



**20 years
of the ZORA
Programme**

Slovenia's path to cervical
cancer elimination

 ONKOLOŠKI INŠTITUT
INSTITUTE OF ONCOLOGY
LJUBLJANA



20 years 
National Cervical Cancer
Screening Programme

20 years of the ZORA Programme

Slovenia's path to cervical
cancer elimination

The 20th anniversary of the National cervical cancer screening programme ZORA is held under the honorary patronage of the President of the Republic of Slovenia, Nataša Pirc Musar, PhD.

November 2023

20 years of the ZORA Programme

Slovenia's path to cervical cancer elimination

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List of abbreviations

HPV - Human papillomavirus
WHO - World Health Organization



The ZORA programme has come a long way in the last 20 years with the aim of reducing the burden of cervical cancer in Slovenia. We have made this journey together and individually, with optimism and confidence that we will succeed. I am proud and grateful for the trust women have in the ZORA programme, which is reflected by the high screening uptake; the expertise and personal commitment of the screening providers, which is reflected in quality and timely services including screening, triage, diagnosis, treatment and follow-up; the support of the Ministry of Health, the Health Insurance Institute of Slovenia and other key stakeholders, including NGOs; and the professional and dedicated team at the ZORA Programme Coordination Office at the Institute of Oncology Ljubljana, which, in collaboration with all stakeholders, has established and manages the National Screening Programme and the ZORA Registry. It wasn't always easy, but we managed to stay on course even at the trickiest junctions and when faced with the most challenging hurdles. My sincere thanks to all those who have walked this path before us and paved the way. Our job is to continue and augment their work. The ZORA programme has succeeded in significantly reducing the incidence of cervical cancer in Slovenia in its first 20 years. In the next decade, new challenges await and hopefully we can achieve that women in Slovenia will no longer get and die from cervical cancer. We are well on our way to eliminating the first cancer in Slovenia and I believe that together we will succeed!

*Assist. Prof. Urška Ivanuš. MD, PhD, Public Health Specialist
Head of the National ZORA Programme, Institute of Oncology Ljubljana*

1. THE ZORA PROGRAMME

The ZORA programme is a cervical cancer **screening programme**. It was introduced nationally in 2003, after several years of preparation and two pilot projects. It contains all elements of **organised population-based screening** and covers the **continuum of health services**, from inviting women for screening, to screening and triage, to additional diagnostics, treatment and post-treatment follow-up.

Our vision

is to reduce the incidence of cervical cancer to less than 4 new cases per 100,000 women, which, according to the World Health Organisation (WHO) definition, means eliminating cervical cancer as a public health problem.

Our mission

is to create a Slovenian society in which women do not get or die from cervical cancer that could have been prevented by HPV vaccination and participation in the ZORA programme.

This will only be possible if all women have equal access to all programme services and if these services meet the same standards, regardless of the provider.

Our goals

- Maintain and further increase the 3-year screening coverage to over 70% in all target age groups and regions.
- Maintain and further increase access to diagnosis and treatment of precancerous lesions and cervical cancer, whether detected through screening or in women presenting with clinical problems.
- Maintain and further improve the quality of all screening, diagnostic and treatment procedures.
- Regularly update programme and clinical guidelines, including screening policies, and align them with new scientific evidence and European recommendations, balancing potential benefits and harms. All procedures should be adapted to the Slovenian context.
- Participate in efforts to achieve 90% HPV vaccination coverage.

Our plans

- To renew the screening policy, taking into account new scientific evidence and European recommendations on HPV screening and tailoring screening to non-attenders. Introduce changes in a way that is sustainable and acceptable in the Slovenian context.
- Decide how to screen HPV-vaccinated women or generations.
- Introduce reflex triage of women with pathological screening results using liquid-based technology.
- Technologically and conceptually renew the ZORA Registry, integrate it into eHealth, and include new clinical and registry data on HPV vaccination.



Programme structure

The organisation of the ZORA programme is defined in the Regulation on the implementation of national screening programmes for the early detection of precancerous lesions and cancer (Official Gazette of the RS, No 57/18 and 68/19). The Steering Committee for Screening Programmes at the Ministry of Health brings together key decision-makers, stakeholders, and representatives of the target groups from NGOs to monitor the results of the programme and ensure the programme's operation and development. The strategic 5-year objectives of the programme are described in the National Cancer Control Programme.

The programme contains all the elements of organised population-based screening. It is managed by the Oncology Institute of Ljubljana, where the programme and the ZORA Registry are based. The Programme Coordination Office plans, implements, manages and coordinates the programme. It is responsible for: programme and clinical guidelines and instructions for providers, monitoring and evaluation of the quality of providers' work and the impact of the programme, central invitation system, activities to increase participation, a call centre for women and providers, promotional and educational materials for women, communication with different sectors, training of programme providers, development of the programme in line with current scientific evidence and European guidelines, international research and networking, planning and reporting on the work carried out and the results, as well as proposing and chairing the ZORA Expert Council, which brings together various experts to support the operation and development of the ZORA programme. ZORA Expert Groups and Working Groups further support ZORA's work on specific projects agreed within the Annual Work Plan.

The ZORA programme covers the continuum of health services, from screening and triage, to additional diagnostics, treatment and follow-up. Cervical screening is carried out every three years with conventional cytology by personal gynaecologists in women aged 20–64 years. Additional diagnostics and treatment are performed by gynaecologists at all levels of healthcare. In addition, the programme also provides services through cytopathology and histopathology laboratories, and two HPV testing laboratories.

Founders

Ministry of Health

The Health Insurance Institute of Slovenia

Cancer Screening Steering Committee

Ministry of Health, The Health Insurance Institute of Slovenia,
Association of health care institutions in Slovenia, NGOs

Programme Management- Institute of Oncology Ljubljana

ZORA Programme and Registry

- central **coordination and management of the programme** at the national level
- programme and **clinical guidelines, standards, instructions**
- **ZORA Registry**
- monitoring and evaluation of the **quality** of providers' work and programme **effectiveness** and their implementation
- central **invitation** of women to screening, measures to **reduce non-response**
- operating a **call centre** for women and providers
- preparation and distribution of **materials for women**
- communication and **promotion** of the programme
- professional **training of providers**
- appointment and management of the ZORA **Expert Council**
- **work planning and reporting**
- **research** and programme development

ZORA Expert Council

gynaecologists

representatives of the laboratory diagnostics (cytopathology, histopathology, HPV)

information technology experts

epidemiologists

Expert and Working Groups

External databases

Central Population Registry

Spatial Units Registry

Cancer Registry of Republic of Slovenia

Laboratories: Conventional cytology, HPV, cervical and hysterectomy histopathology for all Slovenian women, irrespective of the reason for sample collection, findings and age

Gynaecological clinics: invitations, screening, triage and additional diagnostics, treatment, record-keeping

20 years of the ZORA Programme, 2023



ZORA team at the ZORA Programme Coordination Office, Institute of Oncology Ljubljana, 2023
From left: Urška Ivanuš, Tine Jerman, Mojca Florjančič, Blaž Podobnik, Marija Sabrina Kvartuh, Elizabeta Radelj Pepevnik



Members of the ZORA Expert Council, 2023

From left: Špela Smrkolj, Veronika Kloboves Prevodnik, Ana Pogačnik, Maja Primic Žakelj, Igor Josipović, Urška Ivanuš, Urška Gašper Oblak, Mojca Florjančič, Margareta Strojhan Fležar



Maja Primic Žakelj, MD, PhD,
Epidemiology and Public
Health Specialist
First Head of the National
ZORA Programme

Beginnings of the ZORA Programme

In the early 1990s, the European Cervical Cancer Screening Network was launched under the Europe Against Cancer programme, which published the first European Guidelines for Quality Assurance in Cervical Cancer Screening as early as 1993, laying the foundations for organised screening programmes and establishing the concept of quality assurance and quality control.

In Slovenia, women had access to preventive gynaecological examinations with a cervical smear as early as 1960. Despite the large number of smears examined, the incidence of cervical cancer did not decrease significantly. It started to increase again in 1994 and peaked in 1997 at 23.7/100,000, with 241 new cases, mainly among women under 55 years of age (crude rate). The proportion of women screened on a regular basis was unknown and the quality of the screening process was not systematically monitored.

In 1996, a group of experts—cytopathologists, pathologists, gynaecologists and epidemiologists—gathered at the initiative of the epidemiologists of the Institute of Oncology to improve cytology screening results and to reduce the number of cervical cancer cases in Slovenia. In 1996, the Minister of Health appointed a task force to prepare

a proposal for an organised screening programme. It was based on the experience of successfully run organised screening programmes abroad and on European guidelines, and was endorsed by the Health Council in November 1996.

In 1997–2001, the programme was tested at national level with a pilot study in the Ljubljana region, and in 2001 it was extended to the coastal area. In 2002, the Ministry of Health issued updated Guidelines for the Implementation of Preventive Healthcare at Primary Level—Reproductive Healthcare, which also enabled the project to transition into an organised nationwide screening programme, which started in 2003.

Since 2010, we have organised an annual ZORA Education Day for all those involved in the ZORA programme, where international experts from all key fields participate. Slovenian data show that after 20 years, the ZORA programme is having significant public health effects, as evidenced by the high participation of women in screening and in the progressive reduction of the burden of cervical cancer among our women.

ZORA has such excellent results thanks to the commitment of its advocates from all the fields involved, and the good collaboration and expertise of the many professionals—gynaecologists and nurses in women’s primary care, screeners, cytopathologists and pathologists in laboratories, and all the others involved in the multidisciplinary process of women’s care.

Key milestones for organised population-based cervical cancer screening in Slovenia



The first **European guidelines** for quality assurance in cervical cancer screening.

Adoption of the **Healthcare Databases Act**, including the ZORA Registry.

Implementation of the **national organised population-based screening programme**, Registry and Programme Coordination Office ZORA.

1960

1993

1997

2000

2002

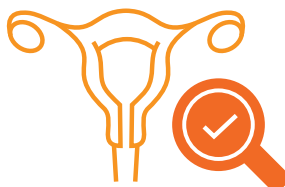
2003

2004

First preventive gynaecological screening in **Slovenia** (opportunistic screening): **24/100,000 new cervical cancer cases (world standard).**



The first organised screening in Slovenia started with a pilot project in the Ljubljana region. In 2001, it was extended to the coastal region.



Publication of **Methodological guidelines for standardisation of results of cervical cytology** and information system of gynaecological cytopathology.

ZORA Registry begins including the results of **histopathological examinations** of cervical tissue samples and hysterectomies.

The programme reached

70%

screening coverage.



All women in Slovenia aged between 20 and 64 years were invited for screening.



26,556 non-attenders to the ZORA programme included in the HPV self-sampling at home randomised controlled trial.



The World Health Organization launched a Global Strategy to accelerate the elimination of cervical cancer.

