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Challenges in starting organised screening programmes for cervical cancer in the new member states of the European Union

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ABSTRACT

Following the 2003 Recommendation of the Council of the European Union on cancer screening, equal access to organised cervical cancer screening is supposed to be ensured for all women at risk in all member states. However, the first IARC report on the implementation of the Council Recommendation suggests that a remarkable proportion of women in the new member states are not yet covered with the free Pap tests offered either in organised or opportunistic manners. Cervical cancer incidence and mortality rates in most of these countries are among the highest in Europe. The purpose of this paper is to identify some common challenges and make further proposals in organising and implementing quality-assured cervical cancer screening programmes in these countries. Based on the responses to a corresponding questionnaire, a summary on cervical cancer prevention policies was established for the seven new European Union member states, Czech Republic, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia, and two candidate states, Croatia and Serbia. In most of these countries there are a lot of challenges to overcome before achieving the level of preventive services as seen in Finland and the Netherlands nowadays.

1. Background

Cervical cancer incidence and mortality rates in the new member states of the European Union (EU) are still an important issue.[1–4] Available evidence on the efficacy of well organised screening programmes in decreasing cervical cancer incidence and mortality is sufficient for all these countries to implement population-based organised screening programmes.[5] Some of the new EU member states have already started large-scale, even though costly and apparently still relatively ineffective, activities whereas in some other countries no real screening activities are in action yet.[6,7]

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Recently, efforts have been made to implement the Recommendation of the Council of the EU on cancer screening.[8] The Second Edition of European guidelines for quality assurance (QA) in cervical cancer screening was released in 2008, including comprehensive recommendations and suggestions to be considered in planning, organising and monitoring new programmes.[9] There is still a huge disparity between member states regarding not only the burden of the disease, but also access to quality-assured screening and related health-care services.

The aim of the current study is to assess the present status of cervical cancer screening in the new member states and two applicant countries, and discuss the challenges and obstacles in planning evidence-based and cost-effective organised screening activities. We also aim to develop new proposals based on these data, which will include the key points necessary for improvement of the overall situation of cervical cancer prevention in Europe.

2. Materials and methods

Data on screening implementation for the new member states were collected from the recently published status report of cancer screening programmes in the EU.[7] Further information on cervical cancer screening was collected through a questionnaire from each of the new member states and two applicant countries. The questionnaire included the following items: country, name and affiliation of responder, screening policy and target population, and coverage (national or regional; defined as the proportion of women in the target population screened at least once in the specified interval). Further questions included information on management and clinical resources; on population, cancer registry and screening database accessibility; and on implementation of the EU quality assurance guidelines,[9] and existence of national guidelines. The questionnaire was sent to 12 new member states (Bulgaria, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia) and two non-member states (Croatia and Serbia). The seven responders for the new member states were: Dr. Ruth Tachezy for Czech Republic, Dr. Ilze Viberga for Latvia, Dr. Juozas Kurtinaitis for Lithuania, Dr. Arkadiusz Chil for Poland, Dr. Florian Nicula for Romania, Dr. Miloš Mlynček for Slovakia and Dr. Maja Primic Žakelj for Slovenia. Two candidate states, Croatia (Dr. Magdalena Grce) and Serbia (Dr. Vesna Kesić) also responded.

3. Results

3.1. Screening policies

Table 1 presents the current situation and the plans of new member states and two non-member states of the EU, based on the recent status report of cancer screening in the EU[7] and the questionnaire responses designed for this study. In addition, Table 1 shows data on the HPV vaccination policies and practices based on authors' personal communications and the recent report edited by the European Cervical Cancer Association (ECCA).[10]

