Original Article

Development and Validation of the Ethiopian Women's Cervical Cancer Awareness and Screening Tool (EWCCaAST)

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Abstract

Background: There is a lack of a standardized tool for assessing barriers to cervical cancer screening uptake. The validation of the tool helps researchers to identify the barriers and facilitators to improve screening uptake.

Objective: this study aimed to develop and validate a tool that can be used to assess the level of awareness, knowledge, and barriers to cervical cancer and screening among Ethiopian women.

Methods: A Cross-sectional study design involving four steps: refining and developing, expert panel evaluation, translation of the tool into the local language, and internal reliability testing was employed. About 16 experts and 366 randomly selected target-aged women were included in the study. Content validity ratio, content validity index, modified Kappa, and Cronbach`s alpha were used to validate the tool. Internal reliability was assessed using Cronbach's alpha, with a minimum acceptable value of 0.60.

Result: A total of 108 items were categorized into 7 validated domains. The overall content validity ratio (CVR) and item-level content validity index ((I-CVI)) were 0.68 and 0.88, respectively, indicating strong essentiality and relevance of the items. The overall item-level content validity index for simplicity and clarity of the items was 0.88 and 0.82, respectively, indicating that the items are too simple and clear. The lowest modified Kappa was 0.49, indicating moderate agreement, while the highest was 0.94, indicating perfect agreement among the experts. The overall Cronbach's alpha was 0.79, reflecting an acceptable level of reliability for the tool.

Conclusion: The refined and developed tool is essential, relevant, simple, and clear. The overall reliability showed an acceptable value. We recommend that the researchers use this comprehensive validated tool to assess the awareness, knowledge of cervical cancer, and socio-cultural barriers to cervical cancer screening service utilization among women. [*Ethiop. J. Health Dev.* 2025; 39(2)]

Keywords: Cervical cancer, screening, socio-cultural barriers, Women, Ethiopia

Introduction

Cervical cancer is a cancer that affects the cervix, accounting for approximately 662,044 new cases and 348,709 deaths globally [1]. It also contributes to economic loss and is the leading cause of preventable death in countries with a medium to low human development index (HDI) [2, 3]. According to the study in 2019, it was the fourth most common female cancer worldwide and represents a major global health problem [4], but according to another study conducted in 2024, it is reported a decline in burden and it becomes the eighth cause of morbidity and ninth cause of cancer-related mortality, globally [5]. It is the second most common cancer among women in Ethiopia [6]. The highest morbidity of the disease, 40.42/ 100,000, and Mortality of 28.87/100,00 women was reported from East Africa. However, the lowest morbidity, 4.1/100,00, was reported from western Asia, whereas the lowest morbidity of 1.44/ 100,000 was reported from Australia (New Zealand)[1]. Cervical cancer most commonly occurs among women aged 30 or older. The most common cause of cervical cancer is sexually transmitted human papilloma virus (HPV), especially HPV 16 and 18 are considered a common cause. High risk HPV infection is responsible for 99.7% of cases of cervical cancer[7].

Validity is a critical factor in the selection and application of an instrument, and it can be categorized as content validity, construct validity, and criterion validity, which are commonly used to develop survey questionnaires[8]. Content validity is a process used to ensure that an instrument (checklist, questionnaire, or scale) measures the content area it is expected to measure[9]. Reliability is another important factor in developing and validating instruments. Reliability refers to the degree to which the results measured by a measurement procedure can be replicated[10]. However, even though reliability is important for the validity of a questionnaire, it may not be a sufficient condition for its validation [11]. Lack of reliability can arise from differences between observers or instruments of measurement, such as a questionnaire, or from the instability of the attribute being measured[10]. This will invariably affect the validity of a questionnaire. Common measures of reliability include internal consistency, test-retest, and inter-rater reliability.

There are tools developed to assess cervical cancer and cervical cancer screening awareness, knowledge, and barriers among women in various study areas,

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including a study conducted in Oman (2021) in which the CVR and I-CVI were measured, and the tool was validated[12]. Another study conducted in Malaysia indicated that the tool validation is important to identify the utilization of cervical cancer screening and its predictors, and measurements like CVR, CVI, and Cronbach's alpha help assess the validity of a tool [13]. In the UK, the tool for the assessment of CCa awareness, knowledge, attitude, and barriers to cervical cancer screening utilization was validated[14]. There is also a tool developed in South Africa and Kenya for African women[15] to assess cervical cancer awareness, knowledge, attitude, and barriers.

In Ethiopia, many studies have been conducted on awareness, knowledge, attitude, and barriers to cervical cancer screening utilization among women to indicate the reasons for low screening uptake.

