

## RESEARCH ARTICLE

# Cervical Cancer Screening and Analysis of Potential Risk Factors in 43,567 Women in Zhongshan, China

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### Abstract

**Objective:** The objective of this study was to establish a program model for use in wide-spread cervical cancer screening. **Methods:** Cervical cancer screening was conducted in Zhongshan city in Guangdong province, China through a coordinated network of multiple institutes and hospitals. A total of 43,567 women, 35 to 59 years of age, were screened during regular gynecological examinations using the liquid-based ThinPrep cytology test (TCT). Patients who tested positive were recalled for further treatment. **Results:** The TCT-positive rate was 3.17%, and 63.4% of these patients returned for follow-up. Pathology results were positive for 30.5% of the recalled women. Women who were younger than 50 years of age, urban dwelling, low-income, had a history of cervical disease, began having sex before 20 years of age, or had sex during menstruation, were at elevated risk for a positive TCT test. The recall rate was lower in women older than 50 years of age, urban dwelling, poorly educated, and who began having sex early. A higher recall rate was found in women 35 years of age and younger, urban dwelling, women who first had sex after 24 years of age, and women who had sex during menstruation. The positive pathology rate was higher in urban women 50 years of age and younger and women who tested positive for human papillomavirus. **Conclusion:** An effective model for large-scale cervical cancer screening was successfully established. These results suggest that improvements are needed in basic education regarding cervical cancer screening for young and poorly educated women. Improved outreach for follow-up is also necessary to effectively control cervical cancer.

**Keywords:** ASC-US - cervical cancer screen - CIN - HPV - ThinPrep cytology test - China

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### Introduction

Cervical cancer is one of the most common gynecological cancers. It is the only gynecological cancer that can be diagnosed early, and early diagnosis increases the chance of cure. Results from many studies have shown that population screening for cervical cancer can significantly decrease the incidence and mortality of the disease, especially when women who test positive for early markers are immediately linked to sources of diagnostic testing and further healthcare. Because incidence of the disease is inversely associated with the recall rate after screening (Parkin et al., 2005), the success of prevention and treatment programs for cervical cancer depends on contacting and directing women to such sources of proper healthcare (Parkin et al., 2005).

Among many important factors, an effective health screening program should include health education, wide coverage of the target population, and a high recall rate for those who test positive. Widespread population screening

programs have just begun in China, and most have not adequately covered target populations.

Since 2011, the city of Zhongshan in Guangdong province, China has conducted a large-scale screening program that uses the liquid-based ThinPrep cytology test (TCT) to screen healthy women 35 to 59 years old for cervical cancer. The program actively promotes collaboration between multiple institutes and encourages integration of regional medical resources. The present study analyzed the effectiveness of the initial phase of this program, focusing on the design and factors that influence its success, based on the screening results of 43567 women.

### Materials and Methods

*The national Ethics Review Committee of Zhongshan approved this study*

In accordance with the national policy on basic services in public health, the municipal government of Zhongshan

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developed a program that integrates social resources to conduct government-sponsored cervical cancer screening. The program involves the collaboration of multiple institutes to integrate medical resources across the region. The aim of the program is to screen 150000 women (35–59 years of age; permanent residents) from January 2011 to December 2013. At the end of the program, the population coverage rate will be 50%. As part of the program, the hospitals developed the necessary software to establish a patient database. Basic information for each woman is recorded on a digital personalized ID card, which allows authorized medical personnel to input screening information simultaneously. The participating hospitals established independent management systems to conduct the program using personnel dedicated for the purpose. In addition, the hospitals formed collaborations with the local Women's Federation, Family Planning Commission, and the Community Board to develop outreach mechanisms that promote participant recall and periodically follow-up with high-risk individuals.