The non-population based or opportunistic screening was still the only modality in place in Bulgaria, Croatia, Czech Republic, Cyprus, Latvia, Lithuania, Malta and Slovak Republic, while the population-based organised screening programme was implemented or piloted in the period from 2003 to 2008 in Estonia, Hungary, Poland, Romania, Serbia and Slovenia. In Croatia, Romania and Serbia regional pilots were ongoing together with the planning of national organised screening programmes. In Latvia, a population-based screening programme has been planned to be implemented in 2009. In the Czech Republic the state of the nationwide organised screening programme was officially announced in February 2008, after completion of the current data collection period. According to the responses to the questionnaire, quality assurance of cytology, national guidelines and/or recommendations, population database and cancer registries are available in each country. Gynaecologists are the main sample-takers in each responder country, and the screening tests were taken in connection with preventive gynaecological examinations or by opportunity. Invitational procedures or pilots were practiced in Poland, Romania and Slovenia. The proportion of women tested at least once during the screening interval was 24% for Poland, 30% for Latvia, 35% for Czech Republic, 62% for Serbia and 70% for Slovenia.

For the Czech Republic the estimate was for a 1-year interval only while for the rest it was a 3-year interval.

3.2. Organised national screening programmes

3.2.1. The situation in Slovenia

In Slovenia, opportunistic screening was introduced in regular gynaecological practice in 1960.[11] According to the data of the Cancer Registry of Slovenia there were no major changes in the incidence rates of cervical cancer from the late 1970s onwards, except that in 1994 the incidence rate started to increase again. This increase was ascribed to inefficiency of opportunistic screening in Slovenia and in 2003, after an initial pilot study, the organised screening programme was established. The programme has its legal basis in several regulations and recommendations.[12]

According to the new recommendations, each woman between ages 20 and 64 years is to be invited to undergo a preventive gynaecological examination together with the Pap smear once every 3 years (after two negative smears) either by her 'personal' gynaecologist, with whom she has already been registered, or by the Screening Registry in case she has not been registered yet.

Four years after the start of the national programme, 70% of women in the target age group (20–64 years) had at least one smear registered in the Screening Registry, located at the Institute of Oncology Ljubljana, Epidemiology and Cancer Registry Unit. The percentage is about 80% till the age of 45 and smaller among older women. According to the data from the Cancer Registry of Slovenia, the whole population-based incidence rate of cervical cancer has started to decrease, especially in the age group 35 to 49 years.

3.2.2. The situation in Poland

In Poland, at the beginning of 2007, an organised national cervical cancer screening programme started.[13] For management of

Table 1 – Cervical screening practice in Europe based on responses to the corresponding questionnaire and the recent report.

Countries	Cervical cancer rates		Cervical screening policy				HPV vaccination policy
	Incidence ASR(W)[a]	Mortality ASR(W)[a]	Organisation	Target population	Target age (years)	Screening interval	
Bulgaria	18.7	8.0	Non-population based	1.9 million	31–65	2-years	No
Croatia[b]	13.3	5.0	Non-population based, one pilot since 2006	1.2 million	25–64	3-years	Yes, a pilot programme since March 2009.
Czech Republic[c]	16.2	5.5	Non-population based	2.9 million	25–69	1-year	Yes, several insurance companies provide partial reimbursement.
Cyprus	11.6	5.3	Non-population based				NA
Estonia	15.5	6.6	Population-based, national since 2003	288,000	30–59	5-years	No
Hungary	15.7	6.7	Population-based, national since 2003	2.8 million	25–65	3-years	Yes, HPV vaccination has been included in the recommended vaccination.
Latvia	12.9	7.4	Population-based, nationwide from 2009	820,000	20–70	3-years	Yes, a pilot programme to vaccinate girls aged 12 is planned for 2010.
Lithuania	17.6	9.0	Non-population based	750,000	30–60	3-years	Yes, starting in 2012.
Malta	4.8	1.6	Non-population based				NA
Poland	18.4	7.8	Population-based, national since 2007	7.8 million	25–59	3-years	Yes, HPV vaccination has been included in the recommended vaccination list.
Romania	23.9	13.0	Population-based, regional pilot since 2002	6 million	25–64	5-years	Yes, since 2008.
Slovak Republic	18.5	6.1	Non-population based, national	2.2 million	>18	1-year	Yes, approximately 10% of the cost of vaccination is covered by compulsory medical insurance.
Slovenia	16.1	4.7	Population-based, national since 2003	630,000	20–64	3-years	Yes, starting in autumn 2009.
Serbia[d]	27.4	10.1	Population-based, pilot 2004–2006 national from 2008	2.3 million	25–69	3-years	No