Studies from Addis Ababa showed that 23.4% of women knew about symptoms and prevention of cervical cancer [16]. Another facility-based cross-sectional study in Addis Ababa showed only 34.2% of women knew about cervical cancer [17]. A study from different parts of Ethiopia; Addis Ababa showed that 41.7% and 72.0% had poor knowledge on cervical cancer and HPV infection respectively [18], Durame (in 2020), 50.2%, had good knowledge about cervical cancer screening [19], The Gurage zone showed that 26.2% of women had good knowledge [20], Aira (in 2021) showed that 46.8% had good knowledge [21] and in Dessie 51.9% had sufficient knowledge[22]. Various sociocultural variables such as lack of knowledge about screening[16, 23, 24], fear of test outcomes[16, 24], perception of not being at risk, feeling healthy or having no symptoms [16, 23], lack of screening service in the area [23] and lack of time were identified as barriers by various researchers from various study areas. The difference in the level of awareness, knowledge, and sociocultural barriers identified by researchers from different areas varies from one study area to another due to the use of various and non-standard tools during data collection. Many researchers use tools that are not comprehensive and may only identify a limited number of barriers to cervical cancer screening in different populations. However, findings from non-validated tools cannot be generalized to the general population because barriers to cervical cancer screening utilization may vary from place to place. It is important to have a comprehensive tool that can help identify and measure barriers that are applicable to the target population and can be used by all researchers. This may create a large number of reasons for the low uptake of cervical cancer screening and various barriers to cervical cancer screening uptake, which cannot be generalized to women in the general population. There is a lack of developed and validated tools for assessing the reasons for the low uptake of cervical cancer screening in Ethiopia.

Therefore, this study aims to develop and validate a tool to assess awareness and knowledge of cervical cancer, including socio-cultural barriers, risk factors, signs and symptoms, prevention methods, confidence in identifying signs and symptoms, and attitudes and beliefs among Ethiopian women aged 30 to 49 years. Vaalidation of this tool will enables researchers to determine whether barriers and facilitators are consistent across different contexts, supporting the collection of generalizable data to enhance screening uptake

Methods and Materials

Study setting

The study was conducted in Adama town, one of the largest towns in Ethiopia, located to the southeast of Addis Ababa, the capital . Adama is situated in the Oromia Regional State and is home to people from diverse nationalities across Ethiopia, making it potentially representative of the broader Ethiopian population. In Adama, there is one comprehensive specialized hospital that offers healthcare services to people from various regions, including Oromia, Afar, Amhara, and other regions. Additionally, there are over 8 governmental health centers and numerous private health institutions. The study was conducted in three randomly selected health centers and one comprehensive specialized hospital.

Study design

A cross-sectional study design was utilized, involving four steps in the process: 1) Generating tools or items, 2) Expert panel evaluation, 3) Translation of the English version of the tool into the local language (Amharic), and 4) Internal reliability testing. These steps were used to develop and validate the tool. Data for the reliability test were collected from four public health institutions in Adama town, including three health centers: Adama, Geda, and Anole Health Centers, and one hospital (Adama Comprehensive Specialized Hospital Medical College.

Sample size and sampling procedure

Two types of sampling techniques were employed in this study. The first was a purposive sampling technique, used to select 16 experts for the expert panel (as described under Step II below). The second technique was used to assess the internal consistency reliability of the tool (as described under Step IV below).

For this purpose, three health centers were randomly selected from a total of eight, and one government hospital was purposively included in the study. The sample size was determined based on the assumption of three participant interviews per question. Initially, 133 questions were developed from various sources. After evaluation by the expert panel, the number of questions was reduced to 122, resulting in a final sample size of $122 \times 3 = 366$.

This sample size was then proportionally allocated among the three health centers and one hospital, based on six months of patient flow data. Finally, women aged 30–49 years who visited the selected health institutions were randomly selected and interviewed.

Tool Validation Process

The tool validation process consists of four sequential steps, each following a specific procedure and building upon the previous one. In the first step, the tool is

generated. In the second step, the generated tool is evaluated by experts. In the third step, the tool is translated into the local language. In the fourth step, the internal consistency reliability of the tool is tested. Each step is interdependent and contributes to the overall validation process. The details of each step are described below.

Step I: Tool Generation process for the EWCCaAS tool

The tool was refined and developed by reviewing the African Women Cancer Assessment Tool (**AWACAN**)[15], Cervical Cancer Awareness Measurement (CCAM) tools [14], and through a literature review of studies conducted in different parts of the world, including Ethiopia[25-32]. The refined and developed tool has a total of **133** questions categorized into 9 domains.

Step II: Expert panel evaluation process

A group of 16 experts was invited to participate in a questionnaire evaluation. The group of experts includes five epidemiologists and biostatisticians (two holding PhD degrees and the rest holding second degrees) who had previously been involved in cancer prevention and control research, three public health researchers holding MPH degrees, three reproductive health experts (one holding a PhD degree and two holding MPH/RH), four gynecologists and one oncologist. All of these experts had more than 10 years of work experience in research performance and clinical activities in reproductive and gynecological services at Adama Comprehensive Specialized Hospital Medical College. The experts evaluated the items based on four criteria: "Essentiality", "Relevance", "Simplicity", and "Clarity". Each item was scored on a three-point Likert scale. The essentiality was scored as " Essential=1, Useful but Not Essential=2 and Not essential=3", Relevance was scored as " Relevant=1, Needs minor modification=2 and not relevant=3", Simplicity was also scored as " Simple=1, Needs minor modification=2 and Not Simple=3 and clarity was scored as " Clear=1, Needs minor modification=2 and Not clear=3" based on the literature [33]. At this stage, Content Validity Ratio (CVR) and Content Validity Index (CVI) were used to select and validate the tool. CVR was calculated for each item; items were eliminated or included based on the critical value of 0.5 for Lawshe's Content Validity Ratio[34]. CVI measures the mean CVR for all items to determine the content validity of the entire tool. Two types of CVI, item-wise content validity index (I-CVI) and scale-wise content validity index (S-CVI), were calculated. I-CVI showed the proportion of agreement regarding the relevance or clarity of each item [35]. Two methods, universal agreement among experts (S-CVI/UA) and the mean of I-CVI (S-CVI/Average), were used to calculate S-CVI. Additionally, modified kappa was used to calculate the agreement among the experts. Items with CVR<0.5, CVI <0.7, and Modified kappa<0.02 were eliminated from the generated items.

