

## Should population program of Pap smear screening tests for cervical cancer be continued in Poland?

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Population screening programs should be efficient and cost-effective. Cervical cancer screening program was implemented in Poland in 2006 and so far it did not achieve the main goal of the screening, which is to reduce the mortality rate of cervical cancer in the entire female population.

The main reason of this are: poor organization that causes low quality of the program at every stage of its activity, low participation of women in screening and lack of reliable program monitoring.

The organization of screening program in Poland significantly deviates from the international recommendations what led to lack of cost-effectiveness of the program. It is time to make a bold decision and end the program until a modern strategy is developed that would account for the latest global recommendations including e.g. vaccinations against HPV virus and HPV test as a screening test.

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Population screening programs for early detection of cervical cancer were implemented in many European countries over 20 years ago (in Scandinavian countries, they have been continued for over 50 years); this enabled determination of principles that allow for constructing the programs in such a way to make them efficient and cost-effective.

A population screening program should fulfill some requirements, including the following [1]:

1. It concerns an important health-related and social problem;
2. The natural history of the disease is well known and understood;
3. The disease can be cured at the early stage (there should be a pre-clinical condition);
4. The treatment results are much better when the therapy is initiated at an early stage;
5. There is an acceptable screening test;
6. The test has applicably high sensitivity and specificity;
7. There are methods to cure the detected disease in an effective manner;

8. The screening test is performed in repeated time increments, until the risk of disease exists;
9. The benefits of the program exceed the risk;
10. Population costs of test are not higher than treatment costs.

The screening program implemented in Poland in 2006 fulfills the first five criteria.

The remaining five requirements are not fulfilled, mainly due to organizational issues, which results in lack of population efficiency of the screening program in Poland.

Failure to fulfill the other conditions and an attempt to evaluate the causes requires a more detailed discussion.

### Item 6. The test has applicably high sensitivity and specificity.

As a screening test for early detection of cervical cancer, conventional Pap smear test (Papanicolaou test) was applied. The sensitivity of this test is on average 50% (30–87%), i.e. in 5 out of 10 women, cytological abnormalities will not be detected [2]. Smear evaluation, according to the interna-

**Table I.** Number of procedures reimbursed by the NFZ; Pap smears performed within the scope of the population program between 2012 and 2014

Year	2012	2013	2014	2015
Total number of tests	764,656	694,762	720,662	685,225
Number of tests that could be assessed	631,694	581,553	691,991	681,555
Incorrect smears	132,962	113,209	28,671	3670
% of incorrectly performed smears	17%	16%	4%	1%
Normal result	740,687	673,028	696,510	662,815
Pathological epithelial cells were found	19,721	18,359	20,202	18,740
Number of tests where abnormal squamous epithelial cells were detected	In total 18,930	17,598	17,983	17,983
	ASC-US 9690	8136	8043	8043
	HSIL (ASC-H) 1481	1445	1574	1574
	HSIL - CIN2 CIN3/CIS 2123	1931	1957	1957
	Squamous carcinoma 153	159	143	143

tional recommendations, is performed using Bethesda system, which is the basis for therapeutic decisions. Inaccurate result may lead to implementation of premature therapeutic steps or failure to implement them when necessary, which can influence the overall effectiveness of the program and potential health issues resulting from participation in the program.

According to NFZ (National Health Fund) data, in the initial years of the screening program, 15–20% of smears were unsuitable for evaluation. In 2012, 17% of 764,656 Pap smears were obtained improperly (Tab. I). The sensitivity of the test in Poland was not estimated. Based on the NFZ data, it may be assumed that its sensitivity is significantly lower than 50%. Lack of publications about this issue means that the problem was not recognized at all.

