International Journal of Gynecology and Obstetrics 123 (2013) 37–41

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

# Women's ability to self-screen for contraindications to combined oral contraceptive pills in Tanzanian drug shops ☆

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ARTICLE INFO

*Article history:*
Received 4 December 2012
Received in revised form 16 April 2013
Accepted 25 June 2013

*Keywords:*
Combined oral contraceptive pills
Contraindications
Hormonal contraception
Injectable contraception
Oral contraceptives
Over-the-counter status
Self-screening

ABSTRACT

*Objective:* To estimate the accuracy of self-screening for contraindications to combined oral contraceptive pills (COCs) and to estimate the proportion of women with contraindications to hormonal methods among those using drug shops in Tanzania. *Methods:* Trained nurses interviewed 1651 women aged 18–39 years who self-screened for contraindications to COCs with the help of a poster at drug shops in Tanzania. Nurse assessment of the women served as the gold standard for comparison with self-assessment. Blood pressure was also measured onsite. *Results:* Nurses reported that 437 (26.5%) women were not eligible to use COCs, compared with 485 (29.4%) according to self-report. Overall, 133 (8.1%) women who said that they were eligible were deemed ineligible by nurses. The rate of ineligibility was artificially high owing to participant and nurse assessments that were incorrectly based on adverse effects of pill use and cultural reasons, and because of the sampling procedure, which intercepted women regardless of their reasons for visiting the drug shop. Adjusted rates of ineligibility were 8.6% and 12.7%, respectively, according to nurse and participant assessment. Both nurses and women underestimated the prevalence of hypertension in the present group. *Conclusion:* Self-screening among women in rural and peri-urban Tanzania with regard to contraindications to COC use was comparable to assessment by trained nurses.


## 1. Introduction

Despite consensus that combined oral contraceptive pills (COCs) are largely safe [1–3], many countries still require prescriptions or impose restrictions on the setting or the type of healthcare worker permitted to provide this method. In the USA, France, and the Republic of Korea, women are required to obtain prescriptions for oral contraceptive pills (OCPs). In Zambia and Rwanda, community-based health workers (CHWs) are allowed to resupply COCs only to women who have already been evaluated at clinics. Because many women lack access to clinics, this effectively poses a medical barrier to family-planning services [4].

The key purpose of clinician screening for contraceptive eligibility is to identify and prevent women with contraindications from using that particular method. Thus, a way of verifying that COCs can be provided safely over the counter is for women to demonstrate the ability to self-screen for medical contraindications to use and apply their assessment to a decision regarding contraception. Studies from the USA and the UK demonstrate that women can accurately self-screen for contraindications to COCs [5–7]. Moreover, comparisons between clinician assessment and women's self-screening in these studies showed that women were more conservative than clinicians—ruling themselves ineligible when clinicians deemed them eligible to use the method.

The shortage of healthcare workers is particularly acute in Sub-Saharan Africa, where demand for family planning has steadily risen [8]. Thus, to meet the 2015 deadline for Millennium Development Goal 5b—to achieve universal access to reproductive health—many countries have turned to task sharing by drawing on CHWs as well as private-sector pharmacies and drug shops to complement and extend the reach of clinic-based services.

As in many Sub-Saharan countries, contraceptive prevalence in Tanzania is low, and pronounced in areas with few clinics/pharmacies and insufficient numbers of trained personnel to staff facilities [9]. At 27%, unmet need for family planning in rural areas is also high among currently married women of reproductive age; for all unmarried women, unmet need is at 6.2% [10]. Most unmet need is for spacing, which is readily provided by short-acting and effective methods such as pills and injectables that can be provided outside a clinic

☆ Results published in part as a research brief: "Women's ability to self-screen for COCs compared to a nurse's assessment: Drug shops in rural and peri-urban Tanzania" (http://www.fhi360.org/sites/default/files/media/documents/tanzania-addo-coc-selfscreen.pdf).

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0020-7292/$ – see front matter 
http://dx.doi.org/10.1016/j.ijgo.2013.04.024

setting. Drug shops are often the first choice for health care in rural Tanzania because these establishments are more accessible and numerous in underserved areas. Thus, a pragmatic and expedient way to respond to the needs of underserved rural communities would be to increase access to hormonal contraceptive methods in these drug shops. Under the accredited drug-dispensing outlet (ADDO) program, the Tanzanian Government permits the dispensing of COCs by drug shops, with the requirement that ADDO providers screen potential users with a checklist to assess eligibility. This special government dispensation allows women access to COCs at ADDOs but reinforces the suggestion that hormonal methods, as a rule, should not be dispensed outside the clinic setting.

With the exception of research conducted in Mexico [11–13], few studies of women's ability to self-screen for contraindications to hormonal contraceptive methods have been conducted in low-resource areas. Evidence is needed to support the removal of medical barriers and to promote greater access to family-planning services, particularly in resource-constrained settings. From 2009 to 2011, FHI 360 collaborated with the National Institute for Medical Research, Muhimbili Medical Research Centre (NIMR-MMRC) based in Dar es Salaam, Tanzania, to gather evidence on women's ability to determine accurately their eligibility for contraceptive use.

The aims of the present study were to determine how well women of reproductive age in Tanzania who used ADDOs could self-screen for contraindications to COCs, and to estimate the proportion of women in the sample with contraindications to hormonal methods.

