



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**COUNCIL RECOMMENDATION**

**on cancer screening**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### EXECUTIVE SUMMARY

1. Approximately one European in four, nearly one million per annum, will die of cancer. This cost of this is enormous, both in human terms for cancer patients and their families and in terms of the resources consumed by the diagnosis, treatment and care of this disease. Combating cancer has, therefore, been a long-standing European priority through the Europe against Cancer programme established in 1985.
2. This innovative programme comprised three key elements: the partnership approach, bringing together all the national actors involved in all areas of cancer prevention in the campaign against cancer; the European Code against cancer, which suggests 10 rules for a healthy lifestyle; and the long-term vision of lowering the cancer-specific mortality of the European population by 15 % for the year 2000. Major progress has been made toward this target: between 1987 and 2000, annual cancer-specific mortality in Europe fell by 10%, equating to around 92,000 lives saved<sup>1</sup>. But differences remain between Member States in the death toll due to cancer in each country . This underpins the expectation that further reductions would be possible by applying best practice uniformly in all Member States.
3. Public health aims to prevent disease at population. While primary prevention aims to reduce the incidence of cancer by avoiding exposure to any kind of carcinogen, secondary prevention aims to reduce mortality by the early detection of cancer through screening of the population at risk of developing the disease. Well-managed population screening should be more effective than individual screening on demand, which also needs to have a science-based, cost-effective approach, built on best practice. It follows that early detection of cancer by screening is one of the strategic areas of cancer prevention. For breast cancer, for example, it is estimated that the lives of about 25,000 women could be saved if best practice in screening were available throughout the European Union. However, organised cancer screening should only be offered to healthy people if the screening has been proved to decrease disease-specific mortality or the occurrence of advanced disease, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.
4. The purpose of this proposal is, therefore, against a background of uncertainty on the benefits of population-based cancer screening, to make recommendations on a sound scientific basis, as summarised in the conclusions of the Advisory Committee on Cancer Prevention, which confirms the proved forms of screening that should therefore be taken up by the Member States. The proposal recommends:
  - mammography screening for breast cancer in women aged 50-69;
  - faecal occult blood screening for colorectal cancer in men and women aged 50-74;
  - and pap smear screening for cervical abnormalities, starting between the ages of 20 and 30;

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<sup>1</sup> Boyle P., d'Onofrio A., Maisonneuve P., Severi G., Robertson C. and Veronesi U.: Measuring progress against cancer in Europe - Has the 15% decline targeted for 2000 come about? *Annals of Oncology* 2003 in press.

5. Other tests may also be recommended once research shows that they meet the criteria for organised cancer screening. Decisions on the implementation of cancer screening programmes must be made as part of a general priority-setting exercise on the use of healthcare resources, and with due respect for the responsibility of the Member States for the organisation and delivery of health services and medical care.

## GENERAL INTRODUCTION

### **The European dimension of cancer**

6. Today cancer is a disease which still kills about one European in four. Some 1,594,379 new cases were recorded in the fifteen Member States in 1997. The situation in the new Member States is expected to be very similar to the present situation in the European Union. Detailed statistical information on the Member States is set out at the end of this explanatory memorandum.
7. In 1997 the most frequent cancers in the European Union were colorectal, breast, lung, prostate, bladder, and stomach cancer, which made up 59 % of all new cancer cases. In the same year the cancers responsible for the most deaths were lung, colorectal, breast, stomach, prostate cancer and pancreas cancer, which made up 57 % of all cancer deaths.
8. These figures, as high as they might appear, only represent a small proportion of the human and social dimension of the suffering caused to cancer patients and their families, as well as the financial and economic dimension of the health resources absorbed for the diagnosis, treatment and care of this disease. These figures also explain why Europe is engaged in the global battle against this disease.

## History of European cooperation under Europe against Cancer in the field of screening

9. In its Resolution of 7 July 1986,<sup>2</sup> the Council expressed its political will to implement a European programme of action against cancer. Among the priorities it identified for attention was the need for the exchange of information and experience, particularly with regard to the preventive and early diagnosis programmes of the Member States. This initiative was taken up and enhanced from June 1988 by the three consecutive European action plans to fight cancer, the "Europe against Cancer" (EAC) programmes.<sup>3,4,5,6</sup> All of these EAC programmes have included secondary prevention, i.e. systematic population-based screening for specific sites of cancer where such interventions had been judged to be effective. Acknowledging that some Member States were already considering national screening programmes, in areas such as breast cancer and cervical cancer, a plan was developed to enable each of the Member States to propose pilot-screening projects within its borders. This has led to the current screening networks, the European Breast Cancer Network (EBCN) and the European Cervical Cancer Screening Network (ECCSN).

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<sup>2</sup> Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council, of 7 July 1986, on a programme of action of the European Communities against Cancer. OJ C 184, 23.7.1986. p.19.

