Feasibility and Safety of IUD Insertion by Mid-Level Providers in Sub-Saharan Africa

CONTEXT: *The copper IUD is safe and effective, but underutilized in Sub-Saharan Africa, in part because of a lack of trained providers. The World Health Organization recommends training mid-level providers—including nurses and midwives—to insert IUDs; however, the safety of such task shifting has not been evaluated in Sub-Saharan Africa.*

METHODS: *Data were drawn from baseline surveys and study charts of 535 sexually active women aged 18–45 who used a copper IUD while participating in an HIV-prevention clinical trial conducted from August 2012 through June 2015 in Malawi, South Africa, Uganda and Zimbabwe. IUDs were inserted by study physicians, nurses and midwives trained as part of the trial, and by local nonstudy providers. Chi-square and Fisher's exact tests were used to compare women's experiences of adverse events—such as irregular bleeding, pelvic pain or device expulsion—by provider type.*

RESULTS: *Half (54%) of women reported experiencing an adverse event; the most common were irregular bleeding and pelvic pain (45% and 25%, respectively). Compared with women who had received an IUD from a study physician or study nurse, greater proportions of women who had received one from a nonstudy provider reported any adverse event (76% vs. 49% and 51%, respectively), irregular bleeding (57% vs. 41% and 45%) and pelvic pain (35% vs. 15% and 32%); the difference between study physicians and nurses was significant only for pelvic pain. Expulsion rates were comparable for study nurses and nonstudy providers (12.3 and 11.9 per 100 woman-years, respectively), but lower for study physicians (7.3 per 100 woman-years).*

CONCLUSIONS: *The findings support task shifting of IUD insertion to mid-level providers to improve IUD access in Sub-Saharan Africa.*

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The copper IUD is one of the most effective forms of reversible contraception—with an efficacy rate of 99% in the first year of use.[1] It is a long-term method that can be used safely by most women around the world,[2,3] as it has a low rate of adverse events. The most common complaints reported by users are pelvic pain and abnormal uterine bleeding;[4] major complications, such as uterine perforation, are rare.[5,6]

Despite its efficacy and safety, the copper IUD is not commonly used in Sub-Saharan Africa: The method is employed by less than 2% of women using contraceptives in all 48 countries in the region, except Guinea-Bissau (4%) and Kenya (5%).[7,8] Such rates are substantially lower than those reported in some other parts of the world: For example, IUD use is higher than 20% in several low- and middle-income Asian countries, such as Vietnam (28%) and Mongolia (24%).[9] Expanding the use of the IUD would benefit women—especially in low-resource settings—by reducing unintended pregnancies, which are associated with greater maternal morbidity and mortality than intended pregnancies.[10]

A number of factors contribute to low copper IUD utilization in Sub-Saharan Africa. Most countries in the region have a general shortage of physicians. Published data show a physician-to-population density of less than the World Health Organization-recommended minimum of 10 physicians to 10,000 population in South Africa (9 to 10,000), Uganda (0.9 to 10,000), Zimbabwe (0.7 to 10,000) and Malawi (0.1 to 10,000);[11] in South Africa, recent data show that there are approximately 35 nurses and midwives per 10,000 people.[12] The available few physicians are prioritized to work on such national interests as infectious disease control or lifesaving surgeries, leading to inadequate numbers of trained physicians for IUD insertion. In addition, providers have limited knowledge of the advantages of the method; their emphasis on disadvantages and risks associated with the IUD, whether real or inaccurate, is a barrier to use.[13,14] Also, potential IUD users may have misperceptions about the risks associated with the method.[15] In a South African study of clients and health care providers at public clinics, 9% of women who had heard about the IUD had false perceptions about the method that dissuaded them from choosing it;[14] similarly, providers believed inaccurate information regarding IUD eligibility and risks. A study in Uganda reported that 52% of women surveyed at public and private health facilities believed myths and had misconceptions about the IUD, including that it could damage the womb, reduce sexual pleasure or cause cancer.[15]And although the cost of an IUD is subsidized

in many resource-limited countries, patients may still experience high costs for IUD insertion.

