EUROCHIP-II

FINAL SCIENTIFIC REPORT

ANNEX 11

REPORT OF

EUROCHIP-2 ACTION IN

LATVIA

CERVICAL CANCER IN LATVIA

Study of the situation, analysis,

and practical recommendations to solve the problems

December 2007

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CONTENTS

PROJECT ANNOTATION

The technical report „The Cervical Cancer in Latvia" has been developed within the framework of the EUROCHIP-2 project and provides the study of the situation in this field during the last years. The aim is to identify problems and propose possible solutions. The report includes experience of other countries in organizing screenings and the key prerequisites for successful implementation in Latvia.

The EUROCHIP-1 and EUROCHIP-2 projects of previous stages and the international cooperation has been taking place since 2001. These projects involve about 150 partners, including Ministries of Health, Cancer registries, and professional associations from several countries. The EUROCHIP projects have continuous financing from the DG SANCO (EC) foundations within the framework of the European Parliament „Community action in the field of public health" program in accordance with the European Parliament resolution No. 1786/2002/EC and the European Council resolution No. 2007/102/EC of 12 February 2007.

In relation to the EU Council recommendation to implement the organized cancer screening in all European Union countries, over the last three years, in Latvia the state funded program of the preventive examinations has been considerably increased with cancer screening-like examinations, including cytological examinations for women at the age between 25 and 70. However, the number of the examinations is insufficient, and the total coverage of the population is low. The report provides analysis of the procedure for receiving services in Latvia, the structure of service providers and identifies limitations and obstacles for effective operation of the program in Latvia. The paper includes output of efforts of several groups of different levels including the group established under the 15 March 2007 order No. 127 of the Prime Minister Aigars Kalvītis „On a work group for developing measures to reduce morbidity and mortality from malignant tumors".

The EUROCHIP-2 activity in Latvia, described in this report, was defined and decided in a meeting organized in Riga on 18th September 2006 in which a list of Latvian associations and institutions participated: Latvian Association of Gynecologists and Obstetricians, Latvian Family Doctors Association, Latvian Oncology Center, State Laboratory of Virology, Health Compulsory Insurance State Agency, Ministry of Health.

The report includes proposals for improving the organization of the screening and measures that could increase the availability of the screening measures considerably.

The English translation of the report is submitted to the EUROCHIP-2 project coordinators. The report has been submitted to the institutions involved in the planning of health care policy, the professional associations, and it will be available to any interested person. Specifically, this report has been submitted to:

1. Ms. Aiga Rūrāne, WHO National Program Officer
2. Ms. Gunta Lazdāne, WHO Regional Adviser in Reproductive Health and Research Issues
3. Ms. Iveta Ķelle, Executive Director of „Papardes zieds", Latvian Association for Family Planning and Sexual Health (LFPSHA)
4. Ms. Monta Forstmane, Head of the Medical Division, Ministry of Health of the Republic of Latvia
5. Mr. Reinis Joksts, Director of the Health Care Department, Ministry of Health of the Republic of Latvia

6. Ms. Skaidrīte Vasaraudze, representative of the Ministry of Health of the Republic of Latvia
7. Ms. Dace Matule, gynecologist, Latvian Association of Gynecologists and Obstetricians
8. Ms. Dace Rezeberga, gynecologist, President of the Latvian Association of Gynecologists and Obstetricians
9. Mr. Pēteris Apinis, President of the Latvian Doctors Society
10. Ms. Ingrīda Circene, Member of Parliament, member of the Social and Employment Matters Committee
11. Ms. Aija Barča, Member of Parliament, Chairperson of the Social and Employment Matters Committee
12. Mr. Vitālijs Orlovs, Member of Parliament, member of the Social and Employment Matters Committee
13. Ms. Marija Zvaigznīte, oncogynecologyst, Riga Eastern Clinical University Hospital, Latvian Oncology Center
14. Ms. Dace Baltiņa, Head of the Education Department, Riga Eastern Clinical University Hospital
15. Ms. Valerija Grjunberga, Head of the Cytology Laboratory, Riga Eastern Clinical University Hospital, Latvian Oncology Center
16. Ms. Vaira Vīķe-Freiberga, Ex-President of the Republic of Latvia
17. Mr. Philip Davies, President of the European Cervical Cancer Association
18. Ms. Lūcija Akermane, Director of the Health Compulsory Insurance State Agency (HCISA)
19. Mr. Egils Lavendelis, Director of the Health Statistics and Medical Technologies State Agency (HSMTA)
20. Mr. Uldis Līkops, Director of the Public Health Agency of Latvia
21. Ms. Līga Kozlovska, President of the Latvian Association of Rural Family Doctors
22. Ms. Sarmīte Veide, President of the Latvian Association of Family Doctors

Chapter 1

Epidemiology: situation analysis of all cancer and cervical cancer in Latvia

All cancer epidemiology

Cancer is increasing problem all over the world and in Latvia, too. Since 1995, the number of the affected people in Latvia has increased by 20.9% annually; the incidence has increased from 320.5 (per 100,000 populations) in 1995 to 430.8 in 2005 and to 451.1 in 2006. Based on the Latvian Cancer Registry data, in 2006, the cancer was diagnosed for the first time in life to 10,321 people. In the structure of causes of death the malignant tumors are the second most frequent cause after cardiovascular diseases. The Latvian Cancer Registry has recorded 54.549 oncology patients as of 1 January 2006.

The oncology situation is formed and described by several features, the main being the following:

1) the frequency indicators for the cancer incidence (the number of people affected during a year and the relation to 100,000 population),
2) the first-year mortality,
3) 5-year survival,
4) mortality in absolute figures and per 100,000 population,
5) the share of late stages,
6) the share of early asymptomatic form diagnostics in preventive checkups.

The key statistics describing the oncology situation are displayed in Table 1.

Table 1. **Oncology situation indicators in Latvia, 1999–2006.**

	1999	2000	2001	2002	2003	2004	2005	2006
Cancer incidence per 100,000 population (crude)	369.5	366.1	363.8	381.2	391.8	431.1	432.9	451.1
Cancer incidence per 100,000 population (stand European)	226,0	215,6	214,4	224,0	225,5	225,5	235,9	232,6
Cancer mortality per 100,000 population (crude)	214.1	213.1	231.3	240.6	245.1	248.3	253.2	263.5
Cancer mortality per 100,000 population (stand European)	130,7	128,5	129,3	126,9	133,8	143,7	142,4	133,8
5-year survival rate (%)	56.5	56.9	57.9	57.8	58.2	57.0	57.8	58.1
First-year mortality (%)	36.0	36.5	38.6	34.5	34.2	34.2	35.8	32.8
Stage IV cancer patients (%)	24.2	24.3	26.0	23.9	24.0	23.6	24.1	22.6
Visual cancer sites, Stages III and IV (%)	29.7	29.4	32.6	30.0	29.9	28.9	29.0	27.2
Oncopathology findings in preventive checkups (%)	1.5	1.8	1.2	1.6	1.4	1.1	0.8	1.1

The table data clearly demonstrate the increasing trend of incidence and mortality rates. The survival (at 5 years after diagnosis) does not reach 60%, and no significant increase can be seen. The share of primarily diagnosed lingering cases is constantly high

(including from visual cancer sites[1]) — the neglect (stage IV; for visual cancer sites — stages III-IV) approaches 50%, which is a very unfavorable phenomenon. At the same time, the very low rate of oncopathology findings during preventive checkups is indicative of inadequacy and inefficiency of preventive measures. Figure 1 shows the overall dynamics of incidence and mortality rates between 1999 and 2006.

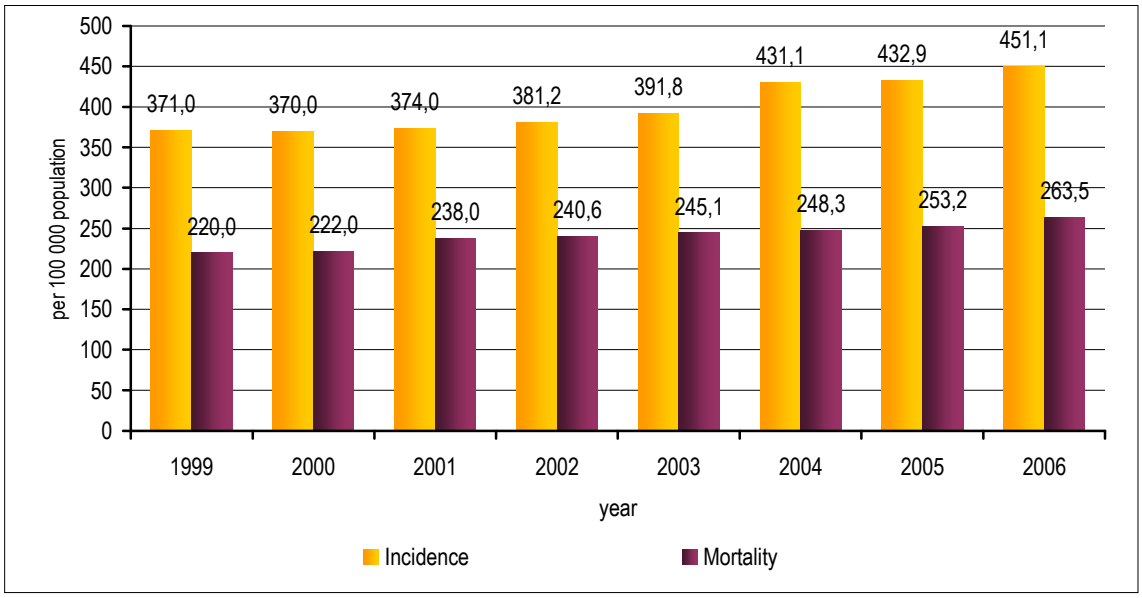
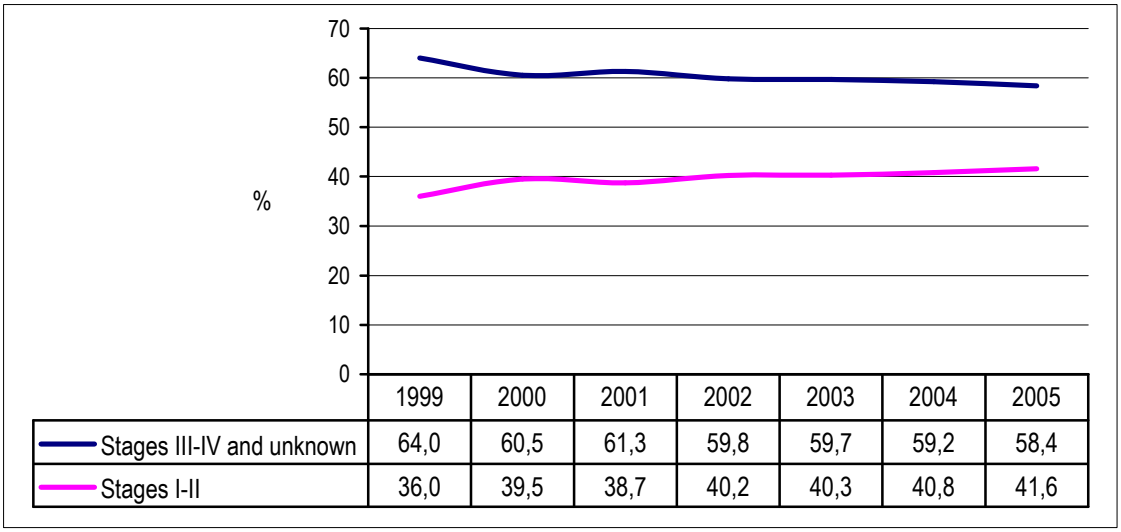


Figure 1. **Crude cancer incidence and mortality in Latvia, 1999–2005, per 100,000 populations.**

It might seem that the cancer incidence in Latvia is lower than in the old European Union (EU) countries, but it is just appearance, because in Latvia unlike in the old EU countries, cancer is very often diagnosed in late, lingering stages — the statistics speak of a very high share of lingering malignant tumors, causing in its turn, high first-year mortality rates, lower five-year survival, and high treatment costs in the oncology field.



	1999	2000	2001	2002	2003	2004	2005
Stages III-IV and unknown	64,0	60,5	61,3	59,8	59,7	59,2	58,4
Stages I-II	36,0	39,5	38,7	40,2	40,3	40,8	41,6

Figure 2. **The share (%) of stages I–II and III–IV in the crude cancer incidence in Latvia, 1999–2005.**

[1] The visual cancer sites include the breast cancer, cervical cancer, oral cavity, rectal, female and male genitals, thyroid gland and peripheral lymphatic gland, and skin tumors. These are tumors that can be found in a checkup without applying any complicated examination methods.

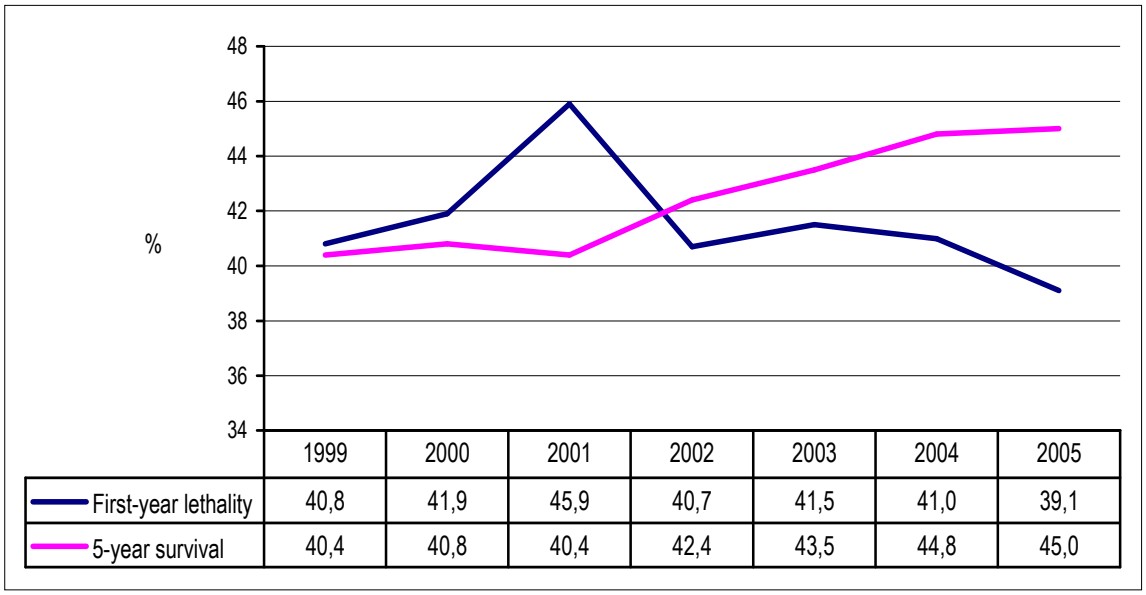
The high rate of lingering cases is the key problem of the oncology. Over the last 10 years, up to 60% of all initially diagnosed malignant disease cases have been diagnosed with delay — in stage III and IV when treatment costs are high and the therapy to reach complete recovery is impossible (Fig.2).

The main cause of the neglect is the poor awareness of the population of risks contributing to the development of oncology diseases, of the ways to prevent them, of the early symptoms of the cancerous disease. Population surveys show that people do not use the opportunities of preventive checkups and often look for a doctor only when the symptoms of the disease begin to affect quality of their lives adversely. In about 53% of all lingering cases, the delayed consulting with a doctor is the reason the patients explain.

