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Validating a questionnaire to identify women in the first trimester of pregnancy during preventive chemotherapy interventions against soil-transmitted helminths in northwestern Tanzania

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ABSTRACT

Objectives: To evaluate the performance of a questionnaire in assessing the pregnancy status of women of reproductive age during preventive chemotherapy interventions.
Methods: A questionnaire (20 questions) was administered to 1217 women of reproductive age (≥18 years) from Ilemela and Buchosa districts, northwestern Tanzania. A single urine sample was collected from each of them and tested using a rapid pregnancy test for presence of pregnant.
Results: Overall, 10.8% (132/1217) of the women reported to be pregnant at the specific question in the questionnaire. The rapid pregnancy test identified 15.1% (184/1217) of the women to be pregnant. In total, 86.4% (114/132) of the women who reported to be pregnant during the interview were confirmed to be pregnant using the rapid pregnant test. The question on pregnancy demonstrated an overall sensitivity of 62% and specificity of 98.3%.
Conclusions: The questionnaire performance was not completely satisfactory; however, it managed to identify pregnant women in the first trimester. The question on the last date of the start of the menstrual period yield the highest sensitivity and appeared to be the key one used in combination with other questions. Further validation of these results in other countries with different cultures are recommended to fully evaluate the performance of this method.

Introduction

Infections with soil-transmitted helminths (STHs) affect approximately 1.5 billion people, particularly, those living in rural areas of low-income countries characterized by poor sanitation and hygiene [1]. Approximately, one quarter of the world's population is infected with at least one species of STHs, which include *Ascaris lumbricoides* (800 million people), *Trichuris trichiura* (600 million people), and hookworm (600 million people) [2]. It is estimated that 700 million women live in areas characterized with a high transmission of STHs [3] and need deworming. In 2008, it was estimated that 37.7 million women of reproductive age (WRA) were infected with hookworm alone [4]. Nutritional and iron status impairment, micronutrients deficiencies (iron deficiency anemia), low birth weight, and maternal and neonatal death are some of the outcomes of STH infection during pregnancy [5]. Montresor *et al.* estimated that more than 600,000 disability-adjusted life years are lost annually by WRA owing to STH infections [6].

Recognizing the impact of STH infections on the health of WRA and pregnancy, in 1994 [7], 2002 [8], and 2017, the World Health Organization recommended regular treatment of WRA with albendazole or mebendazole because as a precautionary measure, the treatment of pregnant women is recommended only after the first trimester [7]. Because of the lack of a low-cost method to assess pregnancy, this approach has resulted in excluding WRA from treatment [9]. To ensure that the entire WRA group is not excluded from deworming programs, the main challenge is to identify women in their first trimester of pregnancy so that they can be excluded from treatment and offered deworming later in their pregnancy.

Rapid pregnancy tests (RPTs), which use urine samples, is the gold-standard approach to accurately identify women in their first trimester of pregnancy; however, these tests are too expensive to be used in large quantities as needed for deworming programs. The use of simple and less expensive tools, such as questionnaires, to identify individuals with a targeted condition has been proposed in the past: the red urine ques-

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Table 1
Demographic characteristics of women of reproductive age from Ilemela and Buchosa districts, northwestern Tanzania.

Variable	n	%
Age groups (in years)		
18-25	435	35.7
26-32	336	27.6
33-39	225	18.5
40-49	221	18.2
Marital status		
Single	129	10.6
Married	756	62.1
Living together as a couple	120	9.86
Living separately as a couple	35	2.8
Others	177	14.5
Have children		
Yes	1073	88.2
No	144	11.8
Number of children		
0	144	11.8
1-5	815	66.9
6-10	250	20.5
11-13	8	0.7
Breast feeding		
Yes	402	33.0
No	815	66.9

Table 2
Reported pregnancy status and related symptoms.