Data regarding increased IUD provision through task shifting, defined by the World Health Organization (WHO) as "the training of cadres who do not normally have competencies for specific tasks to deliver these tasks and thereby increase levels of health care access," in resource-limited settings is sparse, particularly in Sub-Saharan Africa.[16] Despite WHO's endorsement of task shifting to increase IUD access, few countries have succeeded in adopting this approach. For example, even though South Africa adopted guidelines in 2012 recommending nurse-led IUD provision in its public health sector and offering insertion at no cost, only 1% of women aged 15–49 surveyed in 2016 who used contraceptives employed an IUD, and virtually all IUD insertions—whether conducted in the private or public sector—were done by a physician.[17] Low IUD use was also reported in Zimbabwe, as the Ministry of Health acknowledged physician shortages.[18] In both South Africa and Zimbabwe, no recently published data on the feasibility of shifting IUD insertion to nurses are available, even though nurses greatly outnumber physicians in both countries. An early study in Barbados noted no difference in clinical outcomes for IUDs inserted by nurses compared with those inserted by physicians.[19] In addition, a trial conducted in Brazil in the 1990s that compared IUD insertion outcomes among women randomized to receive the copper IUD inserted either by a physician or a nurse reported a higher failure rate for the nurses (3% vs. 1%), but no other differences in nonpain complications, such as cervical lacerations, syncope or perforation.[20]

The aim of our study was to examine whether mid-level providers, such as nurses and midwives, could be trained to safely insert the copper IUD in Sub-Saharan African settings. To this end, we used data from an intervention that trained clinicians to provide long-acting reversible contraceptives (LARCs); this intervention was incorporated into a larger clinical trial of an HIV chemoprophylaxis device. Typically, such trials require that female participants of reproductive age use modern contraceptives to avoid inadvertent embryo exposure to potential teratogens. Previous large-scale HIV prevention trials conducted in Sub-Saharan Africa, however, have not included task shifting of IUD insertion to nurses; in three such studies, the use of IUDs has reflected the low usage in the communities from which the study participants were recruited (<2%).[21–23] Because of the limited data on the feasibility of scaling up IUD insertion in resource-limited settings with outcomes stratified by provider type, training on IUD insertion was provided to study clinicians, including nurses and midwives, involved in the MTN-020/ASPIRE trial—a randomized phase III, double-blinded, placebo-controlled trial assessing the effectiveness and safety of an antiretroviral vaginal ring for HIV-1 prevention in four Sub-Saharan African countries.[24] We hypothesized that this training would be feasible, and that nurses and midwives, as well as physicians, would be able to safely insert IUDs. We also hypothesized that there would be no difference in reports of uterine perforation, IUD expulsion, self-reported bleeding or pelvic pain when comparing IUD insertions performed by study nurses or physicians with those performed by local nonstudy providers.

IUD Training Intervention

In June 2012, prior to sample recruitment for the MTN-020/ASPIRE trial, the study team established a contraception action team, which included 1–3 study clinicians (physicians, including medical officers and gynecologists; nurses; and midwives) at each study site, in addition to family planning experts from the United States. The team's mandate was to improve the diversity of contraceptives—including LARCs—available to study participants. To achieve this goal, the copper IUD and the implant were offered to participants as part of the trial, and study clinicians were trained to provide both methods; however, our focus was on the IUD because its use is consistently low (<2%) in the countries where the study was conducted, compared with the implant (which ranges from 3% in South Africa to 12% in Malawi).[25–28]

Training on IUD insertion was provided between August 2012 and June 2014 to all interested study nurses and midwives,* and all study physicians. The majority of study physicians and almost all study nurses had no prior experience in IUD insertion. The contraceptive action team conducted training in IUD insertion, including techniques, counseling regarding side effects and management of complications. Each study site identified local expert clinicians to provide additional training, as well as hands-on supervision to study staff who were selected to become IUD providers. At all sites, trainee clinicians observed 3–5 IUD insertions by the expert clinicians before performing insertions under supervision on nonstudy participants. Trainees performed insertions until they reached competency, defined as observed successful completion of aseptic technique of IUD insertion to the satisfaction of the trainer; generally, this was accomplished within 3–5 supervised insertions.

METHODS

Study Sample

Data for this study were drawn from the MTN-020/ASPIRE trial; detailed methods for the trial have been described elsewhere.[24] Briefly, between August 2012 and June 2014, female study participants were recruited from 15 clinical research sites across Malawi, South Africa, Uganda and Zimbabwe; sites included STI clinics, family planning clinics and postnatal clinics, as well as community-based locations. To be eligible for the trial, women had to be aged 18–45, HIV-negative, sexually active and nonpregnant. In addition, current use

*Henceforth, in regard to the study providers, the term "nurses" also includes midwives.

of a highly effective contraceptive method (defined as the pill, injectable, implant, IUD or tubal ligation) was required for study enrollment. Potential participants were informed whether they were medically eligible to receive each of these contraceptive methods and counseled regarding the methods' advantages and disadvantages; they then chose a method. Overall, 2,629 women were enrolled in the ASPIRE trial. All participants provided written informed consent, and the ethics review committees and local regulatory authorities in each of the four countries reviewed and approved the protocol.

For our analytic sample, we included all ASPIRE participants who had a successful copper IUD insertion no more than 90 days prior to first screening for the trial or at any point during trial participation. This included women who wished to enroll in the trial and wanted to receive an IUD at a study site. Such women were assigned to the first available study clinician, who inserted an IUD following local guidelines adapted from WHO guidelines;[14] therefore, the overall approach, including the insertion method, was similar across countries. Providers used a uterine sound and cervical block with local anesthesia or preinsertion analgesia at their discretion. Women who used another method at enrollment but switched to an IUD during the trial were also included in our study.

The sample also included participants who had a copper IUD inserted by an off-site (i.e., nonstudy) provider no more than 90 days prior to trial enrollment or at any point during trial participation. Off-site providers were mostly physicians (a few were nurses working for international nongovernmental organizations) trained in IUD insertion according to the same WHO guidelines and techniques as those trained for the study. We included women who received an IUD from an off-site provider to represent the standard of care in the community.

The in-country guidelines for IUD provision encourage all providers to discuss potential normal side effects and offer women analgesia, including acetaminophen or such nonsteroidal anti-inflammatory drugs as ibuprofen, as needed peri-insertion; we assume that this happened with off-site provider insertions, but were not able to confirm. Women were instructed to return to the study clinic if they experienced unusual pain, genital bleeding or discharge, sensed IUD displacement or thought that they may be pregnant. These instructions were also given by study staff to women who had off-site IUD insertion. All participants were also informed that they could have their IUD removed at any time without affecting their study participation.

Of the 2,629 women enrolled in ASPIRE, 651, or 25%, reported using the copper IUD during the trial. We excluded 116 women who had no information on IUD insertion or IUD use during the follow-up period, as well as one woman who had a failed insertion. Thus, the final sample consisted of 535 women who had a copper IUD successfully inserted as part of trial participation and for whom complete data were available.

Data and Measures

Baseline data on women's characteristics were collected at enrollment using an interviewer-administered questionnaire. Measures included woman's age, current marital status, level of education (none, some primary, completed primary, some secondary, completed secondary and some university), travel time to the study site in minutes (less than 30, 30–60, 61–120 and more than 120), number of prior pregnancies and number of prior live births. In addition, participants were also asked whether they had had the same primary partner during the past three months, whether they had had any partner other than their primary partner during the past three months, whether they had used a condom at last vaginal sex (male, female, both or neither) and which highly effective method of contraception they were using at study enrollment. In addition, women were asked at screening whether they had ever used a highly effective contraceptive method.

Data on IUD insertion—including provider type—and adverse events were abstracted from participants' charts using a standardized form; chart review and abstraction was performed by site staff following a standardized remote training. All women in the trial, including women who continued IUD use, made scheduled monthly visits from the time of IUD insertion through IUD removal or trial completion; interim visits occurred when medically indicated. At each visit, women reported on their menstrual history, including bleeding irregularities. Self-reports of pelvic pain and abnormal vaginal discharge were evaluated for a possible diagnosis. Urine pregnancy tests were performed monthly throughout study participation. Pelvic examinations were performed semiannually and when clinically indicated. A vaginal speculum examination was performed at any visit during which a woman reported experiencing symptoms suggestive of cervicovaginal infection.

The presence of IUD strings at the cervical os with no part of the frame visible implied a normally placed IUD. If strings were not visualized and the woman did not report an expelled IUD, a qualified ultrasonographer performed an ultrasound to confirm IUD location. If the IUD was not visualized in the uterus, radiography of the abdomen was conducted. Expulsion of the IUD was considered complete when the device was confirmed to not be within the woman's body; partial expulsion was defined as when the IUD was still within the woman's body but displaced from the endometrial cavity. Uterine perforation was diagnosed if part of or the entire IUD was found beyond the uterine serosa.

We defined adverse events on the basis of symptoms reported by participants or of the results of physical examination, and graded them using the Division of AIDS adverse events toxicity table.[29] The table provides guidance and scoring for assessing the severity of pediatric and adult adverse events (both clinical and laboratory) of participants in clinical trials. Adverse events in our study included those that occurred as a result of the insertion

TABLE 1. Selected characteristics at enrollment of trial participants who received a copper IUD, by type of provider who inserted the device, MTN-020/ASPIRE, 2012–2014

Characteristic	All (N=535)	Provider type		
		Study nurse/ midwife (N=215)	Study physician (N=238)	Off-site provider (N=82)
Mean age (in years)	27	26	28	25
Currently married				
Yes	43	36	61	7
No	57	64	39	93
Education				
None	<1	<1	<1	0
Some primary	8	17	2	2
Completed primary	6	6	8	2
Some secondary	39	37	37	48
Completed secondary	39	28	50	39
Some university	7	12	3	9
Travel time to clinic (in min.)				
<30	27	24	29	29
30–60	49	38	55	61
61–120	21	32	14	10
>120	3	6	1	0
Mean no. of prior pregnancies	2	2	2	1
Mean no. of prior live births	2	2	2	1
Had same primary partner for last three months				
Yes	96	95	95	99
No	4	5	5	1
Had any partner other than primary partner in past three months				
Yes	22	25	19	22
No	78	75	81	78
Condom use during last vaginal sex act*				
Male condom	53	48	53	67
Female condom	2	1	2	1
Both	<1	1	0	1
Neither	44	49	45	30
Ever use of highly effective contraceptive†				
Yes	66	56	77	61
No	34	44	23	39
Ever use of method of contraception				
IUD‡	46	37	63	24
Pill	10	9	5	28
Injectable	38	52	21	51
Implant	6	2	11	0

*Missing data for one participant. †Reported at screening. ‡As part of the Contraception Action Team initiative, women may have received an IUD during the screening process for ASPIRE or switched to an IUD at any point during the trial. Therefore, study participants included women who screened for the ASPIRE trial with an IUD in place (inserted within three months of enrollment), had an IUD inserted during the screening process but prior to enrollment or had an IUD inserted while participating in the trial. *Notes*: All data are percentage distributions, unless otherwise noted.

procedure (e.g., uterine perforation), as well as those frequently associated with IUD use: bleeding irregularities (e.g., menometrorrhagia, postcoital bleeding), pelvic pain, pelvic inflammatory disease with the IUD in place, reports of missing strings and other events (i.e., vaginal discharge with no evidence of pelvic inflammatory disease, nausea and vomiting or vasovagal episode, partner feeling IUD strings during sex, anemia, back pain and low-lying IUD without expulsion). In addition, we included IUD expulsions (complete or partial), pregnancies and difficulties (e.g., breakage of strings) that occurred during IUD removal.

