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Integration of contraceptive services into anticoagulation management services improves access to long-acting reversible contraception

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Abstract

Objective: Integration of services is a promising way to improve access to contraception in sub-Saharan Africa, but few studies have evaluated this strategy to increase access to contraception among women requiring anticoagulation. Our objective was to evaluate a model of care integrating contraceptive counseling and provision within an anticoagulation management clinic in Eldoret, Kenya to determine the impact on LARC use.

Study Design: We performed a prospective observational study of reproductive-age women referred for integrated services from the anticoagulation management clinic at Moi Teaching and Referral Hospital from March 2015 to March 2016. All participants received disease-specific contraceptive counseling and provision, free reversible methods (excluding hormonal intrauterine devices [IUDs]), and follow-up care. We compared LARC use 3 months post-intervention to pre-

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intervention using the proportions test. Logistic regression analysis was used to determine factors related to use of contraceptive implants and copper IUDs.

Results: Of 190 participants, 171 (90%) completed 3-month follow-up. There was a significant increase in contraceptive implant use from 10% to 19%, $p=0.02$ and injectable contraceptive use from 14% to 24%, $p=0.013$. There was a concomitant decrease in the use of no method/abstinence from 57% to 39% (33% decrease, $p<0.001$). Younger age, having at least one child, and discussing family planning with a partner were predictive of LARC use.

Conclusion: Integrating contraceptive services into an anticoagulation management clinic increases the use of highly effective contraceptive use for women with cardiovascular disease. Implementation of similar models of care should be evaluated within other sites for chronic disease management.

Implications: A model of care integrating contraceptive counseling and provision into anticoagulation management services is an effective strategy to improve LARC and overall highly effective contraceptive use among women with cardiovascular disease requiring anticoagulation. This model of care may be utilized to prevent maternal morbidity and mortality among this high-risk population.

Keywords

Family planning; contraception; LARC; integration of care; cardiovascular disease; chronic disease; maternal mortality

1. Introduction

Chronic diseases are the leading cause of death and disability worldwide, including among women of reproductive age [1]. Risks of maternal morbidity and mortality are increased in women with chronic diseases. As maternal mortality rates due to direct obstetric causes decrease due to targeted interventions in developing countries, the proportion attributable to non-obstetric causes is increasing. Approximately 28% of the global burden of maternal mortality is due to non-obstetric causes, of which 70% is due to pre-existing medical conditions exacerbated by pregnancy [1]. Increasing access to contraception is a proven cost-effective strategy to reduce maternal mortality, and it is estimated that providing contraception to all women with an unmet need would prevent 53 million unintended pregnancies and 150,000 maternal deaths annually [2]. There is tremendous opportunity to prevent maternal morbidity and mortality by improving contraceptive access among women with chronic diseases.

One important subset of women with chronic diseases at high risk for maternal mortality are those with cardiovascular diseases (CVD), including venous thromboembolism (VTE), rheumatic heart disease (RHD), congenital heart disease, and stroke. In a recent review of over 900 patients less than 50 years old with RHD from Moi Teaching and Referral Hospital (MTRH), one of two national referral hospitals in Kenya, almost 70% were women [3]. Women with CVD face increased risk of pregnancy-associated maternal and fetal complications, including VTE, cardiac decompensation, prolonged hospitalization, intensive care unit admission, premature birth, and maternal and neonatal death [4, 5]. Therefore, they

require individualized counseling and access to highly-effective contraception to prevent unplanned pregnancy. This is especially important for those on warfarin due to the risk of teratogenesis in early pregnancy [6].

One strategy to prevent unplanned pregnancy is expanded access to long-acting reversible contraception (LARC), including subdermal contraceptive implants and intrauterine devices (IUDs). LARC are the most effective reversible methods and do not contain estrogen and are rarely contraindicated in women with CVD [7]. In developed countries, LARC use has significantly increased over the past 10 years [8], but in sub-Saharan Africa uptake is still low [9]. Reasons for this include patient, partner, provider, and health systems barriers [10]. One proposed strategy to address these barriers is the integration of contraceptive services into HIV care and other medical services. The results have been promising, but none specifically address women with CVD [11–14]. For women with CVD, the anticoagulation management clinic is an important point of care with long-term continuity, creating the optimal service delivery point for an integrated care model.

