

EUROCHIP-II
FINAL SCIENTIFIC REPORT
ANNEX 06

**REPORT OF
EUROCHIP-2 ACTION IN
BULGARIA**

Evaluation of the current status of secondary prevention of cervical cancer in Bulgaria and suggestions for its future

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PART I. Assessment of information level and readiness for implementation of organized population-based cervical cancer screening in Bulgaria

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PART II. Evaluation of the cytological laboratories and their ability to perform cervical screening activities

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EXECUTIVE SUMMARY

Available information

Pelvic examination of women for screening purposes has been implemented in Bulgaria since 1956. A National Cervical Screening Programme was officially launched in 1970, based on an initial “Methodological instruction”, amended with: “Ordinance 6128/1972“, “Ordinance 3939/1976“, and “Instruction 0-23/1980” of the Bulgarian Ministry of Health. At its very start, this programme did not basically differ from similar ones in Western Europe and North America. The targeted populations, screening intervals, etc. were in accordance with the internationally accepted guidelines. Between 1970 and 1985, cervical cancer (CC) incidence and mortality rates in Bulgaria remained relatively stable. Unfortunately, a major collapse in the screening programme occurred, and this predictably led to a serious decline in basic parameters of screening efficacy. In 2000, the Council of Ministers sanctioned a new “National Programme for Oncological Screening in Bulgaria (2001-2006)”. The latter aimed at regulating CC screening for women aged 20 to 60 years, to be covered by the National Health System with an earmarked budget of 7.8 million BGN (3.9 million €). The Programme focused on cytological screening and postulated that cervical smears should be:

- performed either by the primary healthcare providers (GPs) or by the OB/GYN practitioners;
- examined at specialized laboratories throughout the country.

Unfortunately, this programme has never been implemented. Currently, a National programme for cancer prevention in Bulgaria does not exist. There are some local initiatives for free of charge preventive check-ups that are undertaken rather unsystematically. The slow transformation of the healthcare system has led to decreased availability and affordability of CC screening in Bulgaria (Kostova & Zlatkov, 2000; Kostova et al., 1998).

Some characteristics of the current situation are the following (Danon et al. (eds.) 2007):

- There were 1 097 new cases in 2004 (7.6% of all cancer cases in females; 4th place, after breast cancer, non-melanoma skin cancer and corpus uteri cancer).
- There is a 55% increase of new cases in the age group 30-44 years in 2004 compared to 1984.
- There is an increase in the incidence and mortality rates over time. In the age group 30-44 years, age-specific incidence rate is 11.52 (1984) vs. 41.17 (2004) per 100 000 females. The mortality increased threefold, from 3.46 (1984) to 10.13 (2004).
- In 2004, carcinoma *in situ* of the cervix was only 20.4%, and invasive CC was 79.6%. More than 30% of the new cases are in III+IV FIGO stage (UICC, 1998) and this ratio hasn't changed during the last 20 years.
- Estimated age-standardized mortality rates (European standard), for Uterus (C53-55) were 14.4 (Bulgaria), 6.8 (EU25), and 9.3 (Europe) per 100 000 in 2006 (Ferlay J. et al, 2007)

Since institutionally structured preventive programmes are absent, socioeconomic determinants began to play a more obvious role, as well as personal initiative of both providers and clients. This shift is creating significant barriers to regular screening. Disparities in access to screening programmes are being intensified. The current status is characterized by the lack of a functioning screening programme, absent communication between institutions and a financial deficit. Key elements, such as call-recall system, quality assurance, patient follow-up, and evaluation are missing. According to some experts (e.g. Avramova, at all 2005), the capacity of health facilities and laboratories is often underused, which means that there is a potential for expanding coverage.

State regulations in the field of CC secondary prevention

In Bulgaria there is no special law on reproductive health. Matters of quality of healthcare have found place in number of documents, such as the Law on Health, Law on Health Establishments, Law of the Health Insurance, the Act on the Professional Organizations of Physicians and Dentists, the National Framework Contract, different ordinances of the Ministry of Health, etc. According to the Law on Health, "...each Bulgarian citizen shall have right to accessible medical care under the conditions and by the order of the Law of the Health Insurance" Art. 81 (1).

Regarding medical care in the sphere of sexual and reproductive health, the Law on Health states:

“Art. 126 (1) **The State ensures** the legal protection of reproductive health of citizens by:

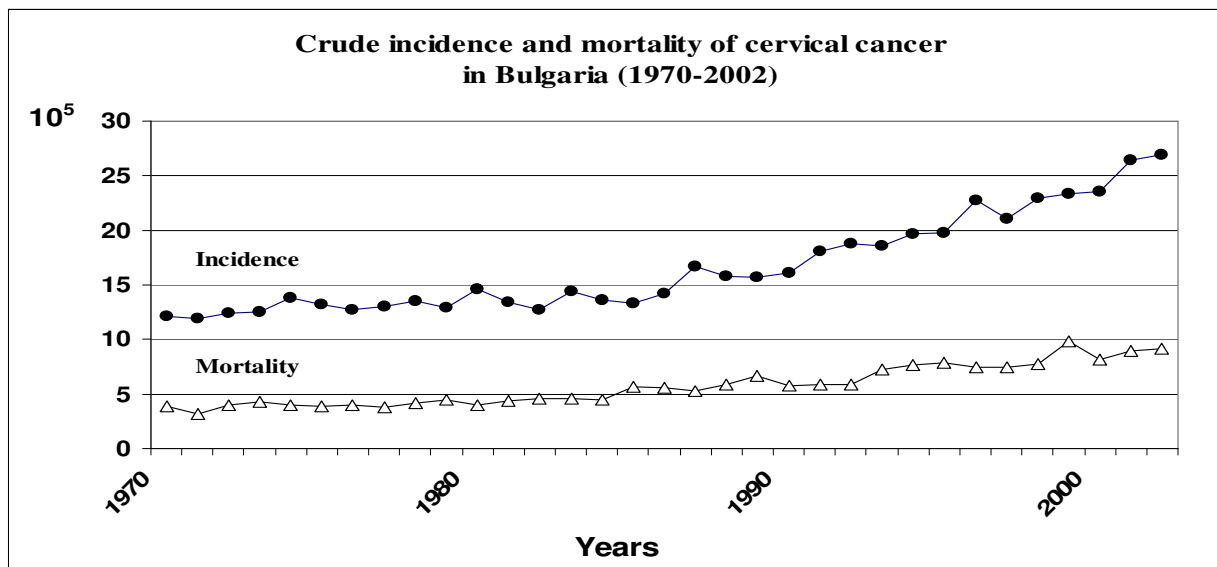
1. Promotion and counseling services for protecting the reproductive health of both children and persons of reproductive age.
2. Ensuring access to specialized consulting and care in the field of reproductive health and family planning.
3. Prophylactics and treatment of sterility.
4. Specialized information, consultations, prophylactics and treatment of STD and HIV/AIDS.
5. **Prophylactics, treatment and monitoring of persons with malignant diseases of the reproductive system”**

These services are free of charge for all health insured persons.

