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Measuring cervical cancer risk: development and validation of the CARE Risky Sexual Behavior Index

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Abstract

Objectives—To develop and validate a risky sexual behavior index specific to cervical cancer research.

Methods—Sexual behavior data on 428 women from the Community Awareness Resources and Education (CARE) study were utilized. A weighting scheme for eight risky sexual behaviors was generated and validated in creating the CARE Risky Sexual Behavior Index. Cutpoints were then identified to classify women as having a low, medium, or high level of risky sexual behavior.

Results—Index scores ranged from 0 to 35, with women considered to have a low level of risky sexual behavior if their score was less than six (31.3% of sample), a medium level if their score was 6–10 (30.6%), or a high level if their score was 11 or greater (38.1%). A strong association was observed between the created categories and having a previous abnormal Pap smear test ($p <$ 0.001).

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All research was conducted at The Ohio State University.

Conclusions—The CARE Risky Sexual Behavior Index provides a tool for measuring risky sexual behavior level for cervical cancer research. Future studies are needed to validate this index in varied populations and test its use in the clinical setting.

Keywords

Cervical cancer; Sexual behavior; Women's health

Introduction

Invasive cervical cancer (ICC) remains the second leading type of cancer death in women worldwide [1]. Even with large reductions in cervical cancer incidence since the 1950s due to Pap smear testing, there will still be an estimated 11,070 incident cases and 3,870 deaths from cervical cancer in the United States during 2008 [2]. One risk factor for cervical cancer is participation in risky sexual behavior.

Risky sexual behavior has been described as any sexual activity that increases the risk of contracting human immunodeficiency virus (HIV), other sexually transmitted infections (STIs), or becoming pregnant (unwanted) [3]. In terms of cervical cancer, participation in risky sexual behaviors increases a woman's risk of infection with human papillomavirus (HPV) [4], of which certain types are recognized as the primary cause of cervical cancer [2]. Furthermore, certain risky sexual behaviors have been shown to increase cervical cancer risk, even after controlling for HPV status [5, 6].

Risky sexual behaviors related to cervical cancer have been identified as engaging in sexual intercourse at an age younger than 18 years, having a higher number of sexual partners, having a history of being treated for an STI, and having a current or past sexual partner who has been treated for an STI [7]. While not specific to cervical cancer, a broader definition of risky sexual behavior has included having unprotected sexual activity, inconsistent use of condoms, having high-risk partners (including drug users), and survival sex (sex in exchange for money, drugs, food, or shelter) [3].

From both a public health and clinical perspective, it is important to accurately measure a woman's level of risky sexual behavior. Previous research, not exclusive to cervical cancer, has measured and analyzed risky sexual behavior in a variety of ways. One method has been to examine each sexual behavior individually [8–11]. However, analyzing risky sexual behavior by individual components may not accurately represent overall risk [12]. Thus, an alternative approach is to measure risky sexual behavior using an index.

Some existing indices have utilized a non-weighted additive method in generating overall scores of risky sexual behavior [13, 14]. Each individual behavior was treated as if it carried the same risk level, which is likely not plausible. Other indices have utilized weighting schemes or more advanced additive methods for generating overall risky sexual behavior scores [15–19]. However, the weighting schemes or additive methods still appeared somewhat limited in terms of how the risk of an individual behavior was quantified relative to the other behaviors.

A risky sexual behavior index designed specifically for cervical cancer research could not be located in the current literature. In response to the lack of such an index, we aimed to create and validate a weighted index using data from the Community Awareness Resources Education (CARE) study.