2006

2010

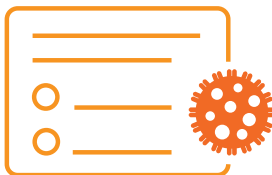
2015

2017

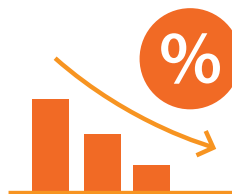
2020

2023

Introduction of HPV triage and inclusion of the HPV test results in the ZORA Registry.



The lowest number of new cervical cancer cases recorded: 4.9/100,000 women (world standard).



ZORA celebrates 20 years



Mojca Florjančič,
Registered nurse, BA of
organisational sciences,
Operational manager of
Registry ZORA

ZORA Registry

The ZORA Registry is managed by the ZORA Programme Coordination Office at the Institute of Oncology Ljubljana. It was established in 1997 and introduced at the national level in 2003 as a centralised database of demographic and clinical data on Slovenian women with nightly synchronisation with the Central Population Registry. The purpose of the ZORA Registry is to support the planning, management, implementation and evaluation of the ZORA programme, to ensure an adequate flow of information between the programme providers and the Registry, to monitor and control the quality of services and procedures, and to support research in the field of cervical cancer control in Slovenia.

All results of cervical smears, HPV triage tests, cervical samples and uterus are routinely recorded in the ZORA Registry, irrespective of the reason for sample collection, findings and age. All ZORA programme providers are obliged to submit data to the ZORA Registry in accordance with the legislation and the ZORA Programme Methodological Guidelines. Cervical smear and HPV triage test results are standardised and received electronically as defined in the methodological guidelines. Histopathological results are not yet standardised, so they are collected in paper form and coded at the ZORA Coordination Office and entered into the ZORA Registry. All the results have a unique personal identification number (EMŠO), which links them to the relevant woman and her demographic data. This allows us to

cross-sectionally and longitudinally monitor and evaluate the scope and quality of health services, as well as the effectiveness of organised and opportunistic screening, including an assessment of the benefits and harms of screening at the population level and the level of individual. The ZORA Registry also manages all central invitations, women's responses to a questionnaire attached to the invitation, and gynaecologists' tracking of any delays in follow-ups and treatment.

We also pay great attention to the quality and completeness of the data; any incomplete data are regularly requested from gynaecologists and laboratories, who are required to correct any discrepancies. At the time of the establishment of the ZORA Registry, 90% of all records were incomplete records, in recent years this number dropped to to 2%. Once a year, The ZORA Registry performs a bilateral exchange of data from all women with high-grade HSIL/CIN3 and cervical cancer with the Cancer Registry of the Republic of Slovenia, in order to check the completeness and quality of the data in both registries.

ZORA Registry

Population registry of female demographic and clinical data

A key element of an organised, population-based screening

The data are used for:



Central invitation of women for screening → Centralised mailing of invitations to women who are overdue for screening **>63,000 per year**, of which **5,000 are bilingual invitations**



Monitoring of the management of individual women → Monitoring of the management according to the guidelines, notifications to gynaecologists that a woman is overdue for screening or treatment **>2,000 per year**



Monitoring the volume and quality of work by providers → Personalised annual reports to providers, clinical overview, requests to providers to complete data in accordance with prescribed ZORA standards **>5,000 per year**



Support to gynaecologists with screening invitations → Informing gynaecologists of women's address change **>400 per year**



Tailored advice for women by phone or email **>3,000 per year**

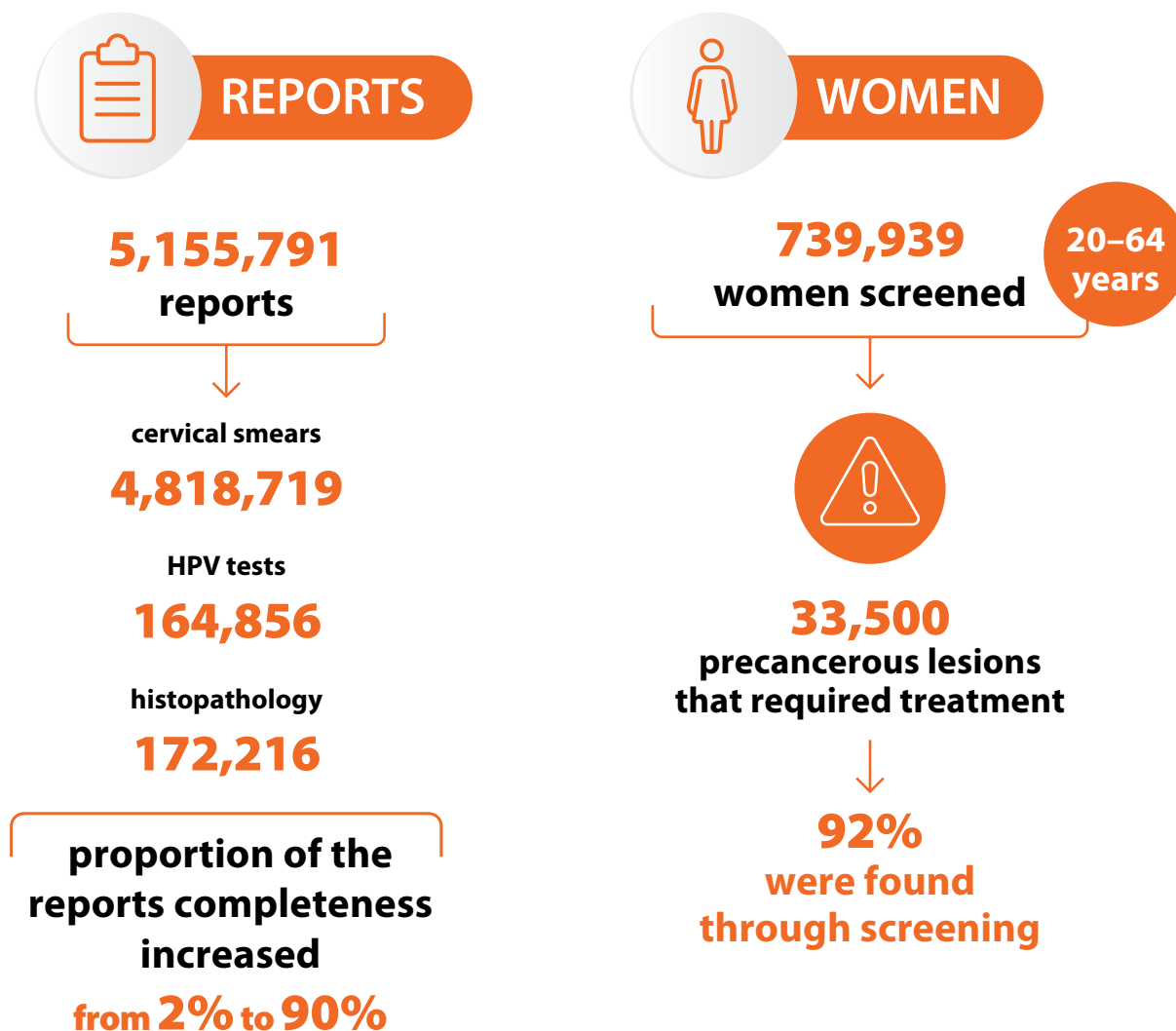


Monitoring of programme activity and performance indicators in accordance with ZORA Programme Guidelines and Methodological Guidance on Indicators → Reporting, system adjustments and programme management



Long-term follow-up of women, in-depth analyses, support for clinical and epidemiological research

20 years of ZORA Registry in numbers



Source: ZORA Registry, 2023
20 years of the ZORA Programme, 2023



Tine Jerman,
MA in Social Informatics,
ZORA Data Analyst

Monitoring and Evaluation

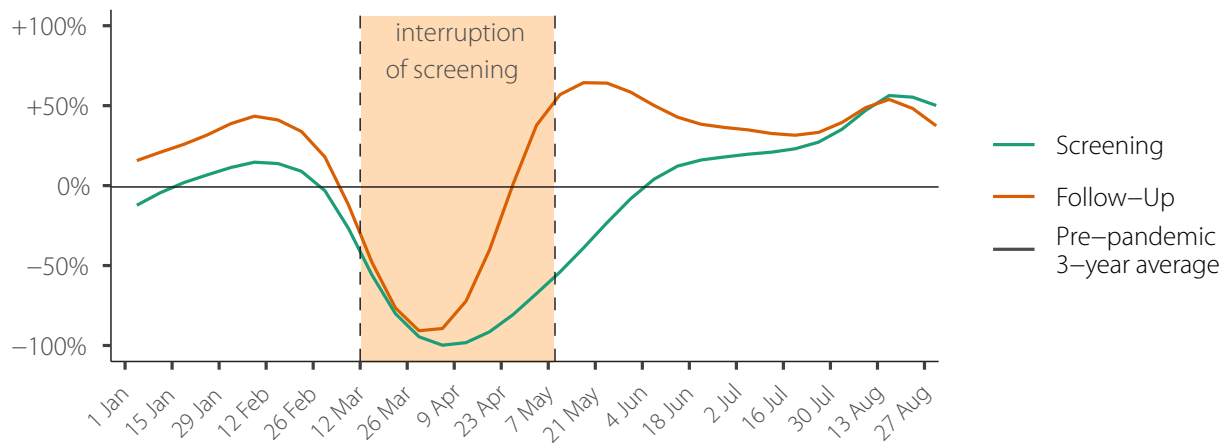
The monitoring and evaluation of the programme is based on the high quality of the data from the ZORA Registry. The indicators that are regularly monitored are compiled and explained in the Methodological Guidelines for the ZORA Programme Indicators and include, among others, the coverage of the target population, the time from sample collection to admission to the laboratory and to the result, the adherence to gynaecological guidelines, the annual number of samples tested per provider, and others. The indicators are included in various reports, including the annual reports sent to the providers, which offer them important feedback. They allow comparison with the results of other providers and the monitoring of performance against quality indicators. The indications are also an important tool for expert groups to identify discrepancies between providers and sections of the programme where quality can be further improved.

Linking the ZORA Registry data with Cancer Registry data enables the identification of women who have developed cervical cancer despite their participation in the ZORA programme. The regular audit of these cases has contributed to improving the quality of work in the cytopathology laboratories and, consequently, to increasing the positive impact of the programme, which is reflected in the reduction of cervical cancer cases from the start of the programme to the present.

ZORA Registry also enables the use of modern research methods in the field of cervical cancer screening. In addition to the Cancer Registry, we can also link to other Slovenian

databases, including data from the Statistical Office to study the demographic and socio-economic characteristics of non-attenders to the ZORA programme. And by joining the international scientific research community, we are contributing to new developments in cervical cancer screening.

In addition to the regular analyses that we carry out to monitor the quality of providers' work and evaluate the epidemiological impact of the programme, we also carry out additional in-depth analyses. One of such analysis was carried out during the covid-19 pandemic to encourage providers to prioritise women at higher risk when the screening was restarted after a two-month interruption. Based on the analyses, we sent providers a tool to determine the risk of an individual woman, in addition to a list of their patients with deferred screening and past screening results.