Step III: Translation of the English version of the tool to the local language

Bilingual language experts translated the tool from English to local languages (Amharic) and back to English to assess the consistency of the tool. Two language experts with a master`s degree in language translated the English version into the local language (Amharic), and other experts with the same level of education translated the Amharic version of the tool back into English. Additionally, two public health experts participated in the translation of the tool. In total, 6 experts participated in the translation and back translation of the tool.

Step IV: Internal consistency reliability test

Reliability tests were conducted to assess the internal consistency of the tool. Women aged 30-49 years who were eligible for cervical cancer screening and visiting four public health institutions in Adama town were randomly selected to evaluate the reliability of the tool. The selected health institution included (three health centers: Adama, Geda, and Anole Health Centers) and one hospital (Adama Comprehensive Specialized Hospital Medical College)

The sample size for the reliability assessment was calculated based on literature assumptions [36, 37]. After an expert panel evaluation, the initial 133 items were reduced to 122 items. Using an assumption of one item to three participants, a total of 366 target women were randomly selected from health facilities. The sample size was allocated proportionally to four public health institutions based on their annual outpatient performance from the previous year. Four data collectors, including nurses and midwives, were trained to collect the data. The study participants were interviewed as they exited the health care service utilization in all institutions. The reliability of the tools was assessed using Cronbach's alpha coefficient. A Cronbach's alpha value equal to or above 0.60 was considered indicative of good internal consistency of the tool [38].

Data Management and Analysis

Content validity ratio (CVR) and content validity index (CVI) were utilized to determine whether items should be included, removed, or modified. SPSS version 26 and Excel software were used to analyze CVR and CVI and assess their validity. To either accept or reject individual items, the content validity ratio (CVR) was calculated as follows [39].

$$CVR = \frac{n_e - (N/2)}{N/2}$$

Where:

CVR = Content Validity Ratio

n_e is the number of panelists identifying an item as "essential" and

N is the total number of panelists (N/2 = half the total number of panelists).

The CVR value ranges from -1 to 1 [40]. Items with a CVR below the critical minimum value (CVR < 0.50) were eliminated from the tool [41]. The CVI evaluates the *relevance*, *simplicity*, and *clarity* of the items [39, 42]. It is assessed at both the item level (I-CVI) and the scale level (S-CVI)[43]. I-CVI is calculated by dividing the number of experts rating an item as "relevant" by the total number of experts, and similar

methods are followed to assess the simplicity and clarity of the items. The I-CVI value ranges from zero to one. An I-CVI value above 0.79 indicates relevance, between 0.70 and 0.79 indicates that the item needs revisions, and a value below 0.70 indicates that the item should be eliminated [43]. The Universal Agreement (UA) among experts (S-CVI/UA)and the Average CVI (S-CVI/Ave) were computed[43]. S-CVI/UA was assessed by adding all items with an I-CVI equal to 1 and dividing by the total number of items, while S-CVI/Ave (Ave=Average) is computed by taking the sum of the I-CVIs divided by the total number of items[43]. An S-CVI/UA ≥ 0.8 and an S-CVI/Ave ≥ 0.9 indicate excellent content validity[44].

Agreement among experts was determined using the modified Kappa coefficient. Cohen's kappa is a widely used index for assessing agreement between raters[45]. The modified Kappa provides the degree of agreement beyond chance, and is calculated as follows:

$$K = \frac{((I - CVI) - (Pc))}{(1 - Pc)}$$

where

K Modified Kappa (Inter-rater agreement)
I-CVI = Item -level content validity index
Pc = the probability of chance agreement

$$Pc = \frac{N!}{A!(N-A)!} * 0.5^N$$ [16].

Where

N = number of experts; and A = number of experts agree that the item is relevant.

The modified Kappa coefficient was used in this study; the value of Kappa ranges from -1 to +1. According to Cohen, the value of kappa will be categorized as follows: values ≤ 0 indicate no agreement, 0.01–0.20 indicate none to slight agreement, 0.21–0.40 indicate fair agreement, 0.41– 0.60 moderate agreement, 0.61–0.80 as substantial agreement, and 0.81–1.00 as almost perfect agreement[46]. Excel software was used to compute chance agreement and modified Kappa agreement among expert raters.

Cronbach`s alpha was used to assess the reliability or internal consistency of the instruments. The value of Cronbach`s alpha ranges from 0 to 1. According to commonly accepted standards, a Cronbach's alpha value of <0.5 is considered unacceptable, 0.5-0.6 is questionable/unreliable, 0.7-0.8 is acceptable, 0.8- 0.9 good, and ≥0.9 is optimum [41]. Based on the above criteria, items with a Cronbach's alpha coefficient above 0.6 were considered reliable. Data collected from study participants for the reliability test were entered into Epi Info version 7.2.5 and subsequently exported to SPSS version 26 to compute Cronbach's alpha.

Ethical Approval

Ethical approval for the study was obtained from Addis Ababa University College of Health Science IRB (AAUMF 081/22/SPH), and a support letter was written by Addis Ababa University School of Public Health (ሕቤ/075/2015 dated ታህሳስ 10/2015according to the Ethiopian calendar to Adama Town Health Office and Adama Hospital Medical College. Letters from the Adama Town Health Office were sent to three health centers. Permission to access health facilities was obtained from all relevant local health authorities. Informed verbal consent was obtained from all participants before the interview.