<sup>3</sup> Decision of the Council and of representatives of the Governments of the Member States, meeting with the Council of 21 June 1988 adopting a 1988 to 1989 plan of action for an information and public awareness campaign in the context of the 'Europe against cancer' programme (88/351/EEC). OJ L 160, 28.6.1988 p. 52.

<sup>4</sup> Decision the Council and the Representatives of the Governments of the Member States, meeting within the Council, on 17 May 1990, adopting a 1990 to 1994 action plan in the context of the "Europe against Cancer" programme. OJ L 137, 30.5.1990. p.31.

<sup>5</sup> Decision No 646/96/EC of the European Parliament and the Council of 29 March 1996, adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000). OJ L 95, 16.4.1996. p.9.

<sup>6</sup> Decision No 521/2001/EC of the European Parliament and of the Council of 26 February 2001, extending certain programmes of Community action in the field of public health adopted by Decisions No 645/96/EC, No 646/96/EC, No 647/96/EC, No 102/97/EC, No 1400/97/EC and No 1296/1999/EC and amending those Decisions. OJ L 79 of 17.3.2001, p.1.

## **European guidelines on quality assurance in mammography and the recommendations for cancer screening of the Advisory Committee on Cancer Prevention**

10. In parallel to the Networks' aim of developing and publishing consensus on best screening practice as a series of European guidelines, the Advisory Committee on Cancer Prevention<sup>7</sup> has reviewed the global scientific evidence and the experience gathered from the screening networks under Europe against Cancer. In 1999 the Committee adopted the Recommendations for Cancer Screening.<sup>8,9</sup> These recommendations establish a set of general principles for best practice in screening, on which the recommendations in this document are based. The Committee's recommendations on specific screening tests are reflected in the Annex to the proposed Recommendation.

### **Europe against cancer**

11. As mentioned above, the fight against cancer follows several strands of action: identifying the causes of cancer, eliminating or reducing exposure to known risk factors for cancer, early detection of cancer through screening, and better treatment of and care for cancer.

### **The success is measurable**

12. Since the European Council had asked for a co-ordinated European action against cancer at the Milan Summit of 1985, new ground was broken. Since then, the European Community has acted in new areas such as disease prevention, information to the public, health education (especially in schools) and the training of health personnel. But the innovative character of the "Europe against cancer" programme, which followed from this initiative, was not just a question of the areas covered. It also concerned the chosen strategy, which had three key elements.
13. First, the partnership approach, which enabled the programme to bring together all the national actors involved in the campaign against cancer, and to group them into European committees and working parties, both scientific and non-scientific. Second, the European Code against cancer, which suggests 10 rules for a healthy lifestyle. Third, the importance of maintaining a long-term vision, linked to the objective of the programme which is to lower the cancer-specific mortality of the European population by 15 % for the year 2000.

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<sup>7</sup> Commission Decision 96/469/EC of 30 July 1996, establishing an Advisory Committee for Cancer Prevention. OJ L 192, 2.8.96, p.31.

<sup>8</sup> Recommendations on cancer screening in the European Union, prepared by the Advisory Committee on Cancer Prevention after the Conference on Screening and Early Detection of Cancer, Vienna 18<sup>th</sup> – 19<sup>th</sup> November 1999. Unpublished. Available on request from the General Directorate Health and Consumer Protection, Directorate Public Health, Unit Cancer, Drugs, and Pollution-related Diseases.

<sup>9</sup> Position paper, Recommendations on cancer screening in the European Union, Advisory Committee on Cancer Prevention, Lyng E. corresponding author: Eur J Cancer 2000, 36, p.1473-1478.

14. This strategy has been both innovative and fertile. Looking back, as a recent epidemiological analysis reveals<sup>1</sup>, the strategy and actions pursued under the three consecutive Europe against Cancer programmes have contributed to a reduction of cancer-specific mortality by 10 % between 1987 and 2000, which equates to about 92,000 European's lives saved. This is despite the considerable increase in smoking among European women, which led to an unforeseen 5 % increase in tobacco-related cancer mortality for women over this period of time.

### **Cancer screening for breast, cervical and colorectal cancer is effective**

15. Since the beginning of Europe against Cancer, clinical trials of specific screening methods have been shown to be effective for three different cancers: breast cancer, colorectal cancer and cervical cancer. For example, each year breast cancer is diagnosed in about 220,000 European women and kills around 75,000. Estimates suggest, however, that the lives of about 25,000 women could be saved if best practice of screening were available to all women in the European Union.
16. In 1999, at the request of the Commission, the Advisory Committee on Cancer Prevention prepared recommendations on cancer screening in the European Union. The Committee reviewed the scientific literature and analysed the experience from the different screening networks established under the Europe against Cancer programme. The Committee also organised an international symposium on cancer screening, in order to be able to take into account the latest progress on cancer screening and to discuss the draft recommendations with the international scientific community. Based on the most up-to-date science, these recommendations established a set of general principles for best practice in cancer screening and made specific recommendations for the implementation of mammography screening for breast cancer, pap smear screening for cervical cancer, and faecal occult blood testing for colorectal cancer. A recommendation on screening with the PSA-test for prostate cancer could not be made at that time, as this depends on the outcomes of large international studies in the USA as well as in Europe, which are expected to become available in 2008.

