are binary or ordinal. Common factors have continuous scales, and binary measured variables cannot be a linear function of continuous common factors. This problem is addressed by obtaining polychoric correlations. [21] Since the EFAs contained a combination of categorical and continuous dependent variables, the weighted least-square parameter estimator was employed using a diagonal weight matrix with standard errors and a mean-adjusted chi-square test statistic that uses a full weight matrix. The Crawford-Ferguson oblique oblimin rotation was used because we expect the factors to be correlated. Missing data were handled using a pairwise present approach. Correlations between repeated observations from the same person were accounted for in the models using a robust variance estimator. This approach enables all of the measured variables for a given construct, irrespective of scale, to be put into the same EFA. Variables were eliminated

from the EFA to enable the model to converge² and the model was re-run. The variables eliminated from the EFAs were assessed individually in the bivariate analyses for their inclusion in the final survival model.

Data from one district (the district with the least missing data) were used to identify the number and nature of the factors for the other district. This assumes the factor structure is the same in the two districts, an assumption that was validated by conducting a separate EFA using the data from the second district. The scree test was used to determine the number of factors to retain. This test involves examining the plot of eigenvalues and looking for the last substantial drop in the magnitude of the eigenvalues. [19] The number of factors above this point suggests the number of factors to be retained. Given the goal of these factor analyses is to create independent variables which can predict the outcome, the number of factors decision will also be influenced by the amount of variance captured by the factors. Finally, the factors retained must make sense and be interpretable. Problematic items which violate Thurstone's criteria for simple structure (e.g., low loadings on all factors, numerous high cross loadings, and free standing) were eliminated and the analysis re-run until a parsimonious solution was obtained. [20]

The estimated factor scores were obtained using the exploratory structural equation model (ESEM) feature of Mplus Version 5.2. [18] For the first site this approach required the user to only specify the number of factors for the model. For the second site each parameter was fixed using the parameter estimate obtained from the ESEM from the first site, and thus measurement invariance is assumed. By using the same variables and same scoring values for both sites the resulting factor scores from the two sites are comparable and intended to measure the same constructs.

Missing data

² Polychoric correlations could not be obtained due to sparseness among the bivariates for these variables.

Missing data can lead to bias in parameter estimates and invalid results. [21] The variable measuring household income was omitted from the analysis because of a high degree of missingness (greater than 20%) in both sites. The default in many statistical programs is deletion of cases with missing data. This approach has been found to lead to bias, reduction of sample size and power, and is not preferred. We used multiple imputation (MI) to handle missing data for the independent variables. Imputation techniques involve replacing missing data with estimates based on values of other variables in the data set. The advantage of multiple imputation over single imputation techniques is that MI adds variability to the process by creating different estimates for a single missing datum resulting in unbiased estimators and standard errors. MI assumes that data are MAR, but it can be used to handle systematic patterns of missing data and is robust to violations of nonnormality of the variables. Specifically, MI was conducted using the Markov chain Monte Carlo method with a single chain to create five imputations. The posterior mode, the highest observed-data posterior density, with a noninformative prior, is computed from the expectation-maximization (EM) algorithm and is used as the starting value for the chain. When missing values do not exceed 20% Rubin suggests that 3-5 repetitions are sufficient. [22] Then, each of these completed datasets was separately analyzed. Finally, the results of these separate analyses were combined to produce final parameter estimates and other model results.

Data analysis

Data analysis was conducted using SAS software, Version 9.2 of the SAS System for Windows. [23] Survival analysis methods were used to test the three hypotheses. Tests were considered statistically significant if p<.05.

For the first and second hypotheses, Cox regression models were fit separately for each study district. [24, 25] The exact likelihood method was used to handle the ties. Multiple tied event times are expected in these data. In reality, there is a window of many

days during which women can receive their next injection and still be protected against pregnancy. It is therefore reasonable to suppose that ties are the result of imprecise measurement of time and that there is a true (but unknown) ordering among respondents that have the same nominal durations. To control for clustering expected at the clinic level, a sandwich estimator was used to obtain robust standard errors.

All study participants were first-time contraceptive injectable users, so time at risk for discontinuation started 98 days after their first injection. Participants who discontinued within 9 months had the event of interest, while those who either dropped out before 9 months or did not discontinue by 9 months were right censored. It is possible that some of this censoring is informative (e.g., those who dropped out of the study earlier may have been more likely to have discontinued). Informative censoring could lead to biases because the reason for censoring may be related to the outcome. One method of correcting for informative censoring is to include in the model all factors that affect both event (discontinuation) times and censoring times. Given that it is impossible to know all of these factors sensitivity analyses were conducted. The final models were re-run at the extreme where those lost to follow-up, and therefore censored in the primary survival analysis, were re-coded to experience an event (discontinuation) at the time of censoring.

Each independent variable was examined in bivariate analyses (i.e., a survival model with only one predictor) to see if it was significantly associated with the dependent variable. This procedure was conducted separately for each study district. Given the long list of independent variables, only those which were significant in the bivariate analyses in <u>either</u> district and those listed under hypothesis 1 were entered into the final models for both districts to predict time to first discontinuation while still in need of FP. Backwards model reduction was then used to eliminate variables that were not statistically significant in <u>either</u> district until the final models contained only significant predictors for either district. [26] In

order to compare the districts for the second hypothesis, both final models must be the same.

The first hypothesis was assessed by qualitatively comparing the list of significant predictors of the dependent variable (time until discontinuation while still in need of contraception) in the two models to those found in previous studies predicting contraceptive discontinuation. The second hypothesis was evaluated by comparing the parameter estimates between the two models using 95% confidence intervals.

The third hypothesis required comparison of the two study districts with respect to the distribution of time until discontinuation while still in need of contraception. To evaluate this hypothesis survival curves were estimated and compared for each district using Kaplan-Meier plots and a log-rank test, stratified by district.

Results

There were 501 women enrolled into the study in Mumias District and 505 women enrolled in Nyando District. Sixty five participants from Mumias and 71 participants from Nyando were eliminated from the data set because they did not have any follow-up data and would be eliminated from the survival analysis models by list wise deletion. In Mumias, no differences in the time invariant (baseline) variables were found between those who where eliminated because they had no follow-up data compared to those who remained (data not shown). In Nyando, those eliminated were less likely to have completed secondary or higher education, more likely to be a spacer (versus a limiter), and were more likely to be younger than those who remained in the data set. In Nyando, three participants were missing their baseline questionnaires and were also deleted. After these deletions, 436 participants remained in the Mumias data set who contributed a total of 970 records and 431 participants remained in the Nyando data set who contributed a total of 876 records.

Two percent of women in Mumias (n=9) and in Nyando (n=10) switched to another modern method during the study. Out of the 436 participants in Mumias, 66 (15%)

discontinued using a modern contraceptive method while still in need of FP during the study (i.e., the event in the survival analysis). Out of the 431 women in Nyando, 34 women (8%) discontinued during the study. The average number of days of continuous use of modern method during study was 212 days in Mumias and 201 days in Nyando.

In Mumias, 163 participants (37%) were lost to follow-up and in Nyando 250 (58%) were lost to follow-up. In both sites those lost to follow-up were more likely to be from urban (versus rural) residences compared to those who remained in the study until the end of data collection (data not shown). In Mumias, those lost were also more likely to be younger than those who were not lost. In Nyando, those lost reported a greater number of contraceptive methods discussed by the provider during enrollment compared to those who were not lost. No other differences in the time invariant (baseline) variables were found between those lost to follow-up and those who remained in the study.