Result

Socio-demography

Two separate participants were involved in the tool development process: one for expert panel evaluation and another for internal consistency (reliability) assessment. The expert panel consisted of 16 professionals with diverse research and clinical backgrounds, including 3 PhD holders, 5 experts with master's degrees in clinical fields, and 8 Master of Public Health (MPH) holders. These experts participated in evaluating the tool for content validity. For the internal consistency (reliability) assessment, a total of 366 women between the ages of 30 and 49 who were eligible for cervical cancer screening, were participated in the study. The mean age of the study participants was 36.98 (SD± 5.52). More than two-thirds (33.1%) of the study participants attended secondary education, 127 (34.7%) were housewives, and 272(74.3%) were married. See Table 1 below.

Table 1: **Socio-demographic characteristics of study participants for internal Consistency (reliability) test assessment of the tool**

Variables	Frequency	Percent
Age Category		
30-39 years	257	70.20%
40-49 years	109	29.80%
Educational status		
Unable to read and write	37	10.10%
Able to read and write	37	10.10%
Primary education	76	20.80%
Secondary education	121	33.10%
Diploma & Above	95	26.00%
Occupational status		
House wife	127	34.70%
Government employee	67	18.30%
Own work	114	31.10%
Private comp. employee	47	12.80%
Student	8	2.20%
Others	3	0.80%
Marital status		
Married	272	74.30%
Not married	33	9.00%
Divorced	33	9.00%
Widowed	28	7.70%
Partners educational status		
Unable to read and write	5	1.70%
Able to read and write	12	4.10%
Primary education	62	21.30%
Secondary education	83	28.50%
Diploma & Above	129	44.30%
Average monthly family income		
≤ 3225 ETB or ≤ $ 2.15/d	122	33.30%
3226-5475 ETB or $ 2.15 – 3.65/d	82	22.40%
5476-10275 ETB or $ 3.65-6.85/d	126	34.40%
>10275 ETB or > $ 6.85/d	36	9.80%

The process of tool development and validation to assess **Ethiopian women cervical cancer awareness and screening (EWCCaAS)** was conducted through four series steps as follows;

Step I: Generating items for the EWCCaAS tool

The tool was refined and developed through a detail review of literature such as the Awareness of CANcer (AWACAN) tool for breast and cervical cancer[15], and the Cervical Cancer Awareness Measurement (CCAM) tools [14], as well as a thorough review of other literature [25-32, 47-53]. Permission was obtained from the developers of the Awareness of CANcer (AWACAN) tool. The generated tool was categorized into 9 domains. The domains include: 1) Socio-demographic characteristics (10 items; 101 to 110), 2) Reproductive related and risk factor (27 items; 201 to 207), 3) Cervical cancer and screening awareness (18 items; 301 to 318), 4) Knowledge of risk factors (16 items; 401, 402 a to 402o), 5), Knowledge of cervical cancer symptoms (13 items; 501, 502a to 502m), 6) Help-seeking behavior (7 items; 601 to 607), 7) Confidence in recognizing symptoms(3 items; 701 to 703), 8) Socio-cultural barriers (23 items; 801 to 823) and 9) Attitudes toward cervical cancer screening (16 items; 901 to 916) The **EWCCaAS** tool was designed to be delivered through a structured interview rather than a self-administered questionnaire in a logical order.

Step II: Expert panel validation

Sixteen experts participated in the expert panel to evaluate the generated items. The 133 items were evaluated in terms of relevance, simplicity, and clarity. The CVR and CVI were used to determine the validity of the items. After the CVR and CVI analysis, four items from the socio-demographic and reproductive and risk factors domains, as well as three items from the knowledge of risk factors domain, were eliminated. The expert evaluation resulted in a 122- item tool (See table 2 below). Modified kappa was used to assess the level of agreement among the experts. The highest agreement was observed in the socio-demographic domain, while the lowest agreement was observed in the awareness domain (see Table 3 below).

Domain one: Socio-demographic domain

The refined and developed socio-demographic domain consists of 10 items numbered 101 to 110. After the expert evaluation, the average CVR of the socio-demographic domain was found to be 0.5, with the lowest value of -0.13(item 102; religion of participant) and the highest value of 0.88 (both educational and marital status). Four items of the socio-demographic

domain [Item 102: Religion of participant (CVR= -0.13), item 103; Ethnicity of participants (CVR= -0.38), item 108; Partner`s occupation (CVR=0.25) and item 110; Average participant (woman) monthly income (CVR=0.38)] were removed from the tool due to low CVR.