#### *Study subjects and methods*

In 2011, the Women's Federation, Family Planning Commission, and Neighborhood Committee invited married women from 24 districts of Zhongshan city to participate in a study to evaluate the success of the initial phase of the program. For inclusion in the study a woman had to be married, 35–59 years old, sexually active for at least one year, and a resident of the screening area for at least one year. All participants signed a written consent form prior to undergoing any examination. Women who had undergone hysterectomies due to non-cervical cancer or non-cervical diseases were excluded from the study. Each subject was given a survey before examination that included their age, address, education, occupation, income, sexual history, and history of cervical diseases. A positive TCT test was defined as any positive pathological result, including adenocarcinoma (AC), high-grade squamous intraepithelial lesion (HSIL), low-grade squamous intraepithelial lesion (LSIL); atypical squamous cell of undetermined significance (ASC-US), atypical squamous cells that cannot exclude HSIL (ASC-H), atypical glandular cell (AGC), and squamous cell carcinoma (SCC). Any woman who tested positive was notified and advised to undergo further examination and treatment in the hospital. The subjects were notified through telephone calls, text messages, and visits by personnel involved in the screening program. The visit was often conducted by members of the local Women's Federation, Family Planning Commission, or the Community Board. The women whose TCT results showed ASC-US or worse pathological changes were contacted by telephone to receive a follow-up colposcopy, testing for high-risk strains of papillomavirus (HPV), and, if necessary, a cervical biopsy. A false-positive TCT test was defined as TCT positive, pathology negative.

To collect cervical cells, exfoliated cells were collected from the external cervical orifice and the cervical canal using an endocervical brush. The cells were washed into vials containing ThinPrep preservative solution, and processed using the ThinPrep2000 system to make a thin-

layer smear. The samples were fixed in 95% ethanol and subjected to Papanicolaou staining, and the slides were screened using the ThinPrep imaging system.

Images were interpreted by pathologists who made a cytological diagnosis, and these were recorded in signed reports. The Bethesda System recommended by the International Cancer Society (Ma, 2008) was used for cervical cytology diagnoses, especially an ASC-US diagnosis. Images that met any of the following characteristics were diagnosed as ASC-US: empty cells with either a large nucleus or double nuclei, which did not meet the criteria for a diagnosis of LISL; enlarged nuclei 1.5–2.5 times larger than normal that contained high density and irregular chromatin distribution; atrophy of the epithelial layer; atypical hyperplasia, nuclear density (slightly stained nuclei, slightly increased nuclear-to-cytoplasm ratio, clear nuclear contour), and increased chromatin; or non-typical squamous epithelial cells or nuclear polymorphism.

Subjects were notified by telephone if their screening results warranted follow-up. Notification was attempted twice for participants who failed to respond to the first contact. The local Women's Federation, who received information regarding subjects who failed to respond to either phone call, sent a third notification. The follow-up was monitored by 24 district hospitals. Women with a positive TCT test who received further treatment within 6 months were considered successfully recalled.

#### *Statistical analyses*

SPSS13.0 software was used for statistical analyses. Data are presented as the frequency and percentage in non-quantitative data analyses. The mean and standard deviation (for normally distributed data) or median and quartile (for non-normally distributed data) were used in quantitative data analyses. For the analysis of factors associated with screening results, the chi-squared ( $\chi^2$ ) test was in the single factor analyses were integrated for multi-factor logistic regression (forward logistic regression, inclusion statistical level = 0.05, and exclusion level = 0.1). In the multivariate regression model >55 years of age was selected as the reference group, as age is a categorical value.

## **Results**

Demographic information of the screening population A total of 44936 women were identified as potential subjects for the study of the initial phase of the screening program from March 2011 to December 2011. However, 1369 women were excluded because of age (<35 years) or incomplete information. Therefore, 43567 women were screened as part of the study (Table 1). The average age of the participants was  $45.52 \pm 6.62$  years. Of the 43567 subjects, 9392 had a history of cervical diseases (21.6%) and 596 had a family history of cervical cancer (1.4%). The average number of times the subjects had given birth was  $1.77 \pm 0.97$ . The average age at which the subjects first had sexual intercourse was  $23.98 \pm 3.44$  years. Condoms were used by 5360 (12.3%) women as the primary method of contraception. A positive TCT result was observed in