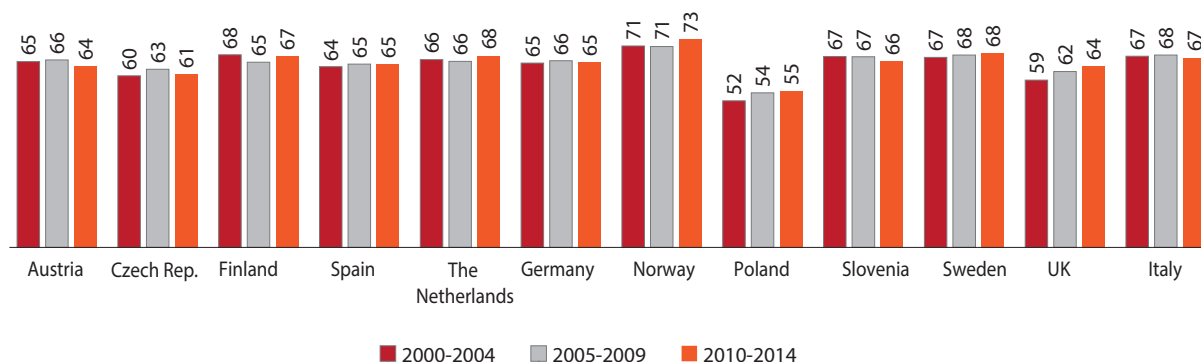
**Item 7. There are methods to cure the detected disease in an effective manner**

Effectiveness of treatment can be assessed using 5-year survival rates. Based on the most recent results from Concord-3 project 5-year, survival rates for cervical cancer patients have increased over the last 15 years in the countries

with the highest rate values (65–70%: Norway, Finland, Sweden, the Netherlands, Italy) by only 2–3 percentage points, which indicates that there is no progress in treatment of this cancer even in the countries where organized screening for cervical cancer is implemented. Survival rate for cervical cancer patients in Poland also increased in Poland in 2000–2014 by 3 percentage points (from 52% to 55%), but the rate value varies from the European values by 10–18 percentage points (Fig. 1). 8-year duration of the screening program included into the Concord-3 analysis did not result in a significant improvement in patient survival in Poland [3]. There were no changes indicating that cervical cancer was detected at an earlier stage during this period, which is the main objective of the secondary prevention. This is one of many arguments showing lack of effectiveness of the screening program in Poland.

**Item 8. The screening test is performed in repeated time increments until the risk of disease exists**

One of the main tasks for the screening organizers is to encourage women to have regular Pap smear tests per-



**Figure 1.** Five-year survival rates for cervical cancer in selected European countries

med. The population effect is noticeable if 70% of female population included in screening (aged 25–59) regularly i.e. every 3 years takes the test within the scope of the program. The program organizers should invite new cohorts of women thus increasing the percentage of the tested population.

Over the whole period of the screening program duration in Poland only 18–22% of female population from the target group underwent the Pap smear within the scope of the organized program (Fig. 2, Tab. II). There is no information whether these are new cohorts of women reaching the age covered by the program or the same health education-prone women who regularly undergo all preventive tests. There is also no information available whether the total number of women participating in the program is increasing and what are the reasons for the limited participation of women in the screening tests. In Finland evaluation of decrease in attendance and its causes led to improvement in attendance by 10 p.p. (from 70% to more than 80%) [4].

**Table II.** Number of collected smears and cervical cancer screening attendance in Poland in 2007–2013 (source: NFZ)

Year	Target population	Screened population	Attendance (in %)
2007	3,227,918	686,036	21.3
2008	3,252,888	793,411	24.4
2009	3,274,036	876,538	26.8
2010	3,289,805	796,446	24.2
2011	3,293,187	804,555	24.4
2012	3,293,976	765,301	23.2
2013	3,290,725	697,407	21.2