Descriptive information for measures

Descriptive statistics for the time invariant (baseline) variables are shown in Tables 3.1 and 3.2. In both districts, the average age of study participants was 25 years. Most participants were members of the majority ethnic group in their respective districts (Luhya in Mumias and Luo in Nyando), Christian, and married at the time of enrollment in the study. Approximately one in five of the participants had used a modern contraceptive method (not injectables) prior to enrollment into the study. On average, women in both districts had three children. Twenty seven percent of Mumias participants reported that they did not want any more children at study enrollment compared to 34% of Nyando participants.

Descriptive statistics for the time-dependent variables are shown in Tables 3.3 and 3.4. For these variables participants contributed multiple records over the study. Seven percent of Mumias participants and four percent of Nyando participants experienced a change in marital status at least once during the study. Forty-two percent of Mumias participants and 33% of Nyando participants expressed a fear of side effects or health

concerns about the contraceptive method they were using. Thirty-nine percent of Mumias participants and 30% of Nyando participants experienced at least one side effect/health concern while using injectables during the study. While participants reported up to six different side effects or health concerns experienced during the study, the average number of side effect/health concerns experienced was one in both districts. Exposure to FP information in both communities was high; 85% and 97% of participants in Mumias and Nyando, respectively, were exposed to at least one message in the community during the study (data not shown). The majority of participants in Mumias (86%) and Nyando (88%) felt "very confident" in their ability to successfully use contraception to avoid pregnancy.

Sixteen percent and 13% of participants in Mumias and Nyando Districts, respectively, reported problems accessing injectables over the study. These problems included having to come to the FP facility more than once to obtain injectables or not being able to obtain injectables at all. However, most participants in both districts reported they were able to ultimately receive their method of choice. Eighty-three percent of participants in Nyando felt there was enough privacy during their last FP appointment compared to 50% of participants in Mumias. Ninety-five percent of participants were "very satisfied" with how they were treated by the provider in Nyando compared to 86% in Mumias. Sixty-four percent of Nyando participants compared to 57% of Mumias participants had all their questions about the FP method answered by providers. The average cost of FP services, including one-way transportation costs to the appointment, was 42 Kenyan Shillings (USD 0.5) in Nyando compared to 53 Ksh (USD 0.7) in Mumias.

Full survival models

All of the variables in Tables 3.1-3.4 with the exception of the outcome (experienced a discontinuation) and lost-to-follow up were examined in bivariate analyses. The first full survival model for each district contained 24 predictors (data not shown), which included the independent variables significantly associated with the outcome, those listed under

hypothesis 1, and the interaction of baseline marriage with the change in martial status variable (this interaction term was included to detect the direction of marital status change). After backwards model reduction, eight predictors remained in the second model for each district (data not shown). After a third round of backwards reduction, the final model for both districts contained six predictors (see Tables 3.5 and 3.6).

We failed to find evidence that any of the factors hypothesized to predict discontinuation, except experiencing side effects or health concern, predicted discontinuation in both of the two study districts. In Mumias, the factors that predicted discontinuation included:

- Experiencing a greater number of side effects or health concerns
- Being nervous about using contraception
- Having never previously used a modern contraceptive method
- Preferring more privacy during the appointment

In Nyando, the factors that predicted discontinuation included:

- Experiencing a greater number of side effects or health concerns
- Being nervous about using contraception
- Paying more for FP services
- Not being married at enrollment

The results assessing whether the associations between predictors and contraceptive discontinuation were the same in the two districts (hypothesis 2) are presented in Table 3.7. Hypothesis 2 is rejected because the associations between predictors and contraceptive discontinuation differed between the two districts. Specifically, the associations differed in at least three respects:

 Nyando women who paid more for FP services were more likely to discontinue compared to Mumias women who paid more for services

- Nyando women who were not married at enrollment were more likely to discontinue compared to Mumias women who were not married at enrollment
- Mumias women with previous contraceptive use were less likely to discontinue compared to Nyando women with previous contraceptive use

Figure 3.1 displays the Kaplan-Meier plots to evaluate hypothesis 3, that the survival curves for each district will not differ. The chi-square for the 1 degree of freedom log-rank test was 9.6330, p = 0.0019. Hypothesis 3 was rejected because the survival functions for time-to-discontinuation of contraception while still in need were significantly different in the two districts. Specifically, time-to-discontinuation in Nyando District was slower compared to time-to-discontinuation in Mumias District. For Mumias participants, 8% discontinued by 98 days, 14% by 196 days and 24% by 294 days. For Nyando participants, 3% discontinued by 98 days, 7% by 196 days and 15% by 294 days. The Kaplan-Meier estimates of discontinuation probability only include those people still at risk for the event at the time of each event.

Sensitivity Analyses

The three hypotheses were assessed again in sensitivity analyses where censored cases in the primary analysis were re-coded to experience a discontinuation immediately after censoring. These sensitivity analyses represent a "worst case scenario" and the truth is probably somewhere in between the two analyses. In both districts, the factors that predicted discontinuation (Tables 3.8 and 3.9) included:

- Having never previously used a modern contraceptive method
- Not being married at enrollment

Hypothesis 2 can not be rejected in the sensitivity analysis because no differences were found between the associations between predictors and contraceptive discontinuation in the two districts (see Table 3.10).

Figure 3.2 displays the Kaplan-Meier plots to evaluate hypothesis 3 in the sensitivity analysis. The chi-square for the 1 degree of freedom log-rank test was 9.7821, p = 0.0018. Hypothesis 3 was rejected because the survival functions for time-to-discontinuation of contraception while still in need were significantly different in the two districts. Time to our revised definition for discontinuation in Mumias District was slower compared to time-to-discontinuation in Nyando District. For Mumias participants, 20% discontinued by 98 days, 47% by 196 days and 55% by 294 days. For Nyando participants, 25% discontinued by 98 days, 54% by 196 days and 67% by 294 days. It is important to note that these results are influenced by the high and differential lost-to-follow-up rates in Mumias (37%) and Nyando (58%) Districts. The pattern of loss was also different between the two districts—the Nyando sample lost a greater proportion of its respondents earlier in the study compared to Mumias. Thirty-five percent of those lost to follow-up in Nyando were lost after the first follow-up interview compared to 21% in Mumias (data not shown).

Discussion

The demographic characteristics of the study participants in the two districts appear similar for most of the variables examined. Surprisingly, approximately a third of participants in both districts say they do not want any more children yet participated in this contraceptive injectable study. A practice recommendation stemming from this finding is to help those desiring to limit childbearing to use longer acting or permanent methods. Looking at the pattern of responses across the two districts for the variables measuring quality of care received at the last FP appointment, participants in Nyando District appear to have higher satisfaction with the quality of care received at their last FP appointment compared to those in Mumias District. However, almost all participants in both districts said they will return to the same facility for their next FP appointment, indicating either that the quality is not that poor or there is a lack of alternative places to obtain FP services in their community. Despite the difference in perceived quality of care, the majority of participants in both

districts continued using injectables over the course of the study. Prospective 9-month discontinuation rates for first-time injectable users in this study were 24% in Mumias and 15% in Nyando. Nationally, 21% of injectable users discontinue use of the method within 12 months of starting, despite still having FP needs. While the rates found in this study are not directly comparable to the 12-month discontinuation rate calculated retrospectively from calendar data in the 2003 DHS, it is interesting to note that they are similar to the national rate.