Variable	n	%
Reported pregnant status		
Yes	132	10.8
No	1085	89.2
Gestation age (in weeks)		
Non-pregnant	1085	89.1
1-12	42	3.4
13-24	40	3.3
25-36	50	4.1
Start date of the last menstrual period		
Less than 1 month	1	0.8
One month	4	3.0
More than 1 month	127	96.2
Reported soreness or tingling of breast		
Yes	191	15.7
No	1025	84.2
Don't know	1	0.1
Reported darkened areolas		
Yes	60	4.9
No	1143	93.9
Don't know	14	1.2
Reported increased fatigue		
Yes	293	24.1
No	924	75.9
Reported nausea		
Yes	205	16.8
No	1012	83.2
Reported vomiting		
Yes	44	3.6
No	1173	96.4

tionnaire has been widely used to detect children with hematuria—a symptom that, in tropical areas, is strictly related to *S. haematobium* infection [10]. Thus, is not surprising to see the red urine questionnaire having a high capacity of detecting cases of schistosomiasis [11]. In pregnant women, one previous study examined the performance of a questionnaire in identifying the pregnancy status of women during preventive chemotherapy (PC) implementation [12]. However, the methodology used in this study was not standardized. Therefore, the current study focused on validating the use of a questionnaire to identify pregnant women during preventive mass chemotherapy against STH infections. Specifically, the study was conducted to compare the sensitivity and specificity of the questionnaire to identify pregnant women using a urine-based RPT (gold standard) in northwestern Tanzania. We hypothesized that if the questionnaire can at least identify >80% of the WRA to be pregnant during PC campaigns, then it will be a useful tool to exclude pregnant women during the mass treatment campaigns.

Methods

Study area

The study was conducted in two districts in Mwanza Region. At Ilemela District, the study was conducted at the Igalagala and Kabangaja villages located on the shorelines of Lake Victoria. In Buchosa District, the study was conducted at Kome Island. The selection of the study areas was based on the accessibility and the history of PC against STHs and schistosomiasis through school-based and community-based approaches [13,14].

Study population and inclusion criteria

The study included women living in the selected sub-villages of Kome Island, Igalagala and Kabangaja of Buchosa, and Ilemela districts. Women aged 18-49 years, residing in the study villages, who were willing to participate, and who gave written informed consent were recruited into the study.

Sample size and sampling procedures

To calculate the sample size, we used the sample size estimator (http://epitools.ausvet.com.au/content.php?page=2Proportions). The size of the sample was determined to detect a significant difference in the two proportions of pregnant WRA (identified by questionnaire and by RPT), with a 95% confidence interval at a power of 80%. We anticipated a proportion of true pregnancy of 10.8% in women (in accordance to crude birth rates in Tanzania that is 5.4%) [15]. A minimum sample of 474 study participants were to be recruited from each site (owing to the availability of diagnostic tests [RPT] and the willingness of WRA to participate in the study, a larger sample of 1217 women meeting all the inclusion criteria were recruited).

Questionnaire

The study adapted a questionnaire developed by the World Health Organization/Neglected Tropical Diseases (supplementary file). The questionnaire comprising 21 questions that collect demographic information of women, parity, menstrual period, personal impression on being pregnant, lactation signs, and symptoms relating to pregnancy. The English version of the questionnaire is attached as a supplementary document (optional). The questionnaire was translated to Kiswahili national language, which is spoken and understood by 98% of the Tanzanian population. Before the start of the study, the questionnaire was pre-tested in a village different from the ones where the study was later conducted to check for clarity of the questions and to identify any possible ambiguity. All data were collected by trained nurses and experienced social scientists.