**Table 1. Subject Demographics**

	Subjects	%
Age group (y)		
35-39	9586	22
40-44	11396	26.2
45-49	10221	23.5
50-54	6780	15.6
55-59	5584	12.8
Residence		
Urban	11238	25.79
Suburban	32329	74.21
Education		
College	3121	7.16
High School	7441	17.08
Middle School	19337	44.38
Elementary School	12601	28.92
Illiterate	926	2.13
Unknown	141	
Occupation		
Housewife	24269	55.71
White collar worker	3651	8.38
Blue collar worker	5111	11.73
Self employed	2230	5.12
Worker, service sector	703	1.61
Government employee or teacher	1135	2.61
Freelancer	6274	14.4
Other	194	0.45
Income (RMB/month)		
≤1,250 RMB	7378	16.9
>1,250 RMB	36175	83.1
Unknown	14	NA

NA: not applicable

1381 women (3.17%), and 875 were successfully recalled. Of the recalled women, 267 were confirmed positive after colposcopic examination and biopsy.

#### Analysis of factors associated with cervical cancer

In single factor analyses, subjects' age, location of residence, education, occupation, income, history of cervical diseases, age at first sexual encounter, and history of sexual intercourse during menstruation were associated with positive TCT results (Table 2). The TCT positive rate was higher in women: younger than 50 years of age, urban residents, self-employed, company white-collar workers, working in service sectors, low-income, with a history of cervical diseases, who became sexually active before 20 years of age, and with a history of intercourse during menstruation ( $P < 0.05$ ). However, there was no association between positive TCT results and family history, average number of births, or condom use (Table 2).

After multi-factor analysis, age, location of residence, income, and age at which women became sexually active were still significantly associated with TCT results, suggesting that these factors are independent factors that influence the rate of positive TCT. Compared with women over 50 years of age, the risk of a positive TCT result was significantly higher for women aged 35–39, 40–44, and 45–49 years ( $P < 0.001$ ,  $P < 0.001$ , and  $P = 0.006$ , respectively). The odds ratios (ORs) and 95% confidence intervals (CIs) of these age groups were OR 1.541 (95% CI

**Table 2. Summary of Single Factor Analyses Influencing the TCT Positive Rate**

	Number Screened	Number Positive	Positive rate (%)	$\chi^2$	P-value
Age (y)					
35-39	9586	346	3.6	49.41	<0.001
40-44	11396	414	3.6		
45-49	10221	343	3.4		
50-54	6780	150	2.2		
55-59	5584	128	2.3		
Residence					
Urban	11238	246	2.19	47.67	<0.001
Suburban	32329	1135	3.51		
Education					
College	3121	110	3.52	9.254	0.026
High school	7441	218	2.93		
Middle school	19337	657	3.4		
Elementary school or less	13668	396	2.9		
Occupation					
Housewife	24269	707	2.91	29.97	<0.001
Company white collar worker	3651	137	3.75		
Blue collar worker	5111	144	2.82		
Self-employed	2230	76	3.41		
Worker of service sector	703	21	2.99		
Government employee/teacher	1135	34	3		
Free lancer	6274	251	4		
Other	194	11	5.67		
Income (RMB/month)					
≤1250	7378	294	3.98	19.54	<0.001
>1250	36175	1084	3		
History of cervical disease					
Yes	9392	322	3.43	38.67	<0.001
No	34168	1056	3.09		
Family history					
Yes	596	22	3.69	0.535	0.464
No	42971	1359	3.16		
Age at first intercourse (y)					
<20	1788	71	3.97	24.04	<0.001
20-23	15748	574	3.64		
≥24	21990	619	2.81		
Number of deliveries					
0	1198	33	2.75	3.479	0.176
1	14667	438	2.99		
≥2	27702	910	3.28		
Use of condom					
Yes	5360	150	2.8	2.746	0.098
No	38207	1231	3.22		
Intercourse during menses					
Yes	448	25	5.58	8.569	0.003
No	43119	1356	3.14		

1.223–1.942), OR 1.532 (95% CI 1.234–1.901), and OR 1.356 (95% CI 1.092–1.683), respectively. The probability of a positive TCT result was higher in rural than urban residents (OR 1.489, 95% CI 1.273–1.742;  $P < 0.001$ ) and in women with a monthly income of \$205.15 (USD) or less (OR 1.218, 95% CI 1.061–1.401;  $P = 0.005$ ). Compared to women who were >24 years of age when they became sexually active, women who were <20 and women who were 20–24 years old had a significantly higher risk of a positive TCT test (OR 1.306, 95% CI 1.015–1.682,  $P = 0.038$ ; and OR 1.165, 95% CI 1.034–1.312,  $P = 0.012$ , respectively).