2. Materials and Methods

2.1 Study Design

We performed a prospective observational study of women actively enrolled in the anticoagulation management clinic at MTRH in Eldoret, Kenya who received integrated contraceptive services between March 2015 and March 2016. After implementation of this model, integrated services were offered to all women of reproductive age (14–50 years) enrolled in anticoagulation management clinic, and all women receiving integrated services were offered enrollment in our study for the purpose of collecting program evaluation data, with no control group. Our objective was to evaluate outcomes after implementation of a model of care for the integration of contraceptive services into the anticoagulation management clinic. Our primary aim was to compare LARC use among this cohort of women prior to and after receiving integrated services. Institutional approval was obtained from the Moi University/MTRH Institutional Research and Ethics Committee and Indiana University Institutional Review Board prior to enrollment, and all participants underwent an approved written informed consent process.

2.2 Model of care design and implementation

The anticoagulation management clinic at MTRH was initiated in February 2009 for the management of patients receiving anticoagulation, working in conjunction with the chronic disease care clinics (specialty clinics in cardiology, hematology-oncology, endocrinology, etc) [15]. The primary anticoagulant used is warfarin due to ease of administration and cost. Two clinical pharmacists, three pharmaceutical technologists, and two clinical officers staff the clinic with an on-call physician. Prior to study initiation, routine care included counseling by clinic staff to prevent pregnancy during anticoagulation use and querying women of reproductive age about contraceptive use. However, comprehensive contraceptive counseling was not routinely performed and content was highly variable. Only injectable contraception and condoms were available on-site, with other methods available through referral to the main MTRH family planning clinic, located in a different building, with no

access to anticoagulation management clinic records and patients were required to pay for services. Given that 35% of anticoagulation management clinic patients travel at least one hour to the clinic, return visits for contraception were challenging [15].

The integrated services model of care was developed through the MTRH Reproductive Health and Pharmacy teams and informed by in-depth interviews with anticoagulation management clinic clients and providers to determine barriers to contraceptive access. Key barriers identified by clients included lack of information regarding safety of contraception, lack of providers knowledgeable about disease-specific medical eligibility, affordability of LARC, myths about contraception in general and LARC specifically, and the importance of partner inclusion in decision-making. Providers cited lack of time to provide counseling and lack of knowledge regarding contraceptive medical eligibility.

After implementation of integrated services, anticoagulation management clinic providers referred all women of reproductive age to the new adjacent family planning clinic during routine visits. A nurse experienced in family planning and trained in medical eligibility criteria for CVD provided all services, with on-call obstetrician-gynecologists. Counseling included information about the importance of planning a pregnancy while on warfarin and individualized counseling about medically-appropriate contraceptive methods using the World Health Organization Medical Eligibility Criteria (WHO MEC) published in 2009 (updated in 2015). Counseling included recommendations for condom use in addition to effective contraceptive use. Counseling also included expected bleeding side effects while using anticoagulation, including irregular but overall reduced quantity with progestin contraceptives and potential increased bleeding with the non-hormonal IUD.[16] Written information in Kiswahili specifically addressing common myths was provided to discuss with partners. The integrated services, including visits and procedures, including same-day LARC initiation when medically appropriate, were provided free of charge through assistance from MTRH. Methods available through the local public health system include the non-hormonal copper IUD, etonorgestrel and levonorgestrel subdermal contraceptive implants, depot medroxyprogesterone acetate (DMPA) injectable contraception, progestin-only oral contraceptive pills, and condoms. The levonorgestrel-releasing intrauterine system (LNG-IUS) is only available through the private sector and is cost-prohibitive. Follow-up visits for contraceptive care were scheduled only as needed; participants continued to attend routine anticoagulation management clinic visits. During those visits all patients are asked about abnormal bleeding and symptoms of anemia and referred for care, as appropriate. Referrals were made to the gynecology clinic for permanent sterilization or when otherwise appropriate.

2.3 Study implementation

In order to prospectively evaluate outcomes, a research assistant recruited participants within the family planning clinic. We excluded women who had previously underwent sterilization, were non-reproductive (underwent a hysterectomy or were postmenopausal), desired to become pregnant within one year, declined enrollment, or did not speak English or Kiswahili. Baseline characteristics and contraceptive method use were obtained via in-person survey at enrollment and confirmed by review of clinic file. Outcomes 3 months post-

enrollment were obtained by participant report via in-person or telephone survey. We chose to evaluate our primary outcome at 3 months post-enrollment to allow time for partner consultation prior to returning for initiation, if desired. Contraceptive method use was classified based on final method used at 3 months post-enrollment.