Unfortunately, the insufficient availability of health care services in Latvia is a significant factor contributing to the lingering cases. The recent studies repeat to emphasize that the population in Latvia evaluate the availability of health care services as poor in general, in particular from the financial point; the number of general practitioners per 10 000 residents is one of the lowest in the new European Union member countries.

The Availability of Health Care Services in Riga City and Vidzeme Region research made by the University of Latvia in 2006 mentions that besides the issues of financial availability, the geographical availability in the rural areas (distance to the medical center, public transportation and travel fees) is a topical issue, as well as the organizational availability (business hours of doctors, long waiting in queues, inconvenient business hours, etc.).

The large number of lingering oncology diseases in the structure of the incidence causes the first-year mortality keeping high and the 5-year survival staying low, although these figures have been improving since 2001 (Fig.3).



	1999	2000	2001	2002	2003	2004	2005
First-year lethality	40,8	41,9	45,9	40,7	41,5	41,0	39,1
5-year survival	40,4	40,8	40,4	42,4	43,5	44,8	45,0

Figure 3. **The first-year mortality[2] (%) and five-year survival[3] (%) in cancer patients in Latvia, 1999–2005.**

[2] The first-year mortality is the patients who died during the first year after diagnosing.
[3] Five-year survival is the patients who are alive five years after the diagnosis date.

Cancer epidemiology in women

Women most often have the breast cancer, skin cancer, uterine cancer, and colon cancer.

The incidence of the breast cancer has increased by 15% over the last ten years. Each year, about 1000 women are diagnosed the breast cancer and about 450 women die of this disease annually. Very often — in about 23–25% of cases, the breast cancer has been diagnosed in lingering — III and IV — stages.

Still, the uterine cancer is an unresolved issue for women — incidence of this cancer (~ 200 new cases annually) in Latvia keeps growing (Fig.4 and 5) unlike in many other European countries where the incidence of this disease has decreased significantly over the last 15–20 years.

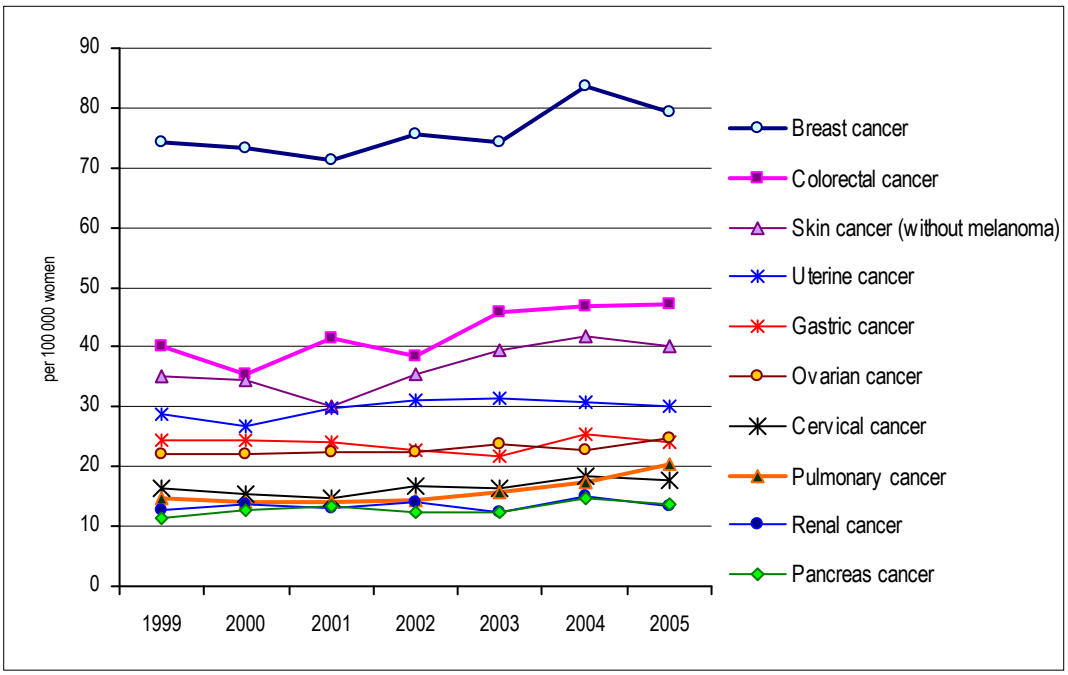


Figure 4. **Crude incidence of the most common cancer sites in women, in Latvia, 1999–2005, per 100,000 women.**

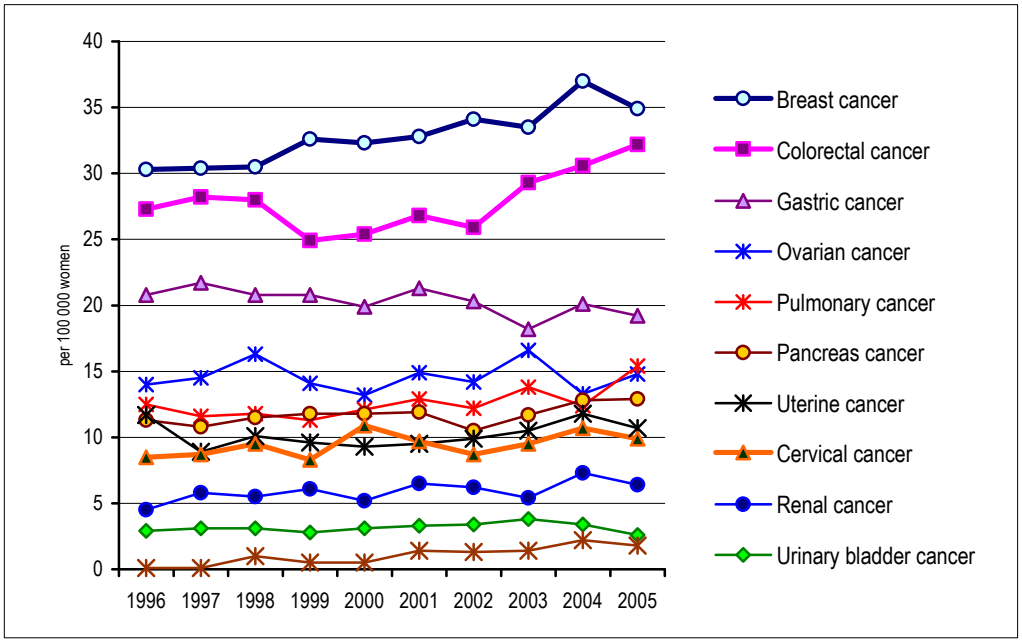
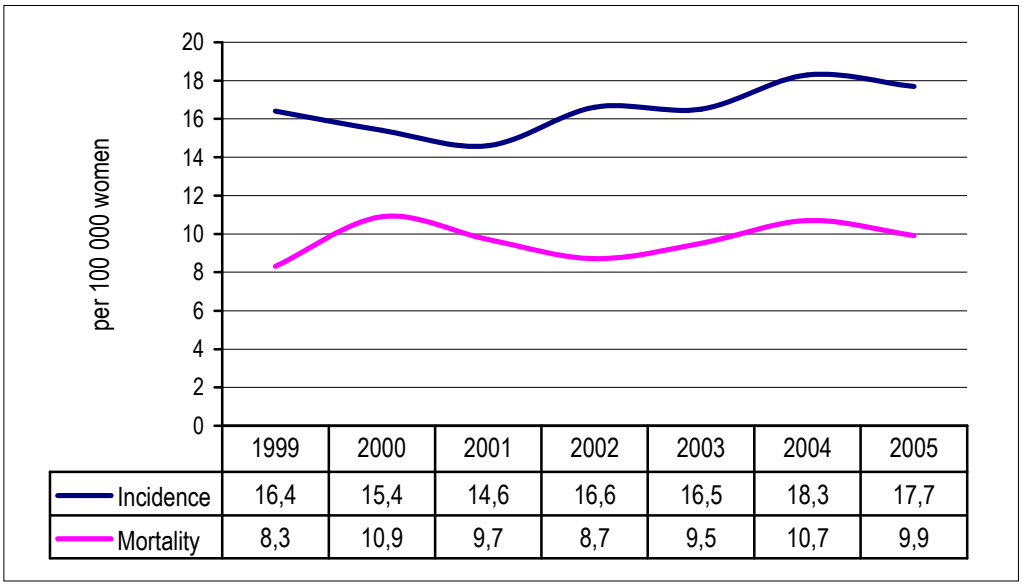


Figure 5. **Crude mortality from the most common cancer sites in women, in Latvia, 1996–2005, per 100,000 women.**

Cervical cancer epidemiology

The cervical cancer is one of a few localizations affecting women in younger ages than malignant tumors of other localizations. Moreover, it can be fully prevented provided it is duly found and the precancerous disease of the cervix is treated, because its trait is the fairly long (up to 10–12 years) stage of natural development from easily treated precancerous lesions to the cancer stage. The diagnosis of this precancerous disease is rather simple and it can be provided by a regular (once in three years) taking of the cytological smear from the external *os* of the *colli uteri* and the examination under a microscope. Therefore, the increasing trend of the cervical cancer incidence in Latvia (Fig.6) is a very adverse phenomenon.

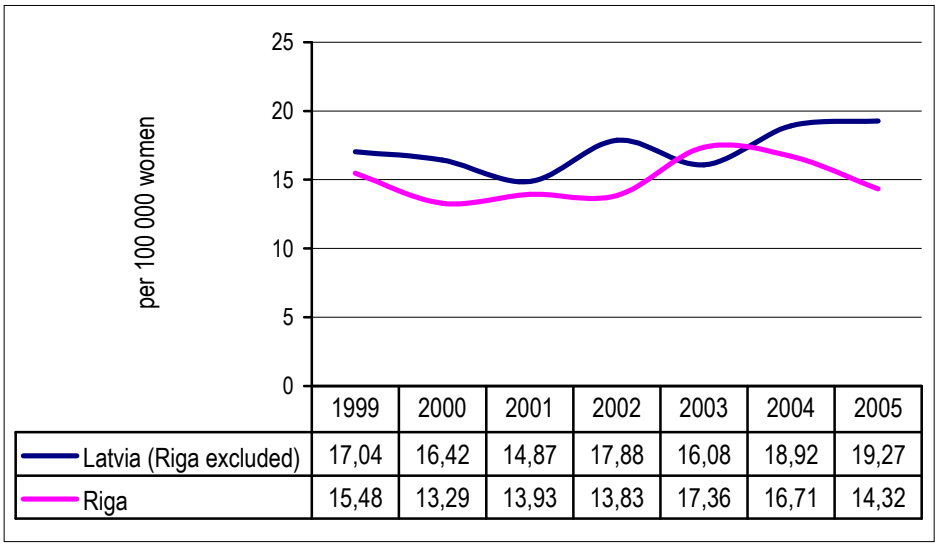


	1999	2000	2001	2002	2003	2004	2005
Incidence	16,4	15,4	14,6	16,6	16,5	18,3	17,7
Mortality	8,3	10,9	9,7	8,7	9,5	10,7	9,9

Figure 6. **Crude cervical cancer incidence and mortality in women in Latvia, 1999–2005, per 100,000 women.**

Statistics show that the potential of early diagnosis is not used at its most in this country. Probably, the permanence of the incidence rate is also caused by the insufficient availability of gynecologists in the female health care organized by the state in Latvia. As researches show, the cultural and historical situation in Latvia still grants the gynecologists the leading role in the primary care of female health, including early diagnosis of gynecologic tumors in spite of the fact that the government has delegated this function and the financial cover for it to the newly established institution of general practitioners as long as 15 years ago. However, according to HCISA (Health Compulsory Insurance State Agency of Latvia) "Yearly books", only 9% of the preventive gynecologic checkups paid by the state (including cytological tests) were performed by general practitioners in 2005 and 2006. The number of gynecologists is insufficient, and most of the gynecologists have their practices in private ambulatory institutions without a contract with HCISA – meaning they provide only commercial services. For a major part of residents, this is a significant obstacle preventing them from regular visits to a gynecologist. Besides, based on the financing conditions, the laboratory testing (cytological analysis) must be also paid by the patient provided if the issuer of the referral (in this case, a gynecologist in a private **outpatient** practice) has no contract relations with HCISA. In 2005, out of 484 certified gynecology practitioners, only 35 gynecologists had **direct contractual relationship** with HCISA. Based on HCISA data, in 2006, 398 gynecologists/obstetricians had indirect contractual relationship with the Agency. They worked in 183 institutions, including in-patient institutions providing mainly in-patient services in gynecology and obstetrics. Since the health care services financing procedure provides that the preventive examinations are not additionally paid above the bed-day rate, they are not performed for inpatients.

Figure 7 displays the increase of incidence in rural areas compared with Riga.



	1999	2000	2001	2002	2003	2004	2005
Latvia (Riga excluded)	17,04	16,42	14,87	17,88	16,08	18,92	19,27
Riga	15,48	13,29	13,93	13,83	17,36	16,71	14,32

Figure 7. **Crude cervical cancer incidence in women in Riga and rural areas of Latvia, 1999–2005, per 100,000 women.**

As we can see, since 2003, the incidence in Riga tends to decrease, while in rural areas — increase. With high probability, the trends represent the impact of availability of quality health care services in Riga (with better diagnostics and treatment of precancerous diseases) on the incidence rate. This may suggest that the insufficient access to gynecologists in rural areas is the cause of the increase in incidence rates compared with Riga. The constantly high rate of mortality from cervical cancer — a possibly preventable disease — is even worse. One fourth of women die in the first year after diagnosing the malignant tumor, because the options of effective treatment are limited due to the lingering of the disease. The cervical cancer incidence and, consequently, the mortality of it may be prevented if precancerous diseases were found early through screening and treated. The high mortality and the first-year mortality rate is contributed by the fact that frequently — in more than 40% cases — the disease is found only in late stages (III–IV) when the chance to achieve good results of the treatment is insignificant. When the malignant cervical tumor is in stage IV, the first-year mortality grows to 80%. In the case of stage IV, the five-year survival was only 4.5% in 2005, while when the cervical cancer was found in stage I, the five year survival was about 90% (Fig.8).

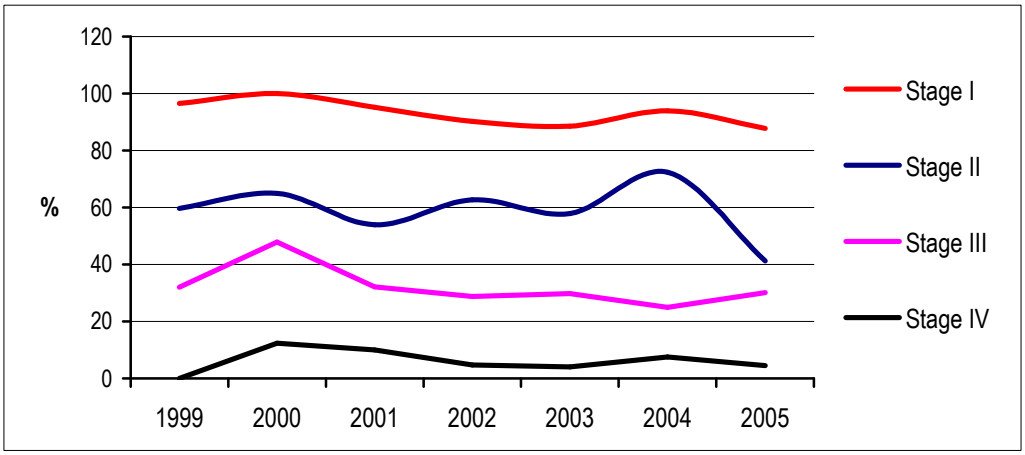


Figure 8. **Observed five-year survival rate of cervical cancer patients in different stages of the disease in Latvia, 1999–2005 (%).**

The analysis of morbidity frequency in various age groups shows that about one half of women diagnosed the cervical cancer is up to 60 years old. The mortality rates in the age group up to 60 years compared with the incidence rates of the respective age group is up to two times lower, however, by the increase of the age the difference decreases and the mortality even exceeds the morbidity (fig. 9). This could be explained by the fact that women in younger age visit doctors more frequently and take tests and, therefore, the cervical cancer is found earlier.