## 2. Materials and methods

A cross-sectional study was conducted in Ruvuma and Morogoro, Tanzania, between July 26 and September 28, 2010, to compare women's ability to self-screen for contraindications to COCs with clinical assessment by nurses at selected ADDOs. The Protection of Human Subjects Committee of FHI 360 and the National Ethical Committee operating under the Medical Research Coordination Committee of Tanzania reviewed and approved the study.

The sample size for the study was estimated based on the precision of estimates rather than power for hypothesis testing. Based on sensitivity observed in a prior study [6], the true sensitivity of the comparison between ADDO user and nurse assessments was conservatively assumed to be 83.2% and the true specificity 88.8%. A sample size of 1347 was required for an estimate of 15% contraindications to COCs in the target population with precision for sensitivity at ±5%.

The estimate of 15% was assumed because the sample of participants included women up to 39 years of age, who may have been more likely than their younger counterparts to have contraindications to COCs such as known hypertension. Age of study eligibility was truncated at 39 years because the most recent Demographic and Health Survey showed that more than 80% of current pill users were 20–39 years of age [10]. To reduce any impact of low literacy, a poster for self-screening by ADDO users was developed; it contained images and text that represented characteristics or conditions specified by WHO as category 3 (relative) or category 4 (absolute) contraindications to COC use (Fig. 1). Pregnancy was also included on the poster, although the condition is not considered a contraindication by WHO: "there is no known harm to the woman, the course of her pregnancy, or the fetus if COCs are accidentally used during pregnancy" [14]. The condition is mentioned in the medical eligibility criteria (MEC) for contraceptive use, however, because a pregnant woman does not need contraception. Before study implementation, the content of the poster was translated into Swahili and its comprehensibility was pilot-tested among 18 women who were interviewed in Mkuranga and Bagamoyo district ADDOs; this enabled the study team to refine the poster and confirm its comprehensibility among ADDO users.

Fifty nurses were trained to use the WHO 2008 update of the Medical Eligibility Criteria for Contraceptive Use [14] to screen women for contraindications to COCs. From July to October 2010, trained nurses intercepted 2395 women who sought a range of services at 50 ADDOs in Morogoro and Ruvuma. This convenience sample in rural and peri-urban areas excluded women who were not 18–39 years of age, who were unable to read Swahili, who had been interviewed previously, or who declined to participate in the study. The poster was presented to women who met eligibility criteria and who gave verbal informed consent; participants were then asked to assess their ability to use COCs based on the content of the poster. Each woman was also asked to give the reason(s) for her responses on eligibility or non-eligibility. During the rest of the interview, which included questions on demographics and contraceptive history, nurse interviewers conducted a clinical assessment (using a checklist corresponding to the poster) to evaluate contraindications to COC use (based on women's health history). After evaluating clinical history, nurses were also asked to provide a "yes" or "no" response for women's eligibility to use COCs and to explain how they arrived at that decision. Nurses then measured each woman's blood pressure with the Omron R3 Intellisense wrist blood pressure monitor (Omron Healthcare, Lake Forest, IL, USA) at 3 separate intervals. Because blood pressure measurements cannot always be obtained in many settings (including ADDOs), WHO allows for assessment of contraceptive eligibility in the absence of blood pressure measurement [14]. Thus, nurse clinical assessment alone was considered the gold standard for comparison.

Analyses were conducted concurrently by staff at FHI 360 and NIMR-MMRC using Stata version 10.1 (StataCorp, College Station, TX, USA). Univariate and bivariate analyses were conducted to describe the sample and to obtain test operating characteristics: sensitivity; specificity; positive and negative predictive values; and $\kappa$ (agreement) statistics. Each woman's self-assessment was compared with nurse interviewer clinical assessment for contraindications based on category 3 and 4 contraindications from the WHO MEC [14], with and without the inclusion of women's average blood pressure readings. Logistic regressions were used to assess the association between selected demographic characteristics and women's assessments of eligibility to use COCs. Significance levels were set at $P \leq 0.05$.

## 3. Results

Of the 2395 women intercepted, 1776 were eligible (literate, 18–39 years of age, and not previously interviewed). Of these, 1651 consented to participate and were enrolled in the study (Fig. 2). The mean age of the sample of female ADDO users was 27.8 ± 5.1 years. Most women were married, had approximately 2 children, and completed primary-school education (Table 1). Although these women did not visit ADDOs expressly for family planning, 1111 (67.3%) were currently using contraceptive methods and 958 (58.0%) reported having used OCPs.

In total, 485 (29.4%) ADDO users reported that they were ineligible to use COCs, while 437 (26.5%) were categorized as ineligible by study nurses. The percent agreement between women's self-screening and nurse assessment was 80.9% (95% confidence interval [CI], 79.1–82.9). Taking agreement by chance into account ($\kappa$ statistic), the estimate would be 52.8% (95% CI, 48.2–57.4). Women who said that they were eligible to use COCs—that is, they had no contraindications (negative predictive value)—were correct 88.6% of the time (95% CI, 86.8–90.4); those who said that they were not eligible—that is, they had contraindications (positive predictive value)—were correct 62.7% of the time (95% CI, 58.4–67.0) (Table 2). Compared with nurse assessments, 181 (11.0%) women misidentified themselves as not being eligible to use COCs and 133 (8.1%) incorrectly identified themselves as being eligible. The validity of women's self-screening was assessed by sensitivity (i.e. has contraindication) and specificity (i.e. does not have contraindication), giving values of 69.6% (95% CI, 65.3–73.9) and 85.1% (95% CI, 83.1–87.1), respectively. Thus, women who were not eligible to use COCs were able to identify themselves correctly 69.6% of the time, whereas women who were eligible to use COCs were able to identify