The item scale content validity index (S-CVI) was computed for all items in the socio-demographic domain. Items 102 and 103 were rated as not relevant (I-CVI =0.13 and 0.06, respectively) by experts and were decided to be eliminated from the tool. The average agreement among raters (S-CVI/Ave) was 0.84, 0.85, and 0.86 for relevance, simplicity, and clarity of items, respectively, indicating very good validity for relevance and excellent validity for simplicity and Clarity. Universal agreement (S-CVI/UA) was computed for Relevance (0.31), Simplicity (0.38), and Clarity (0.50). Finally, six items were included in the tool as they meet criteria for essentiality, relevance, simplicity, and clarity of the item, while four items were eliminated from the tool. (*See supplementary file 1, Table 1).*

Domain two: reproductive and other risk factor domain

This domain is designed to assess reproductive and other risky behaviors that contribute to the risk of contracting cervical cancer. The domain contains 27 items numbered from 201 to 227. The CVR, CVI, and modified kappa were computed to decide whether each item should be included or eliminated from the domain. The average CVR was 0.61 with the lowest (-0.13) for item 205 (*type of delivery*) and 217(*using wood smoking for cosmetic purposes*) and the highest (1.00) observed among item 202 (age *at first sexual intercourse*), 219 (History of STIs (STDs) in life time) and 220(How long since you were treated for STIs). The CVR of four out of 27 items; item 205 (CVR = 0.13), item 208(CVR =0.38), item 217 (CVR = -0.13, and item 224 (CVR 0.38) were found to be below the critical value and were eliminated. The items` average scale (S-CVI/Ave) was computed for relevance of items and was found to be 0.93, indicating excellent agreement, for simplicity 0.87, and clarity 0.89, indicating very good agreement among experts. Finally, 22 items were included in the tool as they were deemed essential, relevant, simple, and clear, while 5 items were eliminated from the tool. *(See supplementary file 1, Table 2).*

Domain three: Awareness domain

This domain is designed to assess women's awareness of cervical cancer and screening in Ethiopia. It contains 17 items numbered 301 to 317. The expert evaluation results indicate that all items meet the minimum critical value required for essentiality, with the average CVR of 0.78. The lowest CVR value of 0.50 was found in items 306, 307, 308, and 309, while the highest CVR value of 1.00 was in items 311, 312, 313, and 316. All items were included in the list of items as they meet the minimum critical CVR value [39].

The average S-CVI was calculated and found to be greater than or equal to 0.70, with relevance at 0.90, Simplicity at 0.96, and Clarity at 0.93. Universal agreement was also computed, showing S-CVI/UA of 0.71 for relevance (Substantial Agreement), 0.41 for simplicity (Moderate Agreement), and 0.35 for clarity (Fair Agreement). Finally, all 17 items were validated. *(See supplementary file 1, Table 3).*

Domain four: Risk factors knowledge domain

The Risk Factors Knowledge Domain was designed to assess various types of risk factors that could contribute to the development of cervical cancer. This domain consists of one open-ended question numbered 401 and 15 multiple-choice questions numbered 402a to 402o. Most of the items scored above the minimum critical CVR value of >0.50 and were deemed essential. However, two items (item 402h: *Does inserting herbs/creams/objects into the vagina increase the risk of developing cervical cancer? Rated as non-essential with CVR value of 0.25 and item 402k: Does having a sexual partner who is not circumcised increase the risk of developing cervical cancer? CVR=0.38)* were excluded from the tool. The average CVR was 0.70, with the lowest CVR found on item number 16 (*Does bewitched/witchcraft/evil spirits increase the risk of developing cervical cancer?*), leading to its removal from the item list. The highest CVR was observed for three items (items 6,7, and 14). All items were evaluated for relevance, simplicity, and clarity, meeting the minimum critical value S-CVI level (0.70). The average agreement (S-CVI/Av) for each included item was 0.94 for relevance, 0.96 for simplicity, and 0.92 for clarity, indicating excellent validity of the tool. Finally, 13 items were included in the tool. *(See supplementary file 1, Table 4).*

Domain five: symptoms knowledge domain

This domain contains thirteen items, including one free listing option and 10 multiple-choice questions. It is designed to assess women's knowledge of cervical cancer symptoms. The items were numbered 501 (open-ended question), 502a to 502l (Closed-ended questions). Two items, item 502f *Persistent diarrhea* (CVR =0.13) and item 502j *Blood in urine or stool or feces* (CVR = 0.38), were eliminated from the tool due to their low CVR value. The average CVR was 0.77. The average agreement (S-CVI/Ave) for the relevance, simplicity, and clarity of the items was 0.93, 0.98, and 0.94, respectively, indicating excellent validity of the items. At the same time, universal agreement (S-CVI/UA) was 0.62, 0.85, and 0.54 for relevance, simplicity, and clarity, respectively. Finally, one free listing option and 10 items were included after eliminating the two items. *(See supplementary file 1, Table 5).*

Domain six: help-seeking behavior domain

The help-seeking behavior of women has an impact on the uptake of screening for cervical cancer. This domain focuses on assessing the help-seeking behavior of women when they recognize symptoms of cervical cancer. Seven items were evaluated by experts. The CVR value of all items was 0.5 or higher, leading to inclusion of all items in the tool. The average CVR value was 0.66, and the average and universal agreement among experts regarding relevance, simplicity, and clarity of the items was 0.91, 0.96, and

0.66, respectively, indicating higher agreement. The result of the expert panel indicates that items are relevant and simple, but the clarity of items 601a, 601c, 602, and 603 was revised, and all items were included in the tool. *(See supplementary file 1, Table 6)*.

Domain seven: confidence skills and behavior in identifying symptoms

The skill and confidence of identifying symptoms are important to increase cervical cancer screening uptake rate. This domain consists of three items, which were refined from the AWCAN tool and rated by experts. All items deemed to be essential with CVR 0.58 and included in the tool. The S-CVI/Ave scores for relevance, simplicity, and clarity were 0.63, 0.67 0.58, respectively. The low S-CVI/Ave values indicate that the items should be modified or eliminated. Finally, after modifying item 3, all three items were included in the domain. (*See supplementary file 1, Table 7*).