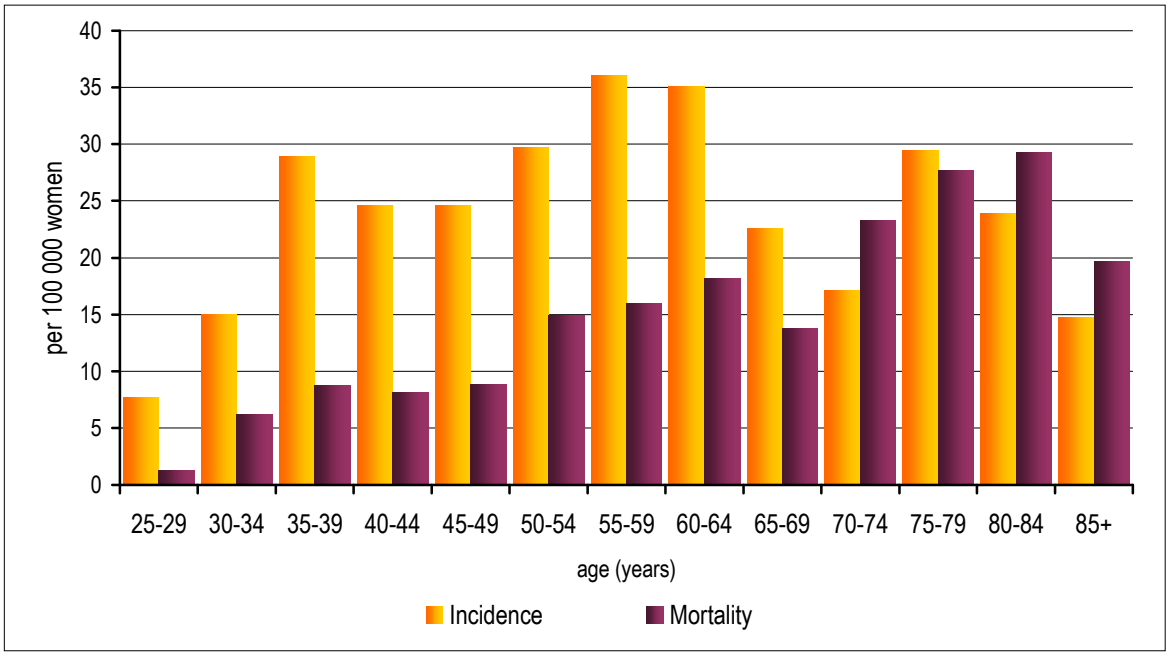


Figure 9. **Crude cancer incidence and mortality in women by age in Latvia, in 2005, per 100,000 women.**

Latvia, as well as Lithuania, Estonia, Romania, and Bulgaria are the countries with the highest number of cervical cancer incidences. The lowest incidence is in Scandinavia where the organized cervical cancer screening is in place already for several decades. Figure 10 displays the summary of comparable data on incidence of cervical cancer in the Baltics and Finland, between 1999 and 2005.

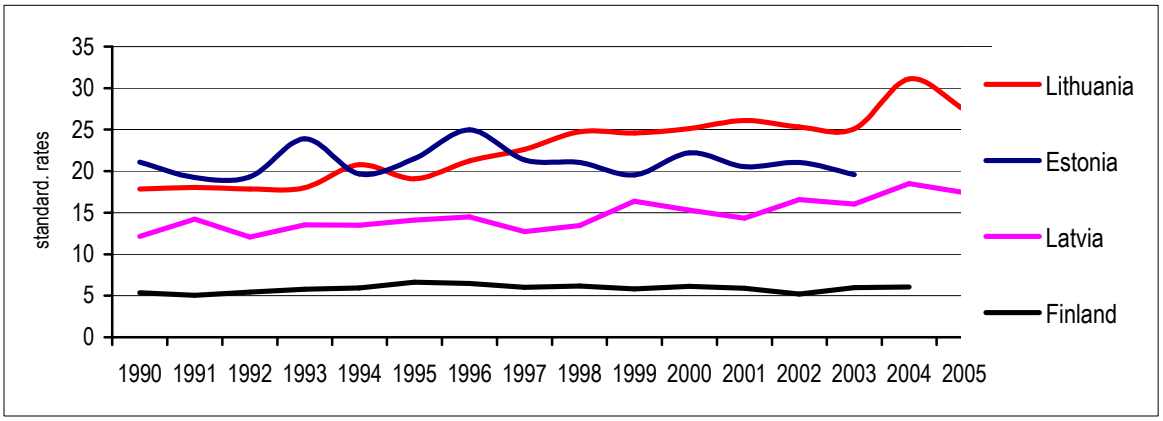


Figure 10. **Cervical cancer incidence in Baltics and Finland, 1990–2005, World Standardized Rate.**

The standardized mortality rates in Latvia like in Lithuania and Estonia are significantly higher than on average in EU–27. The difference is even larger if the Baltics are compared with EU–15, i.e., the „old" member countries, many of which have achieved a relatively low mortality rate of the cervical cancer, for example, Finland (Fig.11).

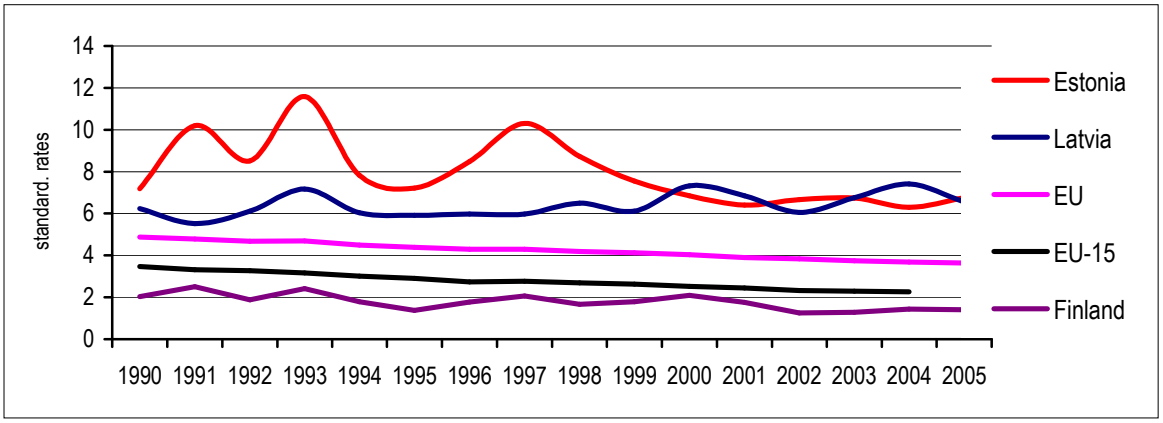


Figure 11. **Cervical cancer incidence in the Baltics and Finland, EU and EU–15 countries, 1990–2005, standardized data per 100,000.**

1.1 Comments

The high cervical cancer incidence and mortality in Latvia and the Baltic countries has not been left unnoticed and it was mentioned in the 27 June 2007 meeting of the MEPs Against Cancer group[4] in Brussels as an unacceptable situation in Europe to be addressed without delay.

We can say that in general, the indicators of oncology diseases, including the incidence and mortality rates for the population of Latvia are unsatisfactory and they tend to deteriorate. A contributing factor to the deterioration is the demographic feature of Latvia — the significant share of older people, because the oncology diseases are more frequent in people over 65. **The oncology situation** in Latvia has been adversely affected by the changes in the economy and the health care system that occurred over the last 15 years, as well as the insufficient availability of health care services.

The analysis of mortality rates in Latvia over the last 10 years allows us to conclude that, regardless the advanced development of the pharmacy industry and medical technologies, we cannot see the improvement in the mortality rates of oncology diseases and that costly treatment of oncology diseases does not provide significant prolongation of survival.

Summary

1. *According to statistics, the total incidence of cancer over the last 10 years increases by 2–2.5% annually, and the share of lingering oncology diseases remains high (around 30%).*
2. *The cervical cancer in Latvia is a serious problem, because all epidemiologic indicators show a continuous deterioration in the oncology situation.*
3. *The screening and early diagnostic of visual cancer site — the cervical cancer — is insufficient; the preventive checkups do not meet their goals.*

[4] MEPs Against Cancer (MAC)

Chapter 2

The National Cancer Control Program and Cervical Cancer Screening

The 7 April 2005, the Resolution of the World Health Organization 58th Assembly emphasized an urgent need to establish a National Cancer Control program in all countries to provide planned and systematic activities in preventing, early diagnosis, treatment, rehabilitation and palliative care of oncology diseases. The establishment of the program should be based on the features of the oncology situation in the respective country, the incidence structure, the health care services providers, and the amount of available funding. The program should contain the minimum recommendations to ensure that the decision making in the oncology and related areas of the health care system would target at a considerable decline in morbidity and mortality using the resources, including human resources, in the most effective way.

On 6 March 2001, the Cabinet of Ministers of Latvia approved the Public Health Strategy. Chapter IV of the Strategy includes Target 8: „Reduction of the Spread of Non-Infectious Diseases" which provides for reduction of incidences of non-infectious diseases including oncology diseases, and reduction of disability and early mortality caused by such diseases. However, this document does not include the implementation plan for the above strategy nor provides for a funding for meeting the goals. Although the 9 March 2004 Instruction No. 150 of the Cabinet of Ministers of Latvia approved the „Action Program on Implementing the Public Health Strategy for 2004–2010", the program did not provide for developing a program in oncology area. The epidemiological situation of cancer in Latvia is indicative of the need to develop and adopt a long-term national cancer control program. The draft of the program guidelines have already been developed and submitted to the Ministry of Health of the Republic of Latvia.

The screening diagnostics within the preventive checkups belong to the secondary prevention measures of a cancer control plan. The objective of the secondary prevention is an early diagnosis of a disease to enable radical treatment of the disease, improve the individual forecast of the disease and possibly reduce the treatment costs. The cancer screening is a method of simple tests applied to the total population of residents targeted in order to isolate subgroups who have an increased probability of a certain asymptomatic or olygosymptomatic disease.

The screening is a meaningful search (filtering off) of a disease (such as cancer) in people who do not have any symptoms related to the disease sought for the time being and who belong to the risk group (mostly — certain age group) with the highest incidence of a particular disease. As far back as in 1968, Wilson and Jungner defined the following criteria to tell whether a disease can be prevented through a mass screening:

1. The disease is an important health problem for the individual and community.
2. The natural history of the disease is explored and known.
3. The disease can be found at an early stage.
4. The treatment at an early stage is of more benefit.
5. There are suitable and acceptable examination methods for wide diagnostics of the disease.
6. The capacity of the health care system enables the treatment of all incidence cases found.
7. The screening diagnostics is performed to individuals at regular intervals over the symptom-less stage of the disease.
8. The screening examinations give more benefit than pose a risk of harm.
9. The total cost of screening is balanced in relation to the benefits of the community in general.

Based on the above principles and the results of numerous epidemiologic studies, it was concluded that the mass screening is most effective in preventing the following diseases: **cervical cancer** and breast cancer in women, colorectal (colon and rectal) cancer in women and men. The experience of the countries with lasting screenings record, confirm the requirements and principles to be set regarding the organization of the screening; provided the requirements and principles are met, the decrease of the mortality rates is achieved and savings of the total financial funding required for the treatment of cancer are gained. The success stories of the screening policy regarding cervical cancer are the examples of Iceland, Norway, and Finland, where the organized cervical screenings have been effectively taking place already for many years and where the lowest mortality of cervical cancer in Europe is achieved — the total mortality has decreased by 60–80%.

When analyzing the adverse rates of the oncology morbidity and mortality in Latvia, we would like to emphasize that tumors of several localizations can be prevented effectively with the implementation of a wide population cancer screening program. At the same time, we regret to say that over the last 10–15 years the number of preventive checkups in Latvia and their effectiveness has declined according to HSMTSA Yearly books data.

The Implementation of Preventive Checkups — the Cervical Cancer Screening Program in Latvia

According to Appendix 2 „The Program of Preventive Checkups" of the Regulations No.1036 of the Cabinet of Ministers of Latvia „Health Care Organization and Financing Procedure" (21st December 2004), 1st April 2005 is the date of the introduction in Latvia of the **cervical cancer screening examinations** for:

- women between age 20 and 35: cytological smear is done once a year; if the findings is normal, the smear is repeated every three years;
- women between age 35 and 70, cytological smear is done once a year.

With these regulations becoming effective, the cancer screening program is started for the first time in Latvia. We regret to say that the adoption of the Regulations of the Cabinet of Ministers has been just a declaration, because none of the measures listed in „The Main Principles of the Cancer Screening Organization" chapter has been implemented. The entire responsibility for organizing and performing the screening examinations was delegated to the general practitioners, who were left to disseminate information, explain the meaning and importance of the screening, refer to examinations, receive the results of examinations and interpret thereof, and make decisions. A centralized database for the screening register and collecting the results was not created. In its terms, the screening model implemented in Latvia, is the so-called opportunistic or decentralized screening with the following characteristics:

- the coverage and realization of the screening is the responsibility of general practitioners, despite that women in Latvia prefer to choose a gynecologist for their gynecological health care (the study *Reproductive health of the population of Latvia,* in 2003, within UNFPA and LFPSHA project) ;
- there is no single screening information system;
- there is no central point of supplying information to the population;
- there is no coordinating institution, since HCISA provides only financing functions;
- there is no single methodology and guidelines to perform screening examinations;
- instead of one target group for the screening, there are two; that does not comply with the evidence-based medicine approach;
- women chose the participation or non-participation without any medical support. No advertising activities are performed to increase their personal interest or awareness;
- the screening examination is performed at woman's request; if she does not apply to the general practitioner for any reason, she is not included in the screening system;

- if woman is well-informed, it is her responsibility to organize the referral from the general practitioner to the screening examination;
- often, the woman has to take charge of delivering the examination results to the general practitioner;
- most of the women find the existing cancer screening system complicated, bureaucratic, and time-consuming (the study *The Availability of Health Care Services in Riga City and Vidzeme Region* made by the University of Latvia in 2006).

The Appendix 5 „The Program of Preventive Checkups" of the 19th December 2006 Regulations No. 1046 „Health Care Organization and Financing Procedure", defining the examinations included in the cervical cancer screening, already provided that the cancer screening program should be organized in compliance with the European Parliament recommendations:

- one target age group — the diagnosis of cervical cancer with an cytological smear for women between age 25 and 70 every three years;
- provides also for a role of a gynecologist/obstetrician in this program.

