

Women's Ability to Self-Screen for COCs Compared to a Nurse's Assessment: Drug Shops in Rural and Peri-Urban Tanzania

Objective

The objectives of the study were to: 1) estimate how well reproductive-age women coming to Accredited Drug Dispensing Outlet (ADDOs) in Tanzania can self-screen for contraindications to combined oral contraceptives (COCs), and 2) estimate the proportion of women in the sample with contraindications to hormonal methods.

Methods

Between July and October 2010, 50 trained nurses intercepted and interviewed 1651 literate female clients ages 18 to 39 who were seeking various services at ADDOs in peri-urban and rural areas in two Tanzania regions. The nurse presented these women with a poster that summarized contraindications for COCs based on the World Health Organization criteria and asked them to determine their eligibility, i.e., to self-screen for using COCs. The nurses took a health history of the women and made a determination of the women's eligibility based on the same WHO criteria. The study compared the two groups and the reasons for their determination of eligibility. The study also measured blood pressure, which can be a contraindication, and compared average BP measurements to both the women's and nurses assessments.

Findings

- The majority of women in Ruvuma (59%) and Morogoro (57%) had used oral contraceptive pills before.
- Of the 1651 women screened, 29% or 485 reported through self-screening that they were not eligible to use the method, while nurses reported 27% or 437 women were not eligible. Women were slightly more conservative than nurses.
- Of the 1651 women, 133 of them (8%) who said they were eligible based on self-screening were found not eligible by the nurses.
- Ineligibility for COC use was not determined correctly in some cases by both the nurses (3% of women) and by the women using the poster to self-screen (14%).
- Women who were pregnant or breastfeeding a child under 6 months old were part of the sample; excluding them lowers ineligible rates to 16% for nurses and 22% for ADDO clients.
- Some ADDO clients said they were ineligible for cultural and pill use reasons.
- Average blood pressure readings found 11% of the women had hypertension, a contraindication for COCs, compared to self-reported hypertension history in only 1% of ADDO clients and 3% of women who nurses ruled ineligible due to this condition.

Conclusion

Women were able to self-screen for contraindications to COCs about as well as nurses. Only 133 represented cases in which women said they were eligible but nurses disagreed. Because pregnancy and currently breastfeeding a child under six months are in the WHO MEC, they are reported, but their inclusion produces an artificially high rate of ineligibility for COC use among this population. Further, precision regarding women deemed ineligible for COC use was difficult to determine since nurses (and more so ADDO clients) did not always use the WHO MEC categories as directed. While the actual blood pressure readings were troublesome, the nurses following the WHO protocol did not do much better than self-screening women on this factor. Finally, while this study looked only at COCs, deductions can be made about injectables, which have fewer MEC restrictions related to hypertension. Thus, allowing the sale of injectables at ADDOs could expand method choice.

Background

Like many countries in sub-Saharan Africa, Tanzania has a high unmet need for family planning, defined as currently married women who want to limit or space their births, but are not using a contraceptive method. Unmet need in the country has increased from 22% in 2004-05 to 25% in 2010.¹ Most of the unmet need is for birth spacing (16%), which can be fulfilled by use of effective short-term methods such as pills and injectables. However, women often have difficulty in obtaining these in rural areas because of limited access to clinics, acute staff shortages, and stock-outs.² In addition, community-based distribution (CBD) of family planning services in Tanzania is generally weak and not available in most regions of the country, a result of government decentralization and a diminished focus on family planning since the 1990s.

One way to address this problem is through private sector retailers, such as drug shops, which are more numerous and accessible than pharmacies in rural areas, and often serve as the first stop for health care services for many rural residents. The Government of Tanzania currently allows drug shops under the Accredited Drug Dispens-

ing Outlet (ADDO) program to dispense combined oral contraceptive pills (COCs) with the expectation that ADDO providers will screen potential clients using a checklist developed to determine contraceptive eligibility. The main objective of this screening is to prevent potential harm that could result if women with contraindications obtained COCs on their own. The government dispensation to ADDOs allows women access to COCs at ADDOs but reinforces the suggestion that hormonal methods should not be dispensed outside the clinic setting. This view limits the options and opportunities for family planning service delivery, particularly among rural populations.

Experts agree that COCs are largely safe.³ Even so, to justify the switch from clinician provision to over-the-counter distribution of COCs, a woman should ideally be able to correctly assess her eligibility to use COCs. One strategy for determining whether COCs could be provided safely over-the-counter is to show that women can screen themselves for medical contraindications to use, and apply the results of the self-screening to a contraceptive decision. Two studies from the USA have demonstrated that many women are able to self-screen

for contraindications.⁴ Both studies showed that in cases of discrepancy, women were more likely to report contraindications than were providers, taking a more conservative approach than health professionals. A study conducted in the UK replicated these findings of a more conservative bent by clients compared to clinicians, and also demonstrated that no woman would have been incorrectly prescribed COCs based on their use of the self-screening questionnaire alone.⁵ No such study had been done in Africa.

