



# Performance Indicators of Cervical Cancer Screening Program Based on The Guidelines of Iran Ministry of Health and Medical Education

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## Abstract

**Background:** Systematic application of a cervical cancer screening program reduces the socioeconomic burden of the disease. Evaluation of screening programs using performance indicator sets and applying cultural, economic, and social considerations minimize the negative impacts of screening and maximize its benefits.

**Objectives:** The present study aimed at developing and evaluating performance indicators of a cervical cancer screening program based on the guidelines of Iran Ministry of Health and Medical Education to identify shortcomings and improve national programs.

**Methods:** A total of 839 out of 2504 care checklists for middle-aged women in Rasht, Iran, from 2014 to 2018 were studied. Indicators were evaluated based on the guidelines of Iran Ministry of Health and Medical Education on care for middle-aged individuals in 6 areas of screening intensity, screening the program performance, the participation of individuals, compliance of the implementation with guidelines, etc.

**Results:** The eligible women coverage index was 34%. The index of participation in the first run Pap test was 45.53% in 2014. The study findings showed that with the implementation of the plan on participants, the test rate increased by 39.1%. The indices of identification of high-risk individuals based on medical histories, identification of abnormal Pap smears, and participation continuity in the program were 54.84, 33.73%, respectively and 1.32% in 2015, which decreased to < 1% in 2016. The compliance rate with the guidelines was 64.94%, and the performance recording index was 22.40%.

**Conclusions:** Due to the low coverage rate and other performance indicators, especially the low continuity index, the attention of policy-makers and program managers should be drawn to potential shortcomings of screening programs, such as active implementation, in order to promote women's health status.

**Keywords:** Uterine Cervical Neoplasms, Papanicolaou Test, Mass Screening

## 1. Background

According to the World Health Organization (WHO) report, about 570,000 new cases of invasive cervical cancer were diagnosed in 2018, accounting for 6.6% of all women cancers (1). According to the National Cancer Registry in Iran, a trend study showed that the incidence of cervical cancer has tripled from 2003 to 2009 (2). Also, a review study indicated that the cervical cancer incidence rate develops between ages 55 and 65 years old. The mortality to incidence ratio was 42% (3). Screening of cervical cancer by taking samples from cervical cells can predict precancerous changes, which increases the 5-year survival rate by 92% (1, 4, 5). Pap smear is the most cost-effective, common, simple, and relatively reliable screening method to detect human papillomavirus (HPV) infection and cervical cancer

(6, 7). Pap smear screening with an annual detection rate of 250,000 new abnormal cases plays a pivotal role in regular health checkups for women (8). Many studies showed different ranges of sensitivity (11% to 99%) and specificity (14% to 97%) for the Pap smear test due to several factors underlie the effect (9, 10). Also, the results of studies showed that human papillomavirus deoxyribonucleic acid (HPVDNA) testing is 40% more sensitive to detect cervical abnormalities than Pap smear. HPV oncogene is a major risk factor for the development of cervical cancer worldwide (11, 12). Several studies in Iran indicated that more than 80% of cervical cancer cases were positive for HPV (13). The findings of several studies showed that the implementation of screening programs reduced mortality and increased survival rates by better detection of patients in the early stages (11, 14-18).

The systematic application of a cervical cancer screen-

ing program and evaluation of its performance indicators based on individuals' health status, disease burden, and the cost of current screening methods, as well as cultural, economic, and social considerations minimize the adverse effects of screening and maximize its benefits (17, 18). In the study by von Karsa et al. (7), 31 experts from 11 European countries provided a list of the key performances to control the screening process, identify new cases, and respond early to potential problems. In a study by Ahmad and Almeida (19), the literature was reviewed to identify performance indicators of screening programs implemented worldwide. The study searched 25 databases from 21 countries that reported performance indicators including participation, the quality of Pap smear samples, incidence and mortality rate, screening intervals, screening history, screening test results, abnormal results, follow-up, and colposcopy. Further studies in the Kurdistan Region of Iraq, North Korea, and European countries were conducted to evaluate the performance of the program. Performance indicators are designed to formulate policies (7, 17, 20, 21).