Based on the Kenya Demographic and Health Survey (KDHS) 2008–2009 [17], we estimated a baseline LARC use of 7.7% and proposed that an increase to 20% would be clinically significant. Using 80% power to detect this difference, given an alpha (type 1) error of 0.05, and accounting for 20% loss to follow-up, we estimated a sample size of 144. All analyses were performed using Stata 13 (StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP). All tests were two-sided with significance level <0.05 deemed statistically significant. Demographic characteristics were summarized using means, medians and proportions. Comparison of contraceptive method use before and 3 months after enrollment was performed using two proportions test. Exploration of factors associated with LARC use was performed using t-test and chi-square test, where appropriate. All factors showing significant association with LARC use were fitted into a logistic regression model with backward elimination, with LARC use or non-use as the binary outcome of interest. Model assumptions were checked and regression diagnostics were performed.

3. Results

During our recruitment period of March 2015 to March 2016, 322 reproductive age women attended anticoagulation management clinic, all of whom were referred for integrated services and we screened 232 (72%) for inclusion (Figure 1). Of the 190 participants enrolled, 3-month outcome data is available for 171 (90%), all of whom were included in final analysis. Most participants had at least primary school education (86%), were married or partnered (70%), and had at least one child (81%) (Table 1). Almost half (49%) desired no future children, 37% had a prior unintended pregnancy, and most (68%) had used a modern method of contraception. The most common indications for anticoagulation were VTE (54%) and valvular heart disease (36%), most often due to RHD. Participants were relatively evenly distributed between new patients (46%), intermediate (23%) and long-established patients (30%).

After implementation of integrated services there was a statistically significant increase in LARC use from 15.2% at baseline to 28.1% 3 months after enrollment (see Table 2). There was also a significant increase in the use of injectable contraception from 13.5% to 24.0%. There was a concomitant significant decrease in the use of no contraceptive use or abstinence from 57.3% to 38.6%. There was no significant change in the use of other non-LARC methods. Only two women used progestin-only contraceptive pills at baseline and continued this method throughout the study and no participants initiated pills. No participants used estrogen-containing methods, including contraceptive pills.

Fifteen participants (8.8%) reported complications related to contraceptive use, including two who discontinued use and one who switched methods. Three women reported heavy bleeding, including one copper IUD user and two implant users; one implant user

discontinued use. Seven women reported irregular bleeding, including 5 implant users, one DMPA user, and one POP user (who was referred to Gynecology clinic due to pain with irregular bleeding), none of whom discontinued use. There was one reported IUD expulsion and she did not initiate a new method. One implant user switched to DMPA due to arm pain. Two IUD users reported vaginal discharge for which they were evaluated and treated for vaginal infections and one DMPA user reported nausea, none of whom discontinued use. Six additional participants discontinued contraceptive use, including five DMPA users (one to become pregnant and four did not report a reason) and one implant user due to the perception that it was interfering with her anticoagulation. One DMPA user switched to condom use on the advice of a physician.

We performed chi-square testing to compare the distribution of participant factors between LARC and non-LARC users (including injectable contraceptive users). Age less than 35 years, being married or partnered, one or more children, and discussing contraception with a partner were positively associated with LARC use (Table 3). There was a significant increase in the proportion of women who discussed contraception with their partner (73% at baseline to 88% at 3 months post-enrollment, $p=0.012$), and 78% reported that their partner was supportive of contraceptive use. There was no difference in LARC use based on indication for anticoagulation. Because relationship status and discussing contraception with a partner were highly collinear during backward regression, relationship status was removed from the final model. After adjusting for other covariates, comparing to non-LARC users, and using age as a continuous variable, we found that younger age (RR_{adj} 0.98, 99%CI 0.97–0.99), at least one child (RR_{adj} 1.46, 99%CI 1.21–1.77), and discussing contraception with a partner (RR_{adj} 1.17, 99%CI 1.02–1.34) were independent predictors of LARC use.

4. Discussion

We found that integrating contraceptive counseling and provision into anticoagulation management increased LARC use by 85% and injectable contraceptive use by 78% among women requiring anticoagulation. The increase in LARC use was primarily driven by an 89% increase in contraceptive implant use. Very few women experienced heavy bleeding or other method-related complications. There was a significant increase in the proportion of women who discussed contraception with their partners and they were more likely to use LARC. Younger women and those with at least one child were also more likely to use LARC. Our study population had a high rate of previous unplanned pregnancy and almost half desired no future childbearing, indicating the unmet need for highly effective contraception. Conversely, almost half of participants did desire future children, pointing to the importance of access to reversible methods.

Previous studies evaluating integrated services have had mixed success due to highly variable designs, ranging from simple referrals between providers to fully integrated community-based delivery of education and services [12]. We attribute the success of our integrated care model to pre-implementation planning and stakeholder input. This allowed us to identify key barriers for which we developed targeted solutions. This reinforces previous evidence that integration strategies must address multi-level barriers to improve access to and acceptability of effective contraception [18–20]. To provide further evidence,

we are currently engaged in analysis of one-year follow-up of study participants to determine contraceptive continuation and unintended pregnancy rates within our cohort.