Also the most recent regulations as of 1 January 2007 do not contain any specific reference as of the organization of the screening program; these regulations actually provide for continuing the screening based on the opportunistic, decentralized screening model. This type of screening is not recommended by the European Parliament — it is considered an ineffective use of funds, because in this case the cancer morbidity and mortality rates are not improved.

In order to involve general practitioners in more active performance of preventive screening examinations and based on the Appendix 16 of the Cabinet Regulations No. 1046 „Methodology of General Practitioner Performance Appraisal and Payment Distribution", the general practitioner annually must examine at least 65% of patients registered in his/her practice without specific indication to the target coverage of the oncology disease screening. For meeting these criteria, general practitioners receive additional payment. The previous years show that the financial incentives alone for general practitioners without changes in the organizational principles of the screening do not bring the expected results, because cooperation of the population in the screening activities is very low, as shown by the information collected by HCISA (Table 2).

Table 2. **The indicators of screening coverage in Latvia, 2005 and 2006.**

Type of manipulations	2005		2006	
	Number of manipulations	Actual coverage, %	Number of manipulations	Coverage, %
Mammography within the preventive checkups	8066	2.60	16616	5.41
Cervical tumor screening:	77379			
– at the age of 20–35		9.52	36656	10.04
– at the age of 36–70		8.62	78612	10.42
Prostate tumor screening	2942	1.20	5709	2.75
Colorectal tumor screening	5033	0.60	9937	1.21

However, it should be noted that the above information refers only to the services paid by the state, and it is not possible to obtain accurate information about preventive examinations paid by the individuals. The small number of preventive screening examinations over the first two years confirm the idea that the decentralized or opportunistic screening cannot guarantee the achievement of goals required, because the actual coverage of female population that can lead to the decrease in morbidity and in,

most important, mortality, is 70-80%, but the preliminary data of cervical cancer examinations coverage in Latvia, in 2007, show that the number of examinations and the actual coverage have not increased significantly.

The inactivity and unawareness of people, insufficient availability of services, the overloaded general practitioners, lack of involvement of gynecologists who have private outpatient practices in the program, and the non-existence of a comprehensive implementation program of the screening are unconquerable obstacles in applying the screening as a tool to decrease the cervical cancer morbidity and mortality. Up to now, there is no detailed individual, including cervical cancer screening, screening programs providing for the screening policy:

1) educating and informing the community about the peculiarities in the course of oncology diseases, preventive measures, destroying myths and prejudices;
2) inclusion and exclusion criteria;
3) guidelines of screening stages;
4) including or excluding permanent residents from the screening target group;
5) measurements of screening results (coverage by visits, coverage by call, interim screening examinations, etc.);
6) setting the minimum requirements and guidelines for the technical performance and quality control of the examinations.

Currently in Latvia, there is no management, coordination, and control of cancer, including cervical, screening programs. According to the professional regulations, ensuring the screening coverage is delegated to general practitioners, and HCISA just pays for the screening examinations performed. There is no institution that would collect and store data about the clinical results of examinations (either paid by the state or by the patient), would control the quality of screening examinations — cytological tests, and generalize data about the impact of the screening program on the oncology morbidity rates, the actual improvement of early diagnostics and the decline of mortality.

In Latvia, up to now, no assessment has been made as to the capacity of human resources and technologies in proportion to the required coverage of the screening (at least 75%). No data have been collected about the geographical distribution of the target group of women and the corresponding regional availability of screening services and the supply of qualified medical staff.

Neither current, nor future financial cost have been calculated and there are no estimations as to the required resources for the long-term implementation of the program, based on the distribution of the absolute number of female population by age groups and the change of cohort. Also, no studies have been made about future financial and economic benefits provided by decreased costs of treatment care of lingering cancer stages.

Summary

1. *The awareness of the community about factors that are hazardous to one's health and may cause cervical cancer, is insufficient; the effectiveness of health promotion campaigns is low, and due to the low awareness, people cannot make independent assessment of the risk posed by the hazardous factors and the threat to one's health.*
2. *The organized cervical cancer screening programs implemented in many European countries reduce the rate of morbidity and mortality from cancer considerably.*
3. *In Latvia, still no national cervical cancer control program has been adopted to coordinate and unit the multisectoral activities of various institutions and government bodies in all aspects of reducing the burden of this disease.*
4. *The opportunistic cervical cancer screening initiated in Latvia, is ineffective because it, by its nature, cannot provide wide coverage of the female population.*
5. *The opportunistic cervical cancer screening existing in Latvia should be transformed into an organized national cervical cancer screening program.*

Chapter 3

The Fundamental Principles of Organizing Cervical Cancer Screening

Prior to implementing the nation-wide organized screening, it is recommended to meet several prerequisites:

1. Identify whether the implementation of such program is in compliance with the priorities of national health care and public health.
2. Identify whether the state has enough human (professionals) and financial resources for implementation of the program.
3. Develop a detailed protocol (guidelines) of the screening organization.
4. Implement a pilot program in order to assess the functionality of the protocol and the suitability for the real situation.
5. Develop a quality control and quality assurance system for the screening test manipulations and all operations.
6. Develop a screening process and progress monitoring system to assess the effectiveness, costs and quality indicators of the system.
7. Solve the organizational, financial and assessment issues found during the implementation of the pilot project.
8. After solving any shortcomings and organizational problems, distribute the program and provide explanations to all residents and start implementation o f the screening.

The keystone of implementing the screening system is the development of the screening policy/guidelines. The structure of health care systems and financing principles differ in different countries, therefore, it is not possible to create a universal standard program to fit well in conditions of any country.

Section 9¹ of the Medical Treatment Law of the Republic of Latvia stipulates that (1) the treatment shall be performed in compliance with the *clinical guidelines* or the assessment of safety and treatment efficacy of methods and medicines applied in the treatment, made according to the principles of evidence-based medicine; (2) the Cabinet of Ministers provides for the procedure of developing the guidelines. By November 2007, the above mentioned procedure stipulated by the Cabinet was not developed yet. Therefore, at the present moment, no guidelines developed by professionals, including the screening guidelines can have legal effect. **The guideline development procedure approved by the Cabinet is an urgent document and the implementation of the organized screening programs would be difficult and delayed without the procedure**.

The policy guidelines of any screening program must define the following issues that actually are required elements of any program implementation and will be discussed in detail below:

1. Creating a screening system coordinating institution.
2. Developing screening program guidelines.
3. Selection of health care institutions providing screening examinations.
4. Data flow organization of screening processes and stages.
5. Cooperation and training of specialists involved in the screening process.
6. The quality control and assurance program.
7. National responsibility.
8. Monitoring system for the assessment of screening program effectiveness.

Creating a screening system coordinating institution

Since the screening process involves an extremely large number of residents in a planned way and a very huge information material is obtained and processed in a centralized manner in case of both the pathology findings and the normal findings, the decentralized data storing at general practitioners or even at health centers is inadmissible. Usually, the functions of a coordinating institution are delegated either to a health insurance agency (in Latvia — HCISA) or to an organization established with such aim capable of creating a screening register. This institution has two main functions:

1) To create the list of screenable residents including a minimum of identity data (year of birth/age, sex, place of residence, the registered general doctor) or selecting based on the population register. This list is the so called screening register that allows accurate calculation of the number of residents subject to individual screenings in various sex and age groups, by place of residence (geographically) to enable planning of resource deployment and the logistics of the screening process;
2) the coordination of the logistics of the entire system of screening processes in all stages — from the registration and sending of an individual invitation to the examination findings — either „norm; moved to the next screening round" or „diagnosed disease and the treatment assigned and received".

The coordinating institution is responsible for creating the text of the standard individual invitations, registering and sending the invitations to the persons to be screened. The invitations are extremely important in the organization of the screening, because a received registered invitation simultaneously is a referral to the examination. The invitation solves the frequent bureaucracy and availability problems and facilitates and hastens the receipt of the screening diagnostics service. The invitation contains short and clear information about the meaning and importance of the screening examinations, indicates the place and time of examinations, as well as the contact telephone numbers and any other relevant information. Moreover, the registered and sent invitation is an individual point of control which is verified after the service is received and the examination results are received in the register. The screening policy guidelines usually provide for the maximum time limit to receive the examination results. The optimum period is six months after which the screenable person is sent a repeated invitation letter.

Developing detailed screening program guidelines

This document contains all the practical information required for the organization of the process. It states the specific age groups subject to each type of screening and specifies whether the age interval is calculated at the beginning of a calendar year (as at 1 January) or the individual entering the age (the birth date). This seemingly irrelevant item, however, is important when planning financial resources for a year and if disregarded, it may cause fluctuations in the financial resources used in case of high population coverage. The information to be included in the screening policy guideline document also includes the established frequency of screening rounds (once a year, once in two years or three years), the performance technology and methodology requirements for each screening, inclusion criteria if previous oncology diseases recorded, inclusion and exclusion criteria for individuals with clinical complaints[5]. The document should contain the action guidelines for cases with pathology findings so that all patients would receive the most appropriate, relevant and timely further medical assistance regardless their place

[5] If the individual has the specific symptoms or complaints of the screened disease, instead of the screening examination she/he should have a diagnostic examination and the results should be delivered also to the screening registry provided the individual has been included in the previous round of screening.

of residence, the competences of the general practitioner and the location of the screening examination.

An important issue of the screening guidelines is the setting of requirements for the staff involved in the screening examinations regarding their qualifications, experience, lowest and highest load rates and the quality control requirements and assurance. This is an essential aspect of the screening policy, because no above manipulations of screening examinations are possible without personal participation of medical staff, therefore, the prevention of possible errors caused by human factor can play a key role in the overall effectiveness of the screening process.

Selection of health care institutions providing screening examinations

Following the qualifications requirements and the technological criteria stated in the screening policy/guidelines, the screening program financing (or coordinating) institution should regularly perform the selection procedure of the health care institutions that provide the screening examinations to ensure high quality and standards of the services.

Data flow organization of screening processes and stages

Although the screening process coordinating institution coordinates and controls the fact, order and relevance of the overall process, the screening examination results information should be also received by the individual and her general practitioner who, if required, will have the leading role in the management of further examinations and treatment.

Cooperation and training of specialists involved in the screening process

An effective screening process is based on compliance with the guidelines, instructions and other directions, therefore, it is important to update and improve them constantly. The specialists involved in the screening process should be able to attend any training on maintenance and improvement of professional skills; the specialists should regularly discuss screening-specific issues. According to the experience of other countries, the involvement of the coordinating institution in this process of cooperation is fruitful and ensures the continuity of education and the exchange of experience.

As mentioned above, at the present moment in Latvia, all guidelines may be considered only as recommendations due to the lack of the regulatory basis.

The quality control and assurance program

A clear and comprehensive quality control and assurance program for the screening processes and manipulations is required to perform the screening activities at the optimum level — following standard methods — and thus exclude any inadequacy and deviation from the protocols in various locations of the screening manipulations. All specialists should take part in the quality control program, including regular testing of individual professional skills. The quality control system should be supervised by an independent institution or the screening coordination center.

National responsibility

The screening policy guidelines document should mention the applicable laws that ensure lasting existence of the program. Upon starting a cancer screening program in

Latvia, there should be government guarantees to ensure sufficient and planned financing. A screening program is an event for many years or even decades that may not be affected by changes in political power, fiscal problems, and inflation. If the financing for the screening is terminated at any stage, the effectiveness and return of all previous stage financing declines sharply and the funds used in the previous stages can be considered as wasted government expenditure. The government is responsible for ensuring effective operation of the screening program all over the country by providing the availability of services to all residents regardless of their place of residence, social status, level of income, nationality, and age. A government-level responsibility is the identifying the targeted screening coverage adequate for the available financial and human resources. Although significant reduction of morbidity and mortality of the screened cancerous diseases can be achieved only if the minimum coverage of the population is 75%, such target without sufficient amount of resources can actually terminate the program that is started smoothly. The government support is very important when providing wide access for mass media, providing information, explaining, reminding constantly and maintaining the awareness of the population about the cancer screening program by any other means.

The legislative initiatives may not jeopardize the logistics and data cycle of the screening. In this case, a reasonable balance should be created between the common goals of the public health, physical well-being of the population, and the personal data protection.

To implement the screening program successfully in conditions of general scarcity of human resources, it is essential to encourage and maintain private and public partnerships. The specialists to be involved in the implementation of the screening program should be selected based on the qualifications and capacity criteria not the legal form and ownership of the institution.

Monitoring system for the assessment of screening program effectiveness

Each of the specific screenings have its own descriptive indicators, however, many indicators are universal and are assessed as common features of the screening program. They mainly refer to the coverage of the population and the frequency of the pathology findings, as well as — from the long-term point of view — the comparison of these indicators in dynamics.

The indicators (figures) applicable to the screening monitoring and program assessment are listed in Table 3.

Table 3. **The key indicators of the screening.**

Indicator	*Acceptable level*	*Targeted level*
The share of persons invited to the screening in a target group (%)	>90%	>95%
The share of persons attending the screening from the invitees (%)	>95%	>100%
The share of invasive cancers found in the screening (%)	90%	80–90%
The share of II+ stage cancers found in the screening (%)	Round 1 on fact	Round 1 <30%
	Round 2 25%	Round 2 <25%
The share of invasive cancers without regional metastases found in the screening (%)	Round 1 on fact	Round 1 >70%
	Round 2 75%	Round 2 >75%

Summary

1. The organizational principles of an organized cervical cancer are summarized in the recommendations on the cancer screening adopted by the European Parliament as well as in many methodology documents issued in other countries.

2. The screening guidelines required for the implementation of the organized cervical cancer screening cannot be applied legal effect due to the lack of regulatory basis.

3. The procedure for the development of guidelines should be created and approved by the Cabinet of Ministers urgently.

4. Prior to implementing the organized cervical cancer screening, there are a range of preparation measures to be carried out, including clear distinction of authority in screening performance stages, training the screening medical staff, and ensuring long-term financing.

5. A comprehensive quality control and assurance system for all screening stages should be developed and implemented.

6. An institution for the coordination and management of the screening should be established to be responsible for creating a screening database and examination results database, and supervising the whole screening process and its stages.

Chapter 4
Political Initiatives to Improve the Oncology Situation in Latvia

In March 2006, the „Report on the Oncology Situation in Latvia" prepared by the State SIA *Rīga Austrumu slimnīca* (Riga East-Region Hospital) was submitted to Gundars Bērziņš, the Minister of Health of the Republic of Latvia. The report was a detailed presentation of the statistics describing the situation, the structure, and operation, technical resources of the oncology service, the scope of services and their availability in various regions of Latvia. The report identified key issues and outlined solutions. Soon after submitting the report, a verbal assignment was received from the Ministry of Health to produce draft guidelines for developing a national cancer control program for a period till 2017. The draft guidelines were prepared in accordance with the previous year "Report on the Oncology Situation in Latvia" with a chapter added about the oncology area human resources issues, the development issues of the oncology research, as well as estimations of the financial resources required to gradually improve the situation in Latvia. In February 2007, the draft guidelines were submitted to the Ministry of Health.