Comparison of the weekly number of screening and control cervical smears in 2020 with the three-year average in the years before covid-19 pandemic. There was a transient, almost 100% decrease in total smears during the interruption of screening compared to the average of the previous three years. After the resumption of screening (period after the second dotted line), gynaecologists prioritised women at higher risk who needed follow-up tests due to already known pathological changes (orange curve). With a delay of a few months, they also resumed screening women who were eligible for screening (green curve). Both curves significantly exceeded the pre-pandemic 3-year average during the summer period (also by more than 50%), which is important as gynaecologists compensated for an important part of the deferred screening during the temporary suspension of screening.

Source: ZORA Registry, 2020

Quality Assurance and Control

Due to a very large number of healthy people invited and screened in order to timely detect and treat a precancer or cancer in a few of people, the rules for quality assurance in organised population-based screening programmes are particularly strict. The ZORA programme follows European recommendations such as those of the Council of Europe and the European Guidelines for Quality Assurance in Cervical Cancer Screening. Quality in the ZORA programme is ensured through standardised forms, instructions and clinical guidelines, regular trainings and quality control of the work by programme providers. This would not be possible without the central coordination of the programme, the ZORA Registry and the legal infrastructure for the management and implementation of the programme and the ZORA Registry.

The ZORA Programme Guidelines describe the organisation, management and healthcare services of the ZORA programme on the continuum of cervical cancer prevention and care, including screening and triage, diagnosis, treatment and post-treatment follow-up. Clinical guidelines and instructions for gynaecologists and laboratories are provided, as well as standardised forms with methodological instructions for performing and recording these services and reporting them to the ZORA Registry. All guidelines are available on the ZORA website.

The Programme Guidelines also provide guidance for regular professional training for all ZORA programme providers at all levels. The best attended is the ZORA Education Day, which has been held annually since 2010. During the COVID-19 pandemic, more than 600 providers, decision-makers and other stakeholders of the ZORA programme participated in the virtual training. We also organise and implement other training courses in collaboration with ZORA expert groups and professional associations, such as workshops for screeners, cytopathologists and histopathologists, basic and advanced colposcopy courses certified by the European Federation for Colposcopy, and many others. All screeners must attend the School of Gynaecological Cytopathology and pass the European QUATE exam.



9th ZORA Education Day
2019, Brdo pri Kranju
Congress Centre



Speakers and lecturers at the 9th
ZORA Education Day 2019 from
Slovenia and abroad

From left: Veronika Kloboves Prevodnik (Institute of Oncology Ljubljana, OIL), Špela Smrkolj (UMC Ljubljana), Vitaly Smelov (WHO Europe), Aiga Rurane (Head of the WHO Office in Slovenia), Marjan Sušelj (Director-General, Health Insurance Institute of Slovenia), Mojca Gobec (Director-General for Directorate for Public Health at the MoH), Zlata Štiblar Kisić (Director-General OIL), Urška Ivanuš (Head of ZORA programme, OIL) Pekka Nieminen (President of the European Federation for Colposcopy) Mario Poljak (Faculty of Medicine, University of Ljubljana), Margareta Strojan Fležar (Faculty of Medicine, University of Ljubljana)

Provider training continued during the covid-19 pandemic. Cytopathology workshop on the occasion of the introduction of liquid technology, Institute of Oncology Ljubljana, 2021

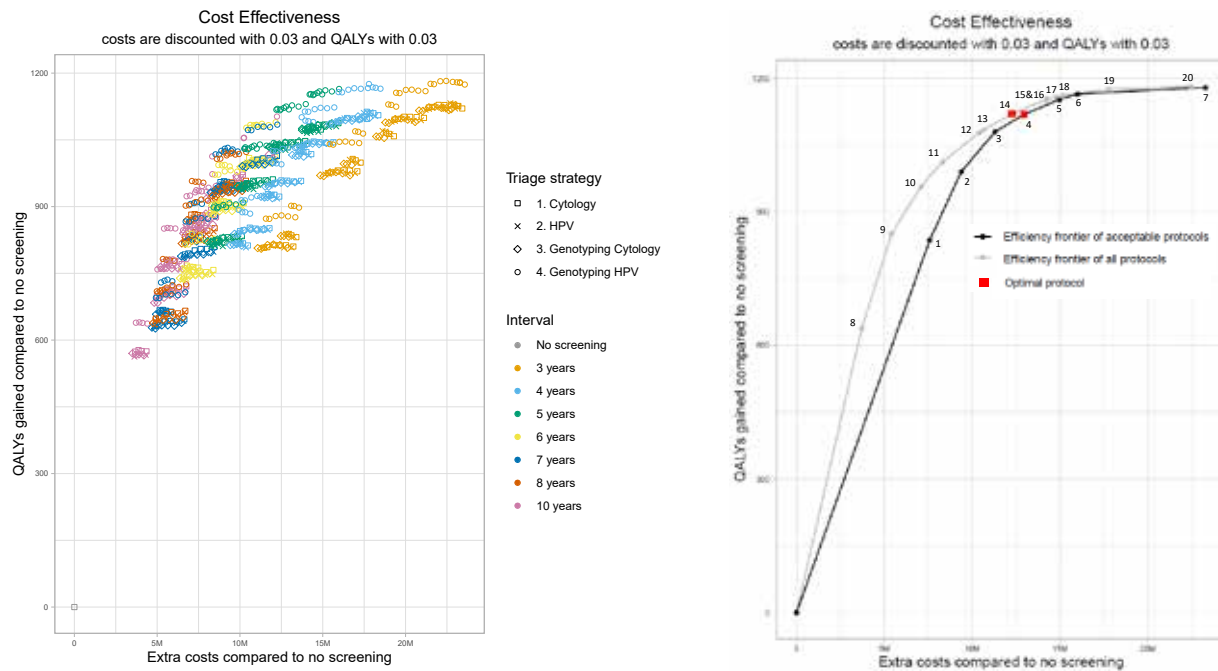


During the covid-19 pandemic, ZORA systematically stopped enrollment and screening for two months. Treatment of symptomatic women and women with high-grade pathological lesions was not stopped. Gynaecologists have adapted their work to the context and together with women worked to ensure that the postponed screening became almost entirely operational by the end of 2020.



Development, Research and Involvement in the International Community

At ZORA Programme Coordination Office, we ensure that the programme is developed in line with the latest professional knowledge and guidelines. We plan and manage research and development projects in collaboration with leading international and Slovenian experts. These projects have evolved over the years, and in preparation for the change in the ZORA



Analysis of the performance of 968 screening strategies for Slovenia using the Dutch mathematical model MISCAN-Slovenia, adapted in the framework of the EU-TOPIA project (Horizon2020). HPV screening from 30 to 65 years of age every 5 years was found to be most effective, and Cervical screening in younger women every 3 years may be an additional option. Source of the figure: Jansen et al. Gynecol Oncol. 2021.

Source: Jansen et al. Gynecol Oncol. 2021

screening policy, the leading development projects encompass the standardisation and regulation of the payment model for colposcopy at the national level, the planning and introduction of multidisciplinary consultation panels for women with discordant findings, the training of Slovene screeners and cytopathologists in the evaluation of liquid cytology slides with the introduction of this technology in Slovenia, and the modernisation of the ZORA Registry. We aim to ensure the high quality of cytopathology during the transition period and to prevent the spread of opportunistic use of the HPV test or co-testing. Since the programme's inception, we have been working with international experts and associations, including in the context of various European projects, in planning and decision-making. We are involved in expert discussions at the international level and participate in the development of international guidelines, which are then adapted and translated into the Slovenian environment in order to ensure that Slovenia remains a country that provides Slovenian women with the best possible evidence-based cervical cancer prevention under the umbrella of the organised population-based screening programme ZORA.

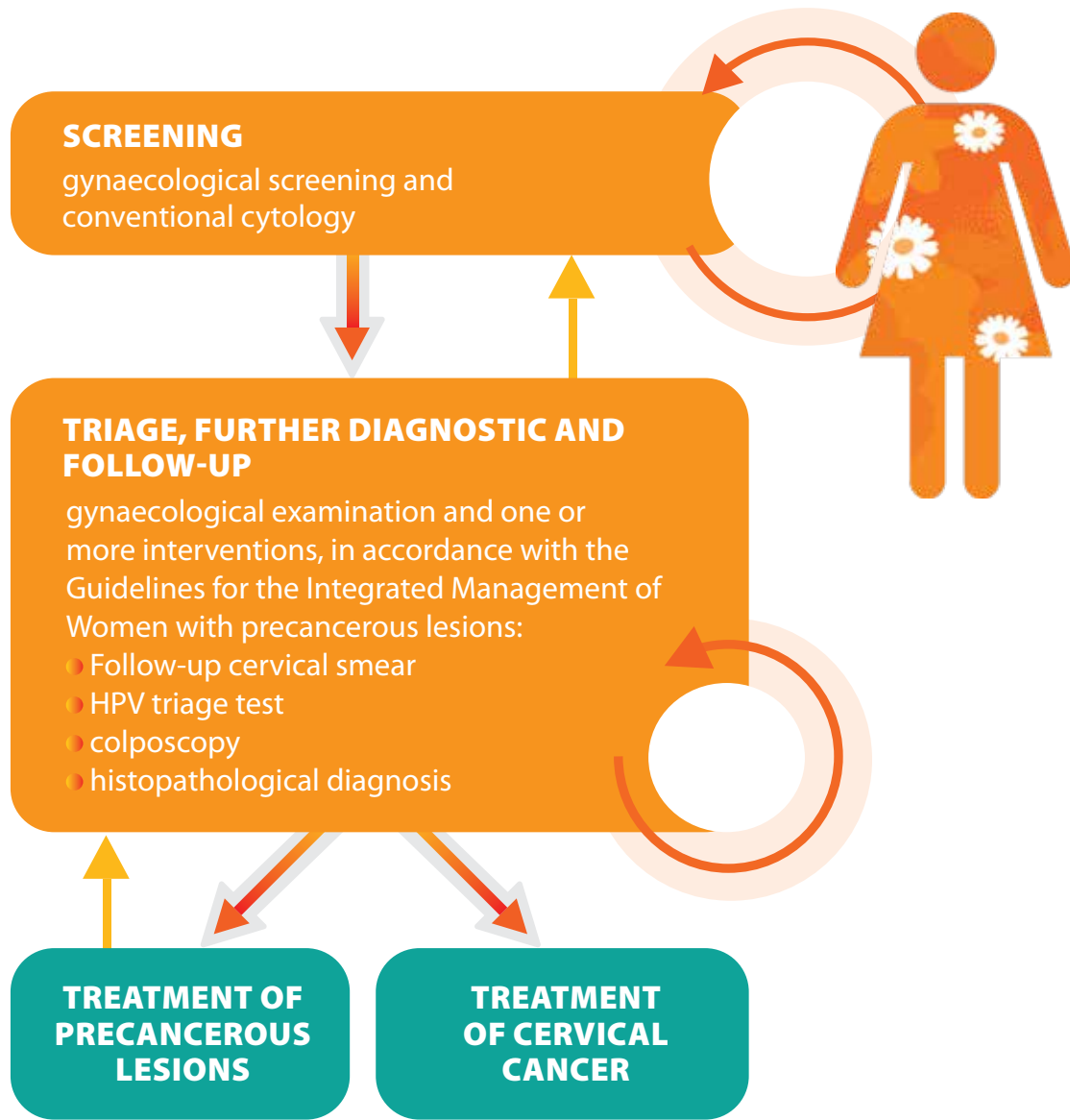


1st Open Day of the Slovenian screening programmes ZORA, DORA and Svit with participants from Romania, Croatia, Montenegro and the Netherlands, 2022. Co-organised by all three screening programmes, the Institute of Oncology Ljubljana, the National Institute of Public Health, the Ministry of Health and the EU-TOPIA-EAST project (Horizon 2020).