#### Analysis of factors influencing successful recall

In single factor analyses the recall rate was associated with age, location of residence, education, age at first intercourse, and history of intercourse during menstruation (Table 3). The recall rate was lower in subjects older than

**Table 3. Summary of Single Factor Analysis Influencing the Recall Rate**

	Number of recalled cases	Rate of recall (%)	$\chi^2$	P-value
Age (y)				
35-39	240	69.4	13.05	0.011
40-44	270	65.2		
45-49	206	60.1		
50-54	82	54.7		
55-59	77	60.2		
Residence				
Urban	173	70.33	6.255	0.012
Suburban	702	61.85		
Education				
College	79	71.82	9.254	0.026
High school	157	72.02		
Middle school	415	63.17		
Elementary school or less	224	56.57		
Occupation				
Housewife	428	60.54	11.26	0.128
Company white collar worker	98	71.53		
Blue collar worker	88	61.11		
Self-employed	53	69.74		
Worker of service sector	14	66.67		
Government employee/teacher	25	73.53		
Free Lancer	160	63.75		
Other	9	81.82		
Income (RMB/month)				
≤1250	192	65.31	0.66	0.416
>1250	680	62.73		
History of cervical disease				
Yes	219	68.01	5.792	0.055
No	653	61.84		
Family history				
Yes	11	50	1.719	0.19
No	864	63.58		
Age at first intercourse (y)				
<20	39	54.9	9.514	0.009
20-23	346	60.3		
≥24	419	67.7		
Number of deliveries				
0	23	69.7	4.876	0.087
1	294	67.1		
≥2	558	61.3		
Use of condom				
Yes	92	61.3	0.298	0.585
No	783	63.6		
Intercourse during menstruation				
Yes	21	84	4.672	0.031
No	854	63		

50 years of age, women residing in urban areas, women with poor education, and women who became sexually active at a young age (<24 y). The recall rate was higher in women with a history of intercourse during menstruation ( $P < 0.05$ ). Occupation, income, history of cervical diseases, family history of cervical cancer, average number of births, and use of condoms were not related to the rate of positive TCT ( $P > 0.05$ ).

It was found after multi-factor analyses that age, location of residence, age at first intercourse, and intercourse during menstruation remained statistically significant, suggesting that these factors were independently contributing to the recall rate. Compared with women over 55 years of age, the probability of recall was higher in women 35 years or younger (OR 1.912, 95% CI 1.224–2.989,  $P = 0.004$ ), which was similar to other groups ( $P > 0.05$ ).

The probability of successful recall was higher in urban residents (OR 1.579, 95% CI 1.140–2.185,  $P = 0.006$ ). The probability of successful recall was also higher in women

**Table 4. Summary of Single Factor Analysis Influencing the Rate of Positive Pathology Tests**

	Number of recalled cases	Rate of recall (%)	$\chi^2$	P-value
Age (y)				
35-39	78	32.5	17.134	0.002
40-44	85	31.48		
45-49	74	35.92		
50-54	10	12.2		
55-59	20	25.97		
Residence				
Urban	65	37.57	5.066	0.027
Suburban	202	28.77		
Education				
College	29	36.71	2.517	0.472
High school	46	29.3		
Middle school	130	31.33		
Elementary school or less	62	27.68		
Occupation				
Housewife	129	30.14	1.117	0.993
Company white collar worker	28	28.57		
Blue collar worker	26	29.55		
Self-employed	15	28.3		
Worker of service sector	5	35.71		
Government employee/teacher	8	32		
Free lancer	53	33.13		
Other	3	33.33		
Income (RMB/month)				
≤1250	56	29.17	0.208	0.648
>1250	210	30.88		
History of cervical disease				
Yes	70	31.96	0.305	0.859
No	196	30.02		
Family history				
Yes	4	36.36	0.18	0.672
No	263	30.44		
Age at first intercourse (y)				
<20	10	25.6	0.658	0.72
20-23	110	31.8		
≥24	128	30.5		
Number of deliveries				
0	5	21.7	1.022	0.6
1	93	31.6		
≥2	169	30.3		
Use of condom				
Yes	23	25	1.474	0.225
No	244	31.2		
Intercourse during menstruation				
Yes	8	38.1	0.583	0.445
No	259	30.3		
HPV results				
Positive	245	42.8	91.314	0
Negative	6	3.5		