### 1.1. History of the Cervical Cancer Screening Program in Iran

In Iran, screening programs for cancers are implemented in accordance with the instructions of the Ministry of Health and Medical Education in the framework of the Iranian Women's Health (SABA) and Iranian Men's Health (SAMA) plans evaluating men and women aged 25 to 60 years in 1990 - 1991. The Pap smear test was also integrated into the health system in the framework of SABA plan (22, 23). The screening program for breast and cervical cancer is currently presented as an integrated program for middle-aged individuals for the target group aged 30 - 59 years at the national level (24, 25). Based on 2 review studies in 2013 and 2016 in Iran, Pap smear intervals are 3 - 5 years (3, 26).

## 2. Objectives

According to WHO, 90% of cervical cancer-related deaths occur in less developed countries, and its main reasons include poor prevention and screening programs, lack of access to effective treatment, and low resources (1). In Iran, cancer screening program is available for free at the national level, but its performance is not regularly studied and is limited to simple statistical reports. Since studies performed in Iran have focused more on the prevalence of cervical cancer, less control is performed on assessing the knowledge and practice of eligible women and risk factors of cervical cancer, and identification of indicators, such as quantification of the effectiveness of the program. The

current study aimed at investigating the important role of evaluation and monitoring of the cervical cancer screening program in improving its quality and quantity.

## 3. Methods

The study was conducted in 2018 - 2019 as soon as its protocol was approved by the Ethics Committee, Shahid Beheshti University of Medical Sciences (code no.: IR.SBMU.SME.RCE.1397.016).

Iran's Comprehensive Health program for middle-aged women and men aged 30-59 years was developed by the Ministry of Health and Medical Education considering the importance of this age group in the family and society, especially to plan for disease prevention and reduce premature mortality based on medical standards, domestic conditions and priorities, and the health needs of the Iranian families. Decision making and putting into action the cervical cancer screening in Iran, based on an integrated program for the health status of middle-aged women and IraPEN (IRNA-Package of Essential Non communicable Disease) program 2017-18, were as follow (24, 25):

If a woman has any of the following 3 symptoms, she should be referred to a midwife for early diagnosis:

- 1) Abnormal vaginal bleeding (including after intercourse, between menstrual periods, and after menopause);
- 2) Strong-smelling vaginal discharge;
- 3) Pain during intercourse.

If a woman does not have any of the above symptoms, the following conditions may occur:

Less than 3 years have passed since the first intercourse:  
A self-care training and subsequent evaluation.

If more than 3 years have passed since the first intercourse:

In the cases where screening has never been done, they should refer to a midwife for screening.

Less than 1 year has passed since the last Pap smear screening: self-care training and subsequent assessment

More than 1 year has passed since the last Pap smear screening: patient should refer to a midwife for screenings.

Less than 10 years have passed since the past screening with Pap smear and HPV: self-care training and subsequent assessment) when 5 years have passed since the last assessment).

More than 10 years have passed since the past screening for Pap smear and HPV: patient should refer to a midwife for screenings.

In all cases, self-care training is necessary, including the risk factors of cervical cancer.

The study site included all of the planned executive centers consisting of 2 rural-urban health centers in Khomam County (1 and 2) and their affiliated health houses, and 2 rural health houses in Katesar and Choukam counties in Guilan Province, Iran. The inclusion criterion, based on the guidelines of Iran Ministry of Health and Medical Education, was all eligible women aged 30 to 60 years ( $n = 2504$ ).

The study population consisted of the eligible women receiving cervical cancer screening services through the middle-aged health plan in 2014 at executive centers and followed up by the end of 2018. The current study employed the census sampling method by examining a total of 839 women subjected to cervical cancer screening.

The data collection instrument was a checklist designed based on guidelines of the Ministry of Health and Medical Education on caring for middle-aged individuals and the research objectives, which was completed after confirming its validity and reliability. To evaluate the quantitative content validity ratio (CVR) and quantitative content validity index (CVI), the comments of 10 experts, including 2 provincial managers and experts, 2 urban and rural experts, and 6 healthcare team members (i.e., health workers, midwives, and physicians) of health centers were used. Validity indices, including CVI = 0.79 and CVR = 0.62, were calculated through relevant formulas and the validity was confirmed.