2.

A WOMAN'S PATH THROUGH THE ZORA PROGRAMME

Women are screened every three years by personal gynaecologists. A woman aged 20–64 can make screening appointment on her own; if she does not, her gynaecologist invites her every three years. If the ZORA Registry does not record a cervical smear result for a woman within the last four years, she will be sent an invitation from ZORA programme Programme Coordination Office. If the woman does not respond to the invitation, she will receive a reminder. Most women can return for a repeat screening in three years' time due to a negative screening result. Women with a pathological screening result are at higher risk of pre-cancerous lesions or cervical cancer, they receive further management and, if necessary, treatment.



Ensuring High Quality of Health Services

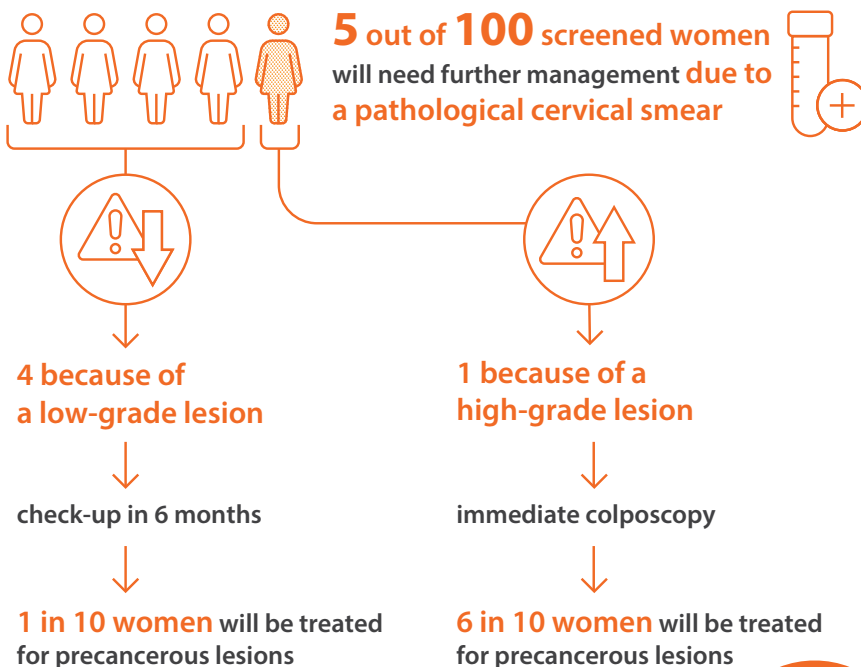
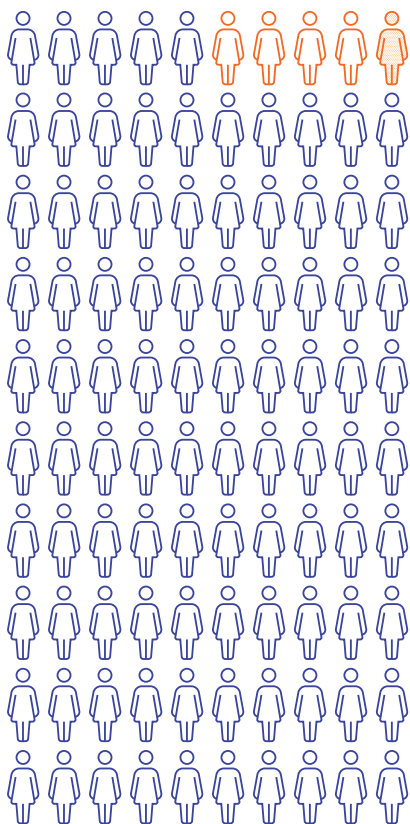
Every year, around 155,000 women in Slovenia undergo cervical cancer screening with conventional cytology by their personal gynaecologist. The gynaecologist sends the smear to a cytopathology laboratory, where the cytotechnicians and cytopathologists assess whether the cervical cells in the smear are normal or pathological, in accordance with the Guidelines for the Cytological Examination of Cervical Smears - Bethesda Classification. Around 95% of women have a negative screening result and can return for a repeat screening in three years.

Around 5% of women have a pathological screening smear. If the smear shows low-grade changes, the gynaecologist invites the woman for a follow-up in six months. If the changes are high grade, the gynaecologist invites the woman for a colposcopy, where, if necessary, a tissue sample is taken for histopathological diagnosis. In accordance with clinical guidelines, the gynaecologist also performs an HPV triage test in women with low-grade lesions or after treatment of precancerous lesions. When high-grade precancerous lesions or cancer are detected in a woman, treatment is required in accordance with the Guidelines for the Integrated Management of Women with Cervical Precancerous Lesions and the Guidelines for the Integrated Management of Women with Cervical Cancer in Slovenia.

Around 1,500 high-grade precancerous lesions are detected and treated in Slovenia every year, preventing cancer in the majority of women. As many as 92% of all precancerous lesions are detected through screening. This is not surprising, as precancerous lesions and early stages of cervical cancer do not cause problems or symptoms in women. The Cancer Registry of Republic of Slovenia registers only around 100-120 new cases of cervical cancer per year, and the link between the Cancer Registry and the ZORA Registry shows that non-attenders are at significantly higher risk than women who regularly participate in ZORA.

Each year **155,000** women are screened in the ZORA programme

95 out of **100** screened women will have a negative cervical smear result and will be invited to the screening again in 3 years



Around **1,500** precancerous lesions are diagnosed and treated in Slovenia each year, of which **92%** are detected through screening.

With this, we prevent the majority of cervical cancer.

Most are between 30 and 39 years of age.

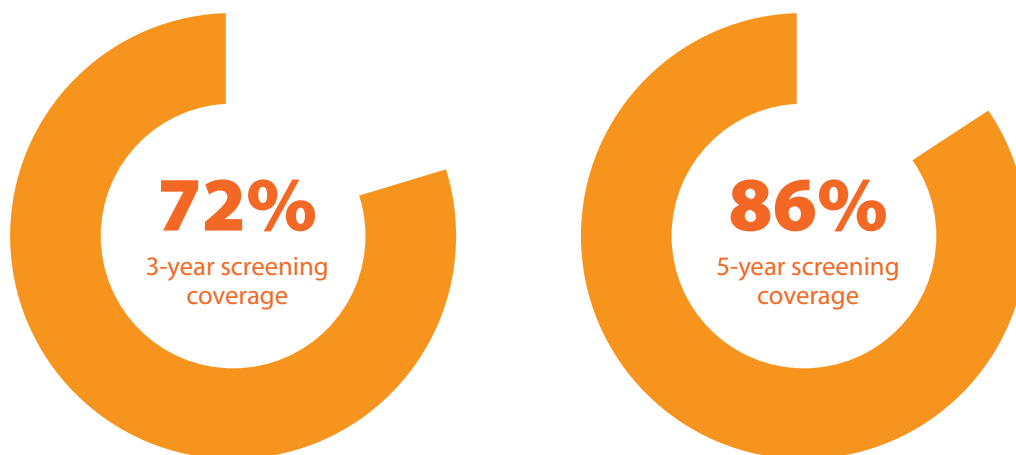
Only **100-120** new cases of cervical cancer are detected in Slovenia annually.

Most after the age of 35 years.

Ensuring High Participation of Women

Women's participation in the ZORA programme is measured by the three- and five-year screening coverage of the target population of women aged 20-64 years, which is one of the main indicators used to assess the success of the ZORA programme. High screening coverage is crucial for effective detection and treatment of precancerous lesions and early cancers, and thus for reducing the burden of cervical cancer at population level.

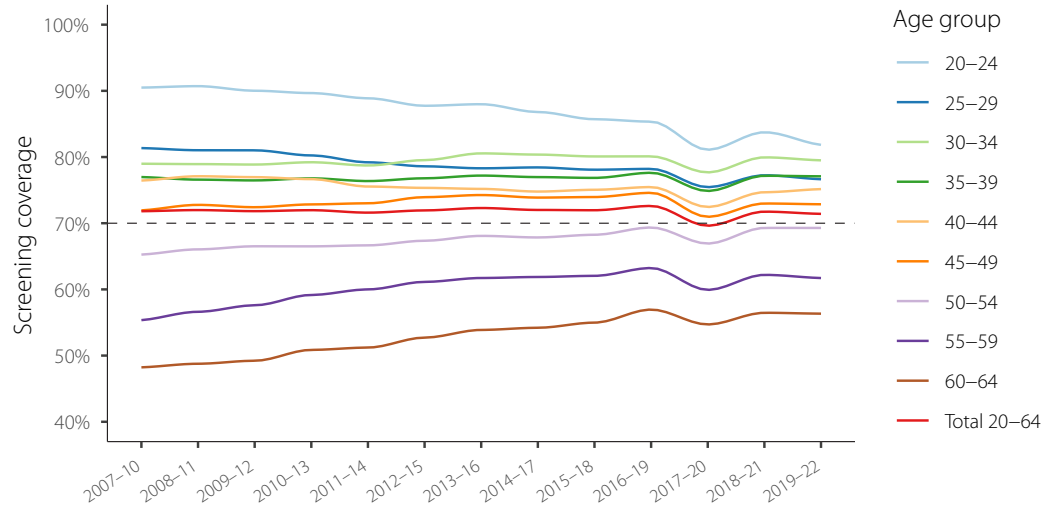
Since 2006, the ZORA programme has exceeded the target of 70% screening coverage at three years' interval. If we calculate the screening coverage at five years, which is the screening interval in some European countries, the screening coverage is around 86%, which is one of the highest in Europe. Such a high screening coverage would certainly not have been possible without the efforts of many gynaecologists and nurses in women's primary health care, supplemented by the central invitation system. The three-year screening coverage is below target in the 50-64 age group and in some parts of Slovenia.



