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

Urszula Wojciechowska

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.

Key words: screening, cervical cancer, incidence, mortality

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.
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  |
| 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     |

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 international 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.

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

| Country          | 2000-2004 | 2005-2009 | 2010-2014 |
|------------------|-----------|-----------|-----------|
| Austria          | 65        | 64        | 63        |
| Czech Rep.       | 68        | 67        | 66        |
| Finland          | 66        | 65        | 66        |
| Spain            | 68        | 67        | 66        |
| The Netherlands  | 71        | 73        | 71        |
| Germany          | 66        | 65        | 66        |
| Norway           | 62        | 54        | 55        |
| Poland           | 67        | 66        | 67        |
| Slovenia         | 68        | 67        | 68        |
| Sweden           | 67        | 66        | 67        |
| UK               | 64        | 64        | 67        |
| Italy            | 65        | 66        | 68        |

Table of values: % of incorrectly performed smears.
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 performed. 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].

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

| 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              |

2015 — 21%

2017 — 18%

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 | 1,376,764 | 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 |

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 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.

**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).

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

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 estima-
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                    |

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 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

**Urszula Wojciechowska, MD, PhD**
Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology
Department of Epidemiology and Cancer Prevention
ul. Roentgena 5, 02–781 Warszawa, Poland
e-mail: urszula.wojciechowska@coi.pl

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