As expected, experiencing side effects or health concerns predicted discontinuation of a modern contraceptive method while still in need of FP in both districts. None of the other factors hypothesized to predict discontinuation based on review of the FP literature was supported in these data. The other reason for discontinuation common across the two districts was the respondent being nervous about using contraception. While most previous research has not found strong effects for indicators of quality of care on discontinuation, in this study two indicators of quality of care—not having enough privacy during the FP appointment and higher cost of FP services— predicted discontinuation in Mumias and Nyando, respectively. The findings in this study may differ from previous studies because the study participants were recruited from MOH clinics which primarily serve poorer women in Kenya (women with more resources often seek FP services from private clinics) and the large attrition.

Given the predictors of discontinuation differed between the two districts in the primary analysis, we suggest a tailored approach be utilized for interventions aiming to increase contraceptive continuation. Qualitative methods such as focus group discussions conducted with members of the intended target audience could be used to gather community-specific information for such interventions. However, the findings from the sensitivity analyses indicated the opposite practice recommendation since no differences were found between the associations between the predictors and discontinuation in the two

districts when we applied our revised definition for discontinuation. Nevertheless, we consider the primary analyses, since they represent the unaltered data, to be superior to the sensitivity analyses in this study. Tailored intervention approaches are more costly in terms of time and resources when compared to universal approaches, and these costs need to be considered when deciding how to stretch limited FP funding.

The results from both the primary and sensitivity analyses suggest that the rates of discontinuation differ between the two districts prior to implementation of the communication campaign. According to the primary analysis Nyando has a slower rate of discontinuation compared to Mumias. However, the results of the sensitivity analysis called into question the direction of this difference. Unfortunately, over the course of this prospective study, loss to follow-up was substantially higher in Nyando (58%) compared to Mumias (37%). Moreover, the pattern of loss was different in the two districts, with Nyando losing a greater proportion of its respondents earlier in the study compared to Mumias. This loss to follow-up was the result of a contractual dispute and has been resolved for the post-intervention fieldwork. Nevertheless, the high and differential lost to follow-up during the pre-intervention influenced the findings presented in this paper and is clearly the study's greatest limitation. While the truth probably lies some where in between the results from the primary and sensitivity analysis, given the interpretation from the two analyses differ, we consider the results from the primary superior since they represent the unaltered data.

We conducted the follow-up interviews every three months or a few days after the study participants would have received their next injection should they desire re-injection. While we reminded women at every encounter that they did not have to continue using any contraceptive method to remain in the study, it is possible that the follow-up interviews influenced continuation by reminding women about their upcoming injections. Thus, the data collection procedures may pose a threat to the external validity of this study.

This study had several strengths, most notably its inclusion of a comprehensive list of independent variables. In addition to measuring those factors researchers included in previous studies of contraceptive continuation, this study also incorporated novel factors based on health behavior theory, using factor analytical techniques. However, with the exception of the variable measuring nervousness of using contraception, we failed to find evidence of effect of these attitudinal and motivational factors on discontinuation. It is possible that the effects of side effects related to contraceptive use, in particular DMPA, are so strong that it is difficult to detect effects from the attitudinal and motivational factors. Or, perhaps differences were not detected because of reduced power due to the loss to followup. Another explanation could be related to the measures themselves. While the items included in the factor analyses had face validity and displayed variability among the study participants, it is possible that they did not accurately measure the intended constructs. The items were not subjected to prior rigorous psychometric testing. In sum, the lack of evidence for the effect of the factors related to behavioral theories in this study does not mean that these factors do not affect discontinuation behavior. Instead, the findings suggest we need to continue using health behavior theory to inform future research on this topic and build on the findings from this study by improving our measures of these constructs.

A second strength of this study is the prospective longitudinal study design combined with the incorporation of time-dependent variables, which should reduce potential recall bias and decreased the threat to the internal validity of the study. The findings from this study advance our understanding of contraceptive continuation behavior in western Kenya, which can be used to inform interventions designed to increase continuation rates in the region. This study contributed to the body of evidence highlighting the importance of side effects and health concerns on premature discontinuation of contraception—clearly these issues must be addressed more strongly in FP services.

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Variable	Mumias	(N=436)	Nyando (N=431)	
	Non-missing observations	% with attribute	Non-missing observations	% with attribute
Urban residence	436	41	430	29
Luhya/Luo	434	92	430	90
At least primary education	436	67	423	59
Secondary education or more	436	24	423	38
Christian	434	86	428	98
Married at enrollment	434	89	428	88
Previous modern contraceptive use	436	22	431	23
Does not want any more children (limiter)	431	27	428	34
Husband disapproves of contraceptive use	422	17	398	21
Experience a discontinuation	436	15	431	8
Lost-to-follow up	436	37	431	58

Table 3.1: Descriptive statistics (percentages) for time invariant variables by site (number of participants)

Variable	M	lumias (N=43	6)	N	yando (N=43 [·]	1)
	Non- missing observa- tions	Mean	Std Dev	Non- missing observa- tions	Mean	Std Dev
Age	436	25	6	431	25	6
Number of living children	427	3	2	417	3	2
Number of methods discussed by provider during enrollment	434	4	2	431	4	3
Number of days participant plans to use injectables	390	1577	1027	419	1840	2118
Number of days of continuous use of modern method during study (max 294)	436	212	73	431	201	75

Table 3.2: Descriptive statistics (means) for time invariant variables by site (number of participants)

Variable	Mumias (N=970)	Nyando (Nyando (N=876)		
	Non-missing	% with	Non-missing	% with		
	observations	attribute	observations	attribute		
Change in marital status	968	7	873	4		
Contraception						
Experienced at least one side	956	39	868	30		
effect/health concern while						
using injectables						
Fear of side effects/health	841	42	729	33		
concerns due to method						
Feels very confident to use	945	86	868	88		
contraception to avoid						
pregnancy						
Fertility intentions						
Wants a child in the next 2	858	16	826	13		
years or less						
Wants a child in 2 or more	858	56	826	53		
years						
Perceived quality of care						
Problem accessing injectables	872	16	778	13		
FP method of choice was	838	99	730	97		
available						
Received method of choice	838	98	730	95		
Overall satisfied with care	835	92	725	97		
Felt there was enough privacy	840	50	725	83		
during the FP appointment						
Very satisfied with provider	839	86	727	95		
Comfortable discussing	810	84	725	89		
questions or concerns with						
provider						
All questions about FP method	831	57	727	64		
answered by provider						
Very satisfied with the level of	852	83	731	89		
cleanliness at the facility						
Willing to return to the same	849	99	722	98		
facility for next FP						
appointment						

Table 3.3: Descriptive statistics (percentages) for time dependent variables by site (number of records)