Domain eight: Socio-cultural barriers domain

A total of 23 items were refined from different literature and evaluated by experts to assess the socio-cultural barriers to uptake of cervical cancer screening. The items were numbered from 801 to 823. The CVR value of all items exceeded the minimum critical value. The experts assessed the average and universal agreement on the relevance, simplicity, and clarity of the items. The assessment demonstrated that the average agreement (S-CVI/Ave) was 0.93, 0.84, and 0.80 for relevance, simplicity, and clarity of the items, respectively. The result of the expert panel indicates that all items are relevant, simple, and clear and can be used to assess barriers to uptake of cervical cancer screening. Therefore, all items numbered 801 to 823 were included in the tool. *(Supplementary file 1, Table 8)*.

Domain nine: Attitude-related domain

This is the final domain generated to assess women's attitudes toward cervical cancer and screening uptake. The domain consists of 16 items numbered 901 to 916. The CVR of all items was found to be above the minimum critical value. The lowest CVR was 0.63 and the highest was 0.88, as observed during expert rating. This result indicates that all items are essential for assessing women's attitudes towards up the uptake of cervical cancer screening. The lowest I-CVI (0.63) was observed among items related to clarity, indicating a need for revision to make the items clearer for women to understand. The average agreement (S-CVI/Ave) was found to be 0.91, 0.86, and 0.82 for relevance, simplicity, and clarity of items, respectively. The expert panel results indicate that all items are relevant and simple, but item 909 needs revision to make it clear so that women can understand it, and it can be used for the assessment of women's attitudes toward the uptake of cervical cancer screening. Finally, all 16 items were included in the tool. *(Supplementary file1, table 9)*

Modified kappa analysis was conducted to assess the level of agreement among experts on each domain of the tool. The highest modified kappa value of 0.98 was observed for the socio-demographic domain, while the lowest value of 0.87 was recorded for the Knowledge of risk factors domain, indicating perfect agreement among expert raters. These results demonstrated strong consistency across the tool's domains. (See Table 3. And supplementary file 2 for each domain)

Table 2: **Expert rating of each domain based on Essentiality, Relevance, Simplicity, and clarity of items validated for CCS among women in Ethiopia**

Domains	Essentiality		Relevance		Simplicity		Clarity				
	Average CVR	S-CVI/Ave	Total Agreement	S-CVI/UA	S-CVI/Ave	Total Agreement	S-CVI/UA	S-CVI/Ave	Total Agreement	S-CVI/UA	No, of items removed
Socio-demographic	0.5	0.84	5	0.31	0.85	6	0.38	0.86	8	0.5	4
Reproductive and Risk Factors	0.61	0.93	6	0.38	0.87	0	0	0.89	1	0.06	4
Awareness CCa* and cervical CCS**	0.78	0.9	2	0.71	0.96	9	0.41	0.93	6	0.35	0
knowledge of risks	0.7	0.94	6	0.38	0.96	6	0.44	0.92	4	0.25	3
knowledge of signs and symptoms	0.77	0.93	8	0.62	0.98	11	0.85	0.94	7	0.54	0
help -seeking behavior	0.66	0.91	4	0.57	0.96	5	0.71	0.66	0	0	0
confidence, skills, and behavior	0.58	0.63	1	0.33	0.67	3	1	0.58	0	0	0
barriers to uptake of CCS	0.8	0.93	15	0.65	0.84	9	0.39	0.8	2	0.09	0
attitudes of women toward uptake of CCS	0.75	0.91	8	0.5	0.86	3	0.19	0.82	1	0.06	0
Overall	0.60	0.88		0.60	0.88		0.49	0.82		0.21	11

*= Cervical cancer, **= Cervical cancer screening, CVR=Content Validity Ratio, CVI=Content Validity Index, UA= Universal Agreement, Ave=Average

Table 3:- **Content Validity Index, Modified Kappa, and interpretation of modified Kappa**

Domains and Items	No of experts (raters)	Average I-CVI	Interpretation of I-CVI about the items	Modified Kappa		Interpretation Modified Kappa
				Average Pc* = [N! /A! (N - A)!] 0.5^{*N}	Average K* = (I-CVI-PC) / (1-PC).	
D1: Socio-Demography						
Items 101 to 106	16	**0.98**	**Relevant**	**0.00031**	**0.98**	Perfect agreement
D2: Reproductive & risky behavior						
Items 201 to 223	16	0.92	**Relevant**	0.00198	0.92	Perfect agreement
D3: Awareness						
Item 301-317	16	0.90	**Relevant**	0.00370	0.90	Perfect agreement
D4: Knowledge of risk factors						
Item 401-402a-m	16	0.88	**Relevant**	0.00241	0.87	Perfect agreement
D5: Knowledge of S/S						
Item 501 – 502a-l	16	0.97	**Relevant**	0.00034	0.97	Perfect agreement
D6: Help-seeking Behavior						
Item 601-607	16	0.95	**Relevant**	0.00059	0.95	Perfect agreement
D7: Confidence						
Item 701- 703	15	0.94	**Relevant**	0.00024	0.94	Perfect agreement
D8: Socio-cultural barriers						
Item 801-823	16	0.97	**Relevant**	0.00043	0.97	Perfect agreement
D9: Attitude						
Item 901-915	16	0.97	**Relevant**	0.00022	0.97	Perfect agreement

Pc* = Chance of agreement, [N! /A! (N -A)!] 0.5^{*N}, N total number of experts who participated in panel evaluation, A number of experts who agreed essential. K* = modified kappa, (I-CVI- PC) / (1- PC). I-CVI itemitem-level content validity index, and PC chance agreement. I-CVI: ≥ 0.79 = Relevant, 0.70-0.79= item needs revision and < 0.70 = item should be eliminated, S/S = Signs/Symptoms

Tool translation

The items were translated by bilingual language experts from English to the local language, Amharic, and then translated back to English to assess the consistency of the tool. Two English language experts with master`s degrees in language translated to Amharic, and other experts with the same level of education translated the Amharic version back to English. Two public health experts also participated in the translation process by ensuring proper contextual translation of medical terms into the local language and cultural context. In total, four experts were involved in the translation and back translation of the tool. Finally, the tools of 122 items were translated into the local language.