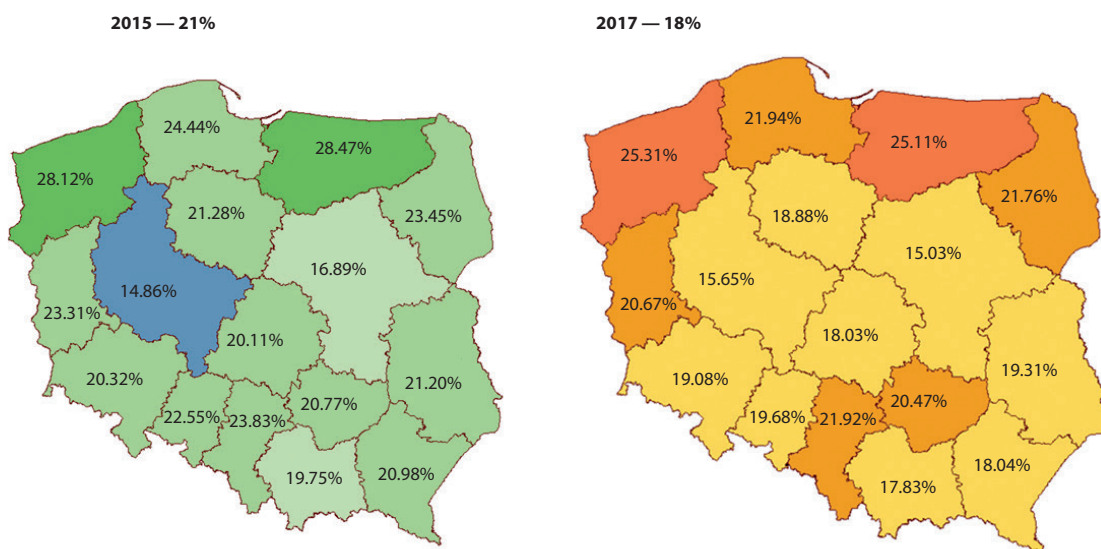
Such a low participation of women in the screening program does not allow for obtaining the assumed objective — decrease of cervical cancer mortality. In 2016 elimination of inviting women for tests which, according to international recommendations, is one of the most important activities ensuring high attendance, led to decrease in attendance by 3 p.p. in the following year (Fig. 2).

As possible reasons for low participation of women in the organized program, the organizers of the screening program indicate performing Pap smears outside the program (within the scope of AOS (Outpatient Specialist Care) and not recording the results in a Screening Program Monitoring System (SIMP). Number of Pap smears performed outside the organized program increases attendance to about 40% (Tab. III).

It is, however, not certain whether the Pap smears reported by AOS as screening tests are not in fact diagnostic smears. It is not known whether the women screened by AOS fulfill all program requirements (age interval).

Even if we assume that the actual screening attendance is close to 40%, then why there is no population effect of the program implemented almost 10 years ago?

Simulation prognosis performed by the KRN (Polish National Cancer Registry) in 2006 i.e. a year before the screening program was implemented shows two scenarios for the course of trends for the cervical cancer mortality: pessimistic (continuation of the trend in case of no intervention) and optimistic (decrease of the mortality trend up to the annual average of 5%, which was observed after the implementation of the screening program in Finland) (Fig. 3). A well-organized screening program in Finland (attendance of over 80% of target female population) led to rapid decrease in mortality due to cervical cancer in the initial years of the



**Figure 2.** Map of cervical cancer screening attendance in Poland in 2015–2017

**Table III.** Number of Pap smears performed within the organized program and AOS (source: NFZ)

Year	Women registered in SIMP		Smears taken by midwives within AOS		SIMP+AOS	
	Number	%	Number	%	Number	%
2010	796,366	24.2	No data	No data	No data	No data
2011	804,494	24.4	No data	No data	No data	No data
2012	765,040	23.2	633,564	12.3	1,137,764	35.5
2013	696,920	21.2	753,948	22.0	1,419,468	43.1
2014	724,598	22.1	736,662	21.4	1,428,344	43.5

program and to annual average decrease in mortality rates by about 5% in the following years. Covering the target population to the greatest possible extent seems to be the key to success.