NA: Data not available.

a Age Standardised Rate (World) according to GLOBOCAN 2002 (Ferlay et al., 2004[1]).

b Non-member states of the European Union, applicant countries; screening targeted within the age of 25–65 years and the 3-year interval is planned to be implemented in the future.

c Population-based since 2008, with the target age of 25–5 years and the 3-year interval is planned to be implemented in the future.

d Non-member states of the European Union, applicant countries.

the programme, coordinating offices were established by the Ministry of Health. About 8 million women aged 25–59 in 3-year intervals will receive invitations for cytology, which will be sent out by the National Health Fund. In order to collect the data of women participating in the organised screening, a computer database of prophylaxis was implemented. Detailed information of the anamnesis and enrolment data of invited women are recorded onto the computer database system including data from cytology laboratories, the outpatient clinics where the Pap smear was taken, and in the case of patients with an abnormal smear, on further diagnostic confirmation within the colposcopy clinics.

As the organised screening was introduced without well-designed pilot programmes, its shortcomings and the adverse impact of opportunistic screening on the organised programme became visible after the first few months. Women and gynaecologists were reluctant to participate in the programme. Therefore, at the beginning of 2008, significant modifications were introduced which aimed to facilitate access to the programme for women and to encourage gynaecologists to participate in the organised screening. Further corrections were also implemented which aimed to improve the invitational system and attendance of women with abnormal smears to colposcopy clinics working within the programme. As the organised programme in Poland is developing and the corrective changes are promptly applied on a large-scale without pilot programmes, there is still no clarity on which model, to organise these interventions, is well workable and efficient.

3.2.3. *The situation in Serbia*

Cervical cancer prevention in Serbia has relied on non-population based screening that is characterised by high coverage in

younger and low coverage in middle-aged and older women. Screening of selected groups of women employed in large companies is performed annually by many regional hospitals but this approach has little effect on morbidity and mortality. A number of pilot projects have been undertaken from 2002–2006 with the results being used for the development of a national programme for cervical cancer screening. In 2006, the Ministry of Health nominated an Expert Group to develop and implement a national cervical cancer screening programme. Work on the national programme was finalised in 2007.[14]

The Serbian Government approved the national programme for organised screening in May 2008, and it became an obligation for all subjects involved in the prevention of cervical cancer.

The target population is women aged 25–69 (approximately 2.3 million women), which will be screened by cytology every 3 years. The primary healthcare units conform to the basis of screening and the programme is run on an organised, even though decentralised, model. Serbia has 162 primary healthcare units, with more than 500 gynaecologists involved in the realisation of the national screening programme. Each primary healthcare unit is responsible for the population they cover and the organisation of invitations and collection of smears is adapted to local circumstances, regarding the available resources. Cytoscreening is performed on the primary level and all abnormal and 10% of all normal samples are referred to second level cytological laboratories to be reviewed by cytopathologists. The criteria for the second level (cytopathology) laboratories are strictly mandated by the programme. The coordination of all issues related to the work of Primary Health Care Units could be managed by a National Screening Centre, which could also collect the final data through the network of the Regional Public Health Institutes.

3.3. *Organised regional pilot and planning organised national programmes*

3.3.1. *The situation in Romania*

In Romania, a regionally organised, population-based pilot has been ongoing since 2002 and planning of a national programme started in 2008. The coverage of the regional pilot was 21% by the end of 2008.[15]

Difficulties appeared at almost all levels: first, in the organisation of the management unit and then subsequently in the implementation unit network, in training people in screening management, in setting standards and criteria, as well as in the protocols for the cytological laboratories, colposcopies and treatment units.