Internal consistency assessment of EWCCaAS

Out of a total of 133 items refined, developed, and evaluated by experts, about 122 (91.7%) of the refined items were agreed upon as essential, relevant, simple, and clear by expert panel evaluation. In order to use these items as a standard tool, the internal consistency of the tool should be assessed. To assess the internal consistency of the items, 366 women were randomly selected based on the assumption of 3 participants per item. Service utilization exit interviews were conducted to collect the data. The collected data were entered into SPSS version 26 to compute Cronbach`s alpha. The Cronbach`s alpha was used to assess the internal reliability of the items. The items were categorized into 9 domains. Except for the socio-demographic domain, the Cronbach`s alpha was computed for all domains. The lowest values of Cronbach`s alpha were 0.33 and 0.43, which were observed in the help-seeking domain and the domain of confidence skills and behaviors in relation to cervical cancer signs/symptoms, respectively. The items with Cronbach`s alpha < 0.50 were considered unacceptable and removed from the tool. The highest Cronbach`s alpha value of 0.93 was found among the items in the socio-cultural domain, indicating excellent item content for measuring th socio-cultural barriers. The average Cronbach`s alpha was found to be 0.79 for all domains, excluding domains 5 (Help-seeking behavior domain) and 6 (Confidence skills and behavior). The socio-demographic domain was not assessed for reliability because the socio-demographic domains are important to be included in the tool, whether or not its Cronbach`s alpha is lower than the minimum critical value. (See table 4 below)

Table 4**: reliability of each domain for the cervical cancer screening assessment tool among Ethiopian women**

No,	Domains	Computed Cronbach` s alpha	Interpretation	Decision
1	Reproductive and risky behavior	0.76	Acceptable	Included
2	Awareness about cervical cancer and screening	0.51	Questionable	Included
3	Knowledge of risk factors for cervical cancer	0.84	Good	Included
4	Knowledge of signs & symptoms	0.83	Good	Included
5	Help-seeking behavior	0.33	Low	**Eliminated**
6	Confidence skills and behavior	0.43	Low	**Eliminated**
7	Socio-cultural barriers	0.93	Optimal	Included
8	Attitudes toward cervical cancer screening	0.86	Good	Included
	Average (Including domains 5 and 6)	0.69	Good	Included
	Final Average (Excluding domains 5 and 6)	0.79	Acceptable	

Final EWCCaAS tool

Expert panel evaluation approved a tool consisting of nine domains: Socio-demographic, Reproductive and risky behavior, Awareness about cervical cancer and screening, Knowledge of risk factors for cervical cancer, Knowledge of signs & symptoms, Help-seeking behavior, Confidence skills and behavior, Socio-cultural barriers, and Attitudes domain. However, following the assessment of internal reliability, two out of nine domains, *help-seeking behavior* and *confidence skills and behavior*, were excluded from the tool due to low and unacceptable Cronbach's alpha values of 0.33 and 0.43, respectively, which fall below the acceptable range. The final version of the **EWCCaAS** tool consists of a total of 108 items categorized into 7 domains. the first domains contains 6 socio-demographic questions while the second domain includes 23 items related to reproductive characteristics and risky behavior which includs reproductive characteristics items, HIV test related items, cervical cancer history related items, modern contraceptive use related questions/items, risky behavior related items, STIs infections related items, and HCPs recommendation and utilization of cervical cancer screening related items); the third domain includes 16 items related to awareness of cervical cancer measures such as items about information of cervical cancer, information of cervical cancer screening, knowledge of cervical cancer screening methods, knowledge of health institution providing cervical cancer screening, utilization of cervical cancer screening, benefits of early screening, to adolescent girls HPV vaccination, and cervical cancer transmission. The fourth domain includes 14 items related to knowledge of cervical cancer risk factors such as HPV infection, HIV infections, Other sexually transmitted infections, multiple unprotected sex, use of oral pills for family planning, not using condom, cigarette smoking, early sex at adolescent age, poor personal hygiene, more than 3 births, perception of curse etc. The fifth domain includes 11 items related to knowledge of symptoms of cervical cancer. The sixth domain consists of 23 items related to socio-cultural barriers to uptake cervical cancer screening, and the seventh domain includes 15 items related to attitudes toward cervical cancer screening utilization. Out of 133 items refined, developed, and validated, 108 items in seven domains were included in the Ethiopian Women Cervical Cancer Awareness and Screening (EWCCaAS) utilization assessment tool. (See the details in supplementary file 3)