Methods

Study design

The CARE study has been described in great detail elsewhere [20]. Briefly, the overall goal of the CARE study was to investigate the interaction of environmental, societal, behavioral, and biological mechanisms as they contribute to understanding the causes and prevention of cervical cancer in Ohio Appalachia. A total of 22 health clinics in Ohio Appalachia were approached to participate, of which 14 (63.6%) agreed. Within each participating clinic, a monthly random sample of women was selected and medical records were reviewed to determine eligibility. A woman had to be at least 18 years of age, reside in an Ohio Appalachian county, not be pregnant, have no history of hysterectomy or invasive cervical cancer, and she had to be seen in that clinic within the prior 2 years to be eligible. A meeting to complete the baseline survey was then scheduled, usually at the participant's home, for women who were eligible and agreed to participate. When recruitment ended in June 2006, a total of 571 women (participation rate = 71.3%) had completed the baseline survey. Data from these cross-sectional surveys were used for these analyses. The study was approved by the Institutional Review Boards at The Ohio State University, the University of Michigan, and the Centers for Disease Control and Prevention (CDC).

Measures

Sexual behaviors to be included in the index were based on descriptions of risky sexual behavior provided by previous research [3, 7]. They included, with the first category for each of the following variables being considered the risky behavior, age at first sexual intercourse (<18 years of age vs. ≥18 years of age), number of sexual partners during one's lifetime (>4 sexual partners vs. ≤4 sexual partners), history of sexual intercourse in exchange for money (yes vs. no), condom use (inconsistent use vs. consistent use), personal history of ever being diagnosed with an STI (yes vs. no), any male sexual partners with a history of STI (yes vs. no), any male sexual partners with a history of having sexual intercourse with other men (yes vs. no), and any male sexual partners with a history of intravenous drug use (yes vs. no). Data for all items were self-reported by participants.

Data on consistency of condom use were collected for two time periods for each woman, before the age of 18 and age 18 and older. For each time period, participants had response options of “Yes, regularly,” “Yes, sometimes,” “Never,” and “No partner.” Data for the two time periods were combined into a variable representing overall condom use with each woman being classified as having either “consistent use” (“Yes, regularly” for both time periods or a combination of “Yes, regularly” and “No partner”) or “inconsistent use” (all other response combinations). If a participant provided data for only one time period, they were classified as having inconsistent use (if indicated “Yes, sometimes” or “Never”) or not assigned a value (if indicated “Yes, regularly” or “No partner” since overall condom use was not known). Three participants indicated “No partner” for both time periods but also reported a history of sexual activity. They were not assigned a value for overall condom use.

Personal history of STIs was determined by combining information on history of infection with chlamydia, gonorrhea, syphilis, genital warts/HPV, genital herpes, trichomoniasis, and HIV. A participant was considered to have a personal history of STI if she indicated a history of any of the above listed infections. If data were missing for one or more infections but a previous infection was indicated for a condition with data, the participant was considered to have a history of STI. If data were missing for one or more infections, and no previous infections were indicated for those conditions with data, the participant was not assigned a value for this variable since overall past STI history was not known. To be

categorized as having no history of STI, a participant had to provide data for all conditions and indicate no prior infection for each one.

CARE Risky Sexual Behavior Index creation

Complete data for all eight risky sexual behaviors were required for a CARE participant to be included in these analyses. In total, 428 of the 571 participants (75.0%) met this inclusion requirement. Of these 428 participants, 300 were randomly selected to create the index and the remaining 128 were used for validation.

For the 300 randomly selected participants, a logistic regression model containing the eight risky sexual behaviors as independent variables and history of an abnormal Pap smear test as the outcome variable was constructed. The model was constructed to assess the strength of each behavior's association with an outcome indicative of prior cervical abnormality while controlling for all other sexual behaviors. A woman was considered to have a history of abnormal Pap smears if she self-reported on the baseline survey at least one prior abnormal Pap smear test. A prior diagnosis of invasive cervical cancer was not used as the outcome variable in this model since women with such diagnoses were not eligible to participate in the CARE study. History of an abnormal Pap smear test provided a viable alternative since it was not part of the study's eligibility requirements and still provided an indication of past cervical abnormality associated with the development of invasive cervical cancer.