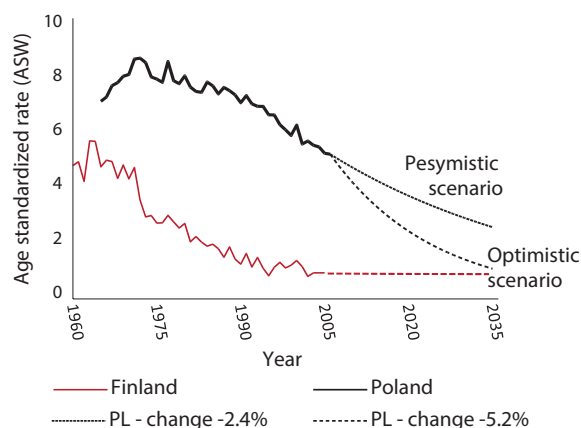
Upon analysis of time trends for cervical cancer mortality in Poland, we observe the pessimistic scenario (no intervention). There is no change in the overall mortality trend; the rate of decrease in the mortality rates remains at the level of about 2% annually (Fig. 3).

More detailed analyses have shown that the screening program brought measurable effects in a group of women aged 25–59 but no population-wide effect was observed and additionally decrease in incidence and mortality trends in women older than 60 who were not screened decelerated after implementation of the program [5] (Fig. 4).

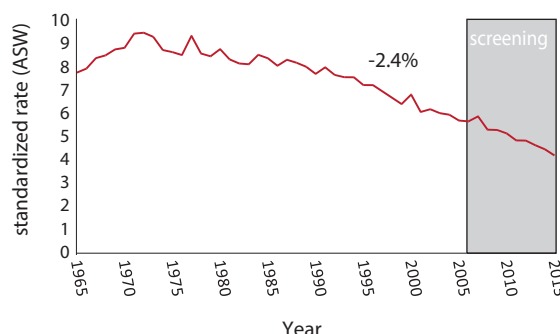
**Item 9. The benefits of the program exceed the risk**

Procedures used in screening tests for detecting cervical cancer may have adverse effect for the physical and mental health of participating women. The following harms are mentioned: pain, bleeding after the examination, vaginal discharge, fear of unfavorable result, premature birth in young women after aggressive procedures within the cervix [6].

In Poland there are no data on the balance of harms and benefits of the program which makes it impossible to modify the recommendations in such a way to minimize the losses related to the program.



**Figure 3.** Simulated prognosis of trend for cervical cancer mortality in Poland (source: KRN)



**Figure 4.** Cervical cancer mortality in Poland in 1965–2015

**Item 10. Population-wide costs of screening are not higher than treatment costs**

Publications on the costs of the cervical cancer screening program are ambiguous. Estimation of treatment costs for 2017 based on NFZ data covering analysis of medical procedures performed in women diagnosed with cervical cancer in 2005–2010 and treated until the end of 2015 suggests that average cost of cervical cancer treatment is about 25 thousand PLN [7].

A different publication using the same source shows that the annual cost of treating cervical cancer regardless of the diagnosis date is 1564 PLN [8] (Tab. IV).

Number of women with cervical cancer treated in 2012 seems overestimated as compared to KRN data. The observed 10-year prevalence estimated by KRN is 17,500 women. Number of cervical cancer patients treated is comparable to the sum of incidences over a period of 11 years (about 3000 per year) if none of the women would die. Maybe this is why the yearly cost of cervical cancer treatment in this publication seems underestimated.

According to NFZ data, the total cost of screening program (diagnostics and administration) in 2012 would be close to 61 million PLN (39 million PLN NFZ and 22 million PLN MZ — the Ministry of Health) (Tab. V). If we estimate the cost of diagnosing 1 advanced cervical cancer in the screening program, we get an extremely high sum of 397,286 PLN, which would cover a yearly cost of treatment for 19 patients. However the point of the screening program is to detect premalignant conditions, hence it would be