Health promotion, prevention and prophylactic activities are included in the basic package for outpatient care (Ordinance 40/2004 of the Ministry of Health). They are included in the common activities of the specialized outpatient healthcare.

Epidemiological characteristics of CC in Bulgaria (1970-2002)

In Bulgaria, according to the National Cancer Registry (2001), CC tends to reach first position (35.21%) in the structure of gynaecological neoplasia, overtaking endometrial cancer (34.2%). These data reproduce the situation of 25-30 years ago, which is still another evidence for the unfavourable trends in the epidemiology of this disease. In a 1970-1986 survey, the number of new CC cases ranged from 509 at the beginning of the period to 969 cases at the end of it while in the next period under study, until 2003, it increased to 1 096. There is a distinct rectilinear increase trend in the number of new cases with an annual increase of 3.03%.



The actual incidence of CC in the period 1970-2002 ranged from 12.7 to 26.9 per 100 000 females and after certain stabilization at the beginning of the period it has marked a rising tendency with an annual increase of 0.32 per 100 000, most significant over the past 15 years. Standardized incidence (1970-2002) was in the range of 9.9 to 19.4 per 100 000 and since 1987 has shown a steady annual increase of 2.34 %. Cervical cancer deaths for the period 1979-2002 ranged from 179 to 411 women, annually. There is a most significant relation between the number of deaths and the time, the annual increase rate in the period until 1996 being 4.9%.

PART I-Assessment of the information level and readiness for implementation of organized population-based CC screening in Bulgaria

This study was designed and conducted by the Health Psychology Research Center.

The sample of respondents was a convenience one, giving a wide representation of different actors involved in CC prevention. The forty six respondents (43.5% men and 56.5% women) were affiliated with the Ministry of Health, the National Health Insurance Fund, the National Centre for Public Health, the Bulgarian Association of Obstetricians and Gynaecologists, three Medical Universities, two major hospitals, two oncological dispensaries, and several non-profit organizations (NGO).

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They included policy makers, heads of clinics, professors, researchers, oncologists and gynaecologists. The study shows that specialists in gynaecology and oncology, as well as health managers/policy makers are aware that the status of CC screening in Bulgaria is alarming and has worsened in the last two decades. The lack of a clear vision on whether CC screening is considered a health priority shows the insufficient efforts of the main stakeholders to address generic system issues related to CC screening. Data show also that linkages between policy-makers and health providers are blocked. Communication and interaction between policy makers and front-line health professionals are insufficient. It is very alarming that a big proportion of the respondents are doubtful about the capacity of the current health system to organize an effective population-based screening programme. The above conclusions should be very useful in the design of a future screening programme. Obviously, health professionals in Bulgaria are not unanimous on some key issues regarding how an effective screening program should be designed, implemented and controlled.

PART II - Availability and equipment of cytology laboratories for completing CC screening

A survey of cytological laboratories, including re-screening, a comparability test and external quality control through a test for the qualification of cytotechnicians and a smear exchange test has been done.

On the basis of the analysis and comparison of the standards in the laboratories under study and international standards, the conclusion is that the required minimum for laboratory cytodiagnosics is available in these laboratories. Unfortunately, effective screening activities require additional conditions such as optimized human resources, implementation of Papanicolaou staining, standardization of the terminology, a storage system of not only positive but also negative smears maintained for a period of 10 years, announcement of results within 15 days, development of computerized laboratory registers, connection with a National Screening Register (which is still inexistent), development of a system of continuing training and evaluation.

The results obtained in the survey show that the observed shortcomings in the laboratories under study are related to the lack of standards and criteria for laboratory activities applied throughout the country as well as to the necessity to introduce a system of continuous training and evaluation.

Recommendations:

1. Coherent policies for CC screening need to be developed in Bulgaria. In order to be viable, a national strategy should define the management of the programme, linkages between institutions, and other related issues.
2. Strategies and policies should be linked to adequate financing. This has to involve negotiations between the planner and the purchaser(s) of care.
3. Institutional and professional responsibility for CC screening needs to be clearly explained in regulatory and policy documents. The rights and the obligations of customers should also be defined. Access to screening has to be facilitated.
4. A system for documentation sharing across different providers involved in CC prevention and treatment is needed.
5. The European standards for screening laboratories have to be implemented and respected in Bulgaria.
6. Greater number of cytotechnicians and cytopathologists need to be trained.
7. Unified terminologies for reporting results have to be introduced and implemented in the country.
8. Intrinsic and extrinsic quality control have to be introduced
9. The continuous training of manpower is a *sine qua non* prerequisite to success.

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PART I. ASSESSMENT OF INFORMATION LEVEL AND READNESS FOR IMPLEMENTATION OF ORGANIZED POPULATION-BASED CERVICAL CANCER SCREENING IN BULGARIA

Introduction

The social and institutional context of healthcare reform in Bulgaria has important implications for cervical cancer screening and prevention. The incidence and mortality from cervical cancer have risen, which is in sharp contrast to the steady decline in most countries. Mortality from cervical cancer in all ages has grown since the 1980s, and in 2001, it was twice the EU levels (6.4 per 100,000, compared to 2.5 EU average), although it started from a lower base during the 1970s (Figure 1).