Variable		umias (N=97			yando (N=87	
	Non- missing observa- tions	Mean	Std Dev	Non- missing observa- tions	Mean	Std Dev
Number of side effects experienced or health concerns reported	956	1	1	868	1	1
Frequency of exposure to FP information in the community during past three months (range 0-12)	881	3	2	826	4	3
Not nervous about using contraception (range 1-5)	948	4	1	867	4	1
Cost of FP services including transportation (in Kenyan Shillings)	855	53	25	731	42	47
Factors from explorate			I			1
Motivations to avoid pregnancy – Husband/partner support of contraception	965	0.10	0.72	876	0.04	0.70
Motivations to avoid pregnancy – Self motivation to use contraception	965	0.07	0.70	876	0.01	0.22
Motivations to avoid pregnancy – Family support of contraception	965	0.04	0.81	876	0.01	0.63
Cohesive family planning expectations	965	-0.03	0.76	876	-0.01	0.72
Empowered decision making about woman's health	965	0.01	0.66	876	0.01	0.68
Information to users about FP method	858	-0.07	0.79	731	-0.09	0.71

Table 3.4: Descriptive statistics (means) for time dependent variables by site (number of records)

Mumias District	Parameter Estimate	Std Error	p-value
Number of side effects	0.35	0.16	0.029
experienced or health			
concerns reported			
Cost of FP services	-0.01	0.01	0.082
including			
transportation			
Previous modern	-0.93	0.23	<.0001
contraceptive use			
Married at enrollment	-0.21	0.22	0.349
Not nervous about	-0.20	0.06	0.001
using contraception			
Felt there was enough	-1.59	0.41	0.0002
privacy during the FP			
appointment			

Table 3.5: Hypothesis 1 – Primary Analysis - Mumias

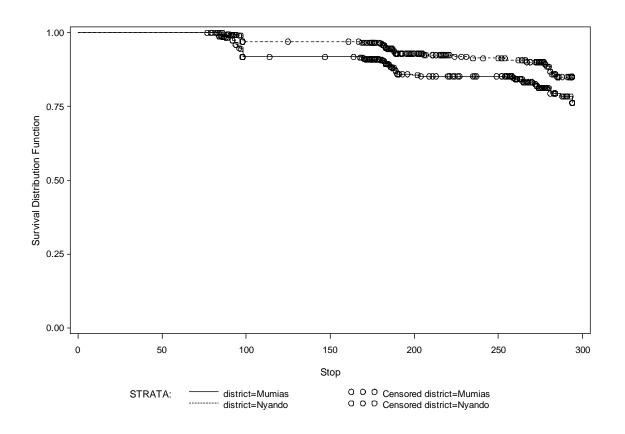
Nyando District	Parameter Estimate	Std error	p-value
Number of side effects	0.50	0.13	0.0001
experienced or health			
concerns reported			
Cost of FP services	0.005	0.001	0.0002
including			
transportation			
Previous modern	-0.17	0.23	0.446
contraceptive use			
Married at enrollment	-1.07	0.34	0.002
Not nervous about	-0.17	0.08	0.029
using contraception			
Felt there was enough	-0.86	0.57	0.151
privacy during the FP			
appointment			

Table 3.6: Hypothesis 1 – Primary Analysis - Nyando

Table 3.7:	Hypothesis 2 –	 Primary Analys 	sis

Variable	Difference (Mumias estimate – Nyando estimate)	Std error of the difference	Lower confidence bound	Upper confidence bound
Number of side effects experienced or health concerns reported	-0.14	0.21	-0.54	0.26
Cost of FP services including transportation	-0.02	0.01	-0.03	-0.00
Previous modern contraceptive use	-0.76	0.32	-1.40	-0.12
Married at enrollment	0.86	0.41	0.06	1.65
Not nervous about using contraception	-0.03	0.10	-0.22	0.16
Felt there was enough privacy during the FP appointment	-0.73	0.71	-2.12	0.65

Figure 3.1: Hypothesis 3 – Primary Analysis



Mumias District	Parameter Estimate	Std Error	p-value
Number of side effects	0.11	0.07	0.103
experienced or health			
concerns reported			
Cost of FP services	-0.00	0.00	0.553
including			
transportation			
Previous modern	-0.32	0.15	0.033
contraceptive use			
Married at enrollment	-0.26	0.13	0.050
Not nervous about	-0.04	0.06	0.500
using contraception			
Felt there was enough	-0.15	0.19	0.420
privacy during the FP			
appointment			

Table 3.8: Hypothesis 1 – Sensitivity Analysis - Mumias

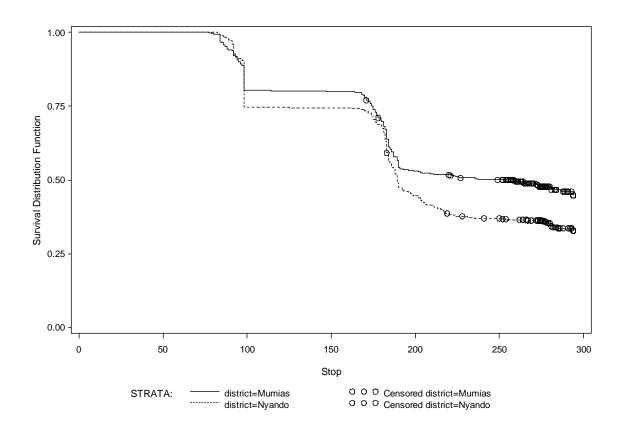
Nyando District	Parameter Estimate	Std error	p-value
Number of side effects	0.08	0.08	0.270
experienced or health			
concerns reported			
Cost of FP services	0.00	0.00	0.092
including			
transportation			
Previous modern	-0.29	0.12	0.013
contraceptive use			
Married at enrollment	-0.38	0.17	0.031
Not nervous about	-0.04	0.08	0.566
using contraception			
Felt there was enough	-0.38	0.24	0.121
privacy during the FP			
appointment			

Table 3.9: Hypothesis 1 – Sensitivity Analysis - Nyando

Table 3.10:	Hypothesis 2 –	Sensitivity Analysis

Variable	Difference (Mumias estimate – Nyando estimate)	Std error of the difference	Lower confidence bound	Upper confidence bound
Number of side effects experienced or health concerns reported	0.02	0.10	-0.17	0.22
Cost of FP services including transportation	-0.00	0.00	-0.01	0.00
Previous modern contraceptive use	-0.03	0.19	-0.41	0.35
Married at enrollment	0.11	0.22	-0.32	0.54
Not nervous about using contraception	0.00	0.10	-0.19	0.19
Felt there was enough privacy during the FP appointment	0.23	0.31	-0.38	0.83

Figure 3.2: Hypothesis 3 – Sensitivity Analysis



CHAPTER 4. Conclusion

This dissertation used qualitative and quantitative research methods to explore reasons for discontinuation of contraceptive injectables in the western region of Kenya. The purpose of this dissertation was to provide the foundation for interpretation of the findings of a four-year prospective, quasi-experimental study being conducted to encourage the continued use of contraceptives by developing, implementing and evaluating a communication campaign intended to increase continuation rates among contraceptive injectable users in Nyando District, Kenya (results expected mid-2010). The pre-intervention research in this dissertation focused on the developmental work and baseline information that is required to interpret the findings from the evaluation of the intervention study.

Using qualitative methods in the form of focus group discussions, the first paper identified the reasons women in Nyando District Kenya discontinue using contraceptive injectables from the perspectives of current users and their salient referents. The second paper used quantitative data from a prospective longitudinal study to describe the factors which predict the occurrence and timing of contraceptive discontinuation among first-time contraceptive injectable users still in need of family planning (FP) in the treatment (Nyando District) and comparison (Mumias District) sites before implementation of the communication campaign; and to determine if the rates and predictors of discontinuation differ between the study districts before implementation of the communication campaign.