On March 15 2007, Aigars Kalvītis, the Prime Minister, issued instruction No. 127 „**On a work group for developing measures to reduce cancer incidence and mortality"** in accordance with the Declaration on the Intended Activities. The instruction requested to develop recommended measures to be implemented in order to early diagnose and treat cancer, and a work group headed by Ilze Stobova, an advisor to the Prime Minister, was created. The work group consisted of representatives from ministries, municipalities, as well as experts, doctors, specialists, and representatives of non-governmental organizations. Debates and discussions resulted in an informative report aimed at assessing the issues and asking the Ministry of Health to make the changes required to implement the transition to a more coordinated planning of health care policy thus preventing the possible decline of the situation in the oncology disease area in Latvia. During the operation period of the work group, an active and effective exchange of opinions and information took place resulting in the collection of issues affecting the spread of malignant tumors and the screening, and the outline of possible solutions to the issues (see Table 4).

Table 4. **Issues affecting the cancer screening (for breast, cervical and colorectal screening), and solution options** (The summary of the Cabinet work group documents regarding the cervical cancer).

Description of the issue	Nature of the issue	Possible solution
1	2	3
Informative	**General public:** – insufficient awareness of factors contributing to malignant diseases and ways to prevent such – inability to assess independently the threat posed to one's health and lack of knowledge about early symptoms of the disease – limited access to the information about the screening examinations available that are paid by the state, their conditions; lack of understanding about the importance – not relating the mass media information to oneself;	Continuous popular information through mass media, including the public TV, local (regional) press, radio. Active involvement of municipalities in disseminating the information. Wide involvement of NGOs. Restoring the health studies subject in schools.

	– low availability of information about health care institution that provide cancer screening examinations paid by the state; – not understanding the point of the screening. **Medical staff:** – not understanding the point of the screening – insufficient information about the methodology and policy of the screening procedures – incomplete understanding of the financing procedure – lack of information about the actual situation of service availability in the institutions performing the screening manipulations.	Recurrent distribution of attractive and clear HCISA information about the possibilities to receive screening services, the meaning and importance of the screening. Active involvement of municipalities in the dissemination the information. Developing a detailed methodology, policy, and guidelines of the screening. Regular posting of up-to-date information in the HCISA homepage about the queues (at least twice a month).
Organizational	– No detailed methodology and program of individual screenings developed – there is no single screening registry of population and, consequently, no clinical database and opportunities to track and control the screening stages – no single system for sending out invitations – unreasonable screening referral system (gynecologists are not authorized to issue referrals!) – no assessment is made about the actual technical, professional, and personnel capacity of the screening services provision in health care institutions – no assessment is made about the quantity and geographical distribution of the screenable age residents and the availability of the respective services – there is no data exchange about the findings of the screening – no data available about the screening examinations paid by the residents themselves and in the private institutions – ignoring the historically developed tradition of direct visits to gynecologists (obstetricians)	Creating detailed screening methodology, policy, and guidelines in accordance with the Cabinet regulations on the procedure for developing clinical guidelines (the Cabinet regulations have not been developed) Creating and maintaining a single screening registry based on the data base of residents registered with the existing HCISA population register. Assess the actual technical, professional and personnel capacities of the screening services provided by the health care institutions against the number of people subject to the screening and the targeted coverage, as well as the geographical population density. Entering of all pathology findings data in the screening registry (including the findings of examinations paid by individuals) Involving private practice

	– disproportion between the private and state service providers in gynecology – bureaucratization of the screening examination service referral and receipt process – unimpactable process of forming advance registration (queues) in mammography	gynecologists and health care providers in the provision of public services. Introduce a system to send out individualized invitation letters — referrals based on the screening registry; abandon the general practitioner referral system; ensure notifying the general practitioners of the examination fact and the results.
Professional	There are no common guidelines on screening methodology and the behavior in case of pathology findings. There are no clear authority defined between general practitioners and specialists in case of pathology findings of the screening. There is no quality control for the screening manipulations and all stages. No requirements regarding the required training and professional experience of the personnel involved in the screening. **Mammography screening:** – lack of radiologists trained in the breast image diagnostics – no information available about the suitability of mammography equipment for the screening examinations (specific requirements) – no single description system of mammograms used; the double description not ensured. **Cytology screening:** – taking of the preventive test —smear is delegated to doctors, though, in other countries, it is taken mostly by trained nurses and midwives – the smear taking control is not in place – there is no single database of all smear examinations and recording of clinical data. **Screening of colorectal cancer:** – lack of testing methodology knowledge and inadequate performance of the test.	Creating detailed screening methodology, policy and guidelines including clear definitions of authority and responsibility between general practitioners and specialists. Develop and implement a quality control system for the screening process and stages and to integrate the system in the requirements of the conformity assessment. Establish requirements of the required training and professional experience of the personnel involved in the screening. Extend the opportunities to take postgraduate training in: – breast image diagnostics, – early diagnostics of colorectal tumors, – cytology. Train nurses and midwives in taking the cervical smear and increase the number of test taking locations.

Financial	– Significant prevalence of private gynecologist services and frequent paying for screening services from personal funds – additional expenses for telecommunication services to obtain information and considerable transportation costs for residents of rural areas – unpredictable consumption of time resource to receive the service.	Find solutions to involve private practice gynecologists in providing also public services (for example, in Germany, private practitioners have obligation to provide also certain number of hours of public services. A doctor is a profession included in the list of regulated professions!). Provide for full or partial reimbursement of travel expenses if the distance to the service provider is more than 30–40–50 km (?).
Geographical	– Uneven distribution of health care institutions providing screening examination services – Differences in availability of health care services availability between Riga and rural areas.	Train nurses and midwives in taking the cervical smear and increase the number of test taking locations. Obtaining at least one digital mammography device to ensure the availability of mammography services in the country.

Two months after the work group created by the Cabinet of Ministers began its work, a work group was created following the 24 April 2007 instruction No. 72 of the Ministry of Health „On a work group". Its aim was to assess the necessity to update and specify the preventive adult checkup program stipulated by the 19 December 2006 Regulations No. 1046 of the Cabinet of Ministers „Health Care Organization and Financing Procedure". The work group consisted of representatives from the Latvian Association of Gastroenterologists, the Latvian Association of Gynecologists and Obstetricians, the Latvian Association of General Doctors, the Rural General Doctors Association of Latvia, the Latvian Society of Laboratory Specialists, The Latvian Association of Radiologists, the Latvian Association of Oncologists, and HCISA. The above work group analyzed the existing program of preventive checkups and its performance, experience of other countries and rates of cancer morbidity. The official memorandum was prepared based on the conclusions of the work group and the „Malignant Tumors that Can Be Found in Due Time Through Screening" report of the Public Health Agency developed in 2007 in the framework of the „Development of Public Health Monitoring and Reporting System" project of the EU Transition facility program 2005. Taking into account the low activity of residents (the examinations included in the program of preventive checkups and paid by the state have been received by only a half of patients registered with general practitioners) and the constantly high morbidity and mortality caused by malignant tumors, the workgroup came to a decision to widen the task assigned to it and review also the necessity of implementing an organized cancer screening.

Both high-level (the Cabinet of Ministers and the Ministry of Health) work groups provided the following output and conclusion:

1) The cancer control can bring better and more lasting results if the **organized cancer screening** is implemented in Latvia. In such case residents come to the test upon receiving a centralized invitations; their attendance is tracked and the test results controlled to find any symptoms of malignant tumors in an early stage of the disease as possible. The transition to such system and first significant results can be achieved through lasting application — at least 15–20 years;
2) the most significant **benefit of the organized screening** is the discovering of precancerous diseases, treatment of which completely prevents the development of cancer, and the diagnostics of cancerous disease as an early stage as possible, reducing potential treatment costs in inpatient clinics, possible disability and mortality. To implement the organized screening, changes are required in the current malignant tumor morbidity reduction policy;
3) By ensuring due finding of precancerous diseases in early diagnostics of cancer, the costs of complex treatment will be reduced and the survival of patients resulting from the treatment will increase considerably.

The solutions in relation to the cervical cancer as developed and suggested by the work groups can be summarized in the following recommendation: **ensure the transition to an organized cervical cancer screening with the goal to achieve maximum coverage of the target group by implementing the following sub-measures**:

- Create an information system in the health care area to enable organized activities and control of the implemented measures, as well as the monitoring of the screening processes. The work group suggests developing such system based on a single approach that should be provided by HCISA in collaboration with the Health Statistics and Medicine Technologies State Agency (HSMTSA). The proposals about the feasibility to develop a joint information system, its structure and financing should be submitted to the Ministry of Health of the Republic of Latvia;
- Develop a draft information campaign with the aim to inform the society about the cancer, the advantages of early finding, opportunities to take preventive checkups free of charge. The work group proposes that the Public Health Agency develop proposals and submit them to the Ministry of Health of the Republic of Latvia;
- Develop proposals for acquiring the mammographs required for the screening, human resources preparation and updating training programs. The work group proposes that this information is collected by HSMTSA and the Medicine Professional Education Center in collaboration with HCISA and the proposals submitted to the Ministry of Health of the Republic of Latvia;
- Develop the output rates and indicators of the estimated costs and benefits, including long-term, of the screening policy (perform a detailed analysis of the estimated costs and benefits, including long-term, of the screening policy). The work group suggests that this model is developed by HCISA in collaboration with HSMTSA and submit to the Ministry of Health of the Republic of Latvia;
- Promote the development of supporting environment in municipalities and local communities; the work group proposes that the Ministry of Welfare in collaboration with the Ministry of Regional Development and Local Government and the Latvian Association of Local and Regional Governments develops a set of measures and submit them to the Ministry of Health of the Republic of Latvia by 1 November 2007;
- Develop the payment terms regarding the service organization and provide a specific contract form for private practices of doctors on providing services of the organized screening and obligating all doctor practices to provide such services.

The work group proposes that the Ministry of Health of the Republic of Latvia develops a set of measures for the transition to an organized cancer screening by developing the Oncology diseases control program (the national cancer control program)

and submitting it for review in the Cabinet of Ministers under the standard procedure. At the same time, it is proposed to establish that the performer and supervisor of the organized screening is HCISA which, in order to provide the operations, need to create a new department: the centralized cancer screening administration unit[6]. The unit can start its operation on 1 January 2008, provided that the financing is granted.

On 27 November 2007, the report was reviewed in the meeting of the Cabinet of Ministers and the decision was made to support the implementation of the organizes cancer screening in Latvia beginning from 2009, providing that the required preparatory work is performed during 2008.

Summing up the above, we can conclude that over the last year a considerable advance is achieved in the attitude of the government and legislators towards the malignant tumor morbidity and mortality situation. The political initiatives and resolutions of the last months give hope that the planned activities will be implemented and an effective control of the spread of oncology diseases in Latvia will begin just like in other European Union countries.

To ensure the availability of screening services all over the country, prior to implementing the organized screening several preparatory works must be completed, including the calculation of available resources and the analysis of the service provider structure and capacity.

Summary

1. *In 2007, a considerable advance in the attitude of the government and legislators was achieved towards the cancer morbidity and mortality situation.*
2. *The existing obstacles and problems for the implementation of the screening program in Latvia are identified.*
3. *The output and conclusions of the work groups fully correspond to the cancer screening recommendations issued by the European Parliament.*
4. *The political initiatives that occurred over one year have resulted currently in written proposals and conclusions being a significant grounds for implementing the organized screening, however, to begin actual screening, long-term financial guarantees are required from the state.*

[6] According to the information in mass media in October 2007, HCISA plans to establish a Screening Monitoring unit in 2008.

Chapter 5

Implementing Cervical Cancer Screening in Latvia

The cervical cancer screening is based on three key elements of the process:

1) active participation of women involved in the population screening program;
2) ensuring availability of gynecologic care services and test-taking;
3) proficient cytological testing in medical laboratories.

Each of above elements is equally important in an effective implementation of cervical cancer screening; therefore, all elements are discussed below in detail in the context of the actual situation in Latvia.

Based on the data mentioned in the previous chapters about the organizational principles of the organized screening, the principal diagram of the cervical cancer screening process was created. It can be used as a matrix for planning of cervical cancer, breast cancer, and colorectal cancer screening.

Age risk group of women

The women in the age risk group who should be subject to regular cervical screening examinations, at present, prior to implementing the organized screening, can be considered a group studied only in the terms of quantity. As mentioned above in previous chapters, the information and invitation system has not yet been developed in Latvia, and the decision to undergo the screening to a large extent depends on the conscientiousness of the woman, her care about her health, her ability to understand the system of current health care service organization, often from her level of education and, accordingly, also from her social and economic status, etc. When the coordinating institution of the organized screening will be created, it will be delegated all functions in providing the availability of services and preventing the differences in availability based on the specifics of the population behavior and social integration. The assessment of the capacity of service providers and the estimations of the possible load at various levels of coverage should be based on the demographic figures of female population in various age groups. The paper uses the 2005 demographic data [source: the Central Statistics Office data]. Based on the European Union recommendations regarding the organization of cancer screening in relation to cervical cancer screening age group between 25 and 69, and the intention to begin the organized screening from 2009, **the target group cohort is calculated for the female population at the age between 20 and 64, and it includes 729,900 women** (rounded — 730,000). The distribution by age groups is displayed in Figure 12.

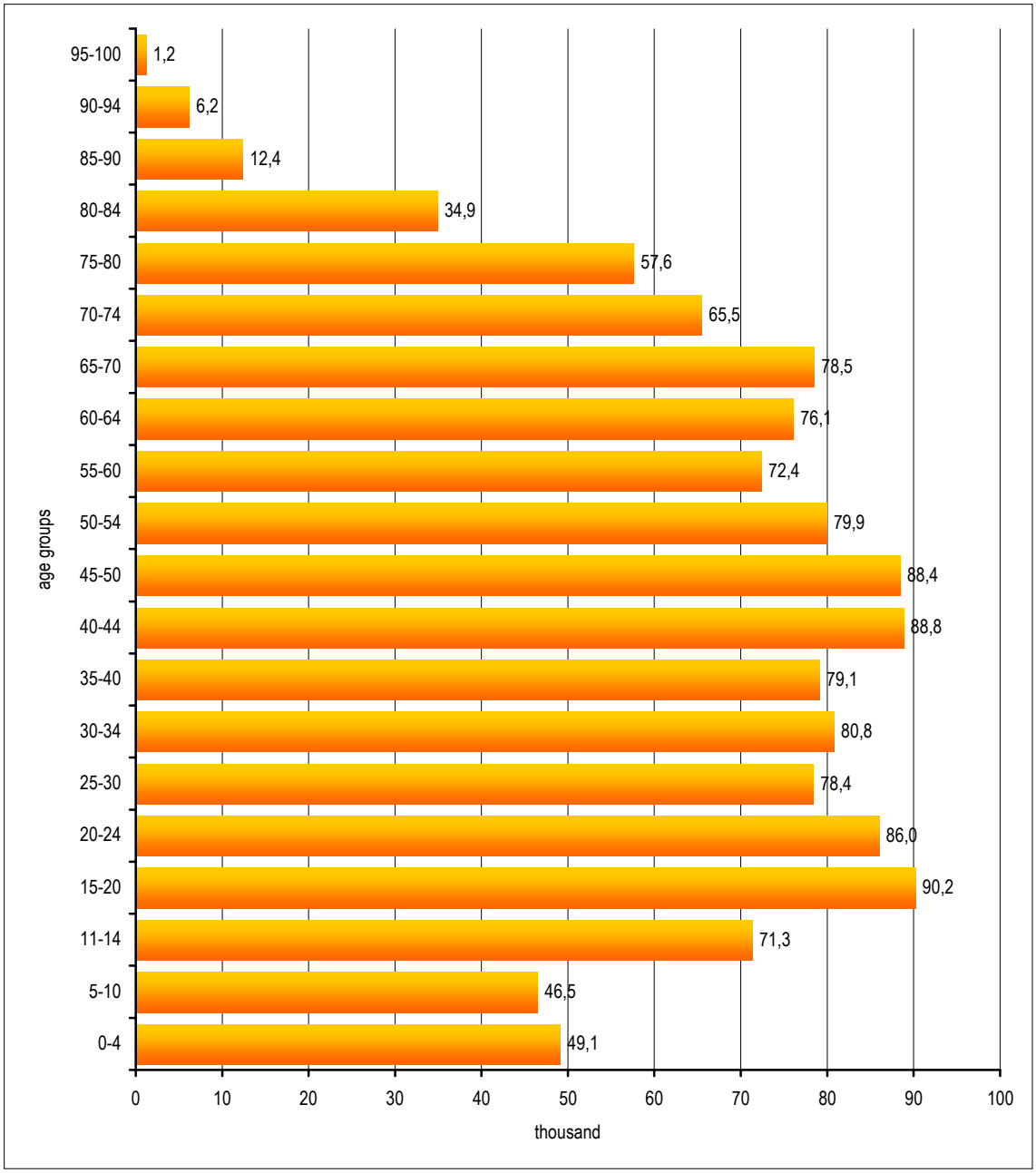


Figure 12. **Distribution of female population by age groups in Latvia, 2005 (the Central Statistics Department data).**

The cohort includes women from age of 20, because by the implementation of the organized screening and the increase of the coverage rates by the targeted 75% they will have been reached age of 25 — the age provided for in the screening program.