The test-retest method was used to test the reliability; for this purpose, the checklist was completed by the author with 2 weeks interval for 30 subjects. Finally, Pearson's correlation coefficient between the pretest and posttest scores was estimated at 70%.

The statistical analysis was performed by Excel software and SPSS version 21. Descriptive statistics, frequency table, and program implementation indicators were used to calculate the results in 6 areas based on the related formulas (Appendix 1 in Supplementary File).

#### 4. Results

In the present study, data from care checklists of 839 middle-aged women were analyzed. The majority of the study samples belonged to Khomam Health Center 1 and its affiliated health houses (67.47%), and the minority to Khomam Health Center 2 and its affiliated health houses (2.97%).

Most of the studied subjects (72.23%) had a high school diploma, and the least (0.36%) had an associate degree; 92.37% were housewives and 56.6% were employed. The rural insurance was the most common type of insurance

coverage (77.71%) and the National Health Insurance was the least common type (0.48%). Most of the samples (34.20%) had a history of two pregnancies; 10.25% were menopausal, and 3.81% underwent hysterectomy (Table 1).

**Table 1.** Demographic Characteristic of the Study Participants

Variables	No. (%)
<b>Education</b>	
Illiterate	124 (14.78)
High school	606 (72.23)
Diploma	99 (11.80)
Associate degree	3 (0.36)
No response	7 (0.83)
<b>Job</b>	
Housewife	775 (92.37)
Employed	55 (6.56)
No response	9 (1.07)
<b>Age</b>	
30 - 35	153 (15.50)
36 - 40	143 (17.04)
41 - 45	125 (14.90)
46 - 50	110 (13.11)
51 - 55	87 (10.37)
56 - 60	51 (6.08)
Unidentified	170 (20.26)
Total	839 (100)

The results of the study showed that only 6.54% ( $n = 54$ ) of the subjects had a history of Pap test before the pilot study in 2014; however, the result of 19.66% ( $n = 165$ ) were unidentified.

According to Table 2, most of the subjects (97.14%) were evaluated for the signs and symptoms of the disease. The most frequent symptom (25.27%) in the cases was abnormal discharge, and the least frequent one (1.77%) was bleeding during intercourse.

Among the eligible subjects participating in the study, 33.73% had abnormal Pap smears, of which 74.7% were referred to higher levels of care due to high-risk symptoms (Table 3).

Related indicators included the status of the Pap smear program that was 6.42%, before the implementation of the plan, which increased to 45.53% after the implementation; 97.14% history taking; and 68.87% gynecologic examination.

The frequency of abnormal Pap smears before the implementation of the plan was 11.11%, which increased to

**Table 2.** Frequency Distribution of the Samples in Terms of Signs, Symptoms, and Risk Factors, Based on the Guidelines

Item Value in the Medical Records/Examination	Yes, No. (%)	Total, F
<b>Examination of the individual in terms of risk factors and warning signs</b>	815 (97.14)	839
Infertility history	18 (2.20)	815
Sexual problems history	16 (1.96)	815
The history of abnormal vaginal discharge	206 (25.27)	815
The history of abnormal discharge of the spouse	7 (0.83)	815
The history of discharging genital ulcer	35 (4.29)	815
The history of discharging genital ulcer of the spouse	3 (0.36)	815
The history of abnormal vaginal bleeding/ irregular menstruation	26 (3.19)	815
The history of amenorrhea	136 (16.68)	815
<b>Abnormal appearance of the cervix or genital ulcer in the gynecological examination</b>	51 (9.04)	564
Abnormal cervix discharge in the gynecological examination	140 (24.82)	564
Bleeding lesions in the gynecological examination	20 (3.54)	564
Bleeding during intercourse	10 (1.77)	564