In the qualitative paper numerous reasons for disconintuation were identified. These reasons were categorized as logistical, social, or medical. Logistical reasons included commodity stock outs, and unecessary and sometimes incorrect provider and/or clinic restrictions which inhibit women from receiving injections. Three clinic restrictions for

injection and re-injection found in this research are parity, hypertension and menstruation requirements.

Social reasons for premature discontinuation of injectables highlight that women in Nyando District do not always have control over the use and continued used of contraception because such decisions are often made by their husbands or other influential people in their community and household. Much of the opposition salient references hold towards the use FP methods stem from a low level of knowledge regarding side effects. Cultural beliefs about gender, sexual behavior and fertility also have an important role in discontinuation behavior. Participants suggest involving men in FP educational efforts might make them understand the advantages of FP, the potential side effects of injectables, and be more understanding if their wife experiences side effects.

Medical reasons for discontinuation in this study were numerous and, similar to previous research, commonly reported side effects of injectables included weight gain and menstrual changes. Participants also reported side effects and health-related fears that are not found in medical literature on injectables like back aches, infertility, delivering a deformed baby, high blood pressure and drowziness. Educational and counseling efforts in this community should be tailored to address these community-specific concerns.

While previous research has primarily focused on user and methodrelated characteristics associated with discontinuation, less attention has been paid to the influence of other people on discontinuation. The research presented in the first paper expands our understanding of discontinuation by examining social influences on discontinuation through incorporating the perspectives of salient reference groups, and demonstrates the power of such groups.

The second paper used prospective, longitudinal data from first-time contraceptive injectables users to measure pre-intervention continuation rates and the factors that predict the timing and occurrence of discontinuation in the treatment (Nyando District) and

comparison (Mumias District) sites. The demographic characteristics of the study participants in the two districts appear similar for most of the variables examined. Surprisingly, approximately a third of participants in both districts say they do not want any more children yet participated in this contraceptive injectable study. A practice recommendation derived from this finding is to help those desiring to limit childbearing to use longer acting or permanent methods.

The majority of participants continued using injectables over the course of the study. Prospective 9-month discontinuation rates for first-time injectable users in this study were 24% in Mumias and 15% in Nyando. Nationally, 21% of injectable users discontinue use of the method within 12 months of starting, despite still having FP needs. While the rates found in this study are not directly comparable to the 12-month discontinuation rate calculated retrospectively from calendar data in the 2003 Kenya Demographic and Health Survey, it is interesting to note that they are similar to the national rate.

The following factors predicted discontinuation in Nyando District: experiencing side effects or health concerns, being nervous about using contraception, not being married at study enrollment, and paying more for FP services. In Mumias District the factors that predicted discontinuation were: experiencing side effects or health concerns, being nervous about using contraception, no previous use of a modern FP method, and preferring more privacy during the FP appointment. These findings can be used to target contraceptive continuation interventions to reach those most likely to discontinue prematurely in the region. The associations between predictors and contraceptive discontinuation differed between the two districts, as did the rates of discontinuation. The findings suggest a tailored approach be utilized for interventions aiming to increase continuation.

The results from both the primary and sensitivity analyses in the second paper suggest that the rates of discontinuation differed between the two districts prior to implementation of the communication campaign. The main objective of the pre-intervention

study was to determine if the rates of discontinuation differed between the treatment and comparison districts before implementation of the campaign so that the evaluation findings (expected mid-2010) would be more robust. According to the primary analysis Nyando has a slower rate of discontinuation compared to Mumias. However, the results of the sensitivity analysis are less clear and call into question the direction of this difference. The high and differential loss to follow-up across the two districts in the pre-intervention study may have influenced the findings of the second paper and must be considered when interpreting and applying these findings to the evaluation of the intervention study.

Loss to follow up in the present study is due to a contractual dispute with a field subcontractor that led to a break in data collection. However, the implications of this situation may be less detrimental than would be the case for the more common circumstance of loss due to factors related to participants. Typically, lost to follow-up occurs because study participants can not be located or refuse to participate in follow-up interviews. In these latter situations participants who are lost to follow-up and those who remain in the study may differ from each other on factors that are related to the outcome of interest. However, the contractual dispute which transpired in this pre-intervention study resulted in data collection being halted in the study districts at specific, but arbitrary, points of time. This decreases the likelihood that the loss is systematic, and therefore not as likely to be strongly associated with the outcome (discontinuation).

The most likely difference between those lost to follow-up in the two study districts and those who remained was urbanicity of study participants' residence (i.e., those lost were more likely to be from urban residences). Because of accessibility and ease of travel, it would take less time to stop data collection in urban areas compared to the more rural areas in the study districts, resulting in fewer urban follow-up interviews. To account for this difference, the urban/rural residence variable should be included in future survival models from these data.

The prospective longitudinal study design combined with the incorporation of timedependent variables employed in the second paper should have reduced potential recall bias and decreased the threat to the internal validity. In addition, this research also incorporated novel attitudinal and motivational factors based on health behavior theory. With the exception of a measure of nervousness about using contraception, however, we failed to find evidence of an effect of these novel factors on discontinuation. Several explanations are possible for this lack of association which are discussed in the second paper, and the absence of an association does not necessarily mean that these factors do not affect discontinuation behavior. Since the findings in the second paper cannot be considered definitive and health behavior theories have been shown to predict numerous other health behaviors, we should continue using health behavior theory to inform future research on this topic and improve our measures of these constructs.

The findings from both the qualitative and quantitative studies add to the body of evidence highlighting the importance of side effects and health concerns on premature discontinuation of contraception. A programmatic recommendation stemming from these findings is that FP services more strongly address side effects and health concerns surrounding FP methods. Both studies also indicate that interventions aimed at increasing contraceptive continuation be tailored to address community-specific concerns. The first study demonstrates how the use of qualitative methods, in particular focus group discussions, can elicit community-specific concerns surrounding FP methods and highlights the need to extend data collection efforts beyond FP users to incorporate the perspectives of their salient referents. It is important to note, however, that tailored intervention approaches are more costly in terms of time and resources when compared to universal approaches, and these costs need to be considered when deciding how to effectively spend limited FP funding.

The findings from this dissertation advance our understanding of contraceptive continuation behavior in western Kenya, which can be used to inform interventions designed to increase continuation rates in the region. The findings may also inform continuation efforts in other locations around the world by suggesting methods to identify community-specific reasons for discontinuation and encouraging researchers to apply health behavior theories to their study design and instruments. Finally, this dissertation will contribute valuable information to interpretation and recommendations generated from evaluation of the intervention.

Next steps

Elements of the communication campaign

The next phase of this research is to determine if a communication campaign can increase contraceptive continuation rates. The formative research presented in the first paper of this dissertation was used to develop a communication campaign that addressed community-specific concerns and targeted current contraceptive users and their salient referents in Nyando District. Six radio spots were developed using information learned through the focus group discussions. One radio spot was targeted at the specific concerns of each of the following six groups: current contraceptive injectable users, husbands of users, mothers-in-laws of users, community leaders, family planning providers, long-term injectable users. For example, the radio spot targeting husbands addressed the specific side effects of injectables which were mentioned by husbands during the focus group discussions, including menstrual changes, weight changes and lower libido. The radio spot also encouraged husbands to support their wives should they experience side effects. The radio spot targeting community leaders focused on how family planning can reduce burden on community resources and attempted to dispel community-specific misconceptions of injectables such as infertility and birth defects. All six radio spots were aired daily on a local radio station for ten months.