Based on regression coefficients (b, the log odds ratio) from this model, each sexual behavior was categorized as having a weak ($b < 0.15$), fair ($0.15 < b < 0.25$), moderate ($0.25 < b < 0.75$), strong ($0.75 < b < 1.50$), or very strong association ($b > 1.50$) with history of an abnormal Pap smear test. Any regression coefficient with a negative value in this multivariable model was classified as having a weak association, as we thought it unlikely that a history of any of these behaviors would reduce the chance of cervical disease. All sexual behaviors also had a positive regression coefficient in univariate models (data not shown), giving us further confidence in this classification decision. Weights were then assigned to each sexual behavior using the following values: weak = 1, fair = 2, moderate = 5, strong = 10, very strong = 20. The concept for the weighting scheme was based on those used to create the Harvard Cancer Risk Index [21].

The weighting scheme was then used to calculate overall index scores for all 428 participants. For each sexual behavior, participants were assigned the appropriate weight if they reported a history of that behavior and a score of ‘0’ if they did not. Overall index scores were calculated for each participant by summing the values from the eight sexual behaviors.

CARE Risky Sexual Behavior Index validation

The overall index scores for participants in the validation dataset ($n = 128$) were entered into a univariate logistic regression model as a continuous variable with history of an abnormal Pap smear test as the outcome. To validate the index, the goodness-of-fit for this model was assessed using the Hosmer–Lemeshow test.

Index cutpoints

Since we believe a categorical indicator of risky sexual behavior may be of more practical use than a continuous risk score, we identified cutpoints that classified participants as having a high, medium, or low level of risky sexual behavior. To accomplish this, a lowess curve was generated for a univariate logistic regression model containing the overall index scores as a continuous independent variable and history of an abnormal Pap smear test as the outcome variable for all participants ($n = 428$). Appropriate cutpoints were identified based

on this lowess curve. The association between the three-level (high, medium, and low) categorical index variable and history of an abnormal Pap smear test was then examined in a logistic regression model to assess the effectiveness of the created categories.

Statistical methods

Descriptive statistics were initially used to provide overall participant characteristics, frequencies of sexual behaviors, and to compare women included in these analyses with those excluded due to missing data. Logistic regression models were used for these comparisons, as well as in the aforementioned situations to create and validate the index. Mixed logistic regression models were utilized since women were clustered within clinics for the CARE study. Model fit was examined using the Hosmer–Lemeshow test during the validation step as already described. Since this test was not available for mixed models, a standard logistic regression model comprised of the same variables was instead used. Analyses were performed using SAS Version 9.1 [22] and Intercooled Stata Version Release 9.2 [23].

Results

Demographic characteristics of the women included in these analyses ($n = 428$) and those excluded due to missing sexual behavior data ($n = 143$) are displayed in Table 1. Compared to women included in the analyses, those who were excluded had lower incomes (assessed using poverty income ratio) and were more likely to reside in an urban county ($p < 0.05$). Women included in the analyses were mostly white (94.2%), married or living as married (63.3%), employed full-time or part-time (65.4%), had private health insurance (64.0%), and resided in a rural county (63.8%). Inconsistent condom use (81.5%), sexual intercourse before the age of 18 (60.3%), and having five or more sexual partners during their lifetime (45.3%) were the most prevalent reported risky sexual behaviors among women included in the analyses (Table 2).

Table 3 displays the regression coefficients and resulting weights obtained from the multivariable logistic regression model containing the eight sexual behaviors and history of an abnormal Pap smear test as the outcome for the index creation sample ($n = 300$). Personal history of STI was categorized as having a very strong association ($b = 2.06$), age at first sexual intercourse ($b = 0.36$) and the number of sexual partners during one's lifetime ($b = 0.39$) were categorized as having moderate associations, and all other behaviors were considered to have weak associations ($b < 0.15$). Personal history of STI was therefore given a weight of 20, age at first sexual intercourse and the number of sexual partners during one's lifetime were given weights of five, and all other sexual behaviors were assigned weights of one. Index scores could range from 0 to 35 using this weighting scheme.