**Table 3.** Performance Indicators of the Program

Performance Indicator	Formula	Value
<b>Target population in 2014</b>	All women in the eligible target population	2045
<b>Participation rate in 2014 (coverage rate), %</b>	Eligible women who participated in the screening program = 839/All women in the eligible target population = 2504 = $\times 100$	34
<b>Risk factors and warning signs, %</b>	Eligible women who examined risk factors and warning signs = 817/Eligible women who participated in the screening program = 839 = $\times 100$	97.14
<b>Pap smear test in the first run, %</b>	Eligible women who did Pap smear testing in the first run = 377/Eligible women who participated in the screening program = 839 = $\times 100$	45
<b>Pap smear test in the second run, %</b>	Eligible women who did Pap smear testing in the second run = 5/Eligible women who did Pap smear testing in the first run = 377 = $\times 100$	1.30
<b>Pap smear test in the third run</b>	Eligible women who did Pap smear testing in the third run = 0/Eligible women who did Pap smear testing in the second run = 5 = $\times 100$	0
<b>Abnormal Pap test, %</b>	Abnormal result Pap smear testing = 113/Total Pap smear tests = 335 = $\times 100$	33.73
<b>ASCUS result, %</b>	ASCUS = 27/Abnormal result Pap smear testing = 113 = $\times 100$	23.89
<b>HSIL result, %</b>	HSIL = 1/Abnormal result Pap smear testing = 113 = $\times 100$	0.88
<b>Referral rate, %</b>	Number of referral = 20/The number of people requiring referral = 27 = $\times 100$	74.7
<b>Data recorded, %</b>	The number of forms that were fully completed = 188/Total number forms registered = 839 = $\times 100$	22.40
<b>Recorded lab test, %</b>	Total number of Pap test recorded on the form = 335/total number of Pap tests referred to lab = 382 = $\times 100$	87.69
<b>Compliance of the program with the guidelines, %</b>	The number of eligible women for Pap test = 377/Total number of women who did Pap smear testing = 382 = $\times 100$	98
	The number of people of therapy according to guideline = 50/Total number of treated = 77 = $\times 100$	64.93

Abbreviation: ASCUS, atypical squamous cells of undetermined significance; HSIL, high-grade squamous intraepithelial lesion.

33.73% after the implementation, including 71.68% mild to moderate infection, 23.89% severe inflammation/ Atypical squamous cells, undetermined significance (ASCUS), 0.88% high-grade squamous intraepithelial lesion(HSIL),

and none low-grade squamous intraepithelial lesion (LSIL).

Coverage indicator for eligible women in the screening program was 34% in 2014 (Table 3).

In terms of the recording performance indicators,

22.40% belonged to demographic characteristics, 87.69% to laboratory results, and 6.31% to history.

Regarding the participation indicators, the calculable items included 87.69% participation in delivering laboratory reports to centers, 100% in referral to higher care levels, and 1.32% in the program continuity in 2015 and < 1% in 2016 (Table 3).

## 5. Discussion

Based on the obtained results, it seems that the implemented program could achieve a good success rate (mean 28%; ranged from 6.42% to 34%) in increasing participation in the screening program and Pap test and improved the Pap smear coverage index. With the implementation of the program, 33.73% abnormal Pap smears and 0.88% cervical cancer cases were detected. The obvious drawback of the cervical cancer screening program was rooted in the complete coverage of Pap smear runs. Although it achieved 34% coverage in the first run for the target population, the above plan failed to sustain individuals' participation in the third year (participation rate reduced to < 1%), indicating low participation of eligible women in the Pap testing timeframe, based on guidelines. The results of the study by Sharifi et al. (27), showed that 54% of the screening program participants underwent the test only once, and only a small percentage of them repeated that at standard intervals. Mohebi et al. (28) reported that 11.25% of the studied women referring to healthcare centers in Qom, Iran, regularly underwent Pap test, and 51.87% participated in the screening program irregularly. Morowatisharifabad et al. (29) by screening for cervical cancer in Chaharmahal and Bakhtiari Province, Iran showed that 36.3% of women underwent this test once and 6% twice.

