

**COUNCIL RECOMMENDATION****of 2 December 2003****on cancer screening**

(2003/878/EC)

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,

Having regard to the opinion of the European Parliament,

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. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.
- (2) Further development of cancer screening programmes should be implemented in accordance with national law and national and regional responsibilities for the organisation and delivery of health services and medical care.
- (3) Cancer is a major disease and cause of death throughout Europe, including the future Member States. An estimated number of 1 580 096 new cancer cases, excluding non-melanoma skin cancer, occurred in the European Union in 1998. Of these, 1,4 % were cervical cancers, 13 % 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.
- (4) Principles for screening as a tool for the prevention of chronic non-communicable diseases were published by the World Health Organisation in 1968 and by the Council of Europe in 1994. These two documents form, together with the current best practice in each of the cancer screening fields, the basis for the present recommendations.
- (5) Additionally, these recommendations are based on the 'Recommendations on cancer screening' of the Advisory Committee on Cancer Prevention together with the experience gathered under the different actions sustained under the Europe against Cancer programme where European collaboration has helped, for example, high quality cancer screening programmes to provide efficient European guidelines of best practice and to protect the population from poor quality screening.
- (6) Important factors which have to be assessed before a population-wide implementation is decided upon include, *inter alia*, the frequency and interval of the application of the screening test as well as other national or regional epidemiological specificities.
- (7) Screening allows detection of cancers at an early stage of invasiveness or possibly even before they become invasive. Some lesions can then be treated more effectively and the patients can expect to be cured. The main indicator for the effectiveness of screening is a decrease in disease-specific mortality. As in the case of cervical cancer, cancer precursors are detected, a reduction in cervical cancer incidence can be considered a very helpful indicator.
- (8) Evidence exists concerning the efficacy of screening for breast cancer and colorectal cancer, derived from randomised trials, and for cervical cancer, derived from observational studies.
- (9) Screening is, however, the testing for diseases of people for which no symptoms have been detected. In addition to its beneficial effect on the disease-specific mortality, 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.
- (10) Ethical, legal, social, medical, organisational and economic aspects have to be considered before decisions can be made on the implementation of cancer screening programmes.

- (11) Due account should be taken of specific needs of persons who may be at higher cancer risk for particular reasons (e.g. biological, genetic, lifestyle and environmental, including occupational).
- (12) 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.
- (13) The cost-effectiveness of cancer screening depends on several factors such as epidemiology, and healthcare organisation and delivery.
- (14) Systematic implementation requires an organisation with a call/recall system and with quality assurance at all levels, and an effective and appropriate diagnostic, treatment and after-care service following evidence-based guidelines.
- (15) 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.
- (16) All procedures for 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<sup>(1)</sup>, as well as in full compliance with the relevant provisions of Member States on the management and processing of health data in accordance with Article 8 of the Directive.
- (17) Quality screening includes analysis of the process and outcome of the screening and rapid reporting of these results to the population and screening providers.
- (18) This analysis is facilitated if the screening database can be linked to cancer registries and mortality databases.
- (19) Adequate training of personnel is a prerequisite for high quality screening.
- (20) Specific performance indicators have been established for cancer screening tests. These should be monitored regularly.
- (21) Adequate human and financial resources should be available in order to assure the appropriate organisation and quality control in all the Member States.
- (22) Action should be taken to ensure equal access to screening taking due account of the possible need to target particular socioeconomic groups.
- (23) It is an ethical, legal and social prerequisite that cancer screening should only be offered to fully informed people with no symptoms if the screening is proved to decrease disease-specific mortality, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.
- (24) The screening methods which presently meet these strict prerequisites are listed in the Annex.
- (25) No screening test other than those listed in the Annex is scientifically justified to be offered to people with no symptoms in an organised population-based programme before it has been shown in randomised controlled trials to decrease disease-specific mortality in particular.
- (26) The screening tests listed in the Annex can only be offered on a population basis in organised screening programmes 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 are available.
- (27) The introduction of the recommended screening tests in the Annex, which have demonstrated their efficacy, should be seriously considered, the decision being based on available professional expertise and priority-setting for healthcare resources in each Member State.
- (28) Once there is evidence that a new screening test is effective, evaluation of modified tests may be possible using other epidemiologically validated surrogate endpoints if the predictive value of these endpoints is established.
- (29) Screening methodologies are subject to ongoing development. The application of recommended screening methodologies should therefore be accompanied by simultaneous assessments of the quality, applicability and cost-effectiveness of new methods if available epidemiological data justify this. In fact, the ongoing work may lead to new methods, which could ultimately replace or complement the tests listed in the Annex or be applicable to other types of cancer.

<sup>(1)</sup> OJ L 281, 23.11.1995, p. 31.

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 appropriate levels. The tests which should be considered in this context are listed in the Annex;
- (b) implement screening programmes in accordance with European guidelines on best practice where they exist and facilitate the further development of best practice for high quality cancer screening programmes on a national and, where appropriate, regional level;
- (c) ensure that the people participating in a screening programme are fully informed about the benefits and risks;
- (d) ensure that adequate complementary diagnostic procedures, treatment, psychological support and after-care following evidence-based guidelines 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) assess and take decisions on the implementation of a cancer screening programme nationally or regionally depending on the disease burden and the healthcare resources available, the side effects and cost effects of cancer screening, and experience from scientific trials and pilot projects;
- (g) set up a systematic call/recall system and quality assurance at all appropriate levels, together with an effective and appropriate diagnostic and treatment and after-care service following evidence-based guidelines;
- (h) ensure that due regard is paid to data protection legislation, particularly as it applies to personal health data, prior to implementing cancer screening programmes.

#### 2. Registration and management of screening data

- (a) make available centralised data systems needed to run organised screening programmes;
- (b) ensure by appropriate means that all persons targeted by the screening programme are invited, by means of a call/recall system, to take part in the programme;
- (c) collect, manage and evaluate data on all screening tests, assessment and final diagnoses;
- (d) collect, manage and evaluate the data in full accordance with relevant legislation on personal data protection.

#### 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 accordance with relevant legislation on personal data protection;
- (c) monitor the screening programmