Medical eligibility, contraceptive choice, and intrauterine device acceptance among HIV-infected women receiving antiretroviral therapy in Lilongwe, Malawi

Lisa B. Haddada,*, Caryl Feldackerb,c, Denise J. Jamiesona, Hannock Tweyab, Carrie Cwiaka, Amy G. Bryantd, Mina C. Hosseinipourd,e, Thomas Chaweza, Linly Mlundirab, Fanny Kachalef, Gretchen S. Studtd, Irving Hoffman, and Sam Phirib

a Emory University, Department of Gynecology and Obstetrics, Atlanta, USA
b The Lighthouse Trust, Lilongwe, Malawi
c International Training and Education Center for Health (I-TECH), University of Washington, Seattle, USA
d University of North Carolina-Chapel Hill, Chapel Hill, USA
e University of North Carolina Project-Malawi, Lilongwe, Malawi
f Reproductive Health Services, Ministry of Health, Lilongwe, Malawi

Abstract

Objective—To determine medical eligibility for contraceptive use, contraceptive preference, and acceptance of a copper intrauterine device (IUD) among a cohort of HIV-infected women receiving antiretroviral therapy (ART).

Methods—All HIV-infected women who received ART and sought contraceptive services at the Lighthouse clinic, an integrated HIV/ART clinic in Lilongwe, Malawi, between August and December 2010 were invited to participate in a structured interview. Eligibility and preference for the following contraceptive methods were assessed: combined hormonal contraceptives, progestogen-only pills, copper IUD, injectable depot medroxyprogesterone acetate (DMPA), and contraceptive implants.

Results—The final sample included 281 women; five were pregnant. The remaining 276 women were eligible for at least three contraceptive methods, with 242 (87.7%) eligible for all five methods evaluated. After counseling, 163 (58.0%) selected DMPA and 98 (34.9%) selected an IUD as their preferred contraceptive method. Regardless of their method of choice, 222 (79.0%) women agreed to have an IUD placed on the same day.
Conclusion—Most methods of contraception are safe for use by HIV-infected women. Approximately 80% of the women were willing to receive an IUD. Efforts must be made to increase education about, and access to, long-acting reversible methods that may be acceptable and appropriate contraceptive options for HIV-infected women.

Keywords
Antiretroviral therapy; Contraception; HIV; Intrauterine contraception; Intrauterine device; Malawi; Medical eligibility

1. Introduction
The prevention of unintended pregnancy among women with HIV infection is critical for two reasons: to decrease the unnecessary morbidity and mortality associated with an unintended pregnancy and to reduce the transmission of HIV infection to infants of HIV-infected mothers. For women with HIV, condoms are often promoted as the contraceptive method of choice because of the benefits of preventing sexually transmitted infections and HIV transmission [1]. However, given a pregnancy rate of 18% per year with typical use among those using condoms alone for contraception [2], a superior strategy is desirable where a highly effective reversible contraceptive is used in conjunction with condoms to provide dual protection. Among women in HIV-serodiscordant couples, the use of injectable contraceptives, such as depot medroxyprogesterone acetate (DMPA), or long-acting reversible contraceptives (LARC), such as intrauterine devices (IUDs) and implants, significantly reduces the incidence of pregnancy compared with the use of condoms alone or oral contraceptives [3]. Given the clear benefits of these methods, it is important to determine which methods can be safely given to women with HIV and to make a range of methods available so that women can choose the best method for them.

In 1996, WHO developed the Medical Eligibility Criteria for Contraceptive Use (WHO MEC), now in its fourth edition [4], to assist providers in determining which contraceptive methods could be safely used by their clients. Although HIV itself does not restrict the use of any contraceptive method [4], other common medical conditions, comorbidities, or medications may limit the options for these women. For example, hormonal contraceptives are considered to be safe overall for use among women receiving antiretroviral therapy (ART), but women taking ART regimens that contain ritonavir-boosted protease inhibitors incur risks with oral contraceptives that may outweigh the benefits because of potential drug–drug interactions that may impact contraceptive efficacy and drug toxicity.

Among the nonhormonal methods, the copper IUD is considered to be safe for use by women with HIV and/or AIDS who are stable on ART [4]. A benefit of this non-hormonal method is that other medications will not impact its contraceptive effectiveness. Studies [5,6] looking at one particular model of the copper IUD, the copper T380A IUD, found no increased risk of infection-related or overall complications among HIV-infected women and no increase in the genital shedding of HIV [7,8]. Unfortunately, despite its high efficacy, safety, ease of use, cost-effectiveness, and reversibility, fewer than 1% of women in Sub-Saharan Africa use an IUD [9].
In Malawi, the prevalence of HIV among women between 15 and 49 years of age is 12.9% [10], with rates of up to 22.7% among women in urban regions. Concurrently, although knowledge about contraceptives is almost universal, the prevalence rate for the use of modern contraceptives is 42% among currently married women using any form of modern birth control, and an estimated 40.6% of pregnancies are unintended [10], with about one-third of unintended pregnancies attributed to contraceptive method failure [11]. With the dramatic increase of women receiving ART in Malawi as a result of Option B Plus [12,13], a policy that recommends all HIV-positive pregnant women begin and remain on lifelong ART, medical eligibility for various contraceptive methods in this population has immediate program and policy implications.

The present study explored the medical eligibility for contraceptive use, preferences for contraceptives, and acceptance of the IUD among a cohort of HIV-infected women receiving ART who presented for integrated HIV and family planning services at the Lighthouse clinic at Kamuzu Central Hospital (KCH) in Lilongwe, Malawi.

2. Materials and methods

The Lighthouse Trust is a center of excellence for integrated HIV management and runs two clinics, one at KCH and another based at Bwaila Maternity Hospital, in Lilongwe. Both Lighthouse clinics provide a continuum of HIV-related services from HIV testing to ART and home-based care. The Lighthouse clinic at KCH has more than 8000 patients who receive ART and more than 1000 patients who are not yet clinically eligible for ART. Before initiation of the present study, the capacity for the provision of comprehensive family planning services was developed because previously only male and female condoms were available at the clinic for family planning. Education strategies to promote family planning both among clinical staff and patients were integrated into clinical care at the Lighthouse clinic. Given that most physicians and clients were well educated about the use of DMPA and oral contraceptives, new educational strategies focused on the efficacy and safety of LARC methods, specifically the IUD and contraceptive implants.

The present analysis is based on a subset of data from a randomized clinical trial conducted at the Lighthouse KCH clinic to compare the copper T380A IUD with DMPA [14]. The study population consisted of HIV-infected women who attended the Lighthouse clinic at KCH and desired family planning. All women provided written informed consent prior to participation in any study activity. For the present analysis, we used cross-sectional baseline data collected from August 2, 2010, to January 2, 2011, from all women recruited to reach a sample size of 200.

The clinical trial and its methods have been described previously [14]. Briefly, Lighthouse staff identified women of reproductive age as they presented for routine ART visits. Women interested in family planning were screened for participation in the trial as part of the routine family planning service provision. Women who consented to participate were asked to complete a structured questionnaire to assess medical eligibility for the use of five modern contraceptives—combined hormonal contraceptives, progestogen-only pills, copper IUD, DMPA, and contraceptive implants—through questions based upon the WHO MEC [4].
Additional questions were included to assess each woman’s first choice of contraceptive, her willingness to have an IUD placed at the same clinic visit or in the future, and reasons for declining IUD placement if applicable. The questions were piloted in the local language, Chichewa, prior to study initiation to ensure question clarity. The questionnaires were completed on paper in Chichewa and translated into English by the study staff.

All data for the present study were entered in Access 2003 (Microsoft, Redmond, WA, USA) using a double-entry system and validated using predetermined queries. SPSS version 17.0 (SPSS Inc, Chicago, IL, USA) was used for the statistical analysis. Descriptive statistics were used to determine the proportion of patients who met the medical eligibility criteria for the various contraceptive methods, to describe the preference for a specific contraceptive method, and to evaluate IUD acceptance. A woman was considered to be eligible for a contraceptive method if she had a condition classified as Category 1 or 2 [4], indicating that the benefits outweigh the risks. By contrast, a women was considered to be ineligible if she had a condition classified as Category 3 or 4 [4], indicating that the risks outweigh the benefits.

Support and formal permission to conduct the study in Malawi was provided by all involved institutions including the Ministry of Health and the National Health Services Research Committee in Malawi, the Institutional Review Board at Emory University in Atlanta, USA, and the Institutional Review Board at the University of North Carolina in Chapel Hill, USA.

3. Results

A total of 281 women were screened for the clinical trial and included in the present analysis. The mean age was 32.0 ± 5.6 years (range, 18–48 years), the gravidity was 3.7 ± 1.8 (range, 0–11), and the parity was 3.3 ± 1.8 (range, 0–11). Thirteen (4.6%) women had never used ART, whereas 156 (55.5%) reported ART use for at least 2 years.

Among the 281 women, medical eligibility for the five contraceptive methods evaluated was high. The proportion of women eligible for contraceptive initiation was 87.2% (n = 245), 95.7% (n = 269), 97.2% (n = 273), 97.9% (n = 275), and 98.2% (n = 276) for combined hormonal contraceptives, progestogen-only contraceptive pills, IUD, DMPA, and contraceptive implants, respectively. Five of the 281 women were found to be pregnant at the time of screening. All 276 non-pregnant women were eligible for at least three methods, with 242 (87.7%) eligible for all five methods evaluated. Reasons for ineligibility for the use of a combined hormonal contraceptive included breast-feeding a child under 6 months of age (n = 20) and use of a ritonavir-containing regimen (n = 6) (Table 1). Of the three women who were ineligible for IUD use, one woman had active cervicitis and two women had cervical lesions on examination.

Of 281 women asked about their contraceptive method of choice, 163 (58.0%) women selected DMPA, 98 (34.9%) chose the IUD, and 16 (5.7%) chose an oral contraceptive. Irrespective of their first-choice method, 222 (79.0%) of the 281 women were willing to have an IUD placed on the same day at that visit. Among the 179 women who had stated either DMPA or oral contraceptives as their preferred option, 122 (68.2%) were willing to have an IUD placed at that visit. Of the 59 women who declined IUD placement at that visit,
22 (37.3%) stated that they would be willing to have an IUD placed in the future. Desiring a different or specific contraceptive method was a common reason for declining IUD placement (Table 2). Many women also feared IUD placement (n = 15, 25.4%) or had heard negative things about the IUD (n = 15, 25.4%).

4. Discussion

In the present study, medical eligibility for contraceptives, including LARC methods, among HIV-positive women attending an ART clinic in Malawi and requesting family planning provision was assessed using a questionnaire developed to identify potential contraindications as outlined in the WHO MEC [4]. Medical eligibility in the present cohort was high for all five family planning methods available, similar to the results found in a cohort of HIV-positive women in Saint Petersburg, Russia [15]. The study demonstrated that despite low countrywide IUD use of 0.3% among married women aged 15–49 years [16], increased uptake of the IUD among HIV-positive women is possible.

The present findings have several important implications for programs and policies aimed at HIV-positive women in Malawi and in the region. From a program perspective, the integration of family planning services with HIV care must begin with an education plan for all clinic staff and clients, with the goal to dispel common misconceptions about contraceptives and to increase provider comfort with LARC methods. Although the majority of women selected DMPA as their contraceptive method of choice, almost 35% of the women indicated a preference for the IUD after appropriate counseling and education about the various methods. Moreover, even if the IUD was not the first choice, most women were willing to have an IUD placed. These findings reinforce the results from previous studies [2] and highlight that when women are given education and a choice, a substantial proportion may choose the IUD.

From a policy perspective, the demonstration of eligibility for, and acceptability of, multiple family planning methods has implications for policies on the promotion and use of specific contraceptives. Concerns have been raised about the potential of hormonal contraceptive methods, specifically DMPA, to increase HIV acquisition, transmission, and disease progression [17–21]. Although not every study reached the same conclusion and a recent WHO consultation [22] found insufficient evidence to support a change in the current guidelines on the use of hormonal contraceptives among women with HIV or at risk for HIV, WHO encouraged further investigation of the relationship between hormonal contraception and HIV risk. Even if this risk is confirmed, the burden from unintended pregnancy would likely outweigh the potential risk of HIV acquisition [23] in most countries with high rates of unintended pregnancy and maternal mortality. However, although the use of hormonal contraceptives is important, effective hormone-free options should also be promoted, and for some women such methods need to be considered as the first choice. As demonstrated in the present study, there is willingness to use a nonhormonal IUD among HIV-positive women. Therefore, proactive policies that promote nonhormonal methods, such as the IUD, are warranted.
Another consideration relevant at the policy level is the WHO conclusion [4] that the risks of hormonal contraceptive pills outweigh their benefits (Category 3) in women who receive regimens containing ritonavir-boosted protease inhibitors, because potential drug–drug interactions may alter the pharmacokinetics with potential effects on drug efficacy and toxicity. The clinical significance of small alterations in hormone bioavailability by non-nucleoside reverse transcriptase inhibitors (NNRTIs) is unclear [24]. For example, although the data remain inconclusive, a case report [25] indicated reduced efficacy of an etonogestrel implant in women using the NNRTI efavirenz. Additional concerns regarding drug–drug interactions between other ART regimens and hormonal contraceptives could emerge as ARTs continue to evolve and other regimens are studied. For example, newer antiretroviral regimens containing the pharmacologic booster cobicistat may affect the cytochrome P450 system and thus influence the plasma concentration and efficacy of hormonal contraceptives. Given the high eligibility for, and acceptability of, the nonhormonal IUD in the present population, increasing the availability of this specific method combined with the provision of education and training will ensure that women with HIV who receive ART will continue to have access to highly effective contraceptives despite their antiretroviral regimen.

The present study has several limitations. Only women who expressed an interest in family planning at the time of the study were included, and hence the study population may not represent all HIV-infected women with family planning needs. Additionally, individuals with certain conditions may have been misclassified as eligible because medical eligibility was determined based on self-reports. The study staff asked sensitive questions about health and sexual behavior; some participants may have given inaccurate answers and recall bias may also have influenced the answers. This type of questioning, however, replicates the history-taking that occurs during a typical clinic visit and therefore likely represents the situation outside of a study setting. Contraceptive implants were not available during the study, so no conclusions can be drawn on the preference or eligibility for this method. Although no clients chose an implant as their first option, it is unclear how the lack of availability might have influenced their decision.

Despite these limitations, the present study highlights important points for contraception care among HIV-positive women. First, in line with WHO recommendations [4], we conclude that most methods of contraception are safe for use by HIV-positive women who present for family planning services at our ART clinic. Therefore, efforts must be made to increase the availability of a broad range of contraceptive options. Second, the present findings highlight the acceptability of the IUD to the majority of HIV-positive women at the present clinic. The results indicate that there is large, untapped potential to increase IUD use in this high-risk group, where pregnancy prevention is important and the impact of hormonal contraception remains unclear. The copper IUD could be promoted as a highly effective nonhormonal method expanding the contraceptive options for HIV-positive women. Given that the present family planning services were provided in the context of routine services at a large, public ART clinic, the findings (in particular in terms of IUD uptake) may be applicable to other similar settings.
Acknowledgments

The present study was funded by an anonymous foundation and the Center for AIDS Research at Emory University, Atlanta, USA. H.T. is supported under the Operational Research Fellowship Program of the International Union Against Tuberculosis and Lung Disease, Paris, France. C.F. is supported with funding from Cooperative Agreement U91HA06801 from the US Department of Health and Human Services, Health Resources and Services Administration.

References


### Table 1

Incidence of conditions in which the use of contraceptive methods is restricted (Category 3 or 4) according to WHO [4].

<table>
<thead>
<tr>
<th>Condition</th>
<th>Contraindicated method</th>
<th>Frequency in the present study (n = 281)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding (≥ 6 weeks and &lt; 6 months postpartum)</td>
<td>CHC</td>
<td>20 (7.1)</td>
</tr>
<tr>
<td>Ritonavir use</td>
<td>CHC, POP</td>
<td>6 (2.1)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>All</td>
<td>5 (1.8)</td>
</tr>
<tr>
<td>Hypertension&lt;sup&gt;b&lt;/sup&gt;</td>
<td>CHC</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Migraine without aura, &gt;35 years of age</td>
<td>CHC</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Cervical mass</td>
<td>IUD</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Rifampicin use</td>
<td>CHC</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Stroke</td>
<td>CHC, DMPA</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Active cervicitis</td>
<td>IUD</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

Abbreviations: CHC, combined hormonal contraceptive; DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; POP, progestogen-only contraceptive pill.

<sup>a</sup> Values are given as number (percentage).

<sup>b</sup>Systolic blood pressure 140–159 mm Hg, diastolic blood pressure 90–99 mm Hg, or history of hypertension if blood pressure could not be evaluated.
Table 2

Reasons for declining IUD placement on the same clinic day (n = 59).\textsuperscript{a,b}

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preference for a different method</td>
<td>23 (39.0)</td>
</tr>
<tr>
<td>Fear of placement, pain, bleeding, infertility, or infection</td>
<td>15 (25.4)</td>
</tr>
<tr>
<td>Heard negative things about the IUD</td>
<td>15 (25.4)</td>
</tr>
<tr>
<td>Previously used the IUD and did not like it</td>
<td>4 (6.8)</td>
</tr>
<tr>
<td>Uncomfortable having something inside body</td>
<td>3 (5.1)</td>
</tr>
<tr>
<td>Need to ask or discuss with partner first</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Desire to get pregnant</td>
<td>2 (3.4)</td>
</tr>
<tr>
<td>Partner does not want to use any contraception</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>A friend was unhappy with the IUD</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Cannot use IUD because of HIV or another medical condition</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Does not believe the IUD is effective for birth control</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Abbreviation: IUD, intrauterine device.

\textsuperscript{a}Values are given as number (percentage).

\textsuperscript{b}Participants were able to select more than one reason for declining.