**Table IV.** Costs of diagnostics and treatment of cervical lesions according to NFZ in 2012

Type of intervention/diagnosis	Number of cases (unique records in NFZ databases — prevalence)	Costs (PLN)	Cost per 1 patient (PLN)
Pap smears	2,053,624	53,621,062	26
CIN1	10,521	6,616,375	629
CIN2	5812	5,071,155	873
CIN3	6487	7,611,062	1173
CIN (undetermined)	36,575	12,352,034	338
Cervical cancer	33,482	52,377,006	1564

good to estimate the cost of preventing the disease. In 2012 within the screening program abnormal squamous epithelial cells being potentially the initial stage of cancer were found in 19 thousand patients. Only some of them would result in invasive cancer in a perspective of 10–15 years (estimated time of disease development). However, even the pessimistic scenario assuming that in 2012 the program prevented 19 thousand future cervical cancer cases allows for estimating the cost of an annual treatment for these patients at a level of about 47 million (19 thousand × 1564 PLN) i.e. 14 million less than an annual cost of cervical cancer screening program.

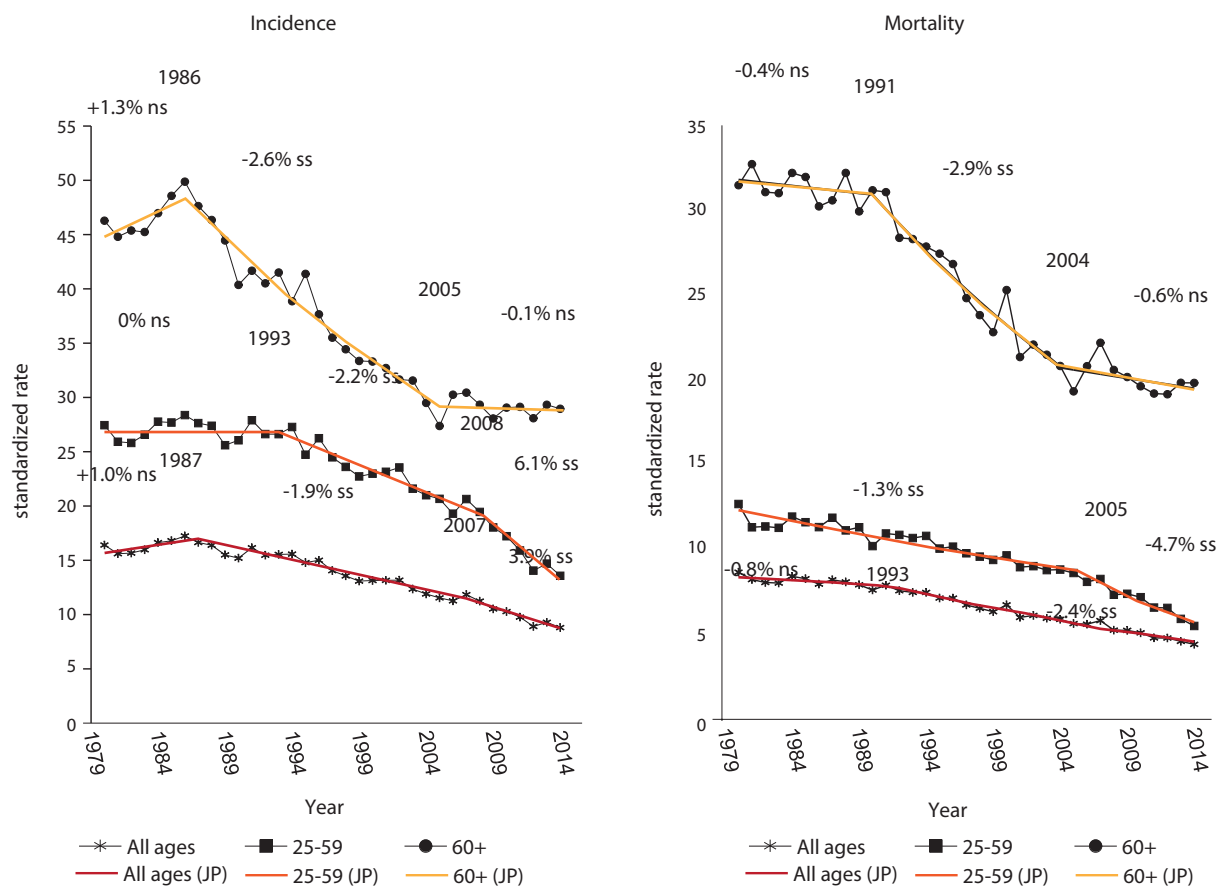
Hence it seems that the discussed program is completely cost-ineffective. The main reason for this is lack of reliable program monitoring and its poor organization. According to international recommendations, organization of a screening program should minimize the negative effects of the program and maximize the program benefits. Benefits may be obtained only when the program quality is optimal at every stage of its activity. One of the main recommendations is regular participation of at least 70% of population covered by screening, which can be obtained only in a program with invitations and regular monitoring of the program for assessment of Pap smear quality. Until now it is not known why Polish women are reluctant to have a free Pap smear.