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The communication campaign also consisted of a brochure for current users and three posters targeting current users, husbands and male community leaders, and family planning providers. The brochure for current users discussed the advantages and side effects of injectables with attention to the specific concerns current users expressed during the focus group discussions, for example menstrual changes, weight changes and low libido. The content of each poster addressed community-specific concerns, as well. For example, the poster for current users discussed menstrual changes associated with injectable use and encouraged users to return to the health clinic to switch contraceptive methods if bleeding changes were not tolerable. The poster targeting family planning providers reminded providers to discuss community-specific misconceptions about injectables, such as infertility and birth defects, with their clients. The campaign also included airing three additional radio spots (one targeting current users, husbands, and mothers-in-law) for a total of 60 times and three longer format, live radio shows that gave community members the opportunity to call in to ask questions to a guest speaker (a family planning expert and/or current family planning user). These radio spots and features were based on the formative research findings and aired on a local radio station (a different station from the station mentioned above). Finally, 195 community-health workers in Nyando District were trained on contraceptive injectables as part of the campaign. On a larger scale, the intervention study serves as an example of how qualitative research methods, namely focus group discussions, can be used to elicit community-specific concerns, and how to use the information to develop and implement a targeted communication campaign for a community. The next step is to determine if such a communication campaign can increase contraceptive continuation rates. Implications for evaluation of the communication campaign

The analysis plan for the evaluation of the intervention study is to fit the preintervention and the post-intervention data from both districts together in a single Cox model

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with terms for treatment (or district, since the two are masked), timing (pre-versus postintervention), and the interaction between treatment and timing. Then we will define a contrast to test whether the discontinuation rates change differently between the Nyando and Mumias Districts, controlling for differences that exist in pre-intervention discontinuation rates. However, given that assignment to treatment groups was not random, we cannot assume that unmeasured variables during the pre-intervention are unrelated to the outcome (discontinuation). In other words, treatment and district are confounded in this study which means that we cannot know for certain if the change in the outcome is due to pre-existing, unmeasured differences between the districts or the treatment. If pre-existing, unmeasured differences between the districts are present, then this induces confounding bias in the study conclusions. This limitation is the disadvantage of quasi-experimental designs compared to randomized controlled trials. Nevertheless, the inclusion of the pre-intervention measurement of discontinuation rates tells us about the magnitude of initial group differences. The primary analysis presented in the second dissertation paper, for example, informed us that the two districts did have different pre-intervention discontinuation rates, with Nyando having a slower discontinuation rate compared to Mumias. We will include this information in the model for the evaluation of the intervention as described above.

One way to improve the study design would be to have multiple treatment and control districts which are randomized to either treatment or control conditions. By having multiple districts in the study we could begin to assess a district effect because we would have variability across districts within treatment group and the randomization of districts to treatment conditions would eliminate bias caused by unmeasured confounders. Of course, this study design would be more expensive than the study design used in this dissertation, especially for outcomes such as discontinuation that are measured over time. However, researchers and funding agencies would have to decide if the cost associated with this improved design is worth the extra resources given the host of other public health priorities.

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Implications for measurement

Another future direction stemming from this research is to further refine measurement of motivational and attitudinal factors that may predict contraceptive continuation behavior. The novel factors used in the second paper of this dissertation were not subjected to prior psychometric testing nor validation, despite use in other contexts. Without psychometric and validation information it is not possible to definitively determine whether associations between motivational/attitudinal factors and discontinuation exist. It is important to determine if these factors influence discontinuation because they could be used by public health practitioners to target limited family planning resources to groups of women most at risk for pre-mature discontinuation. Unfortunately, most public health funding mechanisms do not prioritize the development and validation of measures and scales.

Considering both its strengths and limitations, the intervention study is an important step in addressing the public health problem of contraceptive discontinuation. The intervention study, including the findings presented in this dissertation, will put us closer to understanding the complex factors that affect contraceptive discontinuation and closer to the goal of meeting family planning needs.

Appendix: Description of independent variables

The dichotomous, time-dependent variable **experienced a side effect or report a health concern** was constructed from the following two questions: "Since your last interview approximately three months ago, did you experience any side effects or problems while using injectables?" (Response option: Yes/No) If respondent answered "No" to this question then she was coded "No" to the side effects/health concern variable. If respondent answered "Yes" her response to the following question was evaluated: "What side effects or problems did you experience using injectables?" (Response option: Circle all that are mentioned.) The respondent was coded "Yes" to the side effect/health concern variable if she mentioned any side effect or health concern. A continuous, time-dependent variable was also constructed from this question by summing the number of unique side effects mentioned by the respondent.

A dichotomous, time-dependent measure of **fear of side effects/health concerns** was constructed based on responses the question "What concerns do you have about using this method?" If a respondent reports a fear of any side effect or health concern including fears not found in the medical literature to this question then she was coded "Yes" for the fear of side effects variable. Otherwise, the respondent was coded "No" to this variable.

A dichotomous, time invariant measure of **husband's disapproval** was constructed with following question, "Do you think that your husband/partner approves or disapproves of couples using a contraceptive method to avoid pregnancy?" (Approves/Disapproves)

A continuous, time-dependent measure of **cost of family planning services** was constructed by summing the following questions: "How much were you charged for the services you received at your most recent family planning appointment?" and "How much did you pay for one-way transportation to that appointment?"

A dichotomous, time-dependent measure of **access to injectables** was constructed as follows: Respondents were coded as not having access to injectables if they reported injectables were difficult or impossible to obtain when asked "What side effects or problems did you experience using injectables?" (Response option: Circle all that are mentioned.) during the interview when a discontinuation was reported **OR** if they reported "yes" to the following question: "Did you come more than once to get your most recent family planning appointment?" Otherwise, respondents were coded as having access to injectables.

Urban-rural residence (dichotomous; time invariant) was determined by asking respondents "Where do you currently live?" The name of the town or neighborhood was recorded verbatim. A dichotomous variable coded "urban" or "rural" was created based on the responses to this question with the assistance of in-country field staff.

Age (ordinal in years; time invariant) was measured by asking "How old were you at your last birthday?"

Education (categorical; time invariant) was constructed from the following two questions: "Have you ever attended school?" (Response options: Yes/No) and "What was the highest level of school you completed?" (Response options: Primary, Secondary, Post-secondary). Two dummy variables were created. The first dummy variable was for primary school where the reference cell was no education. Given the few responses for post-secondary school this response option was combined with secondary school to form the second dummy variable where the reference cell was no education.

Ethnicity (dichotomous; time invariant) was constructed by asking "Which ethnic group do you belong to?" The vast majority of respondents were members of the predominate ethnic group in each of the study districts (Luo in Nyando District and Luhya in Mumias District) and therefore the responses were categorized into the dominant ethnic group in the district versus other.

Religion (dichotomous; time invariant) was determined by asking "What religion are you?" The majority of respondents in both study districts were Christian and therefore the responses were categorized into Christian versus other religion.