FHI 360 and the Tanzania Ministry of Health through the National Institute for Medical Research-Muhimbili Medical Research Center (NIMR-MMRC) examined women's ability to self-screen for contraindications to COCs. The study compared self-screening by female ADDO clients of reproductive age to screening performed by trained nurse interviewers to determine whether or not women can accurately self-screen. The U.S. Agency for International Development funded the study through the PROGRESS project.

Study Design, Population, and Methods

The objectives of the study were to: 1) estimate how well reproductive-age women coming to ADDOs can self-screen for contraindications to COCs, and 2) estimate the proportion of women in the sample with contraindications to hormonal methods.

Study staff trained 50 nurses using the World Health Organization's (WHO) Medical Eligibility Criteria (MEC) for Contraceptive Use (2008 update) to screen women for contraindications to COCs.⁶ The study team developed a poster containing images that represented characteristics or conditions specified by WHO as Category 3 (relative) or Category 4 (absolute) contraindications to COC use for self-screening by ADDO clients (see poster). The poster also included pregnancy. While not considered a contraindication, the WHO MEC mentions that a pregnant woman does not need contraception but also notes that "there is no known harm to the woman, the course of her pregnancy, or the fetus if COCs ... are accidentally used during pregnancy."⁷ Prior to study implementation, the team tested comprehensibility of the poster through interviews with 18 women from four ADDOs in Mkuranga and Bagamoyo districts. From this information, the team refined the poster and confirmed its comprehensibility among ADDO clients.

Most Women Can Safely Use OC Pills

You should NOT use the Pill if you:

- May be pregnant
- Are breastfeeding a baby less than 6 months old
- BOTH** smoke cigarettes **AND** are 35 or older
- Have severe headaches
- Had blood clots in your legs or lungs
- Have liver or gallbladder disease
- Had a stroke or heart attack
- Have been told by a doctor that you have lupus
- Have diabetes
- Have high blood pressure
- Gave birth in the last 3 weeks
- Take medicine for tuberculosis, seizures, or HIV/AIDS

Do you think you can use OC Pills?

Table 1: Eligibility for COCs, comparison of women's and nurses' assessment

Women's assessment of eligibility	Nurses' assessment of eligibility		
	Client is not eligible	Client is eligible	
Woman says she is not eligible	304	181	485
Woman says she is eligible	133	1033	1166
	437	1214	1651

Table 2: Reasons why study participants are not eligible to use COCs, reported by clients and nurses (n=1651)

Women's assessment of eligibility	Nurses' responses (%)	Clients' responses (%)
Currently pregnant	6.5	4.7
Have bad headaches*	5.7	2.7
Currently breastfeeding a baby < six months of age	3.9	3.7
Has high blood pressure	3.1	1.4
Other MEC categories**	5.6	3.8
Responses unrelated to WHO MEC	3.0	13.7
Total***	26.5	29.4

* Headaches: often on one side, causing nausea, worsened by light, noise, or moving

** Categories grouped here include: takes antiretroviral medication for HIV /has HIV; has given birth in the last three weeks/has a young child (age of child not specified); takes medications for tuberculosis/has TB; told has diabetes (high sugar in your blood); takes medications for seizures/epilepsy; told has gall bladder disease; has had a either a stroke, blood clot in your legs or lungs, or a heart attack; over age 35 and smokes cigarettes; told has breast cancer; and told has serious liver disease.

*** Percentages do not add to total because a few women had multiple reasons for non-eligibility.

Between July and October 2010, nurses intercepted and interviewed 1,651 literate female clients between the ages of 18 and 39 who were seeking various services at ADDOs in peri-urban and rural areas in Morogoro and Ruvuma districts. The nurse first presented these women with the poster, and asked them to determine their eligibility to use COCs based on the information presented on the poster. Each woman was also asked to give the reason(s) for their "yes, I'm eligible" or "no, I'm not eligible" response. The nurses then interviewed the women on their health history, including information on demographics and contraceptive use. Based on that interview, using a checklist corresponding to the poster, the nurses evaluated their contraindications to COC use. The nurses, like the ADDO clients, were asked to provide a simple affirmative or negative response regarding the woman's eligibility to use COCs based on this interview and to explain how they arrived at that decision. The compari-

son of the women's responses based on the poster and the nurses' responses based on the health history was considered the primary finding for the study.

An additional element to the study was measuring blood pressure (BP) (because measured BP >140/90 is a relative contraindication to COC under the MEC), and comparing eligibility to actual BP measurements. However, BP measurements cannot always be obtained in many settings, and WHO allows for assessment of contraceptive eligibility in the absence of BP measurement. This study followed the WHO standard as the basis for the comparison with self-screening.

Results

The mean age of women in our sample was 28 years. More than 60% of women were currently married, and more than 70% had completed primary school. An overwhelming proportion of women had ever been

pregnant (88%) with an average of two live births. The majority of women in Ruvuma (59%) and Morogoro (57%) had used oral contraceptive pills before. About 17% percent of women identified themselves as sick (illness not specified) on the day they were interviewed at the ADDO.