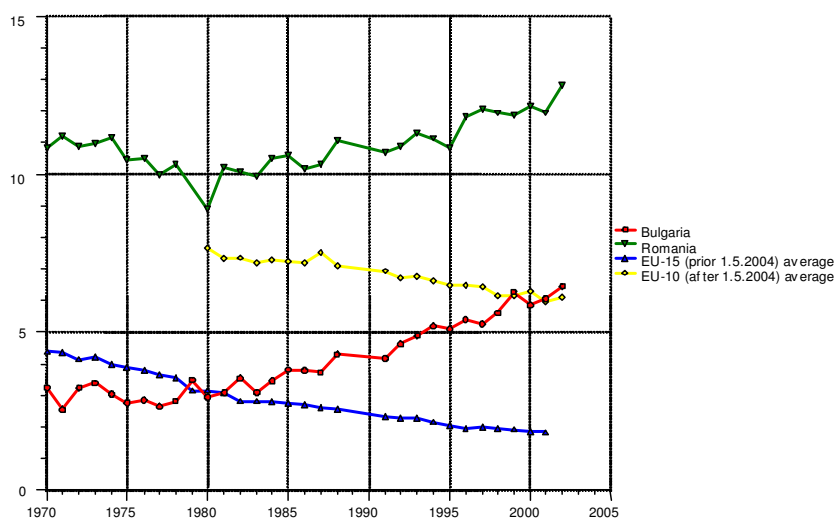


Figure 1. Standardised Mortality Rate, cervical cancer (0-64), per 100,000 (WHO Health for All Database)

Some characteristics of the current situation are the following (Danon et al. (eds.) 2007):

- There were 1097 new diagnosed cases in the year 2004 (7.6% of all cancer cases in females; 4th place, after breast cancer, non-melanoma skin cancer and corpus uteri cancer).
- There was a 55% increase in the new cases in the age group 30 - 44 years in 2004 compared to 1984.
- There is an increase in the incidence and mortality rates over time. In the age group 30 - 44 years age-specific incidence rate is 11.52 (1984) vs. 41.17 (2004) per 100 000 females. The same mortality rates increased 3 times, from 3.46 (1984) to 10.13 (2004).
- *Cancer in situ* of the cervix uteri was only 20.4%, and invasive cervix uteri cancer was 79.6% in the year 2004. More than 30% of the new cases are in III + IV stage (UICC, 1998) and this hasn't changed during the last 20 years.
- Estimated age-standardized mortality rates (European standard), for Uterus (C53-55) were 14.4 (Bulgaria), 6.8 (EU25), and 9.3 (Europe) per 100 000 in 2006 (Ferlay J., et al, 2007)

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The previously existing healthcare system, which was entirely State funded before 1989, has been dismantled, and a new one is in the process of being established. The previously existing population based screening program has been replaced by opportunistic screening.

In Bulgaria, the first official National Cervical Screening Program started in 1970¹. For the period between 1970-1985 cervical cancer incidence and mortality rates remained relatively stable. Soon after, a major collapse in the screening program came about and led to a serious decline in basic parameters of screening efficacy. In 2000 a National Strategy and Program for Oncological Screening in Bulgaria (2001-2006) was voted by Parliament. This program aimed to institute a multifaceted program of cervical cancer screening for women aged 20 to 60 years and to be covered by the National Health System with an earmarked budget of 7.8 million leva and additional yearly budgetary subsidies. It focused on cytological screening methods and proposed that cervical smears are taken at the primary care site (GPs or OBGYN practitioners) and analyzed at specialized laboratories throughout the country. This program has not been implemented in practice in the way it was planned and expired at the end of 2006. Currently, a National program for cancer prevention in Bulgaria does not exist. There are some local initiatives for free of charge preventive check-ups that are undertaken very rarely and unsystematically.

The slow transformation of the health care system has led to decreased availability and affordability of cervical screening in Bulgaria (Kostova & Zlatkov, 2000; Kostova et al., 1998). Since institutionally structured preventive programs are absent, socioeconomic determinants begin to play a more obvious role, as well as personal initiative of both the providers and the clients. This shift is creating significant barriers to regular screening and intensifying disparities in access to screening programs. The current situation is characterized by an out-of-date and non-functioning screening program, lack of contemporary laws, absent communication between institutions and a financial deficit. On the other hand, the conditions considered necessary for wide-ranging cervical screening such as capacity to conduct smear tests (equipment, consumables, network of medical facilities and cytological laboratories), and well trained staff are present in the country (Avramova et al. 2005). However, other key elements, such as call-recall system, quality assurance, patient follow-up, and evaluation are missing. The capacity of health facilities and laboratories is often underused, which means that there is a potential for expanding coverage.

¹ The implementation of the first national cervical screening program was based on “Methodological instruction”, supplemented and revised with “Verdict № 6128/ 04.11.1972“, “Verdict № 3939/ 13.12.1976“, and “Instruction № 0-23/ 30.07.1980” of the Bulgarian Ministry of Health.

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The **aim** of the current study was to expand on the existing data about the situation of secondary cervical cancer secondary prevention in Bulgaria (Avramova et al. 2005) by adding the opinion of key actors – administrative personnel, high level decision makers, specialists in obstetrics, gynecology and oncology from leading health institutions. It aimed to compare positions of these key respondents and to give recommendations for the future development of an effective program for cervical cancer prevention and control.

Methods

The current study was conducted using a structured questionnaire (see annex 1), developed by the Health Psychology Research Center and consulted by leading specialists in cervical cancer prevention. It consisted of 15 questions and was administered as an interview by our research associates. The data were entered and analyzed with the statistical package SPSS.

Sample

The sample of respondents was a convenience sample, aiming to give a wide representation of the different actors involved in cervical cancer prevention, treatment, financing and policy. We have 46 respondents of whom 43.5% were men and 56.5% were women. Geographically, 76% of the respondents were from the capital Sofia, 13% from the city of Plovdiv and 11% from the city of Varna. They were affiliated with the following institutions and organizations: the Ministry of Health (6), the National Health Insurance Fund (5), The Bulgarian Association of Obstetrics and Gynecology (3), The National Oncological Hospital (7), The Medical Universities of Sofia (6), Varna (5) and Plovdiv (5), the National Center for Public Health (2), The Military Medical Academy (3), Oncological Dispensaries of Sofia and Plovdiv, and several non-profit organizations (NGO) such as “HPV Guard” (3). There were 5 non-replying persons and they were from the Parliamentary Health Commission, from the National Center for Public Health, from two leading Gynecological hospitals