Gynecology care services in Latvia

Unlike in many other European countries, the primary preventive gynecological services in Latvia are mostly provided by specialists — gynecologists. In many other places of the world, the customary preventive examinations are conducted and the necessary analysis is taken by trained general practitioners and even nurses and midwifes. For various reasons this general practitioners' area of expertise is limited in Latvia. A woman can receive preventive gynecological care both at her general practitioner and at a gynecologist.

Traditionally, most women request gynecological services for preventive and health promotion reasons or in the case of having a gynecological disease. The role of the general practitioner in such cases is mostly as a mediator between the primary and secondary levels of health care. This work requires additional knowledge and skills. The general practitioner's decision to handle the problem by him/herself or to seek a gynecologist's help is determined by the level of expertise of the professional gynecological services. Every general practitioner is daily confronted with very sensitive questions asked by patients during the visits. According to the data from the Latvian Association of Family Doctors, only 30 out of 1470 general practitioners in Latvia provide gynecological care for their patients. As a result, **the cooperation between general doctors and gynecologists is vital in order to provide complete care for the patients**.

At the moment, there is an additional limiting factor for the availability of gynecological care. According to the Latvian Association of Gynecologists and Obstetricians, **only 34 out of approximately 500 gynecologists working in Latvia in 2007 had direct contracts with HCISA**. Although the gynecological services are partially provided by private companies — health care centers and doctorates, most gynecologists in Latvia have private practices, where preventive examinations are provided at a cost that usually by far exceeds the payment rates for the services offered by HCISA. The situation is made even more complicated by the 19 December 2006 Regulations No. 1046 „Health Care Organization and Financing Procedure", according to which all examinations referred to by a specialist without a contract with HCISA have to be paid for by the patient.

The situation concerning the disproportion between public and private services in Latvia is directly dependant on the existing policies for payment and financing of health care. One of the suggestions from the work groups in the chapter "Political Initiatives for Improving the Oncology Situation in Latvia" was **to change the existing financing rules and procedures in order to facilitate privately practicing gynecologists' interest to get involved in providing screening services disbursed by the state. One solution would be for HCISA to sign cooperation contracts without financial guarantees with these gynecologists in order to give them an opportunity to test the analysis from the preventive examinations within the screening system, i.e., finance it by the means budgeted for the program. This course of action would embody the principle "Money follows the patient".**

When analyzing the regulatory statements concerning financing of health care services, the work team from the Ministry of Health concluded that this principle could only be carried out in practice after **establishing a centralized system for sending letters and referrals**. In that case, upon the arrival at a privately practicing gynecologist with an approved letter of referral from the coordinating institution, the woman will only have to cover the costs of the gynecologist's services, while the laboratory testing will be paid for from the screening program budget directly to the provider of these services (the laboratory). Bringing this principle to life would remarkably improve the availability of preventive gynecological services and would allow to more optimally employing the private practitioners' resources in carrying out the national program.

As taking a cytological smear is a simple procedure and can be performed by nurses and midwives as it happens in most European countries, including the neighboring Finland and Estonia, employment of these resources could further expand the availability of gynecological services.

Establishing authority of a gynecologist and an oncogynecologist

Certain ambiguity exists regarding separation of areas of authority of gynecologists and oncogynecologists in Latvia in cases where the cytological screening results suggest a precancerous stage. In absence of certain proof and diagnosis of cervical cancer, in many

countries the precancerous in-depth examinations, prevention measures and medical attention is provided by gynecologists based on the existing guidelines included in the cervical cancer screening program. Since such guidelines do not exist in Latvia, it is vital that they be developed and followed. There is no database for registration of diagnosed precancerous states and treatment results. When analyzing the present situation in treating precancerous states for cervical cancer in Latvia, we, unfortunately, have to conclude that due to historical reasons, **there is no tradition for widespread and systematic use of colposcopic examinations in outpatient gynecologic practices**. This examination method is vital for successful prevention and observation of precancerous cervical diseases, especially serious cases. **We have to start introducing this method and provide appropriate training in order to implement it in outpatient gynecological care. In that way, within a transitional period of 5 years, the treatment of precancerous cervical diseases should be delegated to oncogynecologists (according to adopted and approved guidelines)**.

The history of cytological testing in Latvia

Cytological testing for the cervix is a widely accepted and employed method for detecting pre-invasive and early invasive changes before the appearance of symptoms. In order to perform the testing, a sample of epithelial cells from the transformational zone of the cervix is taken and examined under a microscope by trained and experienced cytologists. Early and timely diagnostic of cervical intraepithelial neoplasia (CIN) and adequate treatment with minimally invasive procedures can completely prevent the possibility of developing cervical cancer, thus improving women's standard of living and decreasing mortality rates from this type of cancer. As a highly subjective field of expertise, cytological testing fully depends on the qualifications and skills of the cytology specialists, as well as frequent control and maintenance of the quality of these services.

There are long-standing traditions for early diagnostics of cervical cancer. As early as the third decade of the 20th century, upon arriving from a trip to the United States, Professor Pauls Stradiņš pointed out the enormous role that cytological testing has in the diagnostics of tumors and encouraged Latvian doctors to pursue this area of expertise. There was a well-established and morphology school and workforce in Latvia, but cytological testing methods were only seriously introduced after the II World War. The use of cytological testing has been widespread since 1960ies, which has facilitated the propagation of this method within the laboratories of the Latvian health care institutions. At the same time, the necessary steps for performing regular wide-scale preventive cytological examinations in Latvia were taken. In 1960, the first Latvian doctor specializing in cytology was employed at the largest specialized outpatient hospital in oncology in Latvia — the Riga Oncology Outpatient Hospital (ROOH). Already a few years later, ROOH had established a specialized cytological laboratory with several employees. The laboratory had two main tasks:

1) Perform cytological testing of ROOH patients,
2) Participate in the organization of cytological screening together with performing preventive gynecological testing of women throughout the country.

Other tasks included training doctors and laboratory assistants specializing in cytology, as well as instructing nurses, midwives and gynecologists in properly obtaining and dispatching material for cytological testing. Standardized forms were created for dispatching the material for examinations, as well as for designing the response (report of the testing). There were repeated issues of newsletters, methodology recommendations concerning standardized availability of cytological testing, classification of pathology discovered by cytological testing etc. Over ten years, a vigorous cytology tradition had been established, featuring several outstanding specialists in the field. The cytological

testing of that time played an impressive role in the decrease in the cervical cancer incidence. From 1970 to 1978, 2.5 million women had been cytological tested as a part of preventive gynecologic examinations. According to ROOH, the cervical cancer incidence rate decreased from 31.7 cases per 100,000 women in 1963 to 26.5 cases per 100,000 women in 1968. From 1976 to 1978, the incidence rate was further reduced to 23 cases per 100,000. In 1984, the incidence was 16.8 and in 1992 — 11.9 cases per 100,000 women, while the lowest number of cases was achieved in 1989 — 8.9 cases per 100,000 women.

Until the end of the 1980ies, the extent of preventive examinations was increasing. In the beginning of 1980ies, this included complex and periodical population examinations, both organized and unorganized and individual oncology testing for people that sought any help at health centers and hospitals. Starting from1983, preventive gynecological examinations with cytological testing were available for all women aged 18 and over. There were 7 interregional highly operative cytology laboratories, each with a capacity of 200–250 thousand tests per year. In 1984, the cytological screening was recommended as a compulsory part of the system for the prevention and treatment of disease for all inhabitants or the so-called CCPMES (complex computerized population medical examination system).

In 1989, the compulsory preventive examinations were terminated. From the mid-1990ies, when the number of women's preventive examinations and, therefore, also the amount of cytological testing was rapidly decreasing, the incidence rates rose again, amounting to 18.4 cases per 100,000 women in 2004. Dynamics of the incidence rates from 1963 to 2004, following the period of compulsory gynecological examinations are displayed in Figure 13.

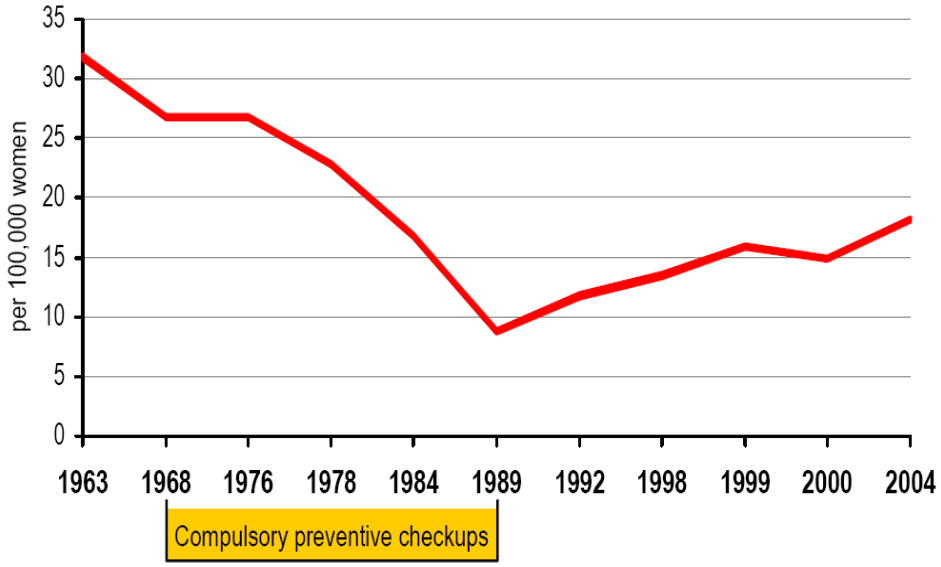


Figure 13. **The dynamics of the cervical cancer incidence rates in Latvia, 1963–2004, per 100,000 women.**

Unfortunately, the last 15–20 years have also brought negative changes on the health care system in Latvia. As in many other fields of medicine in Latvia, also in cytology the numbers of professionals have decreased rapidly, the average age of active specialists is increasing, and training of new specialists is hampered.

This situation is caused by the low salaries in health care, general lack of personnel and consecutive increase in workload, as well as the general decrease in the prestige that medical professions have according to public opinion.

From the once operating 7 regional specialized cytology laboratories, **only three are still open**:

1) Riga East-regional university hospital clinic Latvian Oncology Center,
2) Daugava hospital in Daugavpils city,
3) Seaside Hospital in Liepaja city.

Cytology testing is certified in several other laboratories in Latvia, where testing is performed as one of the laboratory certified compliance areas. Almost everywhere, except the laboratories of the Riga East-regional university hospital clinic and the Seaside Hospital, cytological testing is performed without involvement of cytology laboratory assistants. **In 2007, there has been opened a new cytology laboratory, employing both laboratory assistants and doctors specialized in cytology**.

Availability of human resources for cytology testing

In the framework of the screening program, cytological testing for healthy women without any particular gynecological complaints is performed in two stages in conformity with the experience of other countries. First, the preparation is subjected to initial screening in order to evaluate its quality and conformity with standards for norm or pathology. This stage is completed by laboratory assistants trained in cytology, who in case of high screening coverage have a key role in completion of this work. Doctors–cytologists perform repeated examination under microscope for those preparations that have been labeled suspicious, unclear or clearly pathological by the assistants. In order to avoid testing errors at the initial stage, there is perpetual internal quality control at the laboratory, which includes randomized repeated testing of preparations that have been evaluated as normal. Another procedure used for internal quality control program is assigning the same preparation for analysis at several assistants simultaneously, documenting the process. These control procedures for testing quality have to be recorded and archived.

HSMTSA databases of the medical staff employed in providing cytological services are incomplete and do not give an objective overview of the situation due to several reasons. First of all, these registers include certified laboratory assistants without remarks on special training in cytology, and do not incorporate other laboratory staff working with cytology, such as biologists and laboratory assistants with specialization in cytology. As a result, this official state source does not provide reliable information on the number of specialists who are working in the field and could be involved in carrying out the national program for cancer screening.

Currently, there are only 11 laboratory assistants trained in cytology employed in the Latvian laboratories. Seven of these are working at the Latvian Oncology Center laboratory.

According to the professional regulations approved by the Latvian Association of Laboratory Specialists, cytology is a sub-profession of the laboratory profession. Although the job of a cytologist often involves testing and interpreting clinical material which requires using information from the clinical anamnesis, people occupied as cytologists often lack the relevant medical education — there may be biologists, chemists, geneticists, and even zoologists among them. This situation has resulted from the existing shortage of human resources; however it has to be taken into account when calculating the number and workload of available specialists for implementation of the organized cervical cancer screening on a nationwide scale.

According to the Latvian Association of Cytologists, currently there are about 29 laboratory specialists employed with cytological testing. Calculations that have been made to determine the average age of these employees have estimated it to be 57 years. Therefore, as the national screening is started in 2009, most specialists will be close to retirement. **In addition, 13 of the 29 doctors working with cytology have already passed the retirement limit.** The oldest specialist currently employed is 73; the youngest is 33 years old.

The number and age dynamics of cytology specialists are unequivocal indicators of the necessity to train new cytology specialists. In the training process, it is important to remember that cytological testing is one of the rare laboratory manipulations where quality completely depends on the individuals' professional qualifications, experience and even personality and characteristic traits, as well as the opportunity to consult colleagues in the course of the work when interpreting complex samples.