Of the 1651 women screened, 29% or 485 reported through self-screening that they were not eligible to use the method, while nurses reported 27% or 437 women were not eligible to use COCs (see Table 1). Thus, the proportion of women considered to be ineligible by nurses was similar to that of study participants, with women being slightly more conservative than nurses. However, the women classified as ineligible by nurses were not always the same women who self-screened as ineligible. Of the 1651 women, 133 of them (8%) who said they were eligible based on self-screening were found not eligible by the nurses.

Nurses as well as the self-screening women did not always determine eligibility based on MEC criteria. Despite being trained to use the MEC categories in evaluating COC eligibility, nurses classified 3% of women as contraindicated to COC use based on invalid reasons (see Table 2). These included low blood pressure, side effects, already using a method, woman cannot use, and woman wants to get pregnant. Thus, the gold standard definition of ineligible used in this study actually includes women who may truly be eligible to use COCs. An even larger proportion of ADDO clients (14%) did not identify a WHO MEC condition as the reason for ineligibility. About 6% of those who reported having a contraindication stated that experience with or fear of side effects made them ineligible to use COCs. The remaining 8% of invalid reasons included issues related to religion and partners, fear of infertility, or fear of not remembering to take the pills daily.

Although both nurse and ADDO client reports of ineligibility are high at 29% and 27%, respectively, the WHO MEC contraindications largely associated with these reports are 1) may be pregnant, 2) breastfeeding an infant less than six months, and 3) headaches as illustrated in Table 2. The first two do not pose significant health risks with use of COCs, and all three are experienced firsthand and largely known to and reportable by the potential pill client. For nurses, those three conditions account for 61% of reported reasons for not being eligible, and for ADDO clients, they account

for 38%. Moreover, pregnant women, and in many cases, breastfeeding women would not be expected to present at an ADDO for COCs. As such, the rate of ineligibility is somewhat an artifact of the sampling strategy that intercepted all women of reproductive age—whether or not they were at the ADDO for the express purpose of obtaining contraception.

Thus, if we examine the rate of ineligibility among women who might actually present for COCs (i.e., excluding women who may be pregnant and those breastfeeding a child under 6 months old; n=1394), the rates decrease to 16% for nurses and 22% for ADDO clients. Also, as noted above, many of the reasons that women said they were ineligible to use COCs had nothing to do with the MEC but were related instead to cultural issues and pill use. Excluding these women in the calculations would reduce the rate of ineligibility still further.

With COC use, hypertension is generally the condition of most concern, and as mentioned earlier cannot always be measured at the service delivery point. The study also included taking the client's BP three times and using an average of the three. In this sample, 11% of the women for whom average blood pressure readings were obtained (1,648) had hypertension as defined by the WHO MEC (> 140mmHg systolic/90 mmHg diastolic). Only 1% of ADDO clients who reported that they were not eligible to use COCs self-identified as being hypertensive, while 3% of women were ruled ineligible by nurses due to this condition (Table 2). Thus, neither the nurses nor the self-screening women matched the level of potential ineligibility that an actual BP measurement identified. Other contraindications shown on the poster such as diabetes, lupus, and cancer may not be known to the woman or ever been diagnosed by a doctor. However, these conditions are unlikely to be detected even by nurse interview.

Conclusions

This study showed that women were able to self-screen for contraindications to COCs about as well as nurses. While there was disagreement between nurses and ADDO clients on eligibility, only 133 represented cases in which women said they were eligible but nurses disagreed. Among the most common nurse-detected contraindications for all women in the study were headaches, pregnancy, currently breastfeeding a child under six months, and high blood pres-

sure—the four most common WHO MEC contraindications among these ADDO clients. Because pregnancy and currently breastfeeding a child under six months are in the WHO MEC, they are reported, but their inclusion produces an artificially high rate of ineligibility for COC use among this population. Further, there was no precision regarding women deemed ineligible to use COCs, since nurses (and more so ADDO clients) did not always use the WHO MEC categories as directed.

Reports of headaches and high blood pressure pose more of a concern for safe COC use. The independent measures of blood pressure indicated that both ADDO clients and nurses underestimated the proportion of women with hypertension. Since ADDOs are unlikely to have the means to measure blood pressure, the inability to do so should not pose a barrier to contraceptive provision as recommended by WHO. More importantly, pregnancy is almost always more risky than any ill effects of contraceptive use, especially among women with high blood pressure. Complications associated with high blood pressure during pregnancy are more serious than complications due to hormonal contraceptive use.

The medical issue regarding headaches concerns serious migraines with or without aura. Studies conducted in rural areas of southern Tanzania and northern Tanzania reported prevalence of migraine headaches at 7% and 6.4% respectively,⁸ which were higher than reports from both nurses and ADDO clients in this study.

Notably, while this study looked only at COCs, deductions can be made about injectables, which have fewer MEC restrictions related to BP. Thus, allowing the sales of injectables at ADDOs could expand method choice and allow women to choose a method that reduces the risks associated with COCs and hypertension.

The results from this study support the case for regulatory bodies to allow women to self-screen for hormonal methods, including progestin-only injectables. The poster used by women to self-screen can be used successfully not only for this purpose but also as a counseling aid for ADDO providers. Minor revisions may be needed based on the study results, such as clarifying that issues related to religion or spouse are not related to medical eligibility.

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