Income (continuous; time invariant) was measured with the question "How much household income does your household receive each month, counting all sources?" This variable was log-transformed to rescale the variable so it would not overwhelm the survival analysis model.

Number of living children (ordinal; time invariant) was determined by asking respondents "How many living children do you have?"

Baseline marital status (dichotomous; time invariant) was determined by asking "Are you married". Respondents who said they were married during the baseline (enrollment) interview were coded as "Yes" to this variable and those who said they were not married were coded "No."

A dichotomous, time-dependent measure of the **change in marital status** was constructed by comparing the response to "Are you married?" between two consecutive interviews for each respondent. If there is a change in marital status (either married to not married or vice versa) then the new variable was coded "Yes, change in marital status". If marital status remained the same over consecutive interviews then the new variable was coded "No."

A dichotomous; time invariant variable measuring **previous modern contraception** use was constructed by examining the question "Have you or your partner ever used or tried to use some method to delay or avoid a pregnancy before today?" (Response options: Yes/No) If the response to this question was "No" then the respondent was coded "did not previously use modern method" for the new variable. If "Yes," the response to the next question, "What methods have you ever used or what have you done to avoid getting pregnant before today?", was considered. If the respondent reported previous use of a modern method (defined according to the DHS definition) the respondent was coded "previously used modern method" for the new variable. If the respondent reported using a traditional method in the past she was coded "did not previously use modern method" for the new variable.

A dichotomous, time-dependent measure of **exposure to family planning (FP) information** in the community was constructed by assessing responses to the following four questions:

- In the last three months, have you heard advertisements on the <u>radio</u> about any of the following health topics?
- In the last three months, have you seen advertisements on the <u>television</u> about any of the following health topics?

- In the last three months, did you hear any information about any of the following health topics during <u>theatre performances</u>?
- In the last three months, have you read any information about any of the following health topics on a <u>poster</u>, <u>billboard or in a pamphlet</u>?

Response options for these questions were: Alcohol use/HIV/AIDS/Nutrition/Domestic violence/Malaria/Family planning/Birth spacing/Continuing to use a family planning method/Oral re-hydration for children.

If respondents reported they were exposed to information about the following: family planning, birth spacing, or continuing to use a family planning method for any one of these questions then the new FP exposure variable was coded "Yes" otherwise this variable was coded "No." A continuous, time-dependent variable was also constructed from these four questions by summing the number of affirmative responses each respondent reported being exposed to during past three months. The possible scoring range was 0 (never exposed) to 12 (exposed to all three FP topics through all four mediums) for this continuous variable.

A dichotomous, time invariant variable measuring **fertility intentions (spacer vs. limiter)** was constructed by categorizing respondents as a spacer or limiter based on their response to the following question, "Would you like to have (a/another) child, or would you prefer not to have any (more) children?" Respondents who said they want to have a/another child were categorized a "spacer" and respondents who said they want no more children were categorized a "limiter." This question also included a response option for "undecided" and "don't know" responses because it was expected that many respondents would not be sure of their answer to this question. Respondents who reported they were undecided or did not know were categorized as a "spacer" since conceptually these responses appeared more similar to spacer compared to the more definite response of limiters who stated they did not want any more children.

Factor construction

The aim of the first EFA was to construct time-dependent measures of <u>motivations to</u> <u>avoid pregnancy</u>. The following 19 variables were entered into the EFA based on face validity:

A continuous, time invariant measure of **number of days participant plans to use injectables** was constructed by asking the respondents "How long do you plan to continue using injectables?" Participants could respond in days, months and/or years, however for analysis all responses were converted to years.

An ordinal, time-dependent variable measuring **current fertility intentions** was constructed by asking the question, "How long would you like to wait from now before the birth of (a/another) child? (Response options: Less than 2 years/More than 2 years/No more children). The response "No more children" was coded 3, the response "More than 2 years" was coded 2 and the responses "Less than 2 years" and "Soon" was coded 1.

Husband's fertility intentions (dichotomous, time-dependent) were measured with the question, "Does your husband/partner want to have another child within two years?" (Response options: Yes/No) "Don't know" responses were combined with "Yes" responses.

Problem if became pregnant (ordinal, time-dependent) was measured with the question, "In the next few weeks, if you discovered that you were pregnant, would that be a big

problem, a small problem, or no problem for you?" (Response options: Big problem/small problem/no problem) The response "Big problem" was coded 3, the responses "Small problem" and "Don't know" was coded 2 and the responses "No problem" were coded 1.

Confidence to use contraception (ordinal, time-dependent) was measured with the question, "How confident are you that you will be able to successfully use contraception to avoid pregnancy?" (Response options: Very confident/somewhat confident/not very confident)

Fourteen attitudinal variables (ordinal, time-dependent) were created from the question, "For the following statements, please say whether you strongly agree, moderately agree, neither agree or disagree, moderately disagree, or strongly disagree".

a. I will use contraception to avoid becoming pregnant within the next 12 months.

b. My husband/partner agrees that I should continue utilizing contraception for the next 12 months

c. My husband/partner expects me to use contraception.

d. My husband/partner opposes my using contraception.

e. My family expects me to use contraception.

f. My family opposes my using contraception.

g. My husband/partner would be upset if I became pregnant.

h. My family would be upset if I became pregnant.

i. I am nervous about using contraception.

j. I am using contraception because there are negative consequence to getting pregnant now.

k. I would feel anxious or guilty if I became pregnant now.

I. Using contraception allows me to control when I get pregnant.

m. Using contraception allows me to give better care to my family.

n. Using contraception allows me to pursue educational and/or employment opportunities.

One variable, the number of days participant plans to use injections, was eliminated from the EFA to enable the model to converge and the model was re-run. After examining the scree plot, three factors tapping motivation were retained.

Three variables were eliminated from the EFA because they violated Thurstone's criteria for simple structure: current fertility intentions, confidence to use contraception, and nervousness about using contraception. The variables eliminated from the EFA were assessed individually in the bivariate analyses for their inclusion in the final survival model. For the current fertility intention variable, two dummy variables were created from the original question ("Less than 2 years" and "More than 2 years" where "No More Children" served as the reference cell) prior to including this item in the bivariate analyses.

The EFA was re-run with the remaining15 variables. The first factor was interpreted to measure perceived husband/partner's support of contraceptive use (e.g., husband/male partner does not want to have another child within two years; husband/partner expects respondent to use contraception; and husband/partner would be upset if respondent became pregnant). The second factor was interpreted to measure self-motivation to use contraception (e.g., respondent agrees that she will use contraception to avoid becoming pregnant within the next 12 months; is using contraception because there are negative consequences to getting pregnant now; and the use of contraception allows the respondent

to pursue education and/or employment opportunities). The third factor was interpreted to measure perceived family support of contraceptive use (e.g., family expects respondent to use contraception; family would be upset if respondent became pregnant; and using contraception allows respondent to give better care to her family).

The goal of the second EFA was to construct time-dependent measures of <u>decision</u> <u>making power regarding contraceptive use and health care</u>. The following six variables were entered into the EFA based on face validity:

An ordinal, time-dependent variable measuring **family planning self determination** was constructed from the question, "Would you say that using family planning is mainly your decision, mainly your husband's/partner's decision or did you both decide together?" (Response options: Mainly respondent/Mainly husband/Joint decision/Other person) The response "Mainly respondent" was coded 3, the response "Joint decision" was coded 2 and the responses "Mainly husband", "Other", and "Don't know" were coded 1.