Results

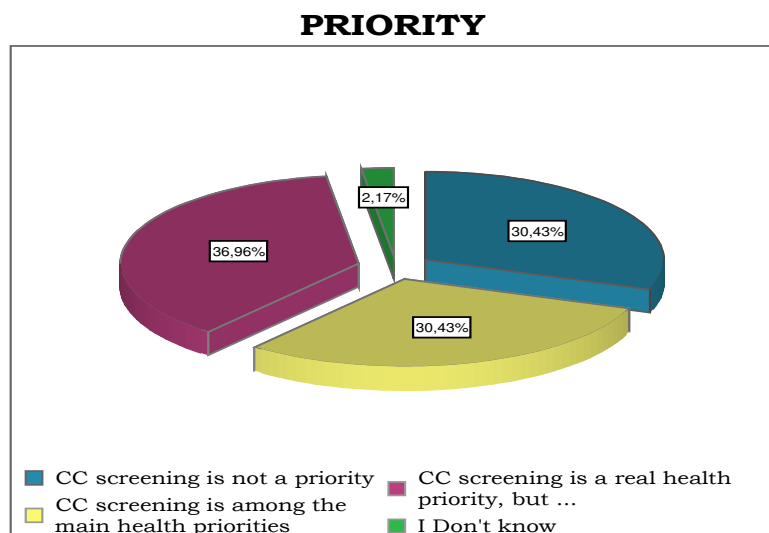
1) Prevalence of Cervical Cancer, Priority & Programs for Prevention

Our first aim was to assess to what extent the respondents were aware of the alarming statistical data on the prevalence of cervical cancer in Bulgaria and where they rank Bulgaria among other European countries. About 60 % of them ranked Bulgaria among the countries with highest levels of cervical cancer in Europe. It is worth noting that most of these were either specialist in oncology and gynecology from the leading institutions in the country, or were from NGO’s dealing with oncological care and patient’s rights.

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A significant number of those who believe that Bulgaria is among countries with medium morbidity and mortality from cervical cancer in Europe are affiliated with the Ministry of Health and the National Health Insurance Fund (NIHF). There were no participants who believed that Bulgaria is among countries with the lowest morbidity and mortality. About 10 percent of participants had no knowledge about the issue.

The respondents in our study were not unanimous in their opinion on whether cervical cancer screening is currently considered a health priority by policy makers and in existing documents. About 30% of respondents stated that it is treated as a real priority and another 30 % stated that it is not considered a priority at all. A slightly larger percent (37%) believe that cervical cancer screening should be a real priority, but this is not reflected anywhere in the currently enacted regulations.

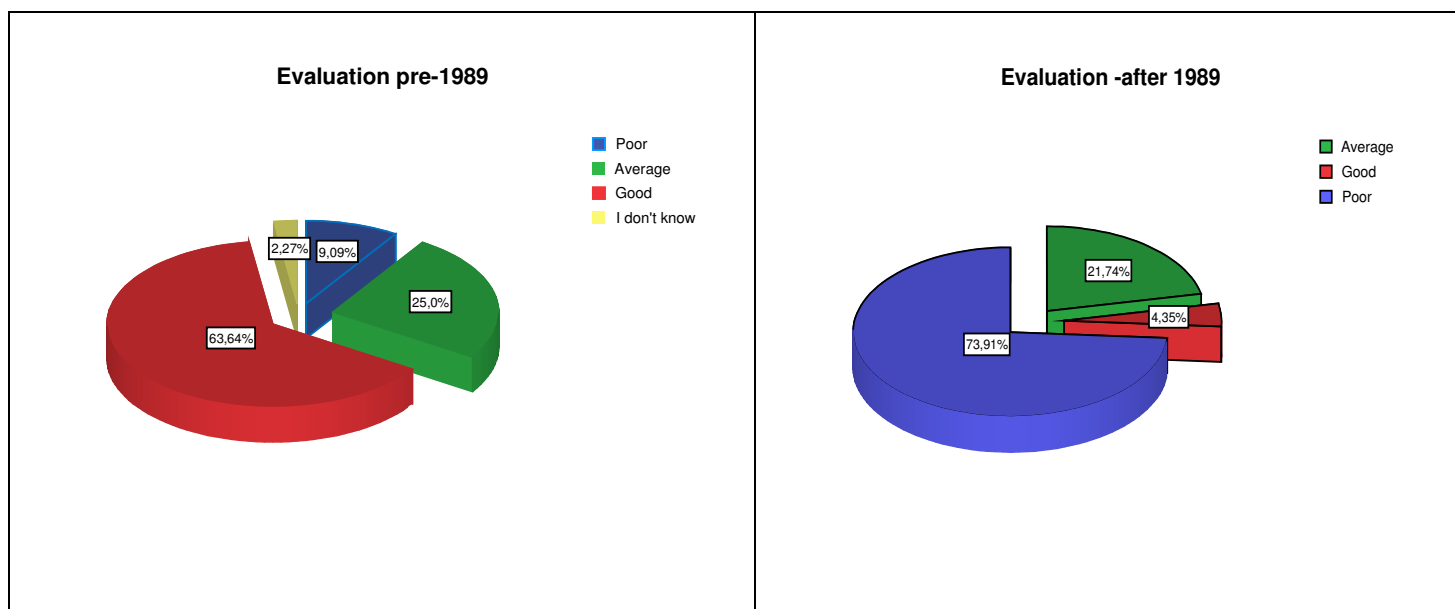


The results also show that it is not clear what programs for cervical cancer prevention exist in Bulgaria. According to 24% of the respondents, there are no functioning programs. According to 26%, there is a national program for cervical cancer prevention, 24% believe that there are yearly national campaigns. Similarly, 22% point to some regional programs. Only 21% were those who stated that there is a national strategy for cancer prevention for specific localizations, including cervical cancer².

² The percentages exceed 100, since more than one answer was possible

2) Evaluation and health system’s ability to cope

An important aim of our study was to compare the evaluation given by the respondents for the screening programs which existed during socialist times (before 1989) and during the period of the transformation of the health system after 1989. The data show that 61% of respondents think that the old system was good, and 74% of them think that the current situation is poor. Another concerning finding is the response to the question of whether the current Bulgarian health system is capable of organizing and implementing mass screening for cervical cancer - 61% of respondents stated that the system has no such capabilities and only 33% believe that it does. It is important to note that the evaluation of the situation pre- and after- 1989 is not related to respondents’ age.