Analysis

We used descriptive statistics to summarize the demographic and clinical characteristics of participants at enrollment. Next, we compared the prevalence of adverse events across the three provider categories—study physicians, study nurses and off-site providers—and between study physicians and nurses. We used chi-square tests or Fisher's exact tests as appropriate, and employed a two-sided significance level of $p<.05$. Exact dates of IUD expulsion were not available; therefore, we estimated expulsion incidence by dividing the number of expulsions over the total number of woman-years of reported IUD use during the study, including up to 90 days of use prior to ASPIRE screening. For women who reported an expulsion, IUD use duration was estimated to be the midpoint of the total use duration. Given the uncertainty regarding the date of IUD expulsion, we performed a sensitivity analysis where the date of expulsion was estimated as the last date of reported IUD use (representing the lower bound of incidence) and where the date of expulsion was estimated as one month following initial IUD insertion (representing the upper bound of incidence). All analyses were conducted using SAS version 9.4.

RESULTS

Descriptive Statistics

Of the 535 women in our sample, 44% had an IUD inserted by a study physician, 40% by a study nurse and 15% by an off-site provider. Participants were followed for a maximum of 2.6 years; the median follow-up period was 1.6 years. On average, women were 27 years old (Table 1). Forty-three percent reported being currently married, and 85% had attended at least some secondary school. More than three-quarters (76%) of women reported traveling 60 minutes or less to the study clinic. The mean number of prior pregnancies reported was two, as was the mean number of prior live births. Nearly all women (96%) reported having the same primary partner for the last three months, and 22% reported having a nonprimary sex partner in the three months before their enrollment visit. Forty-four percent of women reported that they or their partner did not use a condom at last sex. Twelve percent of women whose IUDs were inserted by study nurses attended some university; the figures for women whose IUDs were inserted by study physicians and off-site providers were 3% and 9%, respectively. The male condom was used during the last vaginal sex act by 67% of women whose IUD was inserted by off-site providers, 53% of women whose IUD was inserted by study physicians and 48% of women whose IUD was inserted by study nurses.

Adverse Events

Overall, 54% of participants reported experiencing an adverse event at or following IUD insertion (Table 2). The type of adverse event most frequently reported by women was irregular bleeding (45%), followed by pelvic pain (25%). Pelvic inflammatory disease and other types of adverse events were rare (reported by 3% and 2% of participants, respectively). Fourteen percent of participants experienced a partial or complete IUD expulsion; the overall incidence of IUD expulsion was 10.1 per 100 woman-years (not shown). Only one difficult IUD removal and no uterine perforations or pregnancies following IUD insertion were recorded.

The proportion of women who experienced any adverse event differed across all provider types: Compared with women who had received a device from a study physician or study nurse, greater proportions of women who had received an IUD from a nonstudy provider reported experiencing any adverse event (76% vs. 49% and 51%, respectively). No difference in overall adverse events was found, however, between insertions by study physicians and study nurses. Similarly, the proportion of women who reported bleeding irregularities was greater among women who had received an IUD from an off-site provider than among those who had received a device from a study physician or study nurse (57% vs. 41% and 45%), but did not differ between insertions by study physicians and nurses. In addition, reports of pelvic pain at any time following insertion were higher among women whose IUD was inserted by an off-site provider (35%), followed by women whose IUDs were inserted by a study nurse (32%) or study physician (15%); differences between all groups were significant. Expulsion rates were comparable between women whose IUDs were inserted by a study nurse (12.3 per 100 woman-years; not shown) and those who received an IUD from an off-site provider (11.9 per 100 woman-years); however, the expulsion rate for study physicians was somewhat lower (7.3 per 100 woman-years). Results from sensitivity analyses were similar for all three groups, which eliminated any uncertainty around duration of IUD use resulting from an unknown date of IUD expulsion.