Increased LARC use was primarily driven by an increase in contraceptive implant use, a trend seen more widely in Kenya and the rest of sub-Saharan Africa [9, 17, 21]. Implants have been shown to be highly desirable, especially to younger women and those needing longer protection from pregnancy [22], such as while on long-term anticoagulation or with CVD. The preference for implants over IUDs may be related to provider and patient-level barriers to IUD use as observed in other studies in sub-Saharan Africa [23]. Despite the increase in LARC use, injectable contraception was still the most commonly used method, consistent with the general Kenyan population [9, 17].

The inclusion of an emphasis on partner involvement resulted in an increased proportion of women discussing contraception with a partner, the majority of whom were supportive of contraceptive use. Additionally, participants who discussed contraception with their partner were more likely to use LARC. This is consistent with other studies showing partner involvement, mediated through increased knowledge, improves contraceptive uptake, effective use, and continuation [24].

A strength of our study was the simultaneous implementation and evaluation plan, allowing us to evaluate key portions of the multi-faceted program targeting key barriers to LARC access and use. We also had a 90% follow-up rate, allowing for robust evaluation of outcomes before and after enrollment. Limitations include the small population at one clinical site, with non-randomized study design utilizing convenience sampling. Although all women of reproductive age attending anticoagulation management clinic were referred for integrated services, we were unable to recruit the entire population. There may be important differences between those who enrolled and those who did not, including desire to use contraception. Therefore our results may not be generalizable to the entire population of women attending an anticoagulation management clinic. We did not include measures of satisfaction, though previous studies have reported patient and provider satisfaction with integrated service models [12, 13]. Lastly, providing free contraceptive methods may play a role in decisions to use contraception and method choice. This was possible because contraceptive methods are provided within the public health system without cost. Anticoagulation patients accessing care at MTRH pay a small fee, and therefore MTRH was able to absorb the service-associated contraceptive costs. This may not be reproducible within other systems with differing fee structures. However, there is significant evidence that contraception is a cost-effective public health measure to prevent maternal and newborn morbidity and mortality [2].

The increased use of both LARC and injectable contraception associated with integration of contraceptive services into CVD management adds to the growing evidence that this is an important strategy to improve access to and use of effective contraception for women at high risk of maternal morbidity and mortality. The significant association of partner discussion about contraception with LARC use indicates that integrated models should include interventions to improve partner involvement. Future studies should evaluate how best to

improve partner involvement in contraception and whether integrated models of care can reduce maternal and neonatal morbidity and mortality.

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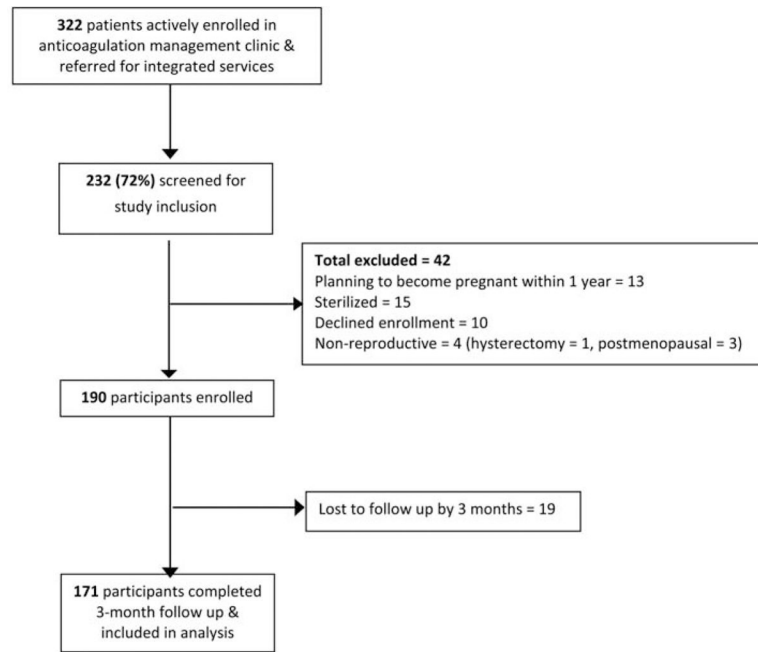


Fig. 1. Study flow diagram for female patients of reproductive age enrolled in anticoagulation management clinic who were referred for integrated contraceptive services, enrolled in the study and completed 3-month follow-up.