3) Responsibility

Another aim of this study was to delineate respondents’ views on which institutions should be involved in the organization of cervical cancer screening in Bulgaria. Almost all of them (91%) identified the Ministry of Health as having to take on the main responsibility. However, all respondents also marked other institutions as being able to help and to have important input in the organization of cervical cancer screening (Local authorities – 20%; The National Oncological Hospital – 35%; The National Center of Public Health – 37%; NGOs - 35%).

Another crucial issue was whether participants had a clear position about who should finance the mass screening in Bulgaria. About two thirds (67%) stated that the main responsibility for funding should go to the Ministry of Health through the national budget. However, one half of the participants foresaw the National Health Insurance Fund as having responsibility for funding. It was not uncommon for both options to be marked by the same respondent.

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Nearly 24% think that there should be special funds, (donations by European and local organizations, private companies, NGOs and individuals) allocated for screening programs and no one believes that women should pay out of pocket for screening.

A key question for the study was who the respondents believe should be performing the cervical smears. The results show that the respondents overwhelmingly believe (90%) that the specialist performing the cervical smears should be those in obstetrics, gynecology and reproductive medicine. In second place are ranked specialists in oncology. Only 35% of the respondents believe that general practitioners should be conducting smears, and only 17% - that midwives should be doing so.

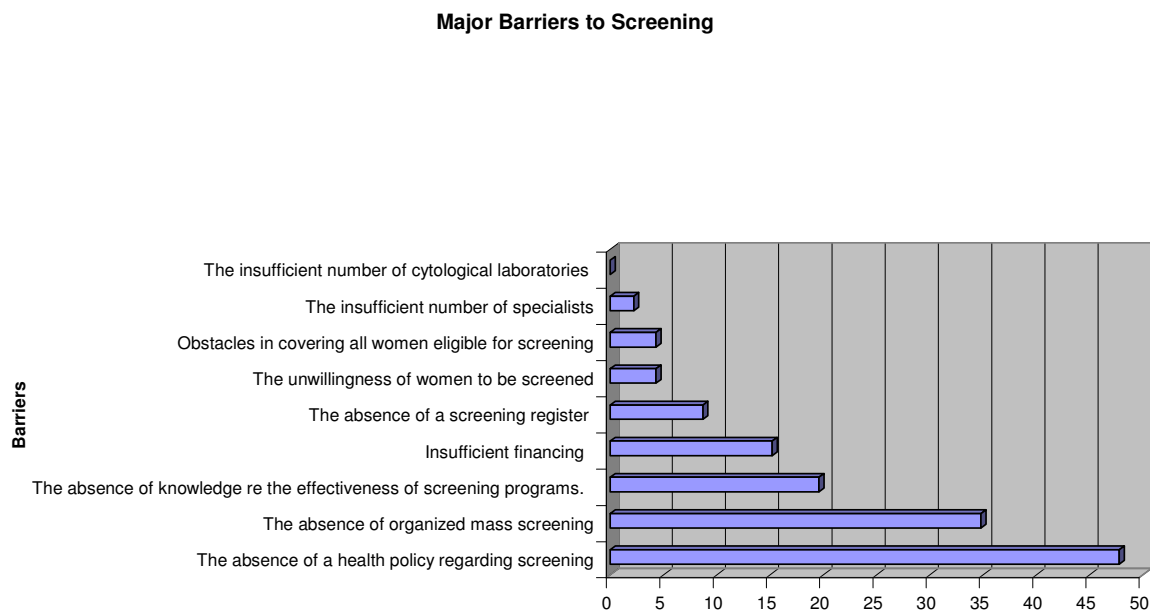
Although most of the participants were definite that Ministry of Health should take the main responsibility for organizing and performing a screening program, only about 20 % think that the controlling body of the Ministry of Health should be responsible for seeking out insured women, who have not appeared for testing. About one half of the respondents state that there should be a separate body that manages, controls and evaluates the screening program. One fifth believes that the regional centers for health services should also be responsible. In a separate question the respondents were asked whose responsibility it should be to seek out uninsured women. Significant differences appear only in the case of the role of the National Health Insurance Fund (NHIF) – 46% think that NHIF should be responsible for seeking out the insured and only 24% - for seeking out the uninsured women.

4) Barriers to screening

Our study also aimed to illustrate the major barriers to screening as reported by the respondents. When asked to rate the most important barriers to organizing effective screening programs in Bulgaria, nearly half of the respondents (47.8%) ranked “the absence of a health policy regarding screening” as the major one. Another 13% ranked this issue as the second most important barrier to effective screening. The “absence of organized mass screening”, was ranked as the number one barrier by 34.8% of the respondents, another 15% identifying it as the second most important barrier. The barrier ranked in third place was “The absence of knowledge regarding the effectiveness of screening programs”, being ranked in first place by 19.6% of the respondents, and in second place by 10.9% of them. “Insufficient financing” was overall ranked as the fourth most important barrier to screening, as it was ranked first by 15.2% of respondents, and second by 21.7% of respondents. Other possible barriers, such as “the unwillingness of women to be screened, in spite of their knowledge”, “the absence of a screening register”, “insufficient number of cytological laboratories”, “insufficient number of specialists” were not considered to be important issues that were preventing the development of effective screening in Bulgaria.

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In the chart below, we present the percentage of respondents that rank each of the possible barriers as the major one.



As is evident from the above graph, policy and organizational issues are considered to be the paramount barriers to effective screening in Bulgaria, and limited financing is also assessed as being important. Additionally, when asked if the current price of the smear test covers its actual expenses, 30.4% of the respondents were definite that it does not cover the expenses at all, while another 32.6% stated that it covers them only partially.

5) Approaches to screening

As far as what type of approach is the most effective for cervical cancer prevention, the majority of the respondents (61%) believe it is mass screening. Strikingly, nearly half (48%) believe effectiveness is achieved by enforcing screening through mandatory preventive check ups. Very few of them selected voluntary preventive check ups or selective screening as options. When asked which approach is most appropriate for Bulgaria, an even greater majority (80%) was in favor of mass screening as compared to opportunistic or selective screening.