TABLE 2. Percentage of trial participants who reported experiencing an adverse event with a copper IUD in place, by type of provider who inserted the device

Adverse event	All	Type of provider			p value	
		Study nurse/ midwife	Study physician	Off-site provider	Study nurse/ midwife vs. study physician	All provider types
Any	54	51	49	76	.10	<.0001
Irregular bleeding	45	45	41	57	.45	.04
Pelvic pain	25	32	15	35	<.0001	<.0001
Pelvic inflammatory disease	3	3	1	5	.20	.13
Missing strings	3	3	3	2	.79	.94
Other*	2	3	1	4	.20	.22
IUD expulsion	14	17	10	17	.04	.05
Partial	9	11	7	9	na	na
Complete	5	6	3	7	na	na
Difficult removal	<1	<1	0	0	.47	.56

*Includes vaginal discharge with no evident pelvic inflammatory disease, nausea and vomiting or vasovagal episode, partner felt IUD strings during sex, anemia, back pain and a low-lying IUD without expulsion. *Notes*: Because the primary focus of the analysis was any IUD expulsion, statistical comparisons were limited to overall IUD expulsion. p values were calculated using chi-square or Fisher's exact tests. na=not applicable.

DISCUSSION

This analysis provides evidence that nurses with no prior experience can be trained to insert a copper IUD with adverse event rates similar to those associated with the local standard of care. Importantly, this was achieved in the context of relatively high use of copper IUDs in the study population (25%), which may challenge the assumption of low demand for the copper IUD in Sub-Saharan Africa. Overall, the most common adverse events were irregular bleeding and postinsertion pelvic pain, which is consistent with previous research.[1,5] Both types of event occurred less often among women whose IUD was inserted by a study physician or a study nurse than among women who received a device from a local nonstudy provider. No instances of uterine perforation or pregnancy after IUD insertion were reported, and only one report of a difficult IUD removal was recorded. Our results support study staff–led IUDs insertion by mid-level providers as a strategy to improve IUD uptake in large clinical trials and offer a model for scaling up IUD uptake in Sub-Saharan Africa.

The rates of IUD expulsion were similar among women who had an IUD inserted by a study nurse and those who had a device inserted by an off-site provider; however, both were higher than the expulsion rate among women who had an IUD inserted by a study physician. One possible explanation for the difference between study nurses and study physicians is that physicians may have had more experience performing gynecologic procedures. For example, physicians may have been more confident in applying adequate traction on the cervix to straighten the horizontal axis of the uterus for IUD placement.[30] Aligning the uterine axis correctly is experience-driven and minimizes low-lying devices, which in turn minimizes the risk of expulsion and pregnancy, as well other adverse events, such as pain and bleeding.[31,32]

Previous research has compared complications following IUD insertion stratified by provider type.[19,20,33] The previously mentioned study conducted in Barbados found no differences in complications or adverse events, including uterine expulsion and pain perception post-IUD insertion, among women whose IUDs were inserted by recently trained nurse-midwives versus physicians;[19] however, in that study, nurse practitioners referred difficult cases to physicians, including experienced gynecologists, which may have contributed to the similarities in complication rates between providers. Studies conducted in Turkey, the Caribbean and the Philippines similarly reported no major differences in complication rates by provider type.[34,35] Of note, the previously mentioned study conducted in Brazil, designed to assess whether recently trained nurses were as safe and effective at IUD

provision as physicians, reported that complaints of pain post-IUD insertion were much greater following insertion by physicians.[20]

The overall IUD expulsion rate found in this study—as well as the provider-specific rates—was lower than the rate reported in other resource-limited settings, including Brazil, Chile, Dominican Republic, Hungary, Thailand, Turkey and Zimbabwe (17.8 per 100 woman-years).[33] The rate of expulsions of copper IUDs inserted by physicians in this 2004–2008 study was similar to the expulsion rate for the copper IUD in a 2007–2013 study conducted in the United States (10.7 per 100 woman-years), where IUDs are commonly inserted by physicians.[36] Additional investigation is required to understand what contributes to IUD expulsion in resource-limited settings. Newly trained personnel may benefit from additional supervision when inserting IUDs to limit expulsions.