### **Translating scientific advice into Community legislation**

17. Public health aims to prevent disease at population level and thus reduce the burden of disease for individuals and for society as a whole. While primary prevention (such as through tobacco control legislation) aims to reduce the incidence of cancer by avoiding exposure to carcinogens, secondary prevention aims to reduce mortality by the early detection of cancer through screening of the population at risk from carcinogens. Well-managed population screening should be more effective than individual screening on demand, and is therefore a key instrument of prevention which also needs to have a science-based, cost-effective approach, built on best practice.

18. The Europe against Cancer programme has enabled best practice approaches in individual Member States to be identified and shared and then tested in the European screening networks. They should now be implemented in other Member States. The new public health programme will help to continue the experimental approach of the screening networks for updating best practice in established screening areas, as well as developing best practice in new screening areas. These networks will contribute to the new public health programme objectives concerning both health information and health determinants.
19. The Commission proposal for a Council recommendation on cancer screening is based mainly on the recommendations of the advisory committee on cancer prevention. To ensure that the proposal is up to date external scientists were extensively consulted in 2002.
20. Based on Article 152 of the Treaty establishing the European Community, this Commission proposal recommends the implementation of best practice principles in cancer screening in all Member States, preferably through following European guidelines. It also aims to define the role of the Community in this important area of disease prevention. The specific screening methods concerned (listed in the annex to the Recommendation) have proved to be effective in reducing the cancer death toll in randomised controlled clinical trials. The Recommendation advocates mass cancer screening by clearly established scientific methods in quality-controlled screening programmes. Such an approach also addresses health inequalities and the need for take-up amongst those most vulnerable and least likely to actively manage their health. It does not cover individual screening on demand.
21. The proposal does not exclude other screening tests currently under development and evaluation, nor does it criticise actions that individuals may wish to take for themselves. Such innovations, which also have to be tested in clinical trials, would nevertheless benefit from being clinically evaluated in the framework of an organised screening programme.

**The benchmark: European guidelines on quality assurance in cancer screening**

22. European guidelines provide a detailed description of all necessary implementation measures to maximise effectiveness and minimise possible adverse effects of any given screening method. They are based on a European scientific consensus arrived at from the partnership approach of the Europe against Cancer programme through the screening networks. The European guidelines for quality assurance in mammography developed since 1992 are a good example of the best practice approach in the early detection of breast cancer. These European guidelines have been produced by the European screening networks with the support of the Europe against Cancer programme. The third edition appeared in July 2001. Public interest in clear messages on screening has been shown by the success of these mammography guidelines, which are among the top ten best selling publications of the Office for Official Publications of the European Communities.

23. This experience demonstrates that it would be useful to have specific European guidelines for each of the priority areas to define specific conditions for organised screening programmes. Work has begun in the European network on cervical cancer screening to follow up the example of the mammography network in drafting comprehensive European guidelines on quality assurance. Discussions are underway to explore the possibility of a similar approach which builds on the former European colorectal cancer-screening network.
24. In 2000 and 2001, the validity of the evidence of the older studies on the efficacy of mammography screening was questioned by two publications.<sup>10,11</sup> Following a lively global debate among the experts, two international conferences reviewed old as well as more recent evidence<sup>12</sup> on the efficacy of mammography screening. The first was organised in March 2002 by the International Agency for Research on Cancer of WHO (WHO/IARC) in Lyons. The second, the Global Summit on Mammography Screening, was organised by the European Institute of Oncology (EIO) in Milan, in June 2002, and was supported by the European Commission. Both conferences concluded that mammography screening is effective if organised and embedded as recommended, among others, by the European Guidelines on Quality Assurance in mammography screening.<sup>13,14</sup>
25. Screening for cancer and the establishment of best practice<sup>15</sup> still vary between Member States. To a certain degree this contributes to the differences in cancer-specific mortality for breast, cervical and colorectal cancer between Member States (see tables below). The introduction of high quality mammography screening for breast cancer in Sweden and Finland has reduced breast cancer-specific mortality by about one third. On this basis, it became clear that the availability of such high-quality screening in all Member States could save the lives of about 25,000 women with breast cancer (provided that compliance of women is as high as in Sweden - over 90%).
26. This proposed Council recommendation aims to close the gap between differences in screening among the Member States to achieve a similar reduction of cancer-specific mortality in all Member States by establishing general principles of best practice for cancer screening as recommended by the Advisory Committee on Cancer Prevention. The intention is to bring about a similar high level of health protection for those cancers where early detection is possible and efficient for all European citizens.

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<sup>10</sup> Goetzsche PC and Olsen O. Is screening for breast cancer with mammography justifiable? *Lancet* 2000; 355: 129-134.

<sup>11</sup> Olsen O, Goetzsche PC. Cochrane review on screening for breast cancer with mammography. *Lancet* 2001; 358: 1340-1342.