Pregnancy rapid test

After the questionnaire interview, participants were requested to submit a urine sample that was tested for pregnancy with an RPT (Core Tests® Care Technology Co. LTD, Beijing, China, LOT number: 20171204). The Core Tests® is a qualitative immune-chromatography test, which detects human chorionic gonadotropin hormone in the urine of pregnant women. The results of the test were interpreted according to the manufacturer's instruction based on color changes in the reagent strip. All test results were recorded in a form with the participant iden-

Table 3
Comparison of the responses to question 13 of the questionnaire and the results of the rapid pregnancy test and the resulting performances (sensitivity, specificity, positive predictive value, and negative predictive value).

		Rapid pregnancy test	
		+	-
Question 13	Yes	114	18
	No	70	1015

Sensitivity	Specificity	Positive predictive value	Negative predictive value
62% (95% CI: 54.5-69.0)	98.3% (95% CI: 97.3-99.0)	93.5% (95% CI: 91.9-94.9)	86.4% (95% CI: 79.3-91.7)

CI, confidence interval.

tification number that allowed to link the RPT results with the results of the questionnaire.

Data management and statistical analysis

All collected data were entered into an Excel sheet. Data analysis was done using Stata version 15 (Stata Corp, College station, Texas, USA).

We judged the sensitivity of the questionnaire to be the main indicator of efficiency: a questionnaire able to identify a large majority (>80%) of the pregnant women could be an extremely useful tool to exclude pregnant women during PC campaigns; in contrast, the misidentification of a number of non-pregnant as pregnant owing to poor specificity (example 50% specificity) and their exclusion from the intervention was considered acceptable in the context of the PC campaign.

Results

Characteristics of the study participants

A total of 1217 women from Igalagala, Kabangaja, and Kome Island participated in this study. The mean age of the study participants was 30.25 ± 8.68 years (age range 18-49 years). Majority of the women reported to be married (62.12%) and 88.2% of the women had children (Table 1). The median number of children was three children (interquartile range 2-5 children) and 75.9% of the women had 1-5 children. Table 1 shows the demographic characteristics of the study participants.

Reported pregnancy status and related symptoms

At the time of interview, 132 (10.8%) women self-reported to believe to be pregnant. The mean gestation age/period for those reported to be pregnant was 21.51 ± 10.18 weeks (range 1-36 weeks), with 37.9% of them reported to be in the third trimester of pregnancy. Details on response regarding other symptoms normally related to pregnancy (soreness of the breast, darkened areolas, increased fatigue, nausea, and vomiting) are presented in Table 2.

Prevalence of pregnancy based on rapid urine pregnancy test

Overall, a total of 1217 women submitted urine samples for the detection of pregnancy using an RPT. Of these, almost 96% of them indicated their willingness to receive the result of the test. Based on the RPTs, 184 (15.1%) results were positive for pregnancy.

Sensitivity and specificity of the questionnaire

Of the 184 women who tested positive for pregnancy using RPTs, 114 had responded “yes” to question 13 (Do you think you might be pregnant?), corresponding to a sensitivity of this question for pregnancy of 62% (95% confidence interval 54.5-69.0). Of the 132 women who responded “yes” to question 13, a total of 114 were confirmed to be pregnant using the RPT, corresponding to a specificity 86.4%. On the other hand, 6.4% (70 of 1085) of the women who reported not be pregnant in the questionnaire were confirmed to be pregnant by RPT. Only 13.6% (18 of 132) of the women who reported to be pregnant during the interview were not pregnant (Table 3).

Table 4 shows the results of the RPTs in relation to the reported symptoms related to pregnancy. None of the signs normally linked with pregnancy (soreness of the breast, darkened areolas, increased fatigue, nausea, and vomiting), alone or combined with others, were a good predictor of an actual pregnancy status (Table 4).

Sensitivity and specificity of reported pregnancy in different sub-groups of participants

The sensitivity of the reported pregnancy (question 13) in the questionnaires was also assessed in different sub-groups (Table 5):

Single women: Of the 130 single women who responded to the questionnaire, four declared to be pregnant and six resulted positive for pregnancy using RPTs. The sensitivity of question 13 was not reduced in this group.