Discussion

The current study shows that health specialists in obstetrics, gynecology and oncology, as well as health managers/policy makers are aware that the situation with the cervical cancer screening in Bulgaria is alarming and has worsened in the last two decades. The lack of a clear vision on whether cervical cancer screening is considered a health priority shows the insufficient efforts of the main stakeholders to address generic system issues related to cervical cancer screening. Data show also that linkages between policy-makers and health providers, which are a very important requirement for a functioning screening program, are blocked. As can be concluded from the data, there is insufficient communication and interaction between policy makers and front-line health care staff. These results are a logical outcome for the Bulgarian health system, which as many other health systems in the region, for many years was based on a "...hierarchically organized, bureaucratically administered, technology-based and expert-centered curative model"(Navarro 1977, cited in Rivkin-Fish 2005). It is very alarming that a big proportion of the respondents are doubtful about the capacity of the current health system to organize an effective mass screening program.

During the last decade there has been an argument in Bulgaria about who should be performing the cervical smears. Initially, this was activity to the general practitioners but a few years later, the responsibility was given back to the gynecologists because of the unwillingness of both women to be tested by GPs and GPs to perform cervical smears. From the data presented here, is very clear that neither policy makers nor specialist in obstetrics, gynecology and oncology, identify the general practitioners as those who should be performing cervical smears in the future screening program. However, for a considerable part of the respondents, GPs should have an active role and should be key actors in the administration of the screening process, because of their role at the entrance of the health system.

This study, as well as our previous research (Avramova et al, 2005), shows that health providers in Bulgaria believe that the role of NGOs is crucial. They see the role of NGO's in organizing informative campaigns, as well as a controlling body.

The conclusions from this study will be very useful in the design of a future screening program. The data show that health specialist in Bulgaria are not unanimous on some key questions regarding how an effective screening program should be designed, carried out and controlled. The data also show that no institution should be excluded from the future program for cervical cancer screening and cooperation between different actors is crucial for the organization of an effective screening program. In our opinion, there is a need for more discussions, round tables and other forms of negotiations in order to standardize the criteria of the future program.

Recommendations

- Coherent and uniform policies and national strategies for cervical cancer screening need to be developed. In order to be viable, a strategy should include clear instructions for the organization and management of the program, linkages between different institutions involved, and patient follow-up..
- Strategies and policies should be linked to adequate financing, which needs to be implemented. This has to involve negotiation between the planners (the Ministry of Health) and the purchaser of care (the National Health Insurance Fund), in order to decide on a realistic coverage.
- Institutional and professional responsibility for cervical cancer screening needs to be clearly defined in regulatory and policy documents, and enforced. The rights and the obligations of the general population should also be defined. Access to screening have to be facilitated by providing convenient and appropriate services for women.
- A system for documentation sharing across different providers involved in cervical cancer prevention and treatment is needed.
- A pilot program organized in certain locations could inform the development of a wider mass-screening program.

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ANNEX 1

**Questionnaire on the Information Level and the Readiness for Implementation of
Organized Population-based Cervical Cancer Screening in Bulgaria**

(You can mark more than one answer)

1. How prevalent is cervical cancer in Bulgaria?

- Bulgaria is among countries with the highest rates of morbidity and mortality from cervical cancer in Europe (such as Romania, Latvia, Lithuania, Albania)
- Bulgaria is among countries with medium morbidity and mortality from cervical cancer in Europe (such as Denmark, Norway, Croatia, Portugal)
- Bulgaria is among countries with the lowest morbidity and mortality from cervical cancer in Europe (such as Finland, Malta, Spain, Netherlands)
- I don't know

2. To what degree cervical cancer is public health priority in Bulgaria?

- Cervical cancer is not among the main health priorities
- Cervical cancer is among the main health priorities
- Cervical cancer is a real health priority, but this is not reflected anywhere
- I don't know

3. What kind of ongoing programs for cervical cancer prevention exist in Bulgaria?

- Yearly national campaigns
- Regional/Local programs
- National programs for cervical cancer prevention
- National strategy for cancer prevention for specific localizations according to the EU requirements, including cervical cancer
- There are no ongoing programs
- I don't know

4. Which institutions should be involved in the organization of cervical cancer screening in Bulgaria?

- The Ministry of Health
- Local authorities
- The National Oncological Hospital
- The National Centre of Public Health
- NGOs
- I don't know

5. Who should finance the organized mass screening in Bulgaria?

- The national budget
- The National Health Insurance Fund
- Women themselves
- Special funds
- I don't know

6. Which are the main obstacles for the organizing of effective screening program for cervical cancer in Bulgaria? (Please, number, marking the main obstacle with one)

- The absence of any health policy regarding screening
- The absence of knowledge regarding the effectiveness of this type of programs.
- The unwillingness of women to be screened, in spite of their knowledge
- The difficulties of covering all women eligible for screening
- The absence of a screening register
- The insufficient number of cytological laboratories
- The insufficient number of specialists
- The absence of organized mass screening
- The insufficient financing
- I don't know

7. Which is the most effective approach for cervical cancer prevention, in your opinion?

- Voluntary gynecological check-ups
- Mandatory gynecological check-ups
- Gynecological check-ups, including pap smear for symptomatic women
- Mass screening
- Selective screening
- I can't assess

8. In your opinion, does the price of the smear test cover the real expenses for it?

- It does not cover the expenses at all
- It covers the expenses partially
- It fully covers the expenses
- I have no idea of the real expenses for the pap smear and I can't assess

9. Who should be performing the screening check-ups in Bulgaria?

- GPs
- Specialists in obstetrics, gynecology and reproductive medicine
- Specialists in oncology
- Specialists in nursing (midwives and nurses)
- I don't know

10. Whose responsibility should it be to seek out the health insured women, who have not appeared for testing?

- Those who carry out the screening program
- The controlling body of the National Health Insurance Fund
- The controlling body of the Ministry of Health
- The district/regional centers for health services
- The controlling body of the Bulgarian Medical Association
- I don't know

11. Whose responsibility should it be to seek out the uninsured women?

- Those who carry out the screening program
- The controlling body of the National Health Insurance Fund
- The controlling body of the Ministry of Health
- The district/regional centers for health services
- The controlling body of the Bulgarian Medical Association
- I don't know

12. Which type of screening do you assess as most appropriate for Bulgaria?

- Opportunistic
- Organized population-based
- Selective (for risk groups)
- I don't know