<sup>12</sup> Nystroem L, Anderson I, Bjurstam N, Frisell J, Nordenskjöld B and Rutqvist LE. Long-term effects of mammography screening: updates overview of the Swedish randomised trials. *Lancet* 2002; 359: 909-919.

<sup>13</sup> IARC Handbooks of Cancer Prevention, Volume 7: Breast Cancer Screening. International Agency for Research on Cancer, World Health Organisation, IARC Press 2002, ISBN 92 832 3007 8.

<sup>14</sup> Global Summit on Mammographic Screening: Statement from the Chair. Published on the Internet at [http://www.ieo.it/inglese/didattica/state\\_1.htm](http://www.ieo.it/inglese/didattica/state_1.htm)

<sup>15</sup> Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee on the Regions on the health strategy of the European Community (COM(2000) 285 final) of 16 May 2000.



## SCREENING SPECIFIC BACKGROUND

27. Screening aims to detect cancers at an early stage of invasiveness or even before they become invasive. Some lesions can then be treated more effectively and patients can expect to be cured. A key indicator for the effectiveness of screening is a decrease in disease-specific mortality or a decrease in the occurrence of advanced disease.
28. Screening means testing healthy people for diseases which have not yet given rise to symptoms. Although it can have beneficial effects and improve survival rates, screening can also have negative side-effects for the screened population, including psycho-social effects (such as anxiety), unnecessary medical interventions in the case of false positive results, and delays in timely detection of disease in the case of false negative diagnosis.
29. Healthcare providers should be aware of all the potential benefits and risks of screening for a given cancer site before embarking on new cancer screening programmes. Furthermore, for the informed public of today, these benefits and risks should be presented in a way that allows individual citizens to decide on participation in the screening programmes for themselves.
30. Principles for screening as a tool for the prevention of chronic non-communicable diseases were published by the World Health Organisation in 1968<sup>16</sup> and by the Council of Europe in 1994.<sup>17</sup> These two documents form, together with the current best practice in each of the cancer screening fields, the basis for the present recommendations.
31. All data on incidence and mortality quoted are regularly updated and published on the Internet by the European Network of Cancer Registries (ENCR)<sup>18</sup>. An estimated number of 1,594,379 new cancer cases, excluding non-melanoma skin cancer, occurred in the European Union in 1997. Of these, 1.4% were cervical cancers, 14% breast cancers, 14% colorectal cancers and 9% prostate cancers. Cervical and breast cancer constituted 3% and 29%, respectively, of new cancers in women, and prostate cancer constituted 17% of new cancers in men.
32. By comparison, the incidence for lung cancer in the EU in 1997 amounted to 197,106 new cases for both sexes, and accounted for 180,751 deaths. Of these, 44,642 were new cases in women, and 41,004 women died from lung cancer. Unfortunately, the specific incidence for lung cancer in women is rising rapidly and will, in the near future, reach the same level as the incidence figures for men. This is the result of women taking up smoking in large numbers. No effective screening test has yet been developed for lung cancer. The Commission is thus fostering a combined approach of primary prevention by health information, health promotion and tobacco regulation policies.

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<sup>16</sup> Wilson JMG, Jungner G. Principles and practice of screening for disease. Public Health Papers 34. Geneva: World Health Organisation, 1968.

<sup>17</sup> Council of Europe: Committee of Ministers. On screening as a tool of preventive medicine. Recommendation no. R (94) 11. Strasbourg: Council of Europe, 1994.

<sup>18</sup> <http://www.iarc.fr>. International Agency for Research on Cancer. Cancer Incidence Data Bases. EUCAN 1997. (retrieved 16 January 2003).

## PRINCIPLES

33. Screening is an effective method of controlling cancer. Whenever possible, primary cancer prevention should be given first priority. When cancer screening is undertaken, it should be offered only in organised programmes with quality assurance at all levels, and good information about benefits and risks. The population/public health benefits of a screening programme will only be achieved if compliance and coverage are high. When organised screening is offered, high compliance should therefore be sought. Screening on demand cannot be recommended as a basis for public health practice since it will not deliver the maximum benefits and may have the negative side-effects referred to above.
34. The need for the proper evaluation of the health outcomes and costs of all screening procedures through randomised controlled trials, including new cancer screening tests, before being implemented in routine health care must be emphasised. It is also essential that an independent body evaluate the results of the screening trials.<sup>19</sup> Once the effectiveness of a new screening test has been demonstrated, evaluation of modified tests (e.g. alternative tests for faecal occult blood or interpretation of cervical specimens) may be possible using surrogate endpoints, providing that the predictive value of this (intermediate/surrogate) endpoint is sufficiently established. The evaluation and monitoring of a screening method may make use of IST tools as developed under the Community research programmes, such as, e.g., soft copy digital screening in mammography.
35. Centralised data systems, including a computerised list of all persons to be targeted by the screening programme, and data on all screening tests, assessment and final diagnoses are needed to run organised screening programmes. Organised screening also involves scientific analysis of the outcome of the screening and rapid reporting of these results to the programme providers and the health authorities. This analysis is facilitated if the screening database is linked to cancer registry data. It follows that cancer registry data in the continuous monitoring and comparing of incidence, mortality and survival should be as complete, accurate and up-to-date as possible. All procedures collecting, storing, transmitting and analysing data in the medical registers involved must be in full compliance with the level of protection referred to in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
36. High-quality screening is possible only if the personnel at all levels are adequately trained for their tasks. Performance indicators should be monitored regularly.