The screening database is connected to the regional cancer registry. Although the cytological results of the screening programme are registered at a rate of almost 100%, histology results and treatment and follow-up data are reported for less then 15% of the lesions found in the programme. The referral rate to colposcopy is high, but few are reported. This is the reason why, since 2008, new rules for data reporting and colposcopy registries were implemented.

Regional QA guidelines are used in line with the European recommendations (Arbyn et al., eds., 2008). Organising a national screening programme needs important EU guidance and assistance; for instance, at the level of screening management, only a few trained specialists are available regionally. The infrastructure of the screening network is insufficient; the estimated available quality assured resources represent less than 10% of the necessary resources.

3.3.2. *The situation in Croatia*

In Croatia, non-population based screening was introduced in 1968 and this was accompanied by decreasing cervical cancer incidence rates until the year 1991 but no further consistent decrease has been observed afterwards. The cervical cancer mortality rates remained at a low level during the entire period but no decrease was observed over the last decade. It is evident that even the opportunistic cervical cancer screening in Croatia had an impact on cervical cancer control. The number of Pap smears taken yearly is still increasing and reached more than 500,000 in 2005 in the whole country.[16] However, in the absence of an organised population-based programme, it is difficult to assess the efficacy of this screening approach and it is clear that a large proportion of the age-eligible target population still remains unscreened or under-screened. The only way to achieve further reductions in cervical cancer cases is through the introduction of an organised population-based cervical cancer screening programme. Following the elaborated 2003 proposals on prevention and early detection of breast, cervical, colorectal and prostate cancer of the Working Groups nominated by the Ministry of Health and Social Welfare of the Republic of Croatia, and the 2006–2011 National strategy on Health Development of the Republic of Croatia, which endorsed the 2003 Recommendations of the Council of the EU and the 2005 World Health Organisation Resolution on Cancer prevention and control,[17] the national programme of prevention and early detection of breast cancer and the national programme of early detection of colorectal cancer were implemented in 2006 and 2007, respectively. The national programme of prevention and early detection of cervical cancer was and still is the next programme planned to be implemented. The proposed programme comprises screening of all women aged 25–64 years every 3 years by conventional cytology in the first phase. In the second phase of the programme, in addition to conventional or liquid-based cytology (LBC), the human papillomavirus (HPV) test would be introduced for women aged 30–64, with 5-year screening intervals. The situation in the country was re-evaluated in 2007 and the consensus recommendation for the implementation of the organised cervical screening programme was established.[18] In 2006, a regional pilot started in the Southern-Western region of Croatia in the Primorsko-Goranska County, but further piloting in line with the proposed programme did not occur.

4. Discussion and conclusions

Despite a voluminous screening activity on-going nowadays in most of the studied applicant or new member states of the EU, the current cervical cancer burden is high compared with most of the old EU member states. Unfortunately, there is only little evidence from population-based incidence and mortality trend studies that the historical screening activity has been effective in those countries.[2,4,19] Evaluation using cohort study designs among screening populations – recommended in the

European QA guidelines for evaluation in the first place – are proceeding in some countries, but results are not available yet. It is not straightforward to assess yet in which degree the current screening activity will affect the cervical cancer burden in the future.