In 2017 the Ministry of Health gave up inviting women to participate in the screening program, which soon resulted in decreased percentage of Pap smear attendance to about 18%. At the same time organization of the program was assigned to the local authorities, who appointed the entities to implement the program by way of competition; however the chosen entities often lacked knowledge and experience in implementing the screening program. As an example, the competitive process in Warmińsko-Mazurskie Voivodship resulted in hiring the Fundacja of Gazeta Olsztyńska. Another example of bad program organization is assigning the quality control of basic and extent diagnostics procedures in Poland to an individual medical practice, thus surrendering the key activity of the screening project to one person not subject to any control. The above-mentioned principles of organization significantly deviate from the international recommendations and are among many reasons for lack of population effectiveness of the screening program in our country, both until now and in future, if the program is continued.

Monitoring of quality efficiency and cost-efficiency of the screening program for detecting cervical cancer in Poland is also poor. With the system for screening program monitoring SIMP, NFZ database, database of the Polish National Cancer Registry (KRN) no reliable analysis was made

**Table V.** Costs of the screening program for detection of cervical cancer (source: NFZ, the Ministry of Health [9])

YEAR	Number of examined women	Costs NFZ	Number of examined women at the step of extent diagnostics	Number of squamous cell carcinomas	MZ costs	Cost of detecting 1 cervical cancer case in PLN
2007	675,633	28,542,144	3309	231		
2008	767,505	32,750,887	3280	243		
2009	827,290	43,196,229	4094	212		
2010	763,880	39,712,388	3099	145	12,505,639	360,124
2011	750,310	39,617,909	3047	165		
2012	729,890	38,990,940	3031	153	21,793,882	397,286
2013	666,197	35,463,714	3032	159		
2014	700,205	27,91,677	3806	148		



**Figure 5.** Trends in cervical cancer incidence and mortality by age in Poland in 1980–2014

to assess justifiability of program continuation, indicating the strengths and weaknesses of the program and providing grounds to build further strategy to prevent cervical cancer in Poland.

Such analyses were not performed mainly because it is impossible to combine and exchange data from the above-mentioned sources. With lack of randomization in the screening program, the assessment of its efficiency should utilize data from the cancer registry. However, information about detection of cancer collected in SIMP is not available for KRN, hence the registry cannot perform the above tasks.

The discussed question must be answered: should a badly organized ineffective cost-inefficient population program of screening Pap smear tests in cervical cancer be continued in Poland? Can we afford further high costs of the program that has no chances of reaching the assumed objectives?

We should make a bold decision and end the program until a modern strategy is developed that would account for the latest global recommendations including e.g. vaccinations against HPV virus and HPV test as screening test.

It is time to reduce losses, develop a new action plan eliminating the errors that were made until now, to set new realistic goals matching financial and organizational capability of Poland (e.g. to put education and primary prevention

first). We should implement monitoring of actions from the initiation of the new strategy implementation and flexible attitude towards the organizational changes in the program that would allow for its correction to quickly obtain the assumed objectives.

**Conflict of interests:** none declared

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