Women with children: Of the 174 women with children who responded to the question 116 declared to feel pregnant and 158 resulted positive for pregnancy using the RPT. The sensitivity of question 13 was not increased in this group nor was the evaluation of sensitivity of question 13 restricted to women with more than two, four, or six children.

Women age: The age of the respondent seems to be not linked to the sensitivity of question 13. Table 5 shows the performances of question 13 (sensitivity, specificity, positive predictive value, and negative predictive value) in the different sub-groups.

Discussion

In this study, we tested the performance of a questionnaire designed to identify pregnant women for its possible use during PC campaigns. This low-cost tool could be useful in reducing the exclusion of WRA from PC campaigns that is frequently resulting from the perceived risk of treatment of pregnant women in the first trimester [9].

The proposed questionnaire comprises 20 questions; some of them (questions 1-7) were included to exactly identify each woman during the study. Other questions (questions 8-12) were included to explore if the answers to the questionnaire were influenced by some other condition; our hypothesis was that, for example, unmarried women would have been more reticent in responding “yes” to a direct question investigating pregnancy status than married women or that a woman with multiple children could better recognize the early signs of pregnancy. The key question was, in our opinion, question 13 “Do you think you might be pregnant?” and in its sensitivity of correctly identify pregnancies in case of the positive reply. We considered a poor specificity (≈50%) to be acceptable as would have resulted in the exclusion of WRA from treatment but not expose them to any (including only perceived) risk. Other questions (questions 16-20) were included to explore if the presence of

Table 4
Prevalence of pregnancy based on rapid pregnancy test in relation to reported pregnancy and symptoms in the questionnaire.

Variables	Rapid pregnancy test		χ^2-test or Fisher exact
	Positive	Negative	
Reported pregnant status			
Yes	114(61.96)	18(1.7)	χ^2 = 585.5990
No	70(38.04)	1,015(98.3)	*P*< 0.001
Reported gestation (in weeks)			
1-12	32(28.0)	10(55.6)	
13-24	37(32.5)	3(16.6)	Exact = 0.071
25-36	45(39.5)	5(27.8)	
Start date of the last menstrual period			
Less than 1 month	0 (0.0)	1(5.6)	
One month	2(1.8)	2(11.1)	Exact = 0.018
More than 1 month	112(98.2)	15(83.3)	
Reported soreness or tingling of breast			
Yes	15 (8.2)	176 (17.0)	
No	169 (91.8)	856 (82.9)	Exact = 0.003
Don't know	0(0.0)	1 (0.1)	
Reported darkened areolas			
Yes	9 (4.9)	51 (4.9)	
No	174 (94.6)	969 (93.8)	Exact = 0.88
Don't know	1 (0.5)	13 (1.3)	
Reported increased fatigue			
Yes	26 (14.1)	267(25.9)	χ^2 = 11.7293
No	158 (85.9)	766(74.1)	*P*< 0.001
Reported nausea			
Yes	16 (8.7)	189 (18.3)	χ^2 = 10.2771
No	168 (91.3)	844 (81.7)	*P*< 0.001
Reported vomiting			
Yes	4 (2.2)	40 (3.9)	Exact = 0.38
No	180 (97.8)	993(96.1)	

Table 5
Sensitivity and specificity of reported pregnancy in different sub-groups of participants.

