

EUROCHIP-II
FINAL SCIENTIFIC REPORT
ANNEX 14

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

**Assessment study on implementation of cervical cancer
organized screening programs**

20 January 2008

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Rationale

Cervical cancer (CC) is a serious public health problem in Romania being the second common cause of death by cancer in Romanian women (after breast cancer) and the first cause of death by cancer in 25-44 years group (Nicula 2002). In the last 20 years, Romania had the highest cervical cancer mortality in Europe (Dobrossy 2002, WHO 2004).

General objective

Romanian activity performed for EUROCHIP-2 was an assessment study to evaluate the possible implementation of cervical cancer organized screening programs (CCS) in Romania.

Specific objectives

The assessment study (addressed all 8 development regions of Romania) aimed to:

- A assess the current epidemiological data on cervical cancer in Romania
- B identify types of CCS in Romania
- C measure the screening coverage in Romania
- D map the existing human resources and infrastructure for CCS
- E identify the existing barriers and problems for implementing an efficient CCS
- F assess the current political decision and methodology regarding CCS.

Data sources

- Medical statistics data^{1,2} (in 2005)
- Review documents related to SCC in Romania
- Semi-structured interviews with key informants³

A. Epidemiological data on cervical cancer in Romania by development regions

Epidemiological indicator (2005)	I	II	III	IV	V	VI	VII	VIII	Total country
CC incidence rate per 100.000⁴	572	417	509	365	431	460	392	376	3522
CC mortality rate per 100.000⁵	315	216	302	209	215	232	159	145	1793

Development regions: I: North East; II: South East; III: South; IV: South West; V: West; VI: North West; VII: Centre; VIII: Bucharest

We can observe that the highest incidence and mortality is registered in region I (572/315:100.000) and III (509/302:100.000) and be explained by a lack of effective screening programs aimed at detecting precancerous conditions, before they progress to invasive cancer. There is one exception regarding incidence: region VI (including county Cluj; 460:100.000) has an artificially higher incidence comparative to the other regions, due to an organized screening program recently implemented.

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B Identification of current cervical cancer screening programs in Romania

- Some pilot screening programs was run in 3 counties:
 - Cluj in 1999-2000
 - Bucharest & surroundings in 2001-2002
 - Iasi in 2002-2003
- The only effective cervical cancer screening program in Romania is implemented in the region of Cluj:
 - It was started in 2002 (Ordinance MSP/CNAS 85/65/2002, annually updated for methodological norms regarding implementation, evaluation, financing);
 - In the period 2002-2006 it was extended to 5 counties (region North-West). This region includes the following counties: Satu-Mare, Maramures, Salaj, Bihor, Bistrita-Nasaud. The total number of women screened was 86.000 women, from which 36.400 women (18%) was tested in the region Cluj;
 - From 2006 the program was connected to the European Network EUNICE for standardization of data related to cervical cancer.
- In the rest of the country only opportunistic CCS is present (without monitoring and evaluation activities).

C Screening coverage of cervical cancer screening by development regions

Indicator (2005)	I	II	III	IV	V	VI	VII	VIII	Total country
Women screened for CC	30265	9125	28528	16941	10179	46231	25991	30413	197673
Target population	1171922	946062	1165411	743834	659090	902847	847313	816071	7252550
Coverage rates* ⁶	2,58	0,96	2,44	2,27	1,54	5,12	3,06	3,72	2,72

Development regions: I: North East; II: South East; III: South; IV: South West; V: West; VI: North West; VII: Centre; VIII: Bucharest
* Coverage rates: women CC screened/target population (women 18-65 years)

We can observe a very low coverage rate per country-2,72. Some few explanations for this figure are: the program screening used was opportunistic; the target group is not correctly defined for the existing resources of the country; the data used was derived only from public institutions (private medical centers often not report screening activity).

Other sources⁷ show a coverage rates per country of 20%.

D Mapping of resources in the field of cervical cancer screening

In order to run a real population screening program, the Ministry of Health has elaborated an internal directive (no 23805/April 11, 2007) at the level of the Health Politics Direction, in order to collect CCS specific data from 42 County Directions for Public Health. The data collected was related to screening activities and existing facilities in each of the 42 counties: size of target population, number of cytology labs, number of histology labs, number of qualified staff/lab and the maximum working capacity/lab.