Source: ZORA Registry, 2023

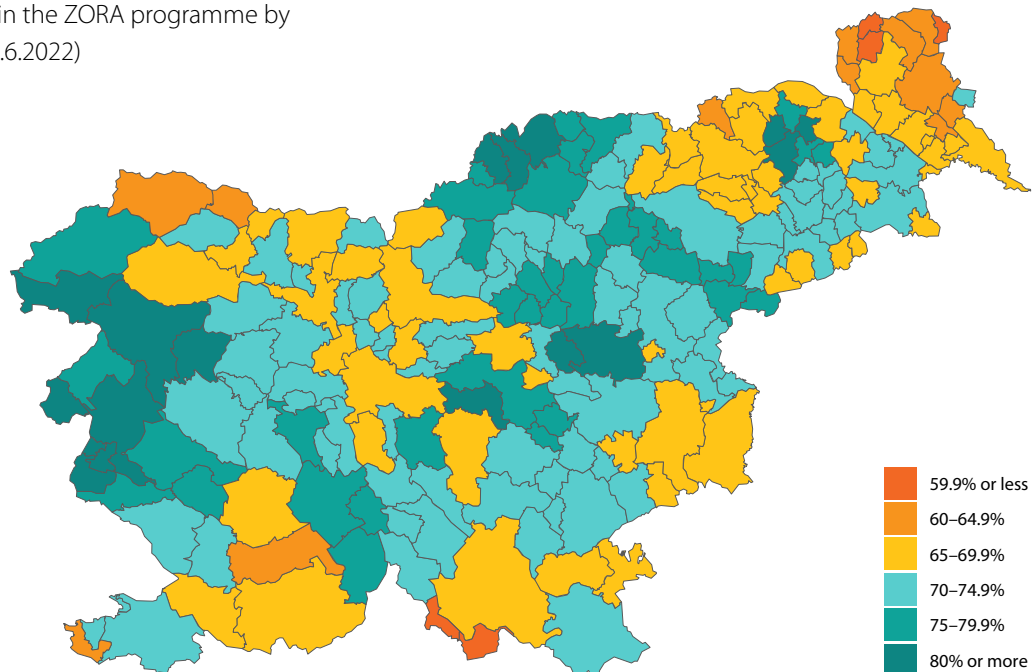
3-year screening coverage in the ZORA programme by age group

Source: ZORA Registry, 2023



3-year screening coverage in the ZORA programme by municipalities (1.7.2019–30.6.2022)

Source: ZORA Registry, 2023



Women's responsiveness to the programme and the resulting screening of the population are closely linked to women's awareness of and acceptance of the programme and the accessibility of services. Good participation in the ZORA programme is ensured by gynaecologists and nurses through their daily work in clinics, where trust between them and women has been established over time. Gynaecology teams invite women for screening and answer many questions, carry out screening, inform women about the results and, if necessary, carry out additional tests or refer women to secondary or tertiary care.

The work of the gynaecology teams is complemented by a central screening invitation from ZORA Programme Coordination Office and by information materials provision to all Slovenian gynaecologists, including Italian and Hungarian materials for women in bilingual regions. Most of the information is also available on the ZORA website and on special notice boards across all Slovenian community health centres.

The ZORA Call Centre answers a wide variety of women's questions on a daily basis, through phone calls and emails. We are also happy to work with local communities, often responding



Trust between gynaecologists and women is key for high participation in ZORA programme

to calls for joint activities to raise awareness of the importance of regular screening, increase screening uptake and reduce fear and stigma in vulnerable groups. Thanks to its excellent results, ZORA also enjoys a good reputation among the general public, which was gradually built over two decades together with all stakeholders, including the media.

Booklets for women with information on screening, HPV testing, colposcopy, cervical precancer treatment, cervical cancer treatment: published by the ZORA Programme Coordination Office





A wide variety of questions are answered by phone or e-mail through our ZORA Call Centre



Raising awareness about the importance of regular screening is done through presentations in response to the many invitations from the local communities and NGOs

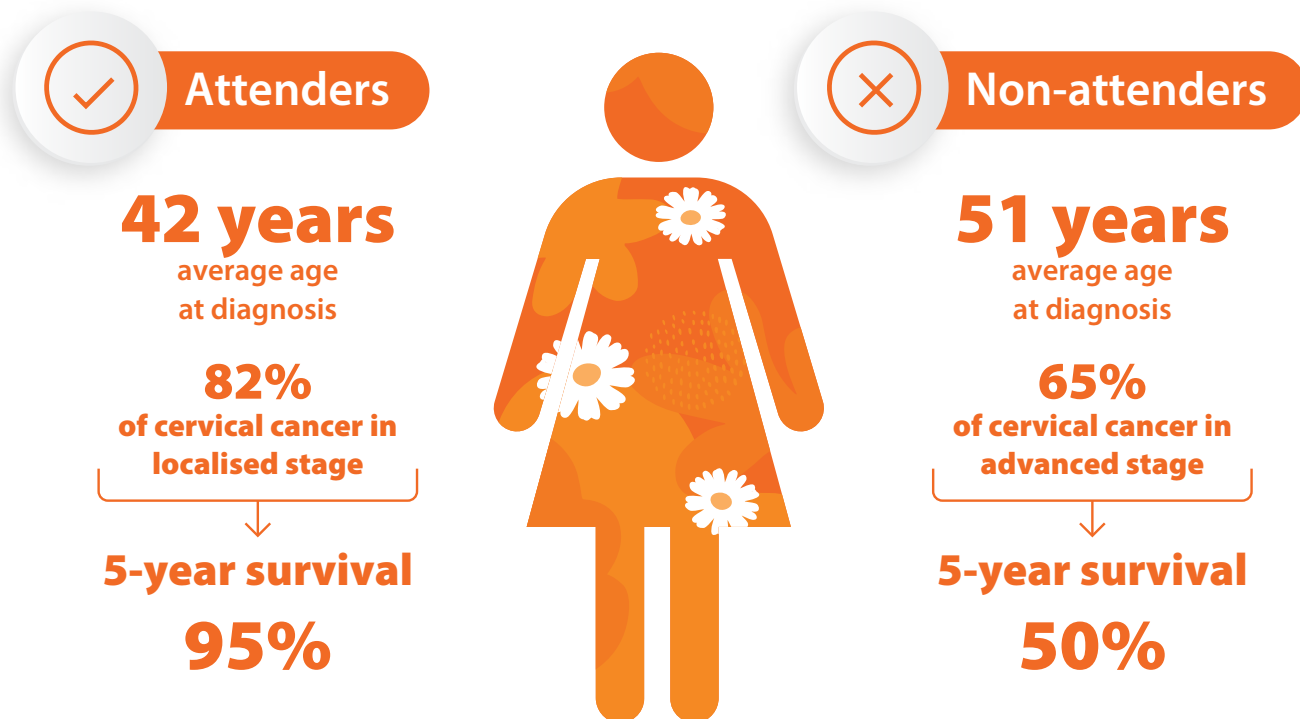
Encouraging Women to Participate in the ZORA Programme

Women who do not regularly participate in the ZORA programme have a significantly higher risk of cervical cancer than those who do. In non-attenders, cancer is usually detected at an advanced stage, corresponding to a higher treatment intensity, poorer outcomes, and lower quality of life during and after treatment.

The lowest participation in ZORA programme is recorded among women aged 50–64, women from the northeastern part of Slovenia, women with lower levels of education, women who are unemployed or hold a migrant status. ZORA programme recognises that the same approach to screening does not work for all women, so to increase participation and reduce inequalities in participation, tailored approaches are needed for those groups of women who are not reached by the regular activities of the programme. A gynaecologist may refer a field nurse to the home of a non-attenders, especially if the woman already has pathological changes and is not responding to invitations for further diagnostic or treatment.

In 2015, we conducted a large randomised controlled trial at the ZORA programme Programme Coordination Office at the Oncology Institute Ljubljana, in collaboration with University Medical Centre Ljubljana and Maribor, offering all non-attenders to the ZORA programme from the Celje and Maribor regions (26,556 women in total) the opportunity to perform a self-sample test for HPV at home. The trial showed that Slovenian non-attenders accepted the home self-sample well, and that twice as many women were screened if they had the opportunity to self-sample at home than if they did not. Women with a positive HPV test result on the self-sample responded well to the invitation to see a gynaecologist.

In the **20** years after the implementation of the ZORA programme in Slovenia **2,664** cases of cervical cancer have been detected



Cervical cancer is detected on average **9 years earlier in ZORA attendees than in non-attendees**. In attendees cancer is diagnosed at earlier stages, prognosis and quality of life are better.

ZORA programme saves lives due to timely detection and treatment of pre-cancerous lesions and early cancers.


26,556 non-attenders from the Celje and Maribor regions

Group A



ordering a self-sampling kit
required (opt-in)

16% 
performed the HPV test at home

16% 
performed the test
at the gynaecologic clinic


2% 
performed both tests

Group B



ordering a self-sampling kit
not required (opt-out)

24% 
performed the HPV test at home


10% 
performed the test
at the gynaecologic clinic

4% 
performed both tests

Group C



received an invitation to visit
a personal gynaecologist

18% 
performed the test
at the gynaecologic clinic

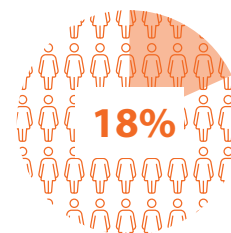
Overall response



Overall response



Overall response



A Slovenian randomised controlled trial to test the acceptability of at-home self-sampling for HPV testing showed that more non-attenders to the ZORA programme underwent screening if they had the opportunity to self-sample at home than if they did not.

Source: Ivanuš et al., Radiol Oncol 2018

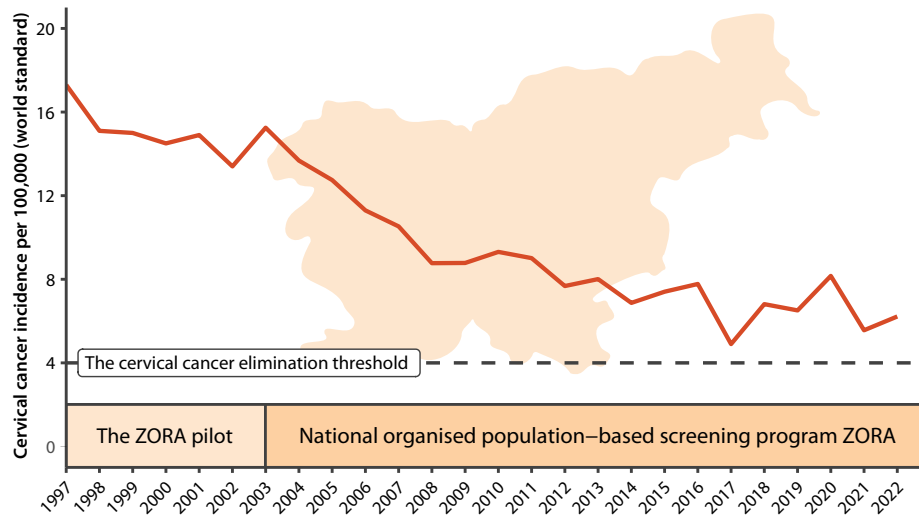
20 years of the ZORA Programme, 2023

3.