Diagnostic tests (sub-groups)	Sensitivity	Specificity	Positive predictive value	Negative predictive value
All study participants	62% (95% CI: 54.5-69.0)	98.3% (95% CI: 97.3-99.0)	93.5% (95% CI: 91.9-94.9)	86.4% (95% CI: 79.3-91.7)
Reported marital status				
Being single	50% (95% CI: 41.4-58.6)	99.19% (95% CI: 97.6-100.7)	75% (95% CI: 67.5-82.5)	97.6% (95% CI: 94.9-100.2)
Being married	67.4% (95% CI: 64.1-70.8)	98.1% (95% CI: 97.1-99.1)	87.8% (95% CI: 85.6-90.2)	93.6% (95% CI: 91.8-95.4)
Reported having children				
Yes	63.3% (95% CI: 60.4-66.2)	98.3% (95% CI: 97.5-99.0)	86.2% (95% CI: 84.1-88.3)	93.9% (95% CI: 92.5-95.4)
No	53.9% (95% CI: 45.7-61.9)	98.3% (95% CI: 96.2-100.4)	87.5% (95% CI: 82.1-92.9)	90.6% (95% CI: 85.9-95.4)
Reported number of children				
1-5 children	64.9% (95% CI: 61.7-68.2)	98.1% (95% CI: 97.2-99.0)	87% (95% CI: 84.7-89.3)	93.4% (95% CI: 91.7-95.1)
6-13 children	54.2% (95% CI: 48.1-60.3)	98.7% (95% CI: 97.4-100.1)	81.3% (95% CI: 76.5-86.01)	95.5% (95% CI: 92.9-98.0)
Women age (in years)				
<30 years	60.6% (95% CI: 56.8-64.5)	98.2% (95% CI: 97.1-99.2)	89.5% (95% CI: 87.1-91.9)	90.6% (95% CI: 88.3-92.9)
>30 years	64.9% (95% CI: 61.1-68.7)	98.3% (95% CI: 97.3-99.4)	80.4% (95% CI: 77.3-83.6)	96.4% (95% CI: 94.9-97.9)
Reported breastfeeding				
Yes	36% (95% CI: 31.3-40.7)	99.5% (95% CI: 98.8-100.2)	81.8% (95% CI: 78.1-85.6)	95.9% (95% CI: 93.9-97.8)
No	66% (95% CI: 62.8-69.3)	97.6% (95% CI: 96.5-98.6)	86.8% (95% CI: 84.5-89.1)	92.2% (95% CI: 90.4-94.1)

symptoms frequently associated with pregnancy could be used to identify pregnant women.

Conclusion

The questionnaire performance was not completely satisfactory; however, it managed to identify pregnant women in the first trimester during mass treatment campaigns. The question on the last date of the start of the menstrual period yield the highest sensitivity and appeared to be the key question to in combination with other questions. In addition, the signs that are normally linked with pregnancy (soreness of the breast, darkened areolas, increased fatigue, nausea, and vomiting) resulted to be not a good predictor of an actual pregnancy status in the current study population. Further validation of these results in other countries with different cultures are recommended to fully evaluate the performance of this method.

Declarations of competing interest

The authors have no competing interests to declare.

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Ethics approval and consent to participate

Ethical approval was obtained from the joint ethical and review committee of Bugando Medical Centre and Catholic University of Health and Allied Sciences (CREC/281/2018). The study received further ethical approval from the National Institute for Medical Research, National

Ethical Committee (MR/53/100/541). The study received further government authority clearance from the district and village administrative authorities. Before the commencement of the study, visits were made to the villages and village leaders were met. The intention of the study was explained to the leaders first, who, in turn, convened with community members to explain the objective of the study. Kiswahili-translated informed consent forms were used to obtain consent from study participants. The objective of the study and study procedures were fully described to the study participants before asking for their informed consent. For illiterate participants, a thumb print was used to sign the consent forms. To maintain confidentiality, all the data of the study participants were kept in a closed cabinet and whenever the data were accessed, no participant name was disclosed, only the identification numbers of the participants were used to identify participants. Participation in this interview were voluntary. Participation in the study was voluntary and free. All study participants were offered to obtain the result of the pregnancy test.

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Author contributions

HDM and AM designed the study, participated in data collection, and analyzed and drafted the first version of the manuscript. All authors read and approved the final manuscript, contributed to the critical review, and made substantial contribution to it.

Consent for publication

Not applicable.

Availability of data and materials

The datasets collected and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijregi.2024.01.010.

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