13. Is the current health system capable to organize and implement mass screening for cervical cancer?

- Yes
- No
- I don't know

14. How would you evaluate the preventive check-ups for cervical cancer conducted in Bulgaria before 1989?

- Good
- Average
- Bad
- I can't assess

15. How would you evaluate the preventive check-ups for cervical cancer conducted in Bulgaria after 1989?

- Good
- Average
- Bad
- I can't assess

<p>City</p> <p>Institution</p> <p>Position</p>

**PART II. EVALUATION OF THE CYTOLOGICAL LABORATORIES AND THEIR
ABILITY TO PERFORM CERVICAL SCREENING ACTIVITIES**

Introduction

In the countries in North America and Western Europe, distinguished for their developed and effective cervical cancer screening programmes, it is accepted that the cytological laboratories included in the screening program apply standards determined by the institutions financing them. According to the recommendations of the WHO and the professional organizations of pathologists and cytopathologists, cervical smears should be screened in accredited cytological laboratories by qualified cytotechnicians supervised by superior medical staff – a consultant-pathologist qualified and experienced in the field of diagnostic cytology. According to their type, these laboratories are divided mainly into laboratories at histopathology departments and independent and regional laboratories. It is recommended that cytological screening laboratories should be centralized so that a number of peripheral screening centres could send smears to them. Presently, the accepted standard of laboratory loading ranges from 15000 to 25000 screening smears per annum for the whole laboratory, which is the required minimum for adequate performance. Cytotechnicians' standard work load also varies from 50 to 100 cervical smears per day.

The international requirements concerning laboratory structure and equipment aim at the achievement of optimal conditions for the performance of laboratory tasks. It is recommended that the smears should be received and registered by storing the information in a database system. Papanicolaou stain is considered to be the most appropriate method and is used in most modern cytological laboratories. The cytological answer is the final stage of professional responsibility. It should be accurate, descriptive when possible, and should include evaluation of the smear adequacy and the characteristics of the morphological findings.

Cytological laboratories are required to build up a register of their patients and to forward the information to the respective institution (the GP, the screening/cancer register, etc.). According to European standards, a storage system should be built and maintained (5 – 10 years) as well as a register of all analyzed smears.

It is widely accepted that the evaluation of quality is a system designed to avoid and control errors in decision making for certain activity before the interpretation of results. The quality assurance is a part of this evaluation which controls each components of the process separately. The major goal of the quality assurance in cytological tests is to provide the required quality and reliability at each stage of the laboratory diagnostics.

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Although the quality assurance increases laboratory costs by 30%, there is enough evidence for the necessity of its implementation because it provides improvement on cytological service quality and reliability, it also saves funds by reducing the amount of expensive retrospective work and decreases the number of unnecessary repeated smears and colposcopy examinations. The quality control is generally divided into internal and external. A system of regular evaluation, quality control and accreditation of cytological laboratories has not been developed in this country so far. In relation to this we carried out the first survey on certain components of the internal quality control (2006) through re-screening and a comparability test and of the external quality control through a qualification test and a smear exchange test.

Methods

The current study was conducted using a questionnaire (see annex 2), administered to the cytological laboratories of National Oncology Hospital and Oncology Dispensary in Plovdiv. We choose them, because they are the two main and biggest all over the country. There are another 11 cytology laboratories in the country, based in the oncological dispensaries.

In the analysis we used the following methods: rapid re-screening, test of comparability, qualification test and exchange test. All of these are known in the system of internal and external quality control of cytological laboratories

Results

Figure 1 presents the results of the qualification test and the score means the summarized digital assessment of each of the cytotechnicians, based on different evaluation steps. We analyzed 20 cytotechnicians (equal number from the two laboratories with the same qualification-biologist in order to achieve comparability of results).

Fig. 1 Results of qualification test of cytotechnicians

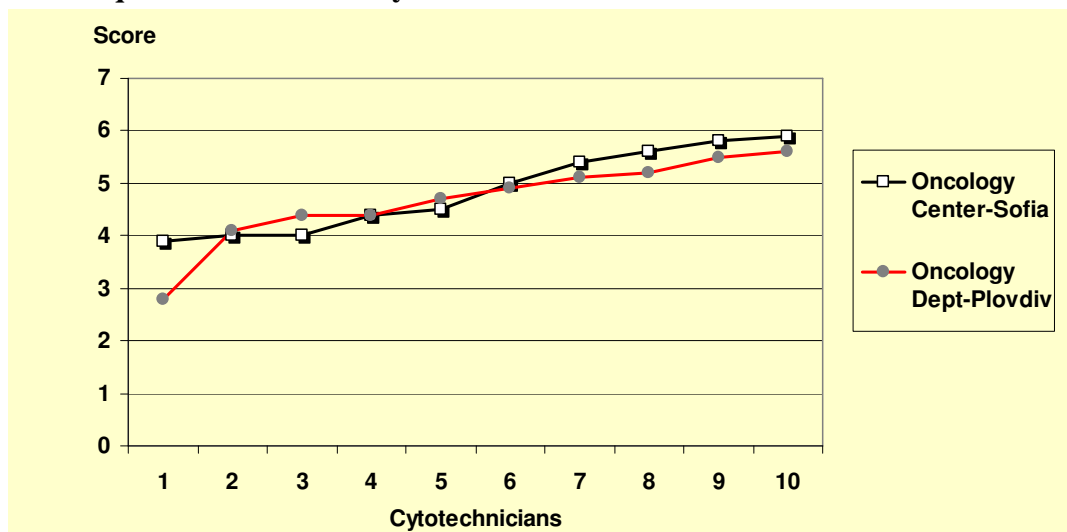


Table 1

Standards in the cytological laboratories in the study – the Laboratory of the National Oncological Hospital and the Laboratory of the Oncology Department city of Plovdiv