An ordinal, time-dependent variable measuring **frequency of talking to husband/partner about family planning** was constructed from the question, "How often have you talked to your husband/partner about family planning in the past 3 months?" (Response options: Never/Once or twice/More often) The response "More often" was coded 3, the response "Once or twice" was coded 2 and the responses "Never" were coded 1.

An ordinal, time-dependent variable measuring **similarity between husband and wife's desired number of children** was constructed from the question, "Do you think your husband/partner wants the same number of children that you want, or does he want more or fewer than you want?" (Response options: Same number/more children/fewer children) The response "Fewer" was coded 3, the response "Same" was coded 2 and the responses "More" were coded 1.

A dichotomous, time-dependent variable measuring **woman's empowerment in her sexual relationship** was assessed with the question, "In general, if you disagree with your husband/partner, should you keep quite or speak up? (Response options: Speak up/Keep quite)

An ordinal, time-dependent variable measuring **health care self determination** was constructed from the question, "Who usually makes decisions about your health care?" (Response options: Mainly respondent/Mainly husband/Joint decision/Other person) The response "Mainly respondent" was coded 3, the response "Joint decision" was coded 2 and the responses "Mainly husband", "Other", and "Don't know" were coded 1.

An ordinal, time-dependent variable measuring **number of children self determination** was constructed from the question, "Who has the ultimate say in your house about the number of children you and your husband/partner should have?" (Response options: Mainly respondent/Mainly husband/Joint decision/Other person) The response "Mainly respondent" was coded 3, the response "Joint decision" was coded 2 and the responses "Mainly husband", "Other", and "Don't know" were coded 1.

The model converged; no variables were eliminated from this EFA. After examining the scree plot, two factors were retained. The first factor was interpreted to measure cohesive family planning expectations (e.g., greater frequency of talking to husband/partner about FP in the past three months; similarity between the husband and wife's desired

number of children) while the second factor measured empowered decision-making about the woman's health (e.g., respondent feels she should speak up if she disagrees with her husband/partner; respondent usually makes decisions about her health care; and respondent has the ultimate say about the number of children she has).

The purpose of the last EFA was to construct time-dependent measures of <u>perceived quality</u> <u>of care at the last FP appointment</u>. Twenty-one variables were entered into the EFA based on face validity. These variables included:

A continuous, time invariant variable was constructed to represent the **number of contraceptive methods discussed with respondent during enrollment** by summing the responses from baseline question, "Which methods of family planning did the provider discuss with you today?"

Availability of methods (dichotomous, time-dependent) was assessed by examining responses to the question, "Why didn't you receive the method you wanted to get?" This new variable was coded "method of choice unavailable" if respondent said, "Clinic did not have my method" or, "Clinic did not have my brand." Otherwise, this variable was coded "method of choice available."

Received method of choice (dichotomous, time-dependent was constructed by comparing the response to the question, "What method did you <u>want</u> to receive when you came to your appointment that day?" to the question, "Which methods of family planning did you receive at this most recent appointment?" at each interview. If the responses to these two questions are different then the variable was coded "did not receive method of choice." If the responses are the same then the variable was coded "received method of choice." Respondents indicating they had no method preference were coded as having received her method of choice.

Satisfied with provider (ordinal, time-dependent) was measured with the question, "Were you dissatisfied or satisfied with how you were treated by this provider? If dissatisfied, somewhat unsatisfied, or very unsatisfied? If satisfied, somewhat satisfied or very satisfied?" (Response options: Very satisfied/Somewhat satisfied/Neither/Somewhat unsatisfied/ Unsatisfied) The response options for Neither, Somewhat unsatisfied, Unsatisfied, and Don't know were combined due to low frequencies.

The ordinal, time-dependent variable **comfort level for asking questions** was measured with the question, "Did you feel comfortable to openly discuss any of your questions or concerns with the provider? (Response options: Yes/Somewhat/No) Responses of "don't know" were combined with the somewhat category.

An ordinal, time-dependent variable assessing the degree to which all the **respondents' questions were answered** during the FP visit was measured with the question, "Were all your questions about this method answered by the provider? (Response options: Yes/No questions/No) The responses "no questions" and "don't know" were combined.

Satisfied with care received (dichotomous, time-dependent) was measured with the question, "Overall, are you dissatisfied or satisfied with the care that you received at this appointment?" (Response options: Satisfied/Dissatisfied) The response "don't know" was combined with "dissatisfied" responses.

Satisfied with cleanliness at the facility (ordinal, time-dependent) was measured with the question, "How satisfied were you with the level of cleanliness at the facility?" (Response options: Very satisfied/Somewhat satisfied/Neither/Somewhat unsatisfied/ Unsatisfied) The response options for Neither, Somewhat unsatisfied, Unsatisfied, and don't know were combined due to low frequencies.

Enough privacy at the clinic (dichotomous, time-dependent) was measured with the question, "Would you have preferred more privacy during the appointment?" (Response options: Yes/No)

Willingness to return to the clinic for next FP appointment (dichotomous, timedependent) was assessed with the question, "Where do you think you will go for your next family planning appointment?" If the respondent said she planned to return to the same facility this dichotomous variable was coded "Yes" otherwise it was coded "No."

Seven variables assessing method specific information provided to users

(dichotomous, time-dependent) was measured with the questions, "Did the provider give you information about the following: (Response options: Yes/No)

- a. Advantages of this contraceptive method
- b. Disadvantages of this method
- c. How to use this method
- d. When to return for your next appointment
- e. What to do if you miss a dose
- f. Possible side effects or problems related to this method
- g. What to do if you experience side effects or problems

Provider assessed respondent's prior experience with contraception (dichotomous, time-dependent) was measured with the question, "Did the provider ask you about your prior experiences with contraception?" (Response options: Yes/No)

Provider asked respondent which methods she preferred (dichotomous, timedependent) was measured with the question, "Did the provider ask you what method you prefer to use?" (Response options: Yes/No)

Travel time to clinic (continuous, time-dependent) was assessed by asking the question, "Thinking about your most recent visit to obtain a family planning method, how long did it take for you to arrive at the facility?" This variable was measured continuously in minutes and log transformed to rescale the variable so it would not overwhelm the factor analysis model.

Wait time in clinic (continuous, time-dependent) was assessed by asking the question, "After arriving, how long did you wait for your appointment?" This variable was measured continuously in minutes and log transformed to rescale the variable so it would not overwhelm the factor analysis model.

Ten variables (number of contraceptive methods discussed with respondent, availability of methods, received method of choice, satisfied with provider, comfort level for asking questions, respondents' questions were answered, satisfied with care received, satisfied with cleanliness at the facility, enough privacy at the clinic, willingness to return to the clinic for next FP appointment) were eliminated from the EFA to enable the model to converge and the model was re-run. After examining the scree plot, a single factor was retained. The factor was interpreted to measure information about the FP method given to the FP user by the provider (e.g., side effects or problems related to the FP method; advantages of the FP method; and disadvantages of the FP method). The variables eliminated from the EFA were assessed individually in the bivariate analyses for their inclusion in the final survival model.