Table 1.

Baseline characteristics of all women of reproductive age enrolled in anticoagulation management clinic who received integrated contraceptive services and completed 3 month follow-up. ($N=171$)

Age	31 (16–50)
Educational level	
None	24 (14.0)
Primary	65 (38.0)
Secondary	41 (24.0)
Post-secondary	41 (24.0)
Marital Status	
Married/partnered	120 (70.2)
Single/never married	33 (19.3)
Separated/divorced/widowed	18 (10.5)
Number of living children	
0	33 (19.3)
1	40 (23.4)
2	34 (19.9)
3	64 (37.5)
Indication for anticoagulation ^a	
Venous thromboembolism	92 (53.8)
Valvular heart disease	62 (36.3)
Atrial fibrillation	25 (14.6)
Stroke	13 (7.6)
Other	16 (9.9)
Time enrolled in anticoagulation clinic	
<3 months	79 (46.2)
3–12 months	40 (23.4)
>12 months	52 (30.4)
Desire for future pregnancy	
No	83 (48.5)
Yes	82 (48.0)
Unsure	6 (3.5)
Discussed contraception with partner ($n=120$)	87 (72.5)
History of unintended pregnancy	64 (37.4)
Previous use of modern contraception	117 (68.4)

Categorical values reported as number of subjects (percentage), continuous values reported as median (range).

^aTotal >100% due to multiple indications for anticoagulation

Table 2.

Distribution of contraceptive method use among all women of reproductive age enrolled in anticoagulation management clinic who received integrated contraceptive services and completed 3 month follow-up. Method use was measured at baseline and 3 months after enrollment. ($N=171$)

	Baseline <i>n</i> (%)	3 months after enrollment <i>n</i> (%)	Absolute Change <i>n</i> (%)	Relative Change (%)	95% CI	<i>p</i> -value*
LARC	26 (15.2)	48 (28.1)	22 (12.9)	84.9	79.5, 90.2	0.004
Non-hormonal IUD ^a	9 (5.3)	16 (9.4)	7 (4.1)	77.4	71.1, 83.62	0.15
Contraceptive implant ^b	17 (9.9)	32 (18.7)	15 (8.8)	88.9	84.2, 93.6	0.020
Injectable contraception ^c	23 (13.5)	41 (24.0)	18 (10.5)	77.8	71.5, 84.0	0.013
Other non-LARC methods ^d	24 (14.0)	16 (9.4)	-8 (-4.6)	-32.9	-39.9, -25.8	0.19
Abstinence/no method	98 (57.3)	66 (38.6)	-32 (-18.7)	-32.6	-39.7, -25.6	<0.001

^aNon-hormonal IUD = copper intrauterine device

^bContraceptive implants included etonorgestrel and levonorgestrel implants

^cInjectable contraception = depot medroxyprogesterone acetate (DMPA)

^dOther non-LARC methods include progestin-only contraceptive pills, condoms and natural family planning methods

* *p*-values obtained using two proportions test

Table 3.Variables associated with contraceptive among women visiting an anticoagulation clinic in Kenya. (*N* = 171)

	LARC use ^a (implant n= 32, copper IUD n= 16)	No LARC use ^b (n= 123)	<i>p</i> -value*
Age <35	37 (77.1)	75 (61.0)	0.046
Age ≥ 35	11 (22.9)	48 (39.0)	
Educational level			0.72
None	6 (12.5)	18 (14.6)	
Any education	42 (87.5)	105 (85.4)	
Marital Status			0.047
Married/Partnered	33 (68.8)	64 (52.0)	
Single/Divorced/Widowed	15 (31.2)	59 (48.0)	
Number of living children			0.002
None	2 (4.2)	31 (25.2)	
1 or more	46 (95.8)	92 (74.8)	
Prior unintended pregnancy (<i>n</i> =149)	25 (52.1)	39 (38.6)	0.12
Desire for future pregnancy			0.92
Yes	22 (45.8)	60 (48.8)	
No	24 (50.0)	59 (48.0)	
Unsure	2 (4.2)	4 (3.3)	
Discussed contraception with partner (<i>n</i> =97)	33 (68.8)	54 (43.9)	0.003

Values reported as number of subjects (percentage)

^aLARC use includes participants using non-hormonal (copper) intrauterine devices and contraceptive implants as levonorgestrel IUDs were not available.

^bNo LARC use includes participants using injectable contraception, progestin-only contraceptive pills, condoms, natural family planning, abstinence, and no method.

* *p*-values obtained using chi-square test