<u>INDICATORS</u>	Laboratory of the National Oncological Hospital	Laboratory of the Oncology Department, city of Plovdiv
<u>TYPE OF LABORATORY</u>	Independent	Independent
<i>Personnel (numbers):</i>		
Consultant Cytopathologists	1	1
Senior laboratory technicians	1	0
Cytotechnicians: biologists and/or laboratory technicians	16 (10+6)	10
Technical staff / staining technicians	2	0
Secretary	1	0
Laboratory load (1998)		
Number of cervical smears	113 044	55 248
Number of liable to screening women	239 000	230 000
Number of other cytological specimens	17 306	5 200
Average number of smears per cytotechnician	5 000 - 11 000	5 700
Number of microscopes		
For routine screening	25	18
For training	2	1
Receiving and registration of the incoming smears		
Organization through:	Technical staff	Cytotechnician on duty
Preparation of the smears for microscope analysis		
Who stains the smears?	Technical staff	Cytotechnician
Which staining technique is used?	Hemalaun-eozin	Hemalaun-eozin
Who controls the quality of staining?	Senior laboratory technicians	Cytotechnicians
How often do you change the staining agents?	1 week	1 week
How do you cover the preventive smears?	liquid paraffin	liquid paraffin
Smear scanning		
Number of smears per woman	2	1
Number of smears per laboratory assistant daily	60	30
Average time (in minutes) for the scanning of one smear	5 min	15 min
Adequacy evaluation	yes	yes
Is there a double check for the suspected smears	yes	yes
Who gives the final evaluation for abnormal smears?	Senior laboratory technicians	Senior laboratory technicians
Period of time (in days) for analyzing and reporting the results	15 days	1 week
Cytological classification in use	Papanicolaou	Papanicolaou
System for discussing problematic cases	Yes	Yes
System for quality control	No	No

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Recording and storing of data		
Method of recording	manually	manually
Who records the data?	technical assistant	biologist
Do you keep the negative samples?	No	No
Time (in years) for keeping the positive samples?	10 years	2 years
Is there an individual register for the women with positive results?	Yes	Yes
Reporting the screening results		
To whom do you report the results of the smear tests	To the physician	To the physician
What is the period of time for reporting the negative results	15 days	15 days
What is the period of time for reporting the negative results	15 days	15 days
How do you report the negative results to women	no regulation	no regulation
How do you report the positive results to women	in a written form	in a written form

Discussion

On the basis of the analysis and comparison of the standards in the laboratories under study and international standards the conclusion can be drawn that the required minimum for laboratory cytodiagnosics is available in these laboratories. Unfortunately, the performance of effective screening activities require the introduction of more conditions such as optimal personnel, implementation of Papanicolaou staining, a storage system of not only positive but also negative smears maintained for a period of 10 years, announcement of results within 15 days, development of a computerized laboratory register, connection with the national screening register, development of a system of continuing training and evaluation.

The summary on the results has proved that the system of internal quality control through complete rapid rescreening in both laboratories has provided better opportunities with a decrease in false-negative results by a total of 5.2%. Parallel with this, the comparability test has shown that the final cytological evaluation is directly related to the three components: smear quality, precise diagnostics of the Pap group and presence or absence of additional components.

The qualification test shows that, as a whole, both leading screening laboratories pass over the accepted limit of 4.50 but only 60% (12/20) of the individual participants were above the limit. The results obtained being independent of the individual characteristics and professional qualifications of the cytotechnicians.

The smear exchange test has not found any significant differences in the interpretation of the results in the two laboratories. The coincidence is full in determining the quality and morphology of graver epithelial changes while incorrect evaluation of papilloma virus cellular changes is related to the lack of unified criteria for laboratory activities in this country.

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The results obtained in the survey show that the observed weaknesses and faults in the laboratories under study are related to the lack of unified standards and criteria for laboratory activities applied throughout the country as well as to the necessity to introduce a system of continuing training and assessment.

Recommendations

- The European standards for the activities of screening laboratory have to be implemented and respected in Bulgaria (monitoring quality of cervical smears, adequate preparation and storage of smears at laboratories, timely cytological answer to clinicians, registration of results in screening registry)
- Greater number of cytotechnicians and cytopathologists to be trained.
- A unified terminology for reporting results have to be introduced and implemented in the country.
- The introduction of internal and external quality control at cytological laboratories have to be implemented
- The continuous training and education of staff to be performed

References

Zlatkov V., P. Kostova-Zlatkova. Prophylaxis, screening and vaccines for precancer and cancer of the uterine cervix. 1st edition, Bulgarian Publishing House, Sofia, 2006, pp.148; ISBN-13: 978-954-91829-1-0

ANNEX 2

**Questionnaire for
Evaluation of the Standards in the Cytological Laboratories**

Please, mark the correct answer

1. Type of the laboratory:
 - cytological laboratory in a histopathology department
 - independent cytological laboratory

2. The laboratory is a unit of:
 - the National Oncological Hospital
 - University hospital
 - Specialized hospital for obstetrics and gynecology
 - Private laboratory

3. Laboratory load
 - number of cervical smears in the last year
 - number of other cytological specimens in the last year

4. Personnel (numbers):
 - consulting pathologists
 - biologists
 - senior laboratory technicians
 - laboratory technicians
 - technical staff / staining technicians
 - secretary

5. Number of microscopes:
 - total number
 - are there microscopes with an extension for training

6. Who receives and registers the incoming smears:

7. Preparing the smears for microscope analysis

- who stains the smears
- which staining technique do you use
- who controls the quality of staining
- how often do you change the staining agents
- how do you cover and enlist the preventive smears

8. Smear scanning:

- Number of smears per woman
- Number of smears per laboratory assistant per day
- Average time (in minutes) for the scanning of one smear
- Adequacy evaluation Yes / No
- Is there a double check for the suspected smears Yes / No
- Who gives the final evaluation for abnormal smears
- What is the period of time (in days) for analyzing and reporting the results
- Which cytological classification do you use in your laboratory
 - The traditional Papanicolaou system Yes / No
 - The Bethesda system Yes / No
 - A combination of both Yes / No
- Does your laboratory have a system for discussing problematic cases

9. Recording and storing the data:

- Method of recording computer based/ manual
- Who records the data
- Do you keep the negative samples
- For how long (in years) do you keep the positive samples
- Is there a individual register for the women with positive results

10. Reporting the results of the screening:

- To whom do you report the results of the smear tests
- How do you report the positive results to women: personally / in a written form
- What is the period of time for reporting the negative results:
 - To women
 - To the physician who has taken the sample
- What is the period of time for reporting the negative results:
 - To women
 - To the physician who has taken the sample

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Name Age

Qualification: MD MA in Biology Medical technician

Major: Total length of service:

Length of service in cervical diagnostics (in years):

Training in cytological diagnostics (where and for how long):

- Regional Oncological Dispensary (number of training courses)
.....
- Medical University (number of training courses)
.....
- Abroad (where – number of training courses)
.....

How many cervical smears do you scan?

- Yearly (average number)
- Daily (average number)