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<sup>19</sup> Evaluation and monitoring of screening programmes, edited by: Sankila R, Démaret E, Hakama M, Lyng E, Schouten LJ, Parkin DM for the European Network of Cancer Registries (ENCR), European Commission, Office for Official Publications of the European Communities, 2001, ISBN 92-894-0253-9.

37. In addition to ethical, legal, social, medical, organisational and economic aspects, scientific analysis and reporting for quality assurance have to be considered before decisions can be made on the implementation of cancer screening. Resources, human as well as financial, must be available in order to assure the appropriate organisation and quality control. Actions have to be taken to ensure that different socio-economic groups have equal access to screening. The implementation of a cancer-screening programme is therefore a decision to be made nationally or regionally, depending on the disease burden and the health care resources.
38. Cancer is a major disease and cause of death throughout Europe. Collaboration on a European level should help high-quality cancer screening programmes to provide a service which is efficient and in accordance with best practice guidelines and protect the population from poor-quality screening.

## CONCLUSIONS

39. Organised cancer screening should be offered to healthy people if the screening is proved to decrease disease-specific mortality and/or decrease the occurrence of advanced disease, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable. At present the following screening tests meet such requirements:
- pap smear screening for cervical abnormalities starting at the latest by the age of 30 and definitely not before the age of 20,<sup>9,20</sup>
  - mammography screening for breast cancer in women aged 50-69<sup>9</sup> in accordance with European guidelines on quality assurance in mammography,<sup>21</sup>
  - faecal occult blood screening for colorectal cancer in men and women age 50-74.<sup>9,22</sup>
40. Decisions on implementation of cancer screening programmes must be made as part of a general priority-setting exercise on the use of healthcare resources.
41. Other cancer screening test are not yet recommended for EU-wide population-based cancer screening, although they already may be used in individual screening on demand. Such tests may provide individual benefits but at the same time may also lead to adverse effects for individuals (e.g. unfounded anxiety) and the public (e.g. additional financial burden). Recommendations for such tests cannot be made until they have shown to have benefits such as reducing disease-specific mortality or improving survival.

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<sup>20</sup> Cervical Cancer Screening in the European Union, special issue of European Journal of Cancer; Guest Editors: A. Linos, E. Riza, M. van Ballegooijen, EJC 2000 36/17 pp. 2175-2275.

<sup>21</sup> European guidelines for quality assurance in mammography screening, 3<sup>rd</sup> Edition. Eds: N. Perry, M. Broeders, C. de Wolf, S. Toernberg. European Commission, Office for Official Publications of the European Communities, Luxembourg 2001, ISBN 92-894-1145-7.

<sup>22</sup> Scholefield J H and Moss S.M., Faecal occult blood screening for colorectal cancer, J Med Screen 2002 9:54-55.

42. Potentially promising screening tests currently being evaluated in randomised controlled trials, include:
- prostate-specific antigen (PSA) testing for prostate cancer,<sup>9,23</sup>
  - mammography screening for women aged 40-49 for breast cancer,<sup>9</sup>
  - immunological Faecal Occult Blood Testing (FOBT) for colorectal cancer,<sup>9,22</sup>
  - flexible colonoscopy for colorectal cancer.<sup>9</sup>
43. Once the effectiveness of a new screening test has been demonstrated, evaluation of modified testing methods may be possible using intermediate/surrogate endpoints, if the positive predictive value of such endpoints is sufficiently established. Some examples of screening methods which fall into this category are listed below:
- any novel alternative tests for faecal occult blood,
  - liquid-based cervical cytology,
  - testing for high risk human papilloma virus (HPV) infection,
  - other novel methods for the preparation or interpretation of cervical specimens.
44. Any screening test which has been demonstrated to be effective should be offered on a population basis only in organised screening programmes, with quality assurance at all levels and full information about the benefits and risks.

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<sup>23</sup> Koning HJ de, Auvinen A, Berenguer Sanchez A, Calais da Silva F, Ciatto S, Denis L, Gohagan J.K., Hakama M, Hugosson J, Kranse R, Nelen V, Prorok PC, Schröder FH; Large-scale randomised prostate cancer screening trials: programme performances in the European Randomised Screening for Prostate Cancer trial and Prostate, Lung, Colorectal and Ovary cancer trial. (submitted) *Int. J Cancer* 2002 .