Based on the analysis of the data supplied by HCISA about the individuals performing cytological screenings, we can conclude that it is not possible to identify the specialists actually working. In the HCISA database, in referral vouchers from several institutions, whose information is filed in the APANS[7] database, can present any laboratory specialist as the one performing the cytological screening manipulations. For example, some institutions list the laboratory manager, owner, administrator or head, as long as this person is a certified laboratory specialist. From the financial reporting perspective, identifying the particular person has no importance, which leads HCISA not to request adequate information on these matters. When the organized screening is implemented and the strict quality control requirements maintained, the lack of this information will disable assessment of the specialists' individual knowledge and skills, since the data on specialists employed in the Latvian Association of Cytologists and HCISA/APANS databases are incompatible.

From the above-mentioned circumstances we can conclude, that at the moment in Latvia there are no objective and trustworthy data available on specialists and laboratory assistants working in the field of cytology. All estimations of the number of specialists are approximations, and from now on it will be assumed that the number of people employed in the field can be deduced from the list of active members of the Latvian Association of Cytologists (that participate in the meetings and of whom there are informal accounts to be employed in the field), that states the known cytologists and laboratory assistants working with cytology.

At the moment, the information available from both HCISA and HSMTSA gives only an approximate estimation of the human resources available in the area of cytology. A well-timed exploration of the available human and material resources has to be performed before implementation of the centralized screening, requesting information from all those health care institutions, where cytology is certified area of expertise. This task should be undertaken by the Screening Monitoring department that is intended to start functioning as a part of HCISA in 2008.

Training of laboratory specialists-cytologists in Latvia

Since 2000, laboratory doctors in Latvia are trained by the Riga Stradins University laboratory specialists' resident-ship. The resident-ship studies last 4 years, during which the resident is trained in all areas of laboratory diagnostics expertise including cytology. The cytology course lasts 2 months and provides theoretical and practical knowledge in the area of cytological testing. The course is led by two experienced cytologists — Valerija Grjunberga from the Riga East-Regional university hospital clinic and Romalda Grigalinovica from P. Stradins University hospital clinic. In discussing residents' training issues with Dr. V. Grjunberga, she gave opinion that within such a short course it is only possible to provide a superficial insight into the field of cytology, while obtaining thorough practical skills would take at least 6 months extra theoretical and practical training. After having completed the residency and passing the certification exam, the laboratory doctor obtains the right to practice in all areas of laboratory diagnostics, including cytological testing. In order to acquire deeper knowledge and more experience in the field of cytological testing, there is an opportunity to take extra training for a tuition fee at a

[7] APANS — ambulatoro pakalpojumu automatizētā noteikšanas sistēma (automated system of outpatient services identification)

cytology laboratory, preferably for at least 6 months. This opportunity is sometimes used by laboratory doctors that already have obtained their certificates.

Although, in theory, all laboratory doctors have the right to work as cytologists after having completed the resident-ship, quality testing can only be carried out by a specialist who has at least 6 months practical experience under the supervision of an experienced cytologist. Since cytological testing may involve detecting grave and potentially lethal pathologies, the cytologist's qualifications and critical approach to one's own practical experience are important factors for being able to undertake a job within cytological testing. **Within the last 7 years (since 2000) 14 specialists have received cytological training as a part of the resident-ship, and 3 of them are currently working in cytological testing.**

In order to evaluate the program available for cytological training in Latvia, the author offers information about the training program for cyto-technicians at Indiana State University's (USA) Department for pathology and laboratory medicine for comparison. There, training takes 3 semesters (1,5 years) and includes sub-programs of normal gynecological cytology, pathological gynecological cytology, methods of medical cytology, pulmonary disease cytology, cytology of body liquids, cytology of the gastrointestinal tract, cytology of the urethra, thin needle aspirate cytology, and cytology research. Practical skills are consolidated and tested in seminars that include individual testing of sets of cytology preparations.

Taking into account the present human resource situation and the need to train new cytology specialists in the nearest future, it is obviously also necessary to expand the cytology training program and prolong the training period, supplying the courses with practical exercises.

When analyzing the methodology aspects of cytology testing in Latvia, one cannot avoid observing a historical peculiarity — Latvia does not use the classical *Papanicolaou* methodology for preparing the testing materials, although this methodology is employed throughout EU countries. **In Latvia, the *Leishman* methodology is applied (and also taught). Thus, it is necessary to include learning, training and implementing of the *Papanicolaou* methodology, as well as the costs of substituting the *Leishman* methodology in the course of the transition period (5 years).**

The Specific Principles of Organizing Cervical Cancer Screening

When organizing cytological screening on a nationwide scale, it is necessary to implement the following **common organization principles** in all laboratories in order to maximally standardize the procedures in the single screening system:

1. Responsibility for all stages of cytological testing.
2. Quality control responsibility.
3. Requirements set for a cytology laboratory.
4. Requirements to cytology laboratory assistants and doctors-cytologists.
5. Required materials.
6. Sample testing process.
7. Workload requirements and limitations.
8. Data recording and database creation.

1. Responsibility for all stages of cytological testing

The management of a cytological laboratory should only be assigned to a certified doctor with specialization and experience within the field. His/her obligations will include supervision of the staff performing cytological testing, randomized quality control of the quality of the tests with no pathologies and supervision of the implementation of the

quality control program. The head of the laboratory should have direct contacts with gynecologists and receive extra information in the cases where pathologies are found, comparing the laboratory testing with results from histological testing. Gynecologists must be frequently informed of the proportion of non-informative samples sent for testing. One must also solve potential technical problems connected to taking samples.

2. Quality control responsibility

The head of the laboratory is responsible for controlling the whole quality system and implementation of work methods, as well as their conformity with existing instructions, methodology and guidelines. The other laboratory staff is responsible for performing compulsory quality evaluations and ensuring constant quality levels, as well as maintaining professional cooperation with colleagues.

3. Requirements set for a cytology laboratory

The cytology laboratory has to perform a sufficient number of tests so as to maintain an adequate level of experience and expertise skills, both regarding normal and pathological samples. Although different countries have different prescriptions for the size of the recommended amount, most guidelines recommend that no less than 15,000 samples be tested annually. In the course of laboratory work multiple microscopic examinations of pathological samples should be performed in order to ensure that all employees obtain experience with different types of samples. When testing non-informative cytological samples with insufficient amount of material, this fact has to be noted in the testing report, along with a recommendation to provide a new sample. Attempts at testing inadequate samples can result in wrong diagnosis and mislead both the gynecologist and the patient. The archive of a cytology laboratory must include both pathology and normal samples. It is recommended to perform periodical random reviews of the archive materials.

4. Requirements to cytology laboratory assistants and doctors-cytologists

Every certified **laboratory assistant with specialization in cytology** has to have had practical training that is evaluated and attested in a written form. The work of the laboratory assistant should be supervised by a doctor with a specialty in cytology, ensuring that the assistant's knowledge and skills are improved. It is recommended to frequently perform randomized reciprocal screening of the tested samples. All cytology laboratory assistants have to perform compulsory quality control routines, documenting and correcting any errors. The **senior cytology lab assistant** has to have at least 5 years experience with cytology, supervise the testing routines of others, and control the quality of the primary screening, devoting special attention to pathology findings. The senior assistant has to periodically discuss specific pathological sample results and their interpretation with the supervising doctor–cytologist. A certified **doctor-cytologist** is responsible for the contents of testing reports and recommendations submitted to the gynecologist, he/she approves all testing reports in case of ambiguities from first-time testing and approves the final content of all testing reports. The doctor-cytologist has to analyze all cases where cytological and histological testing has brought different results. Doctors-cytologists have to take care that the cytology lab assistants' qualifications are updated and raised. All employees working with cytological testing and registration have to follow strict confidentiality rules with regard to the patients' medical and personal information.

5. Material requirements

The laboratory has to be situated in suitable premises that support all work and quality control demands. The premises for taking samples, coloring and microscopic examination have to be separated, well ventilated, lighted and spacious. Adequate and

ergonomic furniture is very important for sedentary work. For cytological testing, one should use high quality binocular microscopes that have to be subjected to regular check-ups and technical maintenance. The objectives of 10X and 100X immersion are required. The laboratory should have cytology manuals and other theoretical reference materials on cytology available. Detailed descriptions of all methods used in the laboratory have to be made available to all employees.

6. Sample testing process

The preventive cytological smears are tested by a certified and trained cytology lab assistant. If abnormal, mutated cells are found, the smear is passed for reexamination to a doctor-cytologist who performs testing until final conclusions and recommendations can be made. The retesting may be performed by two other lab assistants, one of whom is the senior assistant, or the retesting is performed by a doctor-cytologist. It is required if:

- The sample is of unsatisfactory or low quality;
- The sample has been taken repeatedly;
- The referral that follows with the sample includes indications of suspicious phenomena or possible anamnesis of the disease;
- The sample has to be used for internal quality assessment;
- The smear gives the first normal results after previous pathology responses;
- The archived samples that have been labeled normal if pathological changes are found for the same patient within a period of five years.

The primary testing of the smears has to be performed by the doctor-cytologist in the following cases:

- If the smear has been taken from a post-menopausal woman with atrophic, hard to classify and possibly displastic cells following a recommendation for repeated testing after treatment course;
- If the referral contains information about possible disease symptoms or diagnosis;
- If the sample contains endometrial tissue atypical for menopause;
- If the referral contains information about a recommendation for histological examination;
- If the first testing of the sample has produced conflicting conclusions.

7. Workload requirements and limitations

The cytological testing is a completely subjective method, so it is vital to follow the recommended testing capacity and not to exceed the advisable number of testing manipulations during a period of time to avoid mistakes caused by tiredness or eye exhaustion.

Guidelines for cytological testing usually advise that working at a microscope should not exceed 6 hours per day and there should be breaks at least once every two hours. Maximum daily workload can be prescribed differently in different laboratories; however, it is important to remember the basic recommendations that should not be exceeded: 6-8 smears per hour and not more than 100 preparations per specialist within 24 hours. This basic workload allows carrying out internal quality control measures.

International guidelines recommend that any separate cytological sample be tested and a review submitted within up to ten days. In most laboratories in Latvia, testing takes on average not more than 2-3 business days.

8. Data recording and database creation

A cytology laboratory must have an elaborate database, which contains not only information about the patients, but also data of clinical findings, recorded recommendations, inadequate samples, information on the employees performing the tests

and other information that makes it possible to assess the laboratory's work on the whole, allows restoration of previous tests, and can be a valuable source for the cooperating gynecologists when making reports on screenings and cytological testing, as well as for self-evaluations. Every cytology laboratory has to responsibly comprise an archive the tested samples, as well as find resources for storing samples that have been labeled normal.

When implementing such strict procedures for quality control for health services, one always meets opponents claiming that such high standards can only be met in the big and rich countries and that our resources, both financial and human, are too small to afford it. However, the size and wealth of a country cannot excuse neglecting international guidelines, quality demands and high standards for laboratory work. Solutions for many problems start with honest and collegial identification of imperfections and objective awareness of their sources. There are long-standing traditions for cytological testing in Latvia, and they make up a solid base for improving this method of diagnostics to the highest quality standards.

The current geographic distribution of providers of cytological testing services and the number of services

According to the information from HCISA on the amount of the cytological screenings performed in Latvia in the first 9 months of 2007 and the geographic distribution of the providers of these services, a graphical calculation of indirect availability of these services has been made.

Table 5 shows the distribution and the amount services supplied in different areas of Latvia, divided by regional branches of HCISA.

The information provided in the table does not reflect the actual location of the service providers, since the private laboratories (E.Gulbis laboratory, NMS, and the Central laboratory) provide testing services to clients outside their district both in their branches and by transporting the samples with courier services. However, the available information allows us to conclude that two thirds of the total amount of work financed by HCISA is carried out by companies situated in the Riga territorial department, while the remaining work is almost equally divided between service providers in Latgale and Kurzeme regions.

An additional circumstance that does not allow one to evaluate the current situation with respect to amount of work and workload of the individual service providers is the fact that the available information only covers the services paid for by the state (HCISA). Information about services that have been paid for by private means or through insurance companies is not fully available.

Table 6 displays information on women's cytological examinations (on the amount of manipulations performed and the number of cancer incidences found) provided by HSMTSA that annually summarizes data on all health care institutions, including private companies. HSMTSA data on cytological examinations of women are included in Table 6.

Table 5. **The distribution and the amount services supplied in different areas of Latvia, divided by regional branches of HCISA, first six months of 2007.**

Region	*Institution*	*Manipulations*	
		total number	*% of total number*
1	2	3	4
Riga territorial department	Central laboratory	9714	
	E.Gulbis laboratory	16878	
	NMS laboratory	21434	
	P.Stradiņa hospital	974	
	Rīgas Austrumu klīniskā universitātes slimnīca (Riga East-Regional Clinical University hospital)	88967	
	Rīga Regional hospital	1151	
	Salaspils Health Centre	1545	
	Torņakalna outpatient clinic	3399	
	Veselības centrs 4 (Health Centre 4)	2019	
	Jelgava outpatient clinic	6273	
	Total:	**152354**	**64.0**
Kurzeme region	Dobele and surrounding area hospital	3600	
	E.Gulbis Kurzemes laboratory	4043	
	Seaside Hospital (Liepāja city)	20907	
	Talsu hospital	3492	
	Ventspils outpatient clinic	5180	
	Ventspils hospital	3540	
	Total:	**40762**	**17.3**
Vidzeme region	None	0	
Latgale region	Daugava hospital (Daugavpils city)	12505	
	Daugavpils regional hospital	5345	
	Dinas, medical company	1618	
	Grīva outpatient clinic	846	
	Jēkabpils regional central hospital	5381	
	Ludza regional hospital	2175	
	Preiļi hospital	4447	
	Rēzekne laboratory	8781	
	Total:	**41098**	**17.5**

Table 6. **Cytological examinations of women in Latvia, 1997–2005** (HSMTSA data).

		1997	1999	2001	2003	2005
No. of cytological examined women in Latvia:	abs.number	460000	356986	339996	336996	332471
	%	45.6	35.6	34.4	34.2	33.7
from which in Riga:	abs.number	222845	129385	109354	108119	121739
	%	62.2	36.0	30.3	29.9	36.3
Diagnosed cancer (no. of cases)		191	208	177	200	210
Cancer findings in preventive checkups (%)		7.2	4.3	2.3	6.0	2.4

Although the data in the table refers to the total number of cervix uteri smear tests performed in Latvia, it does not allow an accurate estimation of number of cytology screenings and the target population coverage of these tests for several reasons:

1) It shows all examinations in total without specifying the number of patients, which means that total numbers include patients that have given several smears within a year;
2) The age and target groups of women are not mentioned, which means that the numbers include women outside the age group for screening;
3) Data on results from preventive examinations are not completely reliable, since the definition of preventive checkup has changed since 1997 and certainly did not correspond to the traditional definition of cancer screening.

However, **the data from HSMTSA give a general idea of a decrease in the number of screenings, especially in Riga district, with a simultaneous decrease in geographic distribution**. At the same time, the frequency of findings of cancer diagnosis increases, while the number of cancer findings in the preventive checkups is low and tends to decrease. When taking into account the biological development of a cervical cancer (transition from a precancerous stage to a cancer lasts several years), the increase in the cancer findings and seldom findings after preventive checkups indicate that cytological testing is most likely performed on the same target group of women, while cancer is most often found in women that do not attend gynecological checkups frequently.