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The data collected was analyzed and following elements was noted:

- a disequilibrium in the geographic distribution of medical staff
- the shortage in the number of cytologists and histopathologists relative to target group sizes
- the lack of profession of cancer registrars and cytotechnicians
- the lack of evidence for cytology and histology accredited labs per county and consequently the lack for assuring quality control for screening tests and biopsy tests.

E Existing barriers and problems for implementing an efficient cervical cancer screening program

Human resources involved in CCS process are represented by general practitioners (GPs) and specialists (gynecologists, histopathologists, oncologists, radiotherapists, surgeons/oncology surgeons, palliative medicine specialists).

In 2005, the total number of GPs⁸ was 6094- in urban and 4501-in rural/country. These figures underlined an insufficient primary assistance in urban/rural, in 2005, related to the target population. From our national studies^{10,11,12} we noticed that there are insufficient practical skills and theoretical training for smear-takers, insufficient time for preventive activities, inadequate infrastructure, many unpaid activities among GPs involved in CCS. Regarding the specialists in 2005, we have noticed the following figures⁹: gynecologists: 2009/country, histopathologists: 461/country, oncologists: 303, radiotherapists: 81, surgeons/oncology surgeons: 1750, palliative medicine specialists: 5. From our national studies^{3,4,5} we can noticed: unequal covering of the developing regions and insufficient time because of multi-competent tasks for gynecologists involved in screening activities; insufficient number of histopathologists/country and inexistence of cytotechnician profession; very few specialists in the field of treatment/country.

From complex sources^{10,11,12,13,14} we can observe the following barriers: rural areas uncovered for CCS, low-risk women screened frequently, number of smears counted instead of persons, no follow-up system in use, no referral system in use, the lack of a system for quality assurance inside CCS. Other sources^{7,10} showed the low impact of educational campaigns regarding cervical cancer screening.

F Past and current political decision and methodology regarding cervical cancer screening programs

Before 2007:

OMSP¹⁵ No 86/06.02.2006 was the Romanian reference law for cancer screening programs. It focuses on the most frequent cancer types (cervical, breast, prostate, colon-rectal), where screening activities can have an impact. The fundamental elements for the CCS program were not adequately adapted to local conditions and resources or not clearly defined (target age group; frequency of screening; the desired coverage; method for screening and treatment; integrate/vertical programs; regulation for mid-level professional to perform clinical procedures). It does not specify clearly the monitoring and evaluation indicators for each component of the CCS program.

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In 2007:

Romania has approved 8 National Health Programs and defined subprogrammes and objectives, specific indicators and sanitary units involved in each subprogrammes (HG No 292/2007; Ordinance of MSP/CNAS¹⁶ no 570/116/2007). It has been defined the subprogram 1.2. Prevention and control in oncologic pathology, including opportunistic CCS activities. Each county public health authorities¹⁷ (42 DJPS) will make monthly reports regarding specific indicators and the National Agency for Monitoring Health Programs (inside MSP) will be the monitoring and evaluating entity for all programs.

The assessment indicators for oncology subprogram are:

- a) Indicators for results (yearly)
 - decreasing the specific mortality - 197/100.000 people
 - increasing early diagnosis by screening – by 10%
- b) Physical indicators
 - number of cervical cancer screening tests – 130.000
- c) Efficiency indicators
 - medium cost/cervical cancer screening=10 Euro
 - medium cost for activities of information, education, coordination of the program at local level and the management of the National Cancer Registry-14.285 Euro
 - total state budget-3.690 million of Euro

The medical units that will be involved in CCS activities in oncology subprogram:

- a) Oncology Institute "Prof. Dr. Ion Chiricuța" Cluj
- b) Oncology Institute "Prof. Dr. Al. Trestioreanu" Bucharest
- c) Institute for Mother and Child Health, Bucharest
- d) Clinical Institute „Fundeni”, Bucharest
- e) County public health authorities and public health authorities for Bucharest

In parallel with opportunistic CCS, will be financed an organized CCS in the development region Nord-West (Satu-Mare, Maramures, Salaj, Cluj, Bihor, Bistrita-Nasaud). The Oncologic Institute "Prof. Dr. I. Chiricuta" was designated as the National Center for Implementation of Cervical Cancer Screening.