KEY ACHIEVEMENTS OF THE ZORA PROGRAMME

Following the transition from opportunistic to organised population-based cervical cancer screening under the ZORA programme in 2003, the burden of cervical cancer in Slovenia has been significantly reduced, mainly due to an increase in the screening coverage and improvement of the quality of the health services.

Slovenia is on the path to cervical cancer elimination



The incidence of cervical cancer has more than halved since the introduction of the ZORA programme. In recent years, we are approaching the consensus threshold for cervical cancer elimination.

High level of trust among Slovenian women

72%
3-year screening coverage

86%
5-year screening coverage

High quality of work by programme providers

>99%
Pap smears satisfactory for evaluation



8
average number of working days from sample collection to results



5%
of women need additional management due to pathological cervical smear results



11%
of women with low-grade cervical changes need treatment due to precancerous lesions



56%
of women with high-grade cervical changes need treatment due to precancerous lesions



0.5%
of women with negative cervical smear presents with precancerous lesions at the next screening

Transition from Opportunistic to Organised Population-based Screening

Despite the widespread opportunistic screening, the incidence of cervical cancer in Slovenia started to increase again in the early 1990s, based on the Cancer Registry of the Republic of Slovenia, which prompted the introduction of the organised population-based screening programme ZORA. This trend was not observed in the countries of Northern Europe, where screening was already organised. In opportunistic screening, screening is typically attended by more aware and informed women, who have a lower baseline risk. However, the quality of services, the benefit-harm ratio of screening, and the healthcare spending are typically higher than in organised screening.

With the introduction of all the elements of an organised population-based screening programme in Slovenia with the establishment of the ZORA Programme in 2003, we have maintained the same screening method in Slovenia, limited the age of screening participants and extended the screening interval from one to three years. Due to the increase in screening coverage of the target population and the improved quality of the work of providers at all levels, the number of precancerous lesions detected and treated in time increased, leading to a significant reduction in the burden of cervical cancer in Slovenia. In addition, the proportion of women requiring further management after screening due to a pathological screening test result or a poor-quality sample has decreased from 30% (ZORA Registry data from the pilot in the Ljubljana region before 2003) to 5% (ZORA Registry data from recent years) due to the increased quality of smears and work in cytopathology laboratories.

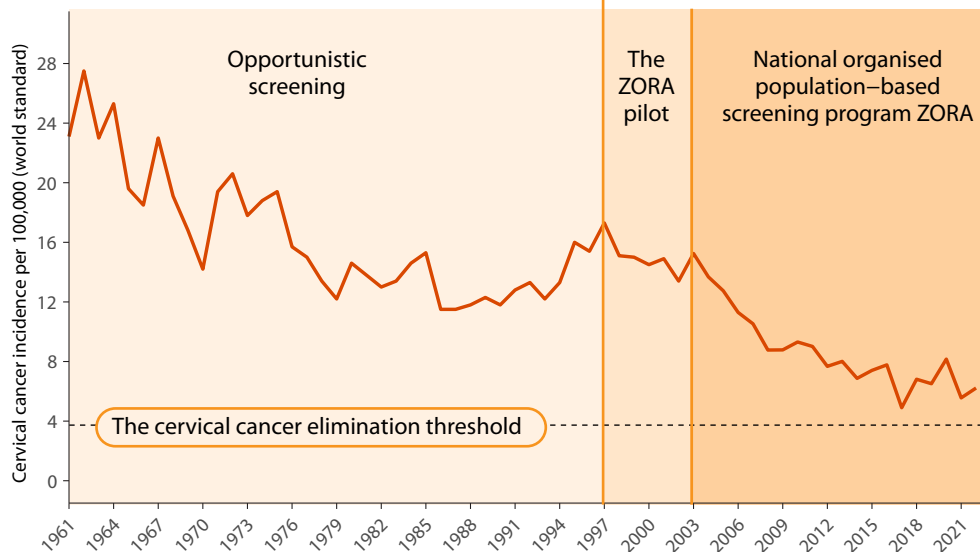
Since the introduction of the ZORA programme, the incidence of cervical cancer in Slovenia has more than halved. In recent years, around 100-120 women have been diagnosed with the disease annually. With an age-standardised incidence rate (world standard) of 5-8/100,000 women and a mortality rate of around 2/100,000 women, Slovenia already ranks among the European countries with the lowest burden of this cancer and is well on its way to eliminating the first cancer ever.

Opportunistic screening

- Conventional cytology
- 1-year screening interval
- Every 3rd woman needs additional management after screening
- Unknown: screening coverage of women, quality of health services

Organised population-based screening ZORA 2003

- Conventional cytology
- 3-year screening interval
- Women aged 20-64 years
- Systems in place to ensure, monitor and evaluate the screening coverage and quality of health services
- Women's screening coverage 72% (3-year) and 86% (5-year)
- One in 20 women needs additional management after screening
- **MORE precancerous lesions detected and treated**
- **LESS cervical cancer**



The pivotal year 2003: the transition from opportunistic to organised population-based screening.

Source: ZORA Registry, 2023, Cancer Registry of Republic of Slovenia

20 years of the ZORA Programme, 2023



Dr. Ana Pogačnik, MD,
Specialist in Cytopathology,
Head of the ZORA Expert
Group on Cytopathology,
Member of the ZORA Expert
Council

Key Achievements in Cytopathology

The first and very important step for the development of Slovenian cytopathology was taken by cytopathologists with the preparation and adoption of the legal basis for quality assurance of cytopathological services in the ZORA programme. After several years of often difficult implementation of high standards between 1997 and 2001, we came to an agreement in 2001 when the Regulations on the Operation of Cervical Smear Laboratories were adopted, and published in 2004. In 2006, the original classification in the Regulations was slightly modified, and in 2011, all further minor differences were resolved, bringing the classification fully in line with the Bethesda classification.

Another landmark improvement in the field of cytopathology is the 2008 introduction of external quality control of cytopathology laboratories. A team of four cytopathologists carried out a double-blind and anonymous audit of cervical smears from women with

cervical cancer who participated in the ZORA programme over a period of ten years in order to identify challenges in the quality of cytopathological diagnosis and to plan and implement activities to improve the quality of cytopathology.

In 2006, the Institute of Oncology Ljubljana, which has been the programme's responsible institution since its inception, launched the School for Screeners, which was renamed the School of Gynaecological Cytopathology in 2022. With the help of experts from Vancouver, we have developed and set up a six-month course in gynaecological cytopathology with a final exam that is mandatory for all screeners. In 2008 and 2009, we also organised one-week refresher courses for all older screeners who had already been examining cervical smears. A small proof of the successful development of our cytopathology is, among other things, the fact that all our screeners have passed the international QUATE test, most of them with distinction.

Between 2020-2023, we organised five training workshops for the evaluation of liquid cytology slides, which were attended by almost all Slovenian cytotechnicians and cytopathologists. The workshops were held under the umbrella of the pilot study on the introduction of liquid technology in the ZORA programme, involving almost 500 Slovenian women.



Prof. Dr. Špela Smrkolj, MD,
Specialist in Gynaecology
and Obstetrics, Head of
the ZORA Expert Group for
Gynaecology, Member of
the ZORA Expert Council

Key Achievements in Gynaecology

Since 1960, gynaecologists in Slovenia have been carrying out preventive gynaecological examinations to detect precancerous cervical lesions. In the early years, the recommendation that every woman should also have an annual gynaecological examination helped to significantly reduce the number of cervical cancer cases. But in the early 1990s, when cancer incidence started to rise again, it became clear that this alone was not enough and that women who did not otherwise opt for preventive checks should also be involved.

Organised screening presented an opportunity to stop the increasing burden of cervical cancer. The ZORA programme has brought clear guidelines for screening, but it has also given gynaecologists a big task—to invite every eligible woman aged between 20 and 64 to a preventive gynaecological examination every three years. Although we ourselves faced the challenge of how to invite women without information support, most of the gynaecologists organised themselves and the programme got off the ground. At first, women were uneasy with the extended interval between examinations, as they were used to annual checks, and doctors had to get used to it too. But the renewed decline in cervical cancer has shown that we are moving in the right direction.

Urška Gašper Oblak, MD,
Specialist in Gynaecology
and Obstetrics, Member of
the ZORA Expert Council



The incidence of cervical cancer in Slovenia is now low, which is a great achievement. All gynaecologists and their teams can be really proud of what we have achieved, even though there are not enough of us and we have been stressing for many years that the network of gynaecologists needs to be expanded, especially at primary level. But the balance is ever fragile. Many challenges still lie ahead. We urgently need a central IT support that will allow gynaecologists to access the women's cytology, histology and colposcopy results and will invite all eligible women for screening. We need colposcopy clinics and modern access to the results of these clinics. We also want to follow the latest recommendations to introduce primary HPV screening instead of smear cytology.

Since 2012, we have co-organised a colposcopy course every year, certified by the European Federation for Colposcopy. In 2019, we organised the 4th Regional Meeting on Cervical Cancer Prevention, which was attended by 75 experts from Croatia, Serbia, Bosnia and Herzegovina and North Macedonia.

We want to be involved in the debate on how the programme will evolve. Everyone involved in the ZORA programme is working towards the same goal. Let cervical cancer be a rare disease for future generations, one they will learn about in books but have little chance of ever seeing.



Each year, 155,000 women attend screening, nurses are usually the first point of contact



1% of all women will need a colposcopy due to high-grade changes detected in screening

Diagnostic cytology and pathology of uterine cervix workshops, Faculty of Medicine UL, 2016



Participants of the final workshop of the pilot Quality Assurance Scheme in Pathology, Institute of Oncology Ljubljana, 2018





Prof. Dr. Margareta Strojan
Fležar, MD, Specialist in
in pathology, head of the
ZORA Expert Group on
Histopathology, member of
the ZORA Expert Council

Key Achievements in Histopathology

The ZORA screening programme uses cytopathologic examination to detect pathological cells in cervical smears. Any precancerous lesions or cancer are further confirmed by histopathological examination of tissue samples, which is the basis for decisions on further diagnosis and treatment of women.

Histopathological diagnosis remains the 'gold standard' for quality control of cytology and colposcopy and is therefore one of the key elements for assessing the effectiveness and efficiency of a screening programme. The ZORA Registry has been collecting the histopathology reports on cervical tissue samples since 2004. It was soon realised that the data set, terminology, format, transparency of results and frequency of transmission varied considerably between laboratories. Therefore, one of the first objectives in the field of histopathology linked to the ZORA programme was to standardise and computerise histopathology reports.