Technical and material coverage of the cytological testing

Adequate laboratory equipment, including minimum room requirements, optimal ventilation, adequate and sufficient lighting, is vital for high quality cytological testing. Ergonomic laboratory furniture and compliance with advisable work and recreation periods within a working day are very important factors for ensuring the necessary efficiency at the lab. These requirements have, however, received low attention in the demands for quality assessment in Latvia, which has resulted in very different working conditions in the various laboratories that could only be summarized after a purposeful inspection. The most important technical equipment at the cytological laboratories is the microscopes and their condition. Unfortunately the HSMTSA database does not contain information on the number of microscopes, their type and date of purchase. Technical maintenance procedures for microscopes have not been well defined, and maintenance is performed at varying time intervals, most often in case of damage of mechanical or optical parts. When implementing a national screening program, data on the existing and acquirable microscopes is very important, since the need to replace out-of-date microscopes can notably increase the costs of the screening program. In order to ensure high quality standards for cytological testing, it is also important to make sure that the necessary reagents, including dyes, are applied and stored correctly, noting their expiration dates. All sample preparation protocols must include descriptions of reagents to use and laboratories must follow these guidelines.

Chapter 6

Estimate of workload and human resources required for implementing national cervical cancer screening in Latvia

The estimation is based on an annual number of cytological tests, assuming that the target population in 2009 will consist of 730,000 women. Taking into account that smears from the cervix of the uterus have to be subjected to cytological testing at least every third year, and assuming, that the population will not change within the three-year period, it means that 33.3% or 243,090 women have to be tested each year, assuming full coverage.

Since the cytological screening has to be carried out with the current insufficient human resources, it would not make sense to share the labor between cytology lab assistants and doctors with a university diploma in biology. For these reasons, it is assumed that the number of specialists available for the implementation of the cytological screening program is 37.

Calculation:

- There are on average 250 working days per year;
- When taking into account vacations and disease periods, one employee works on average 220 days annually;
- It is assumed that all specialists have a single workload that is 160 hours per month within a period of 4 weeks.

Since the cytology laboratory employees perform other tissue and material tests, preparation (dyeing) of samples, internal and external quality control procedures, fill in medical documentation forms, archive preparations, participate in training and education etc. apart from cytological testing, one must assume that every employee will devote approximately 65% of their working time to the cytological testing program:

(220 working days x 8 hours x 37) x 0.65 = **42,328 hours**.

The advisable testing speed is 6 samples per hour, which means that with the current human resources it is possible to test

42,328 x 6 = **253,968 screening cytology samples per year**,

that is 11,000 tests more than planned. Assuming that 100% coverage of the target population is a purely hypothetical assumption that has not been fulfilled in any country using cytological screening the conclusion is that **the human resources in Latvia at present are sufficient for implementation of the screening program**. **At the same time, we need to keep in mind that the age dynamics of the specialists does not allow to count on such optimal workload in long-term or even the next 3-5 years.** When evaluating the possible workload and the current human resource capacity, there is a clear necessity to educate a new generation of cytology lab assistants, as well as doctors – cytologists, since the numbers of these specialists in Latvia are insufficient. One must assume that within the next 3-5 years, at least the 7 specialists that at present time are 70 or more years old will retire. The author does not have access to information on the actual workload and amount of sick-leave of all the specialists that are above the retirement age, but assuming that 7 specialists over 70 work half-time, the total number of tests annually has already diminished to 229,944, which is 13,000 less than planned.

The uneven geographical distribution of the health care institutions with cytological testing laboratories and the expected increase in the amount of cytological testing after implementation of organized screening program indicate that some **alternatives** might be considered:

- Establishing new specialized laboratories, or
- Expanding the capacity of all existing laboratories, or
- Increasing the capacity of some and the largest laboratories, ensuring frequent and fast transportation of the screening cytology samples from the corresponding districts and rural areas.

When organizing cytological testing that corresponds to all quality control and quality insurance demands, as well as considering the available human resources, the last possibility seems the most suited — to concentrate the cytological screening tests in few specialized laboratories. When making selection procedures for providing cytology screening services, HCISA should include the principles described in chapter 5.6 "The Principles of Organizing Cervical Cancer Screening". At the same time, we need to emphasize that the requirement have to be supported by adequate regulatory documents, which have to be prepared and approved by the Ministry of Health of the Republic of Latvia. Among the first documents of this kind should be the "Compulsory requirements for cancer screening".

The to-be-established Screening Monitoring department of HCISA is planning to complete all preparation work over 2008, so that it would be possible to begin the organized cancer screening in Latvia from the 1 January 2009.

Chapter 7

Action Plan for Implementing the Organized Cervical cancer Screening in Latvia

Based on the data mentioned in the previous chapters about the organizational principles of the organized screening, the principal diagram of the cervical cancer screening process was created. It can be used as a matrix for planning of cervical cancer, breast cancer, and colorectal cancer screening (Figure 14).

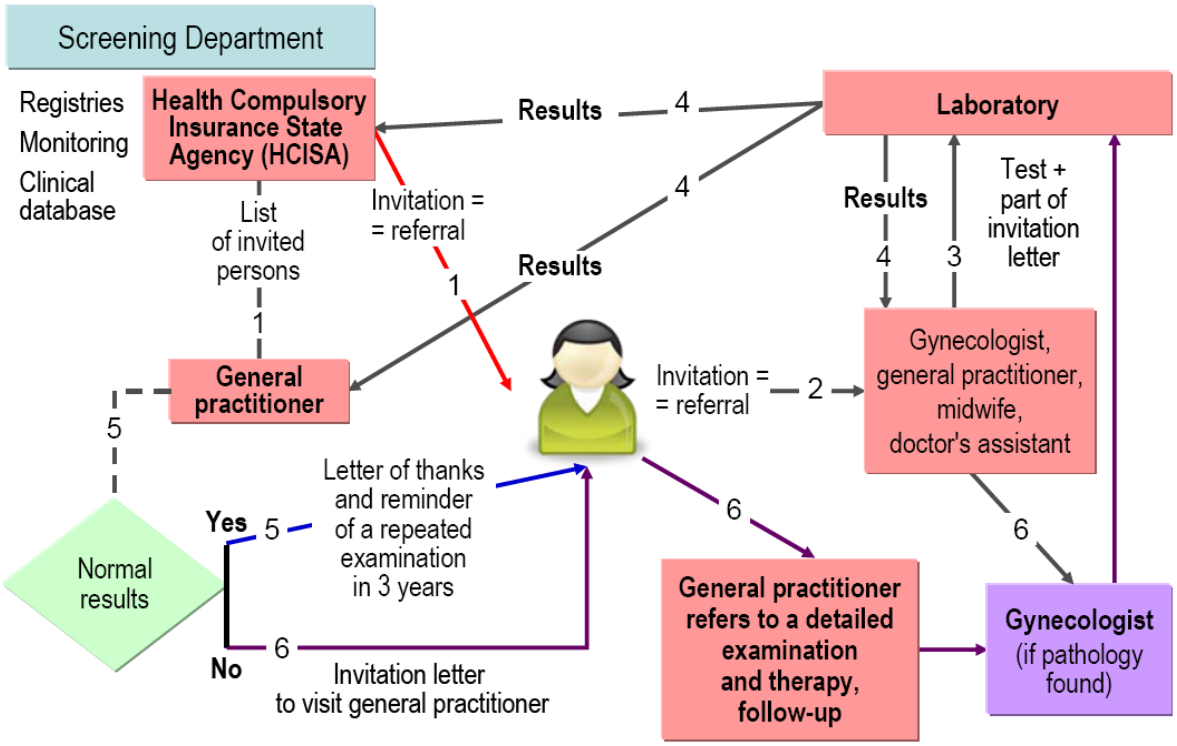


Figure 14. **Basic chart of the cervical cancer cytological screening.**

This chart depicts the most important principles of the organized screening that support a coordinated screening system with the target population — screening subjects — at the center. The organization of the screening system shows the screening subject's passive movement through the stages of the screening. The subject has to partake only one active procedure upon receiving a referral letter to the examination, in this case, giving a cytological smear at a gynecologist, general practitioner or trained midwife (steps 1 and 2 in the chart). In case of pathology findings, the screening subject will receive a referral to further examinations.

Unlike the existing opportunistic screening system, the screening subject is not responsible for correct interpretation of scattered screening information and is released from many bureaucratic obstacles, such being required to sign up for an examination at the general practitioner in order to receive a referral to screening and then signing up for a planned screening procedure. The patient does not have to deliver the results to the general practitioner (this would also require signing up for a visit) in order to receive further referrals. After the scheduled screening interval, the patient will receive the next letter of referral to the examination of the next round of screening.

General practitioners will in turn be spared from regularly controlling the patient information in order to determine examination periods for individual patients. At the same time the practitioners' visiting hours will not be burdened by those patients who come for bureaucratic referrals and discuss normal screening results. In that way, the services of the general practitioners will be made more available, reducing queues and making the doctors more available for treating illnesses and performing preventive examinations.

After implementation of the organized screening and achievement of at least 75% coverage of the population, already after 2-3 rounds (6-9 years after implementation of the screening) there will be achieved a notable decrease in mortality rates from cervical cancer, and the costs of treating this type of cancer. The society as a whole will not lose as many of the women's potential years of life, because their illness and death will be avoided. Many will still be able to reproduce.

Successful implementation of the organized screening demands taking certain steps and doing preparatory work. All of these have to be completed within a year's time, so that the screening program could be implemented in 2009.

The steps are not listed chronologically, because they are equally important and have to be carried out independently of other procedures.

Table 7 displays an action plan with the preferred time schedule.

Table 7. **Action plan and time schedule for preparatory work for implementing the organized screening.**

Action	Executive institution	Due date
1	2	3
Establishment of Screening Monitoring department (SMD)	MH, HCISA	January 2008
Development and approval of a regulatory document in the Cabinet of Ministers that determine the order in which clinical guidelines should be prepared	MH	January 2008
Development of detailed screening methodology, policy and guidelines	SMD, in cooperation with representatives of professional associations	April 2008
Establishing a screening registry for each type of screening	SMD	May 2008
Promotional campaigns involving mass media and in collaboration with professional marketing specialists	HCISA, Public Health Agency, MH	From January 2008 on — constantly, by the moment the optimum screening coverage is reached. Afterwards — continuous maintaining information
Making blueprints for standard invitation letters	SMD	June 2008
Analyzing the contents of the screening registry and service providers in order to improve geographic distribution so that availability is maximized	SMD	May–September 2008

Development of guidelines for quality control and assurance for cytological testing	SMD, in cooperation with experts from the Latvian Association of Laboratory specialists	June–August 2008
Testing of the secondary ambulatory service providers that have passed the selection announced by HCISA and is going to provide screening services — in order to ensure that quality control requirements are met.	SMD	October–December 2008
Training extra specialists for cytological testing — at least 3 new specialists annually	MPIC	2008–2010
Training nurses and midwives for taking cytological smears		January–December 2008
Audit on the system's readiness for commencing the centralized cervical cancer screening from 1 January 2009	MH	December 2008

Chapter 8

Conclusions and Proposals

Conclusions

1. The statistics on incidence and mortality rates for all cancers display a negative epidemiological situation in Latvia in this field.

2. Compared to similar data from the EU, the all cancer incidence in Latvia is lower, but the mortality rates — higher, which indicate that there is insufficient early diagnosis, a large proportion of cases that get diagnosed in late stages and frequently unsuccessful treatment.

3. Despite introduction of advanced equipment and most up-to-date medicines for cancer patients in Latvia, the all cancer mortality rates for the first year are invariably high, and 5 year survival rates have a very low increase trend.

4. The high incidence of oncology diseases is mostly due to the insufficient preventive measures, high prevalence of unhealthy habits among the inhabitants, low awareness of the carcinogenic substances' long-term adverse health effects, as well as insufficient availability of health services.

5. Until now, there has been no general program for cancer prevention on a nation-wide scale in Latvia, which has meant that the procedures for prevention of cancer have been scattered and with no coordination or long-term working perspective.

6. The opportunistic cervical cancer screening program that was started in 2005 has covered a very small part of the population.

7. Experience from many European countries indicates that it is possible to reduce cancer mortality rates by improving early cancer diagnostics, as well as implementing a broad organized cancer screening program. This program has to be based on the data from the population registry and a joint coordinated system that includes sending a letter of referral to each subject that has to be screened. The examination data and results must be archived in centralized manner and used within a special screening coordination institution.

8. There is available ample, evidence-based information on implementing organized cervical cancer screening in many European countries. The European Union Council has elaborated guidelines concerning cancer screening, and WHO recommendation on cervical cancer screening includes methodology for implementation of an organized cancer screening.

9. 2007 has brought several important initiatives for the health care in Latvia that have facilitated the transition from the opportunistic to the organized cancer screening system from 2009, which has to be regarded as an important step for controlling cancer in Latvia.

10. The implementation of organized cervical cancer screening will be facilitated by the long-standing traditions and rich experience for cytological screening in Latvia, as well as the highly qualified laboratory specialists working within the field of cytology.

11. Serious obstacles for implementation of the organized cervical cancer screening include: insufficient availability of gynecological services, especially in rural areas; lack of reliable information on the numbers of trained cytology lab specialists in Latvia and non-existence of guidelines on screening methodology for cytological testing and ensuring and maintenance of quality control.

12. The calculations on human resources and workload indicate that within the next 3-5 years, it is necessary to train at least 3 new specialists each year and ensure a more equal geographic distribution of the screening services.

Proposals

1. Based on the existing project for basic principles of the Cancer Control program, the Ministry of Health of Latvia should immediately develop a long-term program for improving the oncology situation in Latvia, which has to be approved by the government.

2. The Ministry of Health should urgently elaborate and the government approves basic clinical guidelines that will enable setting a unified standard for treatment and diagnostics throughout the country.

3. Guidelines for cancer screening have to be developed in collaboration with professional doctors' associations, so that there would be clarity about compulsory requirements and methodology for screening examinations and quality assessment.

4. One should commence raising public awareness on cancer issues, spreading knowledge about harmful habits and carcinogenic substances' long-term adverse health effects, paying special attention to educating young people and schoolchildren and instilling them to be attentive to oncology issues.

5. The cervical cancer screening in Latvia has to be implemented according to the European Union Council guidelines on cancer screening and WHO recommendation on cervical cancer screening.

6. An institution for coordination and supervision of cancer screening programs has to be established. This institution will complete the necessary preparations for implementation of the organized cancer screening, ensure equally distributed availability throughout the country and will later supervise carrying out of the stages of the screening and monitor indicative measures, frequently preparing reports on the program's progress.

7. The regulations for financing health services have to include instructions for how gynecologists and family doctors with private practice can get involved into the screening process and ensure that the state-financed examinations are available to their clients.

8. A program for extra training and improvement of qualifications in cytology for laboratory specialists has to be introduced, along with providing practical cytological training for laboratory specialists and assistants.

9. Midwives, nurses and paramedics have to be trained in taking cytological smears, along with ensuring that smears can be taken in the rural areas where gynecological services are not available.

10. The screening coordination institution has to duly carry out ample informative campaigns dealing with importance of organized cancer screening for decreasing cancer incidence and mortality rates. These campaigns have to be made in collaboration with professional marketing specialists in order to insure that the information is relevant and comprehensible for the public, and that it is presented in an effective manner.

11. After implementation of the organized screening, the screening coordination institution has to periodically (but at least every third year) provide a broad informative report on the developments, complications and results of the screening program to the Ministry of Health of Latvia. The progress report has to be made available to the public.

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