who became sexually active at ≥24 years compared with women who first had intercourse at <20 years of age (OR 1.905, 95% CI 1.143–3.176,  $P = 0.013$ ) but was not significantly different in the groups aged <20 and 20–34 years ( $P > 0.05$ ). The probability of recall was higher in women who had intercourse during menstruation (OR 3.561, 95% CI 1.037–12.230,  $P = 0.044$ ).

#### *Factors influencing positive pathology examination in recalled cases*

The results of the single factor analyses indicated that age, location of residence, and being HPV-positive were associated with a positive pathological examination (Table 4). The probability of positive pathological results were higher in women <50 years of age, urban residents, and women positive for HPV ( $P < 0.05$ ).



**Table 5. Summary of False Positive Rates**

TCT	TCT+	Recall	CIN1	CIN2	CIN3	SCC	AC	True positive n (%)	False positive n (%)
ASC-US	898	554	56	18	3	3	0	80 (14.44)	474 (85.56)
ASC-H	116	76	25	12	11	1	0	49 (64.47)	27 (35.53)
AGC	40	26	4	2	2	0	2	10 (38.46)	16 (61.54)
LSIL	195	123	41	8	4	0	0	53 (43.08)	70 (56.92)
HSIL	127	91	13	21	29	7	0	70 (76.92)	21 (23.08)
SCC	4	4	0	0	0	4	0	4 (100)	0 (0.00)
AC	1	1	0	0	0	0	1	1 (100)	0 (0.00)
Total	1381	875	139	61	49	15	3	267 (30.51)	608 (69.49)

AC, adenocarcinoma; AGC, atypical glandular cell; ASC-H, atypical squamous cells cannot exclude HSIL; ASC-US, atypical squamous cell of undetermined significance; CIN, cervical intraepithelial neoplasia; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; SCC, squamous cell carcinoma

The multi-factor analyses showed that a subject's age and HPV infection status were significantly associated with the probability of a positive pathologic examination, suggesting that these parameters are independent risk factors. Compared to subjects  $\geq 55$  years or older, the risk of a positive pathology result was similar in subjects aged 50–54 y ( $P > 0.05$ ), but was significantly higher for younger subjects aged  $< 35$  (OR 1.912, 95% CI 1.148–4.108,  $P = 0.017$ ), 35–40 (OR 1.399, 95% CI 1.014–3.584,  $P = 0.045$ ), and  $> 45$  years (OR 1.102, 95% CI 1.018–3.667,  $P = 0.044$ ). In general, subjects under 50 years of age had a higher probability of a positive pathology examination (OR: 1.907–2.172) than older women, and a positive HPV test predicted a higher probability of positive pathology results (OR 22.872, 95% CI 9.931–52.678,  $P < 0.001$ ). The false-positive rate for TCT screening is shown in Table 5.

## Discussion

Cervical cancer has a higher incidence than any other cancer worldwide and is one of the greatest threats to women's health. Appropriate screening programs, early diagnosis, and early treatment are key to cervical cancer prevention and treatment (Wang et al., 2013). Building from the established cervical cancer screening program in Zhongshan, the Cervical Cancer Screening Task Force initiated the "Large-Scale Cervical Cancer Screening and Intervention Model in Adult Women in Zhongshan" project. The program is fully supported and sponsored by the municipal government of Zhongshan city. The initial phase of the program, screening 43567 women in 24 districts and towns, is finished. In the preliminary findings, the TCT positive rate was 3.17% (1381/43567), the rate of successful recalls was 63.36%, and the rate of positive pathology findings in the recalled women was 30.51% (267/875). These data are valuable information regarding the acceptance of the screening test by the women of Zhongshan and the prevalence of the disease in Zhongshan. Through the early stages, the program has established a basis for developing a more effective model for future screening.