Novelties in health legislation in 2007

1. Government decision¹⁸ (HG) No 292/2007: approval of the National Programs for Health in 2007.
2. OMSP No 13/10 ian 2007: approval of the legislative framework of content, presentation form and structure of National Programs for Health. Published in the Oficial Monitor/1 Feb 2007
3. OMSP/CNAS No. 570/116 /29 Mars 2007: approval of the Technical Normes regarding implementation, evaluation, financing the National Programmes for Health, responsibilities in monitoring and their control, subprogrammes and activities, specific indicators as well as sanitary units involved in programmes in 2007, published in Oficial Monitor No. 225/ 2 Apr 2007; Anexes nr. 1, 2 și 3 (3A și 3B) , published in Oficial Monitor, Part I, nr. 225 bis (CNAS=National House for Health Ensurance)
4. Legislative proposal of MSP 27.08.2007-26.09.2007 regarding the activity of registration on a populational bases of cancer patients data and building up the Regional Cancer Registries.
5. At working level: legislative proposal of MSP regarding the methodology of screening for cervical cancer, with the expertise of the Oncology Comissions (Oct 2007)

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Novelties for cervical cancer screening

There are identified two main directions in order to initiate an organized screening program for cervical cancer in Romania: *adequate organization of regional cancer registries* and *redefining and approving the methodology regarding cervical cancer screening*.

- 1 In Romania, The National Cancer Registry, was built in 1981 by the OMSF No 219/1981 - for individual declaration and mandatory registration of patients with cancer. At the level of oncology county offices there are built the Territorial Cancer Registries, in each of the 41 counties and 6 sectors from Bucharest. These data was centralized yearly at CNOASIIDSB, which is subordinated to the Ministry of Public Health. A new legislative regulation was introduced through the Ordinance of MSP No 871/2002, related to institutional structure for registration of cancer cases at county level, but it doesn't succeed to incorporate up-dated recommendations of the European Network of Cancer Registry (ENCR). In this direction, the Ministry of Public Health has emitted the Legislative Proposal 27.08.2007-26.09.2007 regarding the registration on a population bases of cancer patients data and building up the Cancer Regional Registries, which create the framework for implementation the ENCR recommendations and up-dating these regional registries. (source: www.ms.ro)
- 2 At working level: **The Legislative proposal** regarding the methodology in cervical cancer screening, with the support of Commission of specialty from the ministry. Coordinator at the national level will be the Oncology Institute „Prof. Dr I. Chiricuta” Cluj, which has been designated as well as the National Centre for Implementation of Cervical Cancer Screening. There will be organized regional centers for prevention and control of cervical cancer, one per each development region.

Conclusions

This is the first assessment study that follows the development regions of Romania, in order to better co-ordinate regional development and define coverage strategies adapted to local conditions and resources. Although we have obtained the epidemiological data and screening coverage rates per each development region there is still need for a complete mapping of resources and identifying specific barriers by development regions.

In Romania, the new legislative changes build up a favorable framework for implementation of an organized screening program for cervical cancer. First of all, it is mandatory to reorganize the regional cancer registries, to publish in the Official Monitor the methodology for cervical cancer screening and to monitor the implementation of this MSP ordinance in territory.

The program will include the organization of regional centers for prevention and control of cervical cancer (8 centers) and county centers for prevention and control of cervical cancer (42 centers), under the management of the National Centre for Implementation of Cervical Cancer Screening. One main focus will be on human resources involved in the process, with the purpose of forming, educating and adequate planning of those resources but also in quality assuring and quality control at different levels of the program for prevention and control in cervical cancer.

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15. OMSP-Ordinance of Ministry of Health
16. CNAS-National House for Medical Insurance
17. DJPS-County Public Health Authorities
18. HG-Government Decision