Pathologists working on cytology at ZORA also prepared the first drafts of the standardised form for reporting results as early as 2007. These were updated in the following years and

included in the Guidelines for Standardisation of Procedures and Histopathology Reports in Gynaecological Pathology – Cervical Neoplasia in 2014. Standardisation and computerisation of not only the histopathology but also the colposcopy results should take place over time, together with the ongoing entry of all required data into the appropriate computer program. In 2017, the idea was included in the project document for the overhaul of the ZORA information system, which would cover and link all the results of every single woman taking part in the ZORA programme. The latter was recognised as a necessary measure for optimal healthcare.

In conjunction with the ZORA programme, the first training in cervical histopathology was carried out in 2016, starting with an innovative e-course and continuing with a classical microscopy workshop. The very next year, we organised the first pilot Quality Assurance in Pathology scheme with state-of-the-art electronic evaluation of digitised cervical histopathology slides.

The ZORA programme is entering its third decade, which promises major changes and new challenges in screening policy. But there is no doubt that histopathology will retain its key role in assessing the effectiveness and efficiency of the screening programme. That is why pathologists will remain one of the key constructive collaborators in multidisciplinary teams that will continue to strive for optimal care for women until cervical cancer is eliminated with the tools available to us.

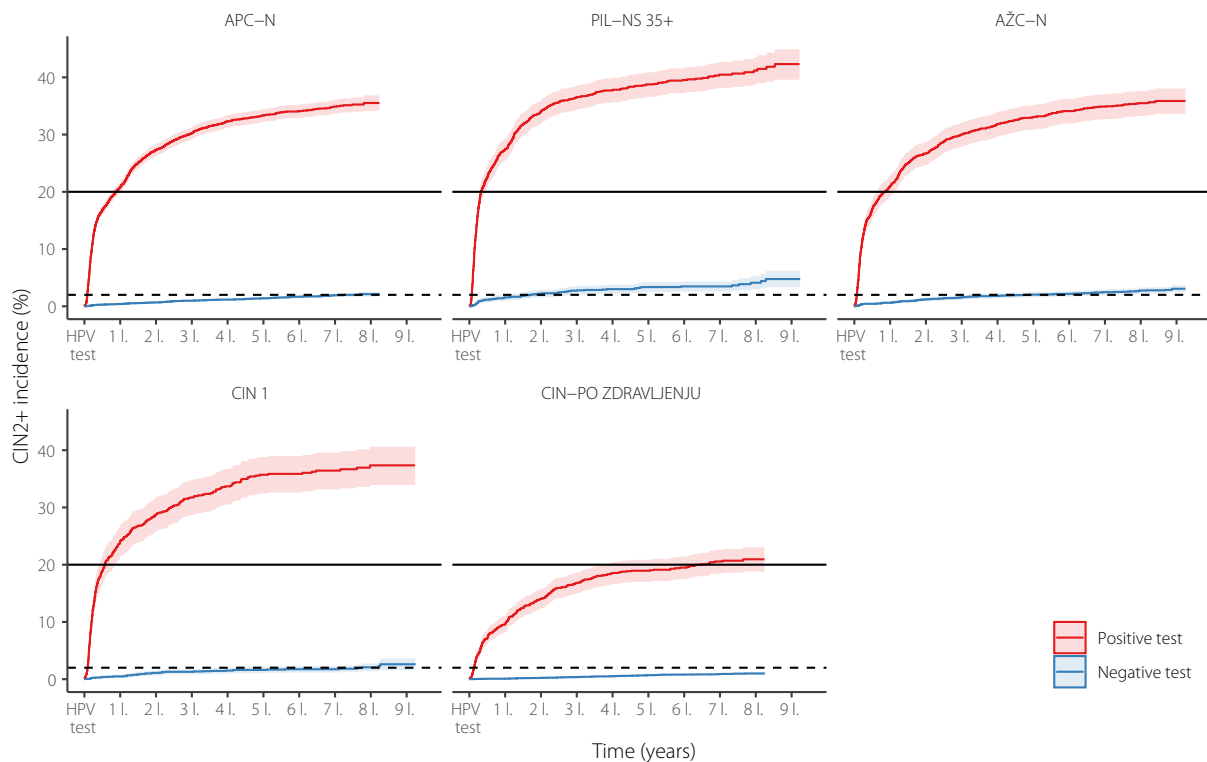


Prof. Dr. Marjetka Uršič Vrščaj, MD, Specialist in Gynaecology and Obstetrics, 1952-2012

Introduction of HPV Testing in Slovenia

In Memory of professor Marjetka Uršič Vrščaj

Despite the remarkable success of organised population-based cervical screening with conventional cytology in Slovenia and abroad, evidence from international studies began to accumulate shortly after the introduction of the ZORA programme that the well-thought-out inclusion of molecular testing for HPV infection in screening algorithms could further improve these results. In Slovenia, the main voice calling for HPV tests in the screening programme belonged to professor Marjetka Uršič Vrščaj, a specialist in gynaecology and obstetrics from the Oncology Institute in Ljubljana, who introduced the use of the HPV test for triage purposes into the professional guidelines for the care of women with pathological findings in low-grade cervical changes and after treatment of precancerous lesions. Since 2010, the HPV triage test has been part of the national guidelines and covered by compulsory health insurance, and all data on the use of the test on the cervix in Slovenia is aggregated in the ZORA Registry.



Nine-year follow-up of cervical precancerous lesion accumulation in women with low-grade lesions and after treatment for precancerous lesions according to the baseline HPV triage test results. With a negative HPV triage test result (blue curve), the risk of precancerous lesions is low and does not reach the threshold for early follow-up (dashed black line), even though women had pathological lesions at the time of testing. In women with a positive HPV triage test (red curve), the accumulation is significantly higher, with differences between the test indication.

Source of the figure: Varl J, Oncology Institute Ljubljana, PhD thesis at the Faculty of Medicine, University of Ljubljana.

Source of data: ZORA Registry, 2021

4.

ZORA PROGRAMME THROUGH PERSONAL EXPERIENCE

"I am very grateful that we have the ZORA programme in Slovenia and I encourage all women to take up the invitation for screening, as it could save their lives."

Nevenka, Novo mesto



ZORA Saved My Life

I had regular screenings with my gynaecologist and for a long time the results were fine, so I went back every three years. I was surprised when my gynaecologist informed me that the smear showed initial changes, so she also took a smear for the HPV triage test at the check-up, which came back positive. After that, I had regular check-ups and a colposcopy, but there was no sign of any serious illness. As the HPV test was still positive after two years, my gynaecologist referred me to the Clinic of Gynaecology and Obstetrics at University Medical Centre Ljubljana, where it was decided that I needed to conisation with an electric loop. And to my surprise, it turned out that the removed part of my cervix was CIN 3, which is still a precancerous lesion, but of the highest grade. It had been cut out in time and completely. Although I was shocked, I was also relieved, as this lesion would very likely have progressed to cancer if it had not been detected and removed in time. I am very grateful that we have the ZORA programme in Slovenia and I encourage all women to take up the invitation for screening, as it could save their lives. I am also very grateful for the incredible work of my gynaecologists. When one of my gynaecologists told me that she had a PhD in HPV and that she recommended the HPV vaccine, I told my daughter, because my granddaughter was in the 7th grade of primary school at the time and they were discussing whether to opt for the vaccine. Today my granddaughter is vaccinated, and my mind is at ease.

Nevenka, Novo mesto



She Lived Many Years Ago

She lived many years ago... as if I were starting a fairy tale, which this story certainly isn't. We, the on-call doctors, visited her (let's call her Maja) in the last stage of metastatic cancer. At the time, we were relieving patients' suffering with morphine and corticosteroids. I see her lying in the oversized bed... tiny body, sunken face, eyes full of pain staring at us, begging for redemption... struggling and hoping... unable... fainting... The memory still hurts. She fell ill at 18, cervical cancer. At the time, few experts knew that this cancer could be associated to human papillomavirus infection. And there probably hadn't been many scientists working on vaccine development. Then we got the vaccine and I swore to myself that no girl or woman would ever have to die from HPV again. And so, a few years later, I decided to vaccinate the boys. We had already started vaccinating with municipal funds six years before they were included in the national vaccination programme. The great opportunity and challenge was recognised throughout the entire Carinthia region. Teamwork, training ourselves in teams, cooperation with the regional unit of the National institute of public health and the Carinthian Cancer Society, lectures for parents, writing articles for various media, also at the national level, appearances on the radio, television... extraordinary personal efforts and work of everyone involved. I can't even list everything. In Carinthia, too, not everything is running smoothly anymore. The covid-19 pandemic has made parents untrusting, sensitive and hesitant. But we persevere and we work... and we wish for strength, knowledge, compassion and patience.

TOGETHER WE CAN END CERVICAL CANCER!

Miroslava Cajnkar Kac, MD, Specialist in School Medicine



Marjeta's Victory

I am a mother of two grown-up daughters and a grandmother of a beautiful grandson. Despite my age, I feel OK, I don't have any serious health problems, but it hasn't always been this way.

I was 26 years old and had regular gynaecological examinations. After two births, I had an intrauterine device inserted, but the gynaecologist soon removed it because I wasn't feeling well. Then the bleeding started and lasted for almost two months. I went back to see my gynaecologist and a histological examination of the cervical tissue showed a lesion that required conisation. Histological examination of the excised tissue showed a cancerous lesion, so my whole uterus was removed. All the cancerous tissue was removed surgically, so I didn't need chemotherapy or radiation. Unfortunately, I had a lot of complications after the operation (bleeding, urinary incontinence for a few years, extremely low body weight, impaired kidney function, abdominal growths, lower back pain). At home, my two girls, aged eight and six, were waiting for me. My loving husband cared for them during that time. It was mainly because of my girls that I fought the disease and survived.

It has just been 42 years since I was born again, so to speak. Unfortunately, not all women are so lucky. The disease was also intolerant of the fact that I was still very young and could still have children. I am glad that the ZORA programme is available to Slovenian women now and that it prevents many stories like mine. And I am very happy that the HPV vaccine, which protects against cervical cancer and precancerous lesions, is available to Slovenian girls and boys. Trust medical experts and science!

Marjeta, Radenci

5.

SLOVENIA ON THE PATH TO ELIMINATING CERVICAL CANCER

The World Health Organization has launched the Global Strategy to Accelerate the Elimination of Cervical Cancer in 2020. Cervical cancer is the exception, as we know enough about it to prevent almost every new case with HPV vaccination, screening and treatment of precancerous cervical lesions. Slovenia has already met two of the three World Health Organization targets for eliminating cervical cancer, i.e. more than 70% of women participating in the ZORA programme and more than 90% of precancerous cervical lesions detected being adequately treated. The third target, 90% HPV vaccination of girls, has not yet been achieved.