## Statistical Annex to the Explanatory Memorandum

Cancer in the European Union 1997 (All Sites and all ages)

Cancer site	No. of Cancer Cases	Cancer Cases per 100,000	No. of Cancer Deaths	Cancer Deaths per 100,000
Oral cavity and pharynx	52682	12.63	19835	4.62
Oesophagus	24736	5.42	22793	4.88
Stomach	74604	15.02	56429	11.00
Colon/Rectum	221042	45.16	111013	21.50
Liver	30892	6.44	33743	6.82
Pancreas	40611	8.30	44957	8.99
Larynx	24000	5.63	10600	2.35
Lung	197106	42.71	180751	38.08
Melanoma of skin	36224	8.54	8673	1.91
Breast	220836	51.67	74984	16.06
Cervix uteri	22838	5.45	10446	2.26
Corpus uteri	38270	8.55	8934	1.72
Ovary etc.	34335	7.81	23295	4.90
Prostate	145065	28.14	55658	9.78
Testis	9661	2.46	695	0.17
Bladder	75033	15.23	30653	5.67
Kidney etc.	46617	10.27	22306	4.57
Brain, nervous system	27277	6.56	21093	4.90
Thyroid	15441	3.80	3144	0.62
Non-Hodgkin lymphoma	51509	11.42	25418	5.22
Hodgkin's disease	9199	2.32	2474	0.55
Multiple myeloma	20791	4.28	14185	2.77
Leukaemia	42435	9.37	29120	5.92
All sites but skin	1594379	345.09	925387	187.88

Incidence and mortality figures for breast, cervical and colorectal cancer in all Member States.

Breast Cancer 1997 (All Ages)

Member State	No. of Cancer Cases	Cancer Cases per 100,000	No. of Cancer Deaths	Cancer Deaths per 100,000
European Union	220836	97.25	74984	29.12
Austria	4605	90.14	1651	28.81
Belgium	7092	116.03	2562	37.28
Denmark	3535	113.24	1421	40.59
Finland	3171	102.32	788	23.22
France	36738	109.56	10831	27.89
Germany	50551	94.71	18374	30.48
Greece	4450	70.64	1512	21.62
Ireland	1622	96.34	634	35.38
Italy	34629	93.37	11339	27.01
Luxembourg	242	99.67	78	27.12
The Netherlands	10524	120.76	3574	36.96
Portugal	4272	73.84	1561	24.91
Spain	15906	69.98	5766	22.67
Sweden	5821	107.28	1494	22.88
United Kingdom	37678	108.25	13399	33.64

Cervical Cancer 1997 (All Ages)

Member State	No. of Cancer Cases	Cancer Cases per 100,000	No. of Cancer Deaths	Cancer Deaths per 100,000
European Union	22838	10.48	10446	4.13
Austria	529	11.18	302	5.52
Belgium	612	10.31	321	4.60
Denmark	438	14.62	226	6.63
Finland	159	5.06	78	2.12
France	3813	11.58	1674	4.25
Germany	6167	12.14	2943	4.95
Greece	493	8.13	219	3.13
Ireland	171	10.10	88	4.88
Italy	3183	9.06	1297	3.14
Luxembourg	10	4.24	2	0.97
The Netherlands	733	8.31	264	2.77
Portugal	952	17.34	349	5.69
Spain	1665	7.72	742	3.15
Sweden	537	10.78	242	3.68
United Kingdom	3376	10.17	1699	4.46

Colon/Rectum Cancer 1997 (All Ages)

Member State	No. of Cancer Cases	Cancer Cases per 100,000	No. of Cancer Deaths	Cancer Deaths per 100,000
European Union	221042	45.16	111013	21.50
Austria	5022	49.60	2586	24.12
Belgium	6204	46.08	3198	22.46
Denmark	3486	52.21	2150	30.69
Finland	2075	33.35	984	15.01
France	32956	43.32	16134	19.70
Germany	56040	50.78	29767	25.84
Greece	3416	24.49	1620	11.14
Ireland	1847	52.75	971	26.78
Italy	35185	44.16	16126	19.21
Luxembourg	244	48.66	133	25.29
The Netherlands	8966	50.34	4274	22.89
Portugal	5549	46.47	2706	21.78
Spain	20688	42.16	10639	20.16
Sweden	5046	39.77	2395	17.33
United Kingdom	34318	44.95	17330	21.62

Proposal for a

**COUNCIL RECOMMENDATION**

**on cancer screening**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4), second subparagraph, thereof,

Having regard to the proposal from the Commission,<sup>24</sup>

Having regard to the opinion of the European Parliament,<sup>25</sup>

Whereas:

- (1) Article 152 of the Treaty provides that Community action is to complement national policies and be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health.
- (2) Principles for screening as a tool for the prevention of chronic non-communicable diseases were published by the World Health Organisation in 1968<sup>26</sup> and by the Council of Europe in 1994<sup>27</sup>. These two documents form, together with the current best practice in each of the cancer screening fields, the basis for the present recommendations.

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<sup>24</sup> OJ C [...], [...], p. [...].