Limitations

The study's findings should be interpreted in the context of several limitations. This was a secondary analysis of clinical trial data, and the primary study was not designed to answer the question of whether contraceptive complications varied by provider type. Thus, health changes reported by women during monthly visits were recorded in their charts, but events potentially associated with IUD insertion and use were not specifically interrogated (e.g., any reports of pelvic pain were recorded, but women were not asked "Did you have pelvic pain?"). Even though IUD-related adverse events were not specifically targeted, the present study may actually have had more robust reporting of adverse events related to IUD use than would be present in an observational study or a study based on medical chart abstraction.

In addition, the majority of data were taken from participants' charts, resulting in some missing or incomplete data. Confounders for IUD insertion-related adverse events, such as history of prior cesarean section and distorted uterine cavities, were not examined. While we included all data on pelvic pain and bleeding irregularities, data were not collected on the exact timing of these adverse events following insertion. Initial spotting and possible heavier menses following copper IUD placement are anticipated; similarly, some cramping in the first few months after IUD insertion may be normal.[37] Also, some provider data on women whose IUDs were inserted offsite were missing or provided by participants through self-report; however, this potential limitation was mitigated by the standardized guidelines for IUD provision that were followed across the study countries. Considering the rigor with which possible adverse events were explored at monthly visits, we believe the effect of missing data to be minimal. Furthermore, we were unable to link complications by individual providers and assess trends in IUD insertion proficiency over time. It is conceivable that a few providers may have been responsible for most adverse events or that adverse events decreased as providers gained more experience with IUD insertion. Finally, data were not available on the exact date of IUD expulsion; however, our sensitivity analyses yielded similar results across various incidence calculations, demonstrating the robustness of our incidence estimates.

Conclusions

Findings from this study add to the limited body of evidence assessing the feasibility of IUD insertions performed by nurses and midwives. We found that with appropriate training, these providers in resource-limited settings in Sub-Saharan Africa successfully performed IUD insertions, filling an important resource gap and improving access to women interested in LARCs. IUD insertion by newly trained nurses and midwives facilitated increased access to IUDs in four Sub-Saharan African countries with no increased risk of adverse events compared with the local standard of care. In countries with a low physician-to-patient ratio, shifting contraceptive service provision to nurses, who are more numerous, may allow physicians to dedicate more time to essential life-saving duties. Health ministries in the region may consider training additional providers, including nurses and midwives, with the method used in this study in low-resource settings to expand IUD use and mitigate the unmet need for contraception.

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) trial results highlight the significance of being able to expand use of the nonhormonal copper IUD to most women.[38] This trial randomized 7,800 women seeking contraception in high-HIV-burden Sub-Saharan African countries to a copper IUD or levonorgestrel implant, and showed no increased HIV risk with either after 18 months of follow-up. Our findings could also help inform new efforts underway to introduce the hormonal IUD (LNG-IUS) in low-resource settings. Since WHO listed the levonorgestrel IUD as an essential medicine in 2015, Mozambique, Madagascar and Zambia have allowed the device to be used in their countries. Donor-funded pilot projects from organizations, such as Marie Stopes International, International Contraceptive Access Foundation and Medicines360, have played a major role in demonstrating the feasibility of distributing IUDs in these countries. Zimbabwe is currently in the follow-up phase of an acceptability study aiming to inform possible licensure and national rollout.

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RESUMEN

Contexto: *Aunque el DIU de cobre es seguro y efectivo, está subutilizado en África subsahariana, en parte debido a la falta de proveedores de servicios de salud capacitados. La Organización Mundial de la Salud recomienda capacitar a los proveedores de nivel medio –incluidas las enfermeras y parteras– para insertar los DIU; sin embargo, la seguridad de tal cambio de tareas ha sido evaluada en África subsahariana.*