The Hosmer–Lemeshow goodness-of-fit test did not indicate a lack of fit for the validation model ($n = 128$, $p = 0.30$), successfully validating the weighting scheme in this subsample of women from the CARE study. Among all study participants ($n = 428$), the mean index score was 9.71 (SD = 9.40), the median score was 6.00, and scores ranged from 0 to 35.

Based on the lowess curve, participants were considered to have a low level of risky sexual behavior if their overall index score was less than six, a medium level if their index score was 6–10, and a high level if their index score was 11 or greater. Using these cutpoints, 134 women (31.3%) were classified as having a low level of risky sexual behavior, 131 (30.6%) were classified as having a medium level, and 163 (38.1%) were classified as having a high level. The three-level index variable was significantly associated with history of an abnormal Pap smear test among the entire sample ($n = 428$, $p < 0.001$). The percent of women with a prior abnormal Pap smear test increased as the level of past risky sexual

behavior increased (low group = 17.2%, medium group = 27.5%, high group = 49.1%) (Fig. 1). Similar associations and percents were observed when the index creation ($n = 300$, $p < 0.001$) and index validation ($n = 128$, $p = 0.001$) samples were examined separately (Fig. 1).

Discussion

Sexual behavior is an important risk factor to accurately measure when conducting cervical cancer research or making recommendations for surveillance. Our primary goal was to develop and validate the CARE Risky Sexual Behavior Index in response to the lack of an existing weighted index specific to cervical cancer research. Using a random subsample of participants, weights for eight risky sexual behaviors were assigned based on each behavior's association with a prior abnormal Pap smear test, which served as a proxy for cervical cancer risk. The weighting scheme was then validated using the remaining participants. Cutpoints were determined to classify participants as having a high, medium, or low level of past risky sexual behavior based on their overall index score.

We believe the created index offers a few distinct advantages over existing indices for future cervical cancer research and practice. The assigned weights for each behavior were based on the associations with an outcome indicative of past cervical disease. In contrast, past indices used no such methods in assigning weights, if a weighting scheme was used at all [13–19]. We therefore believe that the weighting scheme created and validated here offers an improvement in measuring the risk, in terms of cervical cancer, of each individual sexual behavior. To confirm this, exploratory analyses were conducted comparing the area under the receiver operating characteristic (ROC) curve for our index to that of an index score calculated using simple additive methods (one point for each reported behavior). We found the area under the ROC curve for our index to be higher compared to the simple additive method (data not shown), indicating our index is a more effective way to measure risky sexual behavior.

The index is also comprised of an extensive list of risky sexual behaviors that could affect cervical cancer risk. By including eight risky sexual behaviors, the index is able to address the risky behaviors of both the female and her male sexual partners, which is crucial since male partner behaviors affect a woman's risk for cervical cancer [24, 25].

In addition to providing a tool for cervical cancer research, this index also has potential applications at both the clinical and community health level. Among healthcare providers, the index could serve as an assessment tool of cervical cancer disease risk since it would allow for easy classification of female patients based on their level of risky sexual behavior. This would help both the healthcare provider and patient to better understand the patient's potential risk for cervical disease. At the community health level, the index could be used to identify populations at increased risk for cervical disease due to large percentages of women classified as having a high level of risky sexual behavior. Public health programs designed to reduce cervical disease, such as those aimed at increasing HPV vaccination or cervical cancer screening, could then be targeted towards these populations.

There were a few limitations to the data and methods used in this research. As with any research addressing sexual behaviors, there was concern over the validity of the self-reported data since women may underreport sexual behaviors [26, 27]. To offset this concern, the baseline survey utilized a computer-assisted personal interview (CAPI) system with an audio portion for sexual history items. Computer-assisted data collection methods have increased accuracy for reporting sexual behaviors compared to paper questionnaires [28]. It was not possible to account for change in condom use due to marital status changes or to estimate a percent or absolute number of times a condom was used during sexual

intercourse. Items addressing female sexual partners were also not included, which may be important due to potential HPV transmission between female sexual partners [29].