In the present study, the laboratory results of the Pap test in the pilot study indicated 23.88% ASCUS/severe inflammation, 0.88% HSIL, and none LSIL, which were consistent with the results of the study by Masoumi et al. reporting 1.67% abnormal Pap smears with 78% ASCUS and 1% LSIL as the most and least frequent findings, respectively (28, 30). Abnormal cell changes in the study by Allameh et al. (31), was reported in 0.7% of Pap smear samples, of which 39.8% were ASCUS, 18.08% cervical intraepithelial neoplasia I (CINI), 3.6% CINII, 4.8% CINIII, and 6.02% invasive carcinoma that were consistent with the results of the present study.

According to the results of research by Almassi Nokiani and Akbari (32), ASCUS rate was 205.4 per 100,000 (0.2%), LSIL 73.4 per 100,000 (0.07%), HSIL 21.6 per 100,000 (0.02%), and carcinoma 5.4 per 100,000 (0.05%) Pap smear samples.

The prevalence of HSIL was 4 times higher than that of carcinoma; the overall prevalence of HSIL and carcinoma was 26.9 per 100,000 smears (0.02%), consistent with the findings of the current study, except for ASCUS (32).

The other weaknesses of the program were in the performance recording index by 22.40% and compliance with the current guideline by 64.94%, which were far from optimal limits, considering the importance of treating the patients. According to the manual of midwifery practices, the patient should be referred to level 2 of care following the completion of a non-urgent referral form if 3 symptoms of abnormal vaginal bleeding, vaginal discharge, and pain during intercourse were reported. The findings of the present study were inconsistent with the available guidelines as in the pilot program, patients with genital ulcers and the noted symptoms underwent the level 1 treatment and then were referred to level 2 of care in case of recovery failure.

According to studies by Ahmad and Almeida and those performed in North Korea and European countries, today the evaluation of the performance indicators of preventable cancer screening programs for optimal implementation is considered as the best preventive and cost-benefit measure (17, 19-21). Many studies in several countries showed higher rates of mortality from cervical cancer due to the lack of screening resources (8).

In Iran, guidelines for cancer screening programs are developed and customized by the Ministry of Health and Medical Education. These guidelines are implemented for several years by the community health workers (Behvarz), midwives, and physicians at the national health center level (25).

These efforts should be improved. Since screening programs are expensive and require infrastructures and manpower, their evaluation seems essential. Assessment of the performance using appropriate indicators reduces wasting resources and helps to implement a cost-effective program. The present study results showed a low coverage rate, low and weak registration record, and low compliance with guidelines. The awareness of the target population of local health preventive programs should be increased and the health-seeking behavior has to be improved in order to have a high participation rate and promote women's health status. It is necessary to actively implement the plan in order to meet the goals of screening programs- e.g., increasing participation and coverage rate, prevent the imposition of costs on the health system and families, besides the social effects of cancer. Since the main limitation of the present study was the lack of sufficient information about the studied samples, it is recom-

mended that system administrators take some measures to familiarize all personnel involved in the program implementation with the importance of carefully recording health information and data, by holding training courses and teaching the principles and procedures of registration and archiving, considering the importance of information available in the archive.

Considering the launch of the Integrated Health system (the SIB system) and the creation of electronic records in it, to better understand the quality of the program and meet the goals, it is necessary to conduct studies in other regions of the country.

### 5.1. Conclusions

According to the results of the present study, such as negligence of the target population to participate in the next Pap smear program, the lack of compliance with the guidelines, and the lack of awareness of the target population of the importance of screening programs, particular attention should be paid to the manner of its implementation from various aspects, such as working actively, informing, and actively recruiting the target group, and above all, paying attention to the performance indicators of the programs-i.e., the input, executive, and output indicators, in order to timely diagnose the patients in the early stages of the disease and take advantages from the golden opportunity to maintain patient survival to prevent the overwhelming mental and economic burden and suffering on families and the health system.

### Supplementary Material

Supplementary material(s) is available [here](#) [To read supplementary materials, please refer to the journal website and open PDF/HTML].

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### Footnotes

**Authors' Contribution:** All authors contributed equally.

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