Discussion

The Ethiopian Women's Cervical Cancer Awareness and Screening (EWCCaAS) measures were developed to provide, for the first time in Ethiopia to the best of the authors' knowledge, a validated tool to assess awareness of cervical cancer and screening among age-eligible women. The **EWCCaAS** tool was designed and follows a similar format to AWACAN[15]. The items assessing knowledge of risk factors and symptoms were designed to assess using open-ended questions with a checklist of known risk factors and a list of common symptoms, as well as multiple-choice risk factors and symptoms questions. This sequence of questioning allows respondents to freely express their views without the chance of guessing pre-existing options. The findings of this study are supported by a study conducted in South Africa, Kenya, and Uganda by AWACAN[15]. This may be attributed to the fact that most of the items were refined from the same study, and an African woman may experience similar social and cultural influence, educational status, and economic status, which can affect their health care seeking behavior. The method of assessing knowledge of risk factors and symptoms, which involves starting with open-ended questions and then using a checklist of known risk factors and symptoms, is a valuable approach in health studies. It is especially effective for identifying awareness of disease risk factors and symptoms. This method allows participants to freely express their understanding without being influenced by predetermined options, resulting in more genuine information about their level of awareness and knowledge.

The overall CVR and S-CVI/Ave of this study showed good validity, indicating that the tool can effectively assess awareness, knowledge level, attitude, and socio-cultural barriers related to cervical cancer screening. This validation is supported by the study titled "Development and Validation of a Questionnaire to

Assess Knowledge about Cervical Cancer among Women Aged 20 to 65 years in Oman" (2021)[12]. This suggests that knowledge about cervical cancer may be similar across different regions. The study findings this study demonstrated that the assessment tool is robust and reliable, as evidenced by the overall Content Validity Ratio (CVR) and Scale-Content Validity Index/Average (S-CVI/Ave). This validity ensures that the tool accurately measures awareness, knowledge level, attitudes, and socio-cultural barriers associated with cervical cancer screening. Internal reliability in this study was assessed using Cronbach`s alpha. The results showed that Cronbach`s alpha is 0.84 for knowledge of risk factors and 0.83 for knowledge of signs and symptoms of cervical cancer. These values are slightly higher compared to a study conducted in the UK (2012) [26]. This difference may be due to variations in the type and number of items, the study area, the socio-economic status of study participants, and socio-cultural differences among the women who participated in the study. The higher Cronbach's alpha in this study suggests that the tool is more reliable for assessing knowledge about cervical cancer risk factors and symptoms, particularly in the target population. This increased reliability strengthens the validity of the results, making them more trustworthy for informing public health interventions.

The result of this study indicated that the **EWCCaAS** showed moderate overall reliability (Cronbach's Alpha 0.69), indicating acceptable reliability according to Hinton et al. (2014), in which the minimum internal consistency value as measured by Cronbach's Alpha value is 0.57. According to Hinton and colleagues, an Alpha score above 0.75 indicates high reliability, between 0.50 and 0.75 is a moderate reliability [54]. The internal reliability of this tool is somewhat lower compared to studies conducted in Oman (2021) and Poland (2013) [12, 55]. These differences could be attributed to variation in sample size, levels of awareness among study participants, and differences in the number and content of items. Existing literature has shown that there is a wide range of knowledge differences among women, as well as various types of barriers to the uptake of cervical cancer screening in Ethiopia [56-58]. This variability may be due to the use of different unstandardized, unreliable, and non-validated measurement tools. The EWCCaAS tool demonstrates acceptable reliability. It meets acceptable standards and can be used to assess awareness and risk factors of cervical cancer, as well as socio-cultural barriers to uptake cervical cancer screening. Finally, a total of 108 items, categorized into 6 domains, have been validated. Socio-demographic items were also included in the final validated items, resulting in 7 domains.

Limitations of the study

There is a lack of similar studies to compare the findings of this study. The study was conducted in a single study area, assuming that there were various ethnic groups of population in the study area. Even though various ethnic groups of the population live in Adam city, there may not be proportional participation of various ethnic groups. Further studies, including multiple study points or centers, may be required to enhance the strength of the tool.

Conclusion

The overall CVR and CVI indicate that the tool is essential, relevant, simple, and clear. The overall Modified Kappa indicates that there is perfect agreement among the experts, and Cronbach`s alpha of items indicates the tool is good and acceptable. We, the authors, recommend that all researchers use this tool to assess the level of awareness, knowledge of risk factors, knowledge of symptoms of cervical cancer, socio-cultural barriers, and attitudes toward cervical cancer screening in Ethiopia so that the results of their study will be generalized to the study population. The use of this tool helps generate evidence for policymakers to design strategies for the prevention and control of cervical cancer among target women. We recommend a multicenter study and application of exploratory factor analysis for further development and validation of the tool.

Acronyms/Abbreviations

Ave-Average
AWCAN-African Women Cancer Assessment Tool
CCAM- Cervical Cancer Awareness Measurement
CVI-Content Validity Index
CVR-Content Validity Ratio
EWCCaAS-Ethiopian Women's Cervical Cancer Awareness and Screening
I-CVI-Item-level Content Validity Index
S-CVI-Scale level Content Validity Index
UA-Universal Agreement

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Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

Consent for publication

NA

Availability of data and materials

All data extracted from systematic review and meta-analysis, as well as the data collected from study participants, are available to the corresponding author and can be provided to anyone upon request at any time.

Authors' contribution

Ebrahim Mohammed, Girma Taye, Adamau Addissie, Ahmedin Jemal, Mathewos Assefa participate from conceptualization to manuscript writing.

Competing interests

The authors declare that they have no competing interests

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