<sup>25</sup> OJ C [...], [...], p. [...].

<sup>26</sup> Wilson JMG, Jungner G. Principles and practice of screening for disease. Public Health Papers 34. Geneva: World Health Organisation, 1968.

<sup>27</sup> Council of Europe: Committee of Ministers. On screening as a tool of preventive medicine. Recommendation no. R (94) 11. Strasbourg: Council of Europe, 1994.

- (3) Additionally, these recommendations are based on the “Recommendations on cancer screening” of the Advisory Committee on Cancer Prevention<sup>28,29</sup> together with the experience gathered under the different actions sustained under the Europe against Cancer programme<sup>30,31,32,33,34</sup> where European collaboration has helped, e.g., high-quality cancer screening programmes to provide efficient European guidelines of best practice and to protect the population from poor-quality screening.
- (4) Screening allows detection of cancers at an early stage of invasiveness or even before they become invasive. Some lesions can then be treated more effectively and the patients can expect to be cured. The key indicator for the effectiveness of screening is a decrease in disease-specific mortality or in the occurrence of advanced disease.
- (5) Evidence exists concerning the effectiveness of screening for breast cancer and colorectal cancer, derived from randomised trials, and for cervical cancer, derived from observational studies.
- (6) Screening is, however, the testing of healthy people for diseases, of which no symptoms have been detected. In addition to its beneficial effect on the disease-specific mortality or occurrence of advanced disease, screening can also have negative side-effects for the screened population. Healthcare providers should be aware of all the potential benefits and risks of screening for a given cancer site before embarking on new population-based cancer screening programmes. Furthermore, for the informed public of today, these benefits and risks need to be presented in a way that allows individual citizens to decide on participation in the screening programmes for themselves.

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<sup>28</sup> Recommendations on cancer screening in the European Union, prepared by the Advisory Committee on Cancer Prevention after the Conference on Screening and Early Detection of Cancer, Vienna 18<sup>th</sup> – 19<sup>th</sup> November 1999. Unpublished. Available on request from the General Directorate Health and Consumer Protection, Directorate Public Health, Unit Cancer, Drugs, and Pollution-related Diseases.

<sup>29</sup> Position paper, Recommendations on cancer screening in the European Union, Advisory Committee on Cancer Prevention, Lynge E. corresponding author: Eur J Cancer 2000, 36, p.1473-1478.

<sup>30</sup> Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council, of 7 July 1986, on a programme of action of the European Communities against Cancer. OJ C 184, 23.7.1986. p.19.

<sup>31</sup> Decision of the Council and of representatives of the Governments of the Member States, meeting with the Council of 21 June 1988 adopting a 1988 to 1989 plan of action for an information and public awareness campaign in the context of the ‘Europe against cancer’ programme (88/351/EEC). OJ L 160, 28.6.1988 p. 52.

<sup>32</sup> Decision the Council and the Representatives of the Governments of the Member States, meeting within the Council, on 17 May 1990, adopting a 1990 to 1994 action plan in the context of the "Europe against Cancer" programme. OJ L 137, 30.5.1990. p.31.

<sup>33</sup> Decision No 646/96/EC of the European Parliament and the Council of 29 March 1996, adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000). OJ L 95, 16.4.1996. p.9.

<sup>34</sup> Decision No 521/2001/EC of the European Parliament and of the Council of 26 February 2001, extending certain programmes of Community action in the field of public health adopted by Decisions No 645/96/EC, No 646/96/EC, No 647/96/EC, No 102/97/EC, No 1400/97/EC and No 1296/1999/EC and amending those Decisions. OJ L 79 of 17.3.2001, p.1.



- (7) Cancer is a major disease and cause of death throughout Europe including the future member States. An estimated number of 1 594 379 new cancer cases, excluding non-melanoma skin cancer, occurred in the European Union in 1997. Of these, 1.4% were cervical cancers, 14% breast cancers, 14% colorectal cancers and 9% prostate cancers. Cervical and breast cancer constituted 3% and 29%, respectively, of new cancers in women. Prostate cancer constituted 17% of new cancers in men.
- (8) The public health benefits and cost efficiency of a screening programme are achieved if the programme is implemented systematically, covering the whole target population and following best practice guidelines.
- (9) This requires an organisation with a call-recall system and with quality assurance at all levels, and an effective and appropriate diagnostic and treatment service.
- (10) Centralised data systems, including a list of all categories of persons to be targeted by the screening programme and data on all screening tests, assessment and final diagnoses, are needed to run organised screening programmes.
- (11) All procedures collecting, storing, transmitting and analysing data in the medical registers involved must be in full compliance with the level of protection referred to in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- (12) Quality screening includes analysis of the process and outcome of the screening and rapid reporting of these results to the population and screening providers.
- (13) This analysis is facilitated if the screening database is linked to cancer registry data.
- (14) Adequate training of personnel is a prerequisite for high quality screening.
- (15) Specific performance indicators have been established for cancer screening tests. These should be monitored regularly.
- (16) Ethical, legal, social, medical, organisational and economic aspects have to be considered before decisions can be made on the implementation of cancer screening programmes.
- (17) Adequate human and financial resources should be available in order to assure the appropriate organisation and quality control.
- (18) Different socio-economic groups often do not have equal access to screening. Therefore, action should be taken to ensure equal access.
- (19) It is an ethical, legal and social prerequisite that cancer screening should only be offered to fully-informed healthy people if the screening is proved to decrease disease-specific mortality or the incidence of advanced disease, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.
- (20) The screening methods which presently meet these strict prerequisites are listed in the Annex.