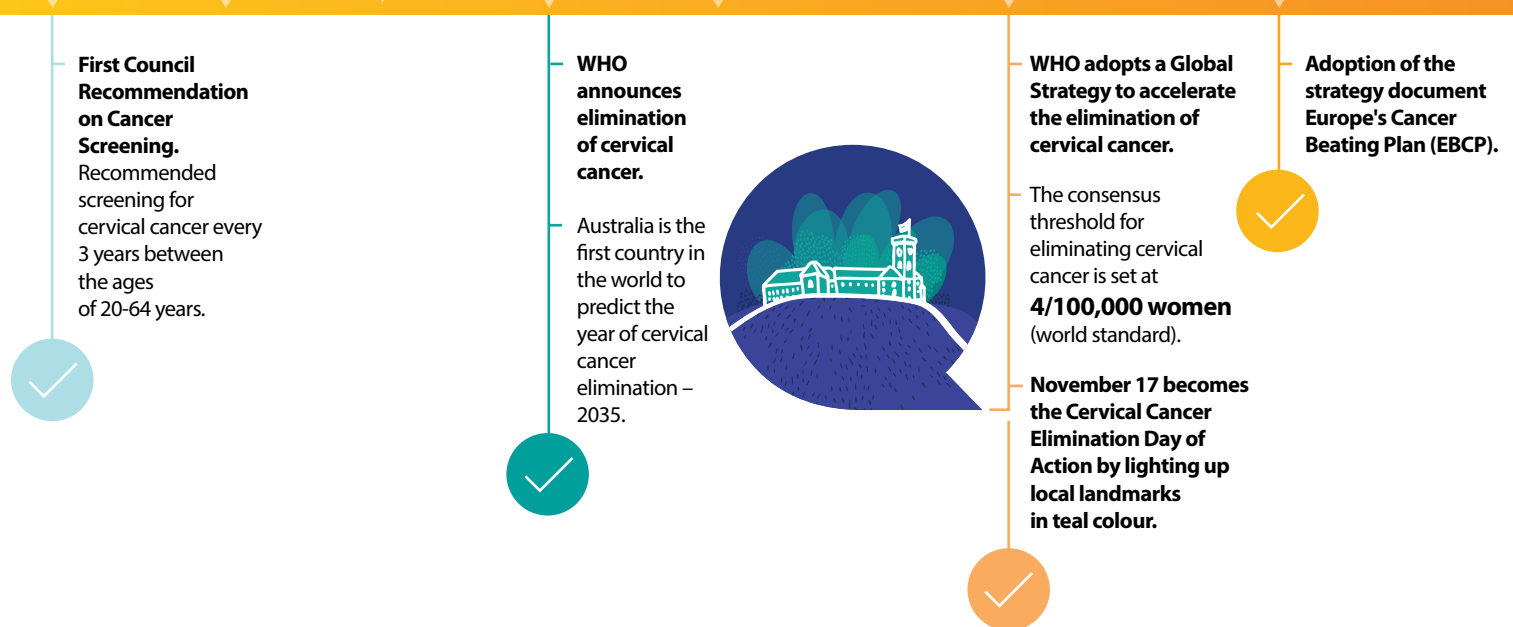
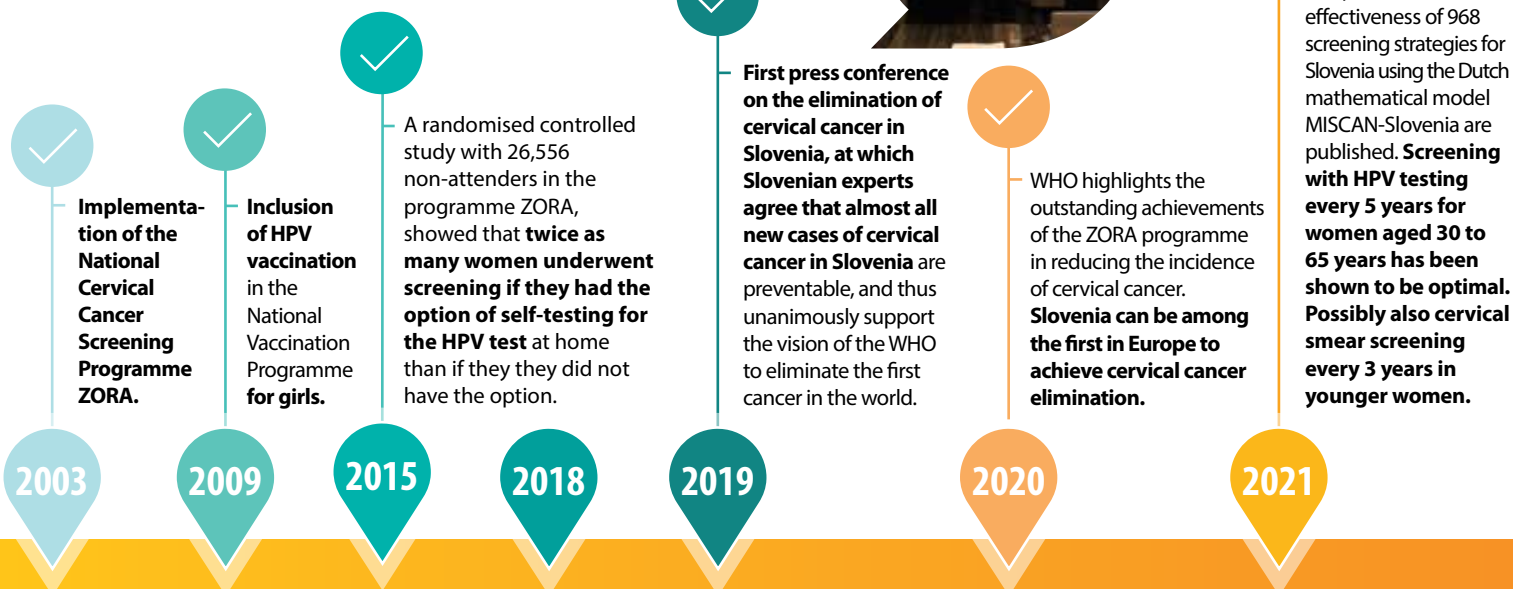
Due to the successful detection and treatment of precancerous cervical lesions under the ZORA programme in recent years, Slovenia is already approaching the threshold for the elimination of cervical cancer as a public health problem, which will be reached when the age-standardised incidence rate of cervical cancer (the world standard) falls and stays below 4 new cases per 100,000 women. With these results, Slovenia aims to become one of the first European countries to eliminate cervical cancer and other HPV-related cancers. To achieve this, we need to increase HPV vaccination coverage and make a deliberate shift towards HPV screening of women in the target group.

In 2019, at the first press conference on the elimination of cervical cancer in Slovenia, Slovenian experts voiced their support of the World Health Organization's global campaign to eliminate the first cancer ever and called for increased HPV vaccination

From left: Miroslava Cajnkar Kac, Maja Primic Žakelj, Maja Jurjevec, Leon Meglič, Urška Ivanuš, Mario Poljak, Nadja Šinkovec Zorko.



Milestones for the elimination of cervical cancer in Slovenia and worldwide



2022

Slovenia is cited as an example of good practice for the transition from opportunistic to organised screening in the WHO publication "A short guide to cancer screening: increase effectiveness, maximize benefits and minimize harm".

2023



Enrollment of two new cohorts of boys in the HPV vaccination programme.
Very Seriously about HPV: the first national HPV vaccination campaign with the participation of writer Desa Muck.

2024

Calculation of the year of elimination of cervical cancer in Slovenia based on the HPV vaccination rate and women's participation in the ZORA screening programme by using the MISCAN-Slovenia mathematical model in collaboration with ERAMUS Medical Center, Rotterdam, NL.

Launch of a pilot screening programme with the HPV test. Supported by the Targeted Research Programme 2023, co-funded by the Ministry of Health of the Republic of Slovenia and the Slovenian Research and Innovation Agency.

2026

Adoption of new ZORA strategy and screening policy: HPV testing and adapted approaches for non-attenders.

2030

FUTURE

The WHO Roadmap to accelerate the elimination of cervical cancer in the European Region 2022-2030 is adopted.

Launch of the European project PERCH - Partnership to Contrast HPV, with the aim of increasing HPV vaccination, in which Slovenia also participates.

Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening, 9.12.2022, replacing Council Recommendation from 2003: recommended screening with HPV test every 5 years between the ages of 30-65 years and consideration of adapting screening for non-attenders.

90%

of girls fully vaccinated with HPV vaccine by age 15 years.

70%

of women are screened with a high-performance test by 35 years of age and again by 45 years of age.

90%

of women identified with cervical disease receive treatment (90% of women with precancer treated, and 90% of women with invasive cancer managed).

Goal achieved:
90-70-90

Europe's Beating Cancer Plan initiative: least 90% of girls fully vaccinated with HPV vaccine and a significant increase in HPV vaccination of boys. Continued investment in adequate infrastructure to eliminate HPV cancers.

Annual Illumination of Slovenian Landmarks with the Symbolic Colour of Cervical Cancer

Every year on 17 November, on Cervical Cancer Elimination Day of Action we commemorate Slovenia's commitment to eliminate cervical cancer by illuminating Slovenian landmarks in teal, the symbolic colour of cervical cancer.



In 2020, Bled Castle was illuminated in teal.

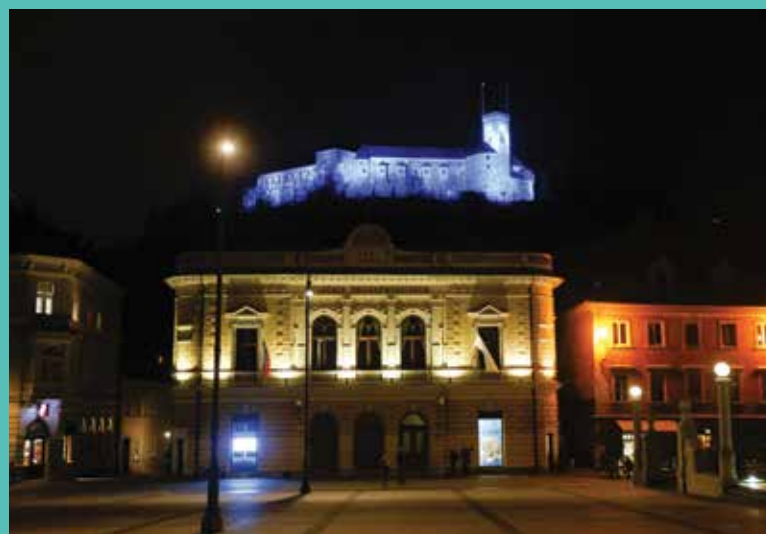
Photo: Miro Zalokar






The photo of Bled Castle was also used by the World Health Organization.

The illumination of landmarks every 17 November demonstrates the unity of many countries around the world in this historic commitment to eliminate the first cancer ever. In Slovenia, activities on this day are coordinated by the Association of Slovenian Cancer Societies with eleven regional associations.





CeCEliAH (Cervical Cancer Elimination Action Hero) – World Health Organization Action heroine fighting to eliminate cervical cancer and other HPV-related cancers

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