Métodos: *Se obtuvieron datos de encuestas de línea de base y cuadros de un estudio de 535 mujeres sexualmente activas, de 18 a 45 años, que usaron un DIU de cobre en un ensayo clínico de prevención del VIH realizado entre agosto de 2012 y junio de 2015 en Malaui, Sudáfrica, Uganda y Zimbabue. Los DIU fueron insertados por médicos participantes en el estudio, enfermeras y parteras capacitadas como parte del ensayo, así como por proveedores de servicios de salud locales no relacionados con el estudio. Las pruebas exactas de Chi-cuadrado y Fisher se usaron para comparar las experiencias de las mujeres con eventos adversos –como sangrado irregular, dolor pélvico o expulsión del dispositivo– por tipo de proveedor.*

Resultados: *La mitad (54%) de las mujeres reportaron haber experimentado algún evento adverso; los eventos más comunes fueron sangrado irregular y dolor pélvico (45% y 25%, respectivamente). En comparación con las mujeres que habían recibido un DIU de un médico o de una enfermera del estudio, una gran parte de las mujeres que lo habían recibido de un proveedor no relacionado con el estudio reportaron algún tipo de evento adverso (76% vs. 49% y 51%, respectivamente), sangrado irregular (57 % vs. 41% y 45%) y dolor pélvico (35% vs. 15% y 32%); La diferencia entre los médicos y las enfermeras del estudio fue significativa solo para el dolor pélvico. Las tasas de expulsión fueron comparables para las enfermeras del estudio y los proveedores no relacionados con el estudio (12.3 y 11.9 por 100 años-mujer, respectivamente), pero más bajas para los médicos del estudio (7.3 por 100 años-mujer).*

Conclusiones: *Los hallazgos respaldan el cambio de tareas de inserción del DIU a proveedores de nivel medio para mejorar el acceso al DIU en África Subsahariana.*

RÉSUMÉ

Contexte: *Bien qu'il soit sûr et efficace, le DIU au cuivre est sous-utilisé en Afrique subsaharienne, faute, en partie, de prestataires formés. L'Organisation mondiale de la Santé recommande la formation de prestataires de niveau intermédiaire – personnel infirmier et sages-femmes – pour la pose du DIU. La sécurité de cette délégation de tâches n'a cependant pas été évaluée en Afrique subsaharienne.*

Méthodes: *Les données proviennent d'enquêtes de base et de graphiques d'étude concernant 535 femmes sexuellement actives âgées de 18 à 45 ans qui utilisaient un DIU au cuivre dans le cadre d'un essai clinique de prévention du VIH réalisé d'août 2012 à juin 2015 en Afrique du Sud, au Malawi, en Ouganda et au Zimbabwe. Les DIU avaient été posés par les médecins, infirmières et sages-femmes de l'étude, formés dans le cadre de l'essai, ainsi que par des prestataires locaux extérieurs à l'étude. Le test chi carré et la méthode exacte de Fisher ont servi à comparer l'expérience d'effets indésirables – tels que saignements irréguliers, douleurs pelviennes ou expulsion du DIU – vécus par les femmes suivant le type de prestataire.*

Résultats: *La moitié (54%) des femmes ont signalé un effet indésirable, les plus courants étant les saignements irréguliers et les douleurs pelviennes (45% et 25%, respectivement). Par rapport aux femmes dont le DIU avait été posé par un médecin ou une infirmière de l'étude, de plus grandes proportions de celles qui avaient obtenu leur dispositif d'un prestataire extérieur à l'étude ont signalé un effet indésirable quelconque (76% contre 49% et 51%, respectivement), des saignements irréguliers (57% contre 41% et 45%) et des douleurs pelviennes (35% contre 15% et 32%). La différence entre les médecins et le personnel infirmier de l'étude n'est significative que pour les douleurs pelviennes. Les taux d'expulsion sont comparables pour les infirmières de l'étude et les prestataires extérieurs (12,3 et 11,9 pour 100 femmes-années, respectivement), mais il est moindre pour les médecins de l'étude (7,3 pour 100 femmes-années).*

Conclusions: *Les résultats sont favorables à la délégation de la pose du DIU aux prestataires de niveau intermédiaire pour améliorer l'accès au DIU en Afrique subsaharienne.*

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