- (21) No screening test other than those listed in the Annex is scientifically justified to be offered to healthy people in an organised population based programme before it has been shown in randomised controlled trials to decrease disease-specific mortality or the occurrence of advanced disease.
- (22) The screening tests listed in the Annex can only be offered on a population basis in organised screening programme with quality assurance at all levels, if good information about benefits and risks, adequate resources for screening, follow-up with complementary diagnostic procedures and, if necessary, treatment of those with a positive screening test is available.
- (23) The introduction of the recommended screening tests , which have demonstrated their effectiveness, should be seriously considered, the decision being based on available professional expertise and priority setting for healthcare resources;
- (24) Once the effectiveness of a new screening test has been demonstrated, evaluation of modified tests may be possible using other endpoints, if the predictive value of these endpoints is established,

HEREBY RECOMMENDS THAT MEMBER STATES:

1. Implementation of cancer screening programmes
  - (a) offer evidence-based cancer screening through a systematic population-based approach with quality assurance at all levels. The cancer screening tests listed in the Annex fulfil these requirements;
  - (b) implement screening programmes in accordance with European guidelines on best practice and should facilitate the further development of best practice for high-quality cancer screening programmes on a national level;
  - (c) ensure that the people participating in a screening program be fully informed about the benefits and risks before interventions;
  - (d) ensure that adequate complementary diagnostic procedures and treatment of those with a positive screening test are provided for;
  - (e) make available human and financial resources, in order to assure appropriate organisation and quality control;
  - (f) take decisions on the implementation of a cancer-screening programme nationally or regionally depending on the disease burden and the healthcare resources available;
  - (g) set up a systematic invitation and follow-up system and quality assurance at all levels, together with an effective and appropriate diagnostic and treatment service;
2. Registration and management of screening data
  - (a) make available centralised data systems needed to run organised screening programmes;

- (b) set up a computerised list of all categories of persons to be targeted by the screening programme;
- (c) collect, manage and evaluate data on all screening tests, assessment and final diagnoses;
- (d) collect, manage and evaluate the data in full compliance with the level of protection referred to in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data in the procedures collecting, storing, transmitting and analyzing data in the medical registers involved;

### 3. Monitoring

- (a) regularly monitor the process and outcome of organised screening and report these results quickly to the public and the personnel providing the screening;
- (b) adhere to the standards defined by the European Network of Cancer Registries in establishing and maintaining the screening databases in full compliance with the level of protection referred to in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data in the procedures collecting, storing, transmitting and analyzing data in the medical registers involved;
- (c) regularly monitor performance indicators at a predefined and adequate frequency;

### 4. Training

adequately train personnel at all levels to ensure that they are able to deliver high-quality screening;

### 5. Compliance

- (a) seek a high level of compliance, based on fully-informed consent, when organised screening is offered;
- (b) take action to ensure that different socio-economic groups have equal access to screening;

### 6. Introduction of novel screening tests

- (a) evaluate new cancer screening tests in randomised controlled trials before their implementation in routine healthcare;
- (b) run trials, in addition to those on screening-specific parameters and mortality, on subsequent treatment procedures, clinical outcome, side effects, morbidity and quality of life;

- (c) decide on the introduction into routine healthcare of potentially-promising new screening tests, which are currently being evaluated in randomised controlled trials, once the evidence is conclusive;
- (d) decide on the introduction into routine healthcare of potentially promising new modifications of established screening tests, once the effectiveness of the modification has been successfully evaluated, possibly using surrogate endpoints.

7. Implementation report and follow-up

- report to the Commission on the implementation of this Recommendation within two years of its adoption and subsequently at the request of the Commission with a view to contributing to the follow-up of this Recommendation at Community level;

HEREBY INVITES THE COMMISSION:

1. To report on the implementation of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the third year after the date of adoption of this recommendation, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action.
2. To encourage cooperation between MS and exchange of best practices as regards cancer screening with a view to developing new screening methods or improve existing ones.

Done at Brussels, [...]

For the Council  
The President

## **ANNEX**

### **RECOMMENDED SCREENING TESTS:**

- pap smear screening for cervical abnormalities starting at the latest by the age of 30 and definitely not before the age of 20;
- mammography screening for breast cancer in women aged 50-69 in accordance with European guidelines on quality assurance in mammography;
- faecal occult blood screening for colorectal cancer in men and women age 50-74.