In all new member states, screening by the Pap test is primary method for early detection and prevention of cervical cancer. Despite the ongoing opportunistic or organised screening, a lot of women in those countries are still not covered by cervical screening. Some major barriers and challenges in organising cervical screening programmes are common for most of the new EU member states and for other countries of Central and South Eastern Europe:

- Coverage of invitations, as well as attendance based on invitations, are generally at a too low level for the programmes to be effective.
- Shortcomings in the information and awareness among women in the target population.
- Shortcomings in the management of organised population-based programmes, e.g. in identifying and inviting, in piloting, and in registration, monitoring and evaluation activities; all the necessary resources of epidemiological quality control are often not understood well enough by decision makers;
- The quality of the test is crucial: there are opportunistic practices which have been on-going for a long time with limited, or sometimes without any quality control, much more so than the organised screening activities in some of these countries. Some of these countries even have an over-capacity; often it has not yet been clarified in detail whether the screening methods are the same as the currently recommended standard methods and whether acceptable quality standards were adopted.[9,20]
- Inadequate understanding and involvement of all key medical groups and specialties of the population-based programmes; difficulties in reaching consent on decisions regarding the cost-effectiveness, population-based policy and organisation of the activity.
- Low application of colposcopy, treatment and follow-up protocols may also be a problem in some settings.
- Shortcomings in the availability of financial resources.

Building-up comprehensive quality-assured screening programmes from the identified target populations up to successful call-recall and fail-safe systems is still in a rather early phase in the herein analysed country situations. Systematic evaluation of activities of the whole screening chain are proceeding but only in a few settings and there are no systematic evaluation reports available yet based on the screening and cancer registry records and other related information sources.

How to respond to the barriers and draw-backs? Nowadays organised screening is still the only method that can be expected to timely reduce cervical cancer burden over the main age groups contracting the disease during the next few decades.[18] In contrast, non-population-based screening programmes have been shown to promote health inequalities and to be less effective, less efficient and to waste scarce healthcare money and resources.[5] How to define the screening chain optimally and how to share the various medical and population-based responsibilities, both at national and lower-level geographical units are still unsettled issues in the new EU member countries. Founding national screening coordination and evaluation centres with adequate resources and with appropriate institutional and legal backgrounds is one key. Intensive and coordinated education and training in all relevant fields for screening programmes and campaigning among populations at large and among decision makers and key medical groups are other key components. There is a need to support coordination between these centres at European level. Without these supportive mechanisms the current recommendation by the European Council is likely to be ineffective.

Most of the studies in Europe on new technologies in cervical cancer screening and prevention have been done in the old well-to-do member states, i.e. Finland, Netherlands and UK. These countries do not share similar characteristics with the new member countries in many important aspects. The disease burden is lower in the old member states of the EU and, at the same time, there are lots of resources and even wide overuse of resources, thereby having consequences on cost-effectiveness.[4,21–23] There are some benefits in the new member countries for evaluation purposes of new methods of cervical cancer screening, i.e. HPV DNA testing as primary screening with cytology triage of screen positives.[24] The disease burden is high in the new EU member states. This indicates not only a higher priority, but also the context and settings that need to be directly addressed in the evaluations. The systematic population and cancer registries and the linkage systems, which can be based on this, exist in almost all of the new EU member states. This enables very good possibilities for using convincing population-based evaluation methods.

The decision makers in public health at national level should recognise the benefit of population-based organised screening programmes and the importance of the screening management units; their existence, as well as a European School of Screening Management and related training programmes, is mandatory for the quality of all national screening programmes. Moreover, the future cervical screening programmes should take into consideration the primary prevention of cervical cancer by HPV vaccination and adapt the programmes according to the vaccination policies in respective countries. It could be speculated that in HPV vaccination high coverage populations, like in some old EU member states, cervical screening could be postponed till later on in life and be performed in wider intervals, while in those countries where the HPV vaccination coverage will be very low, like the new member states, i.e. Romania, cervical screening will still remain the main strategy for cervical cancer prevention.

Conflict of interest statement

Florian Al. Nicula – None declared; Ahti Anttila – None declared; Luciana Neamtiu – None declared; Maja Primic Žakelj – None declared; Ruth Tachezy – Membership of GSK advisory committee; Arkadiusz Chil – None declared; Magdalena Grce – None declared; Vesna Kesić – None declared.

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