The initiation and pathogenesis of cervical cancer is a complex biological process. However, it is possible by screening to achieve early diagnosis, treatment, prevention, and control of the disease. The TCT has proven to be an effective method of screening for

cervical cancer and precancerous lesions in numerous studies. The current work has shown that in single-factor analyses, a woman's age, place of residence, education level, occupation, income, history of cervical diseases, age at first sexual intercourse, and history of intercourse during menstruation are all significantly associated with a positive TCT result. In more stringent logistic regression analyses, the prominent risk factors related to a positive TCT result were 1) age, particularly 35–49 y, which is consistent with previous reports (Lu, 2007; Sun, 2010; Wei, 2012); 2) rural residence, possibly attributable to poor hygiene, multiple pregnancies, and lack of formal screening, consistent with work by Wang (2004); 3) multiple births, which could cause mechanical injuries to the cervix, squamous metaplasia of the transitional area, and increase in vulnerability to carcinogenic factors during the process of tissue repair; and 4) becoming sexually active at a young age ( $< 20$ , which is likely due to puberty-associated cervix squamous metaplasia, repeated exposure to infections, injuries, and cell changes induced by sperm, consistent with work showing intercourse before 15 years of age is associated with higher risk (5–10 fold increase) of cervical cancer (Junej, 2003). These factors, alone or in combination, could be significant factors in the etiology of cancer after a latency period.

The effectiveness of cervical cancer prevention and treatment programs is directly related to the successful recall of women who receive further testing and healthcare after a positive TCT test. This is the first investigation from China of the factors that affect the recall rate of women who test positive during screening. Results of the current study suggest that the recall rate is significantly influenced by the age of the patient, location of residence, and positive HPV infection status. A higher rate of positive TCT test results was found in women aged 35–49 years (33.1%, 237/712), and a lower rate (18.83%, 30/159) was observed in women 50 years of age and older. These results suggest that pathologic changes may occur in the cervix of younger women. This may be due to the higher rates of HPV infection in younger women. In the current study, 42.8% of women who tested positive for HPV also had positive pathology test results.

Lack of knowledge about cervical cancer and precancer screening are major reasons for low rates of participation and recall (Besler, 2007). A woman's age, location of residence, age at first sexual encounter, and intercourse during menstruation influence were found to

influence the recall rate. In particular, the recall rate was higher in women 35-45 years old and in urban residents. However, the recall rate was lower in less educated women and in women who began having sexual intercourse before 20 years of age. This may be due to the inconvenience of traveling long distances to the screening centers and lack of knowledge about the benefits of cervical cancer screening.

Our findings suggest that government and medical institutes should consider including women 35 years and younger in cervical cancer screening, improve education about cervical cancer screening in target populations to promote a high response rate, and improve accessibility to screening centers for those who live in remote areas. Furthermore, improvements are necessary in medical service coverage and accessibility of care for women identified through screening, recall outreach, and case management for women once they are in care. These factors are crucial to the core social mission of large-scale screening programs in healthy populations and are key to the effective prevention and treatment of cervical cancer.

In ongoing work, the cervical cancer task force is planning to initiate outreach programs to promote follow-up visits for patients recruited in the rest of the program. The women in high-risk populations will be identified and computer software with access to the database of screened women will remind hospital personnel to contact patients by telephone. The task force will collaborate with the local women's federation, family planning commission, and the local community board to establish a dedicated database of screening records to ensure that high-risk women are notified, to collect feedback, and periodically perform follow-ups.

In conclusion, the goal of cervical cancer screening is the early detection of precancerous lesions and related abnormalities. The program described in this study is a unique, city-wide, free screening program that is trying to establish a community-medical services network for managing high-risk women and connecting them to care. Our aim is to develop the best model for large-scale screening in otherwise healthy populations in China. This program is being conducted under the guidance of the government, and will be accomplished through close collaborations among different institutes and organizations which allowed the integration of regional medical resources. The experience gained here in Zhongshan can serve as a solid basis for a nation-wide cervical cancer-screening program.

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