Few women reported sexual intercourse for money, a male sexual partner with a history of intravenous drug use, or a male partner with a history of sex with other men. Therefore, there were concerns regarding small numbers in the multivariable model used in determining the weighting scheme. We still believe, however, that these variables were correctly classified as having weak associations with history of an abnormal Pap smear test. At the univariate level where smaller numbers are of less concern, these three sexual behaviors were only modestly associated with history of an abnormal Pap smear test (data not shown). It is unlikely that these behaviors would have stronger associations in the multivariable model after controlling for history of STI, number of lifetime sexual partners, and age at first sexual intercourse, all of which are established risk factors for cervical disease [2, 5, 6, 30].

While the index was validated in this research, the validation dataset was comprised of participants from the CARE project, which was conducted among the mostly white population living in Ohio Appalachia [31]. Despite this low level of racial diversity, we believe the scale may still be applicable for varied populations. Women from the CARE study reported similar levels of inconsistent condom use, sexual intercourse before the age of 18, having five or more sexual partners, and previous STIs when compared to female populations containing large percentages of minority women [8, 32–34]. The percentage of women reporting a prior abnormal Pap smear test was also comparable to more diverse populations [35, 36]. Thus, while there remains a definite need to validate this index in different populations, the external validity cannot be dismissed strictly due to the lack of diversity of the women in this study.

In summary, the CARE Risky Sexual Behavior Index was developed and validated to provide a specific tool for measuring risky sexual behavior for cervical cancer research and practice. The created index allows for the classification of women as having a high, medium, or low level of risky sexual behavior related to cervical cancer. Using this index may help clinicians identify women at an increased risk of cervical disease, and it may be important in future cervical cancer research, educational programs, and recommendations for HPV and Pap smear screening. Future research is needed to validate this index in varied populations and test its use in the clinical setting.

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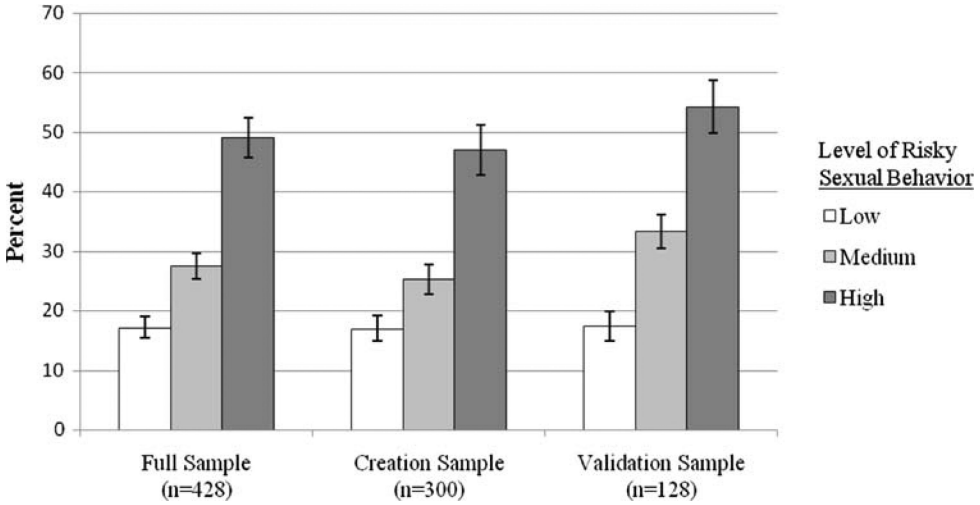

Fig. 1.

Percentage of women reporting a history of an abnormal Pap smear test within each category of the CARE Risky Sexual Behavior Index. *Note: Bars* indicate the standard errors of the proportions

Table 1

Characteristics of Community Awareness Resources Education (CARE) participants included in (n = 428) and excluded from (n = 143) the CARE Risky Sexual Behavior Index

	Included *n* (%)	Excluded *n* (%)	*p*
Age			0.63
18–30	137 (32.0)	47 (32.9)	
31–50	194 (45.3)	69 (48.2)	
51+	97 (22.7)	27 (18.9)	
Race			0.45
White	403 (94.2)	137 (95.8)	
Non-white	25 (5.8)	6 (4.2)	
Education			0.45
High school degree or less	185 (43.2)	67 (46.9)	
More than high school degree	243 (56.8)	76 (53.1)	
Marital status			0.20
Married/living as married	271 (63.3)	78 (54.9)	
Never married	70 (16.4)	30 (21.1)	
Divorced/widowed/separated	87 (20.3)	34 (23.9)	
Employment status			0.12
Full-time/part-time	280 (65.4)	89 (62.7)	
Unemployed/disabled	69 (16.1)	33 (23.2)	
Other employment	79 (18.5)	20 (14.1)	
Occupation type			0.65
Unskilled labor/never employed/other	210 (49.2)	73 (51.4)	
Professional/skilled labor	217 (50.8)	69 (48.6)	
Religion			0.87
Does not belong to church/religion	172 (40.2)	56 (39.4)	
Belongs to church/religion	256 (59.8)	86 (60.6)	
Poverty income ratio			0.03
Less than 2.00	217 (53.1)	86 (64.2)	
2.00 and higher	192 (46.9)	48 (35.8)	
Health insurance status			0.09
No coverage (self-pay)	62 (14.5)	27 (19.0)	
Medicaid or medicare only	92 (21.5)	39 (27.5)	
Private insurance (job or purchased)	274 (64.0)	76 (53.5)	
County of residence type			0.04
Urban	155 (36.2)	66 (46.2)	
Rural	273 (63.8)	77 (53.8)	

Totals may be less than stated numbers due to missing data

Table 2

Frequency of risky sexual behaviors among participants in the Community Awareness Resources Education (CARE) study ($n = 428$)

	n **(%)**
Age at first sexual intercourse	
Less than 18 years of age	258 (60.3)
18 Years of age or older	170 (39.7)
Number of sexual partners during lifetime	
5 or more	194 (45.3)
4 or fewer	234 (54.7)
Any male sexual partners with history of sex with other men	
Yes	14 (3.3)
No	414 (96.7)
Any male sexual partners with history of intravenous drug use	
Yes	12 (2.8)
No	416 (97.2)
Any male sexual partners with history of sexually transmitted infection	
Yes	37 (8.6)
No	391 (91.4)
History of sexual intercourse in exchange for money	
Yes	4 (0.9)
No	424 (99.1)
Condom use frequency	
Inconsistent use	349 (81.5)
Consistent use	79 (18.5)
Ever been diagnosed with a sexually transmitted infection	
Yes	74 (17.3)
No	354 (82.7)

Table 3

Regression coefficients from the multivariable model and associated weights for the risky sexual behaviors included in the CARE Risky Sexual Behavior Index (n = 300)

	b	Weight
Age at first sexual intercourse		
Less than 18 years of age	0.36	5
18 Years of age or older	–	0
Number of sexual partners during lifetime		
5 or more	0.39	5
4 or fewer	–	0
Any male sexual partners with history of sex with other men		
Yes	<0.01	1
No	–	0
Any male sexual partners with history of intravenous drug use		
Yes	<0.01	1
No	–	0
Any male sexual partners with history of sexually transmitted infection		
Yes	<0.01	1
No	–	0
History of sexual intercourse in exchange for money		
Yes	<0.01	1
No	–	0
Condom use frequency		
Inconsistent use	0.08	1
Consistent use	–	0
Ever been diagnosed with a sexually transmitted infection		
Yes	2.06	20
No	–	0

b represents the log odds ratio from the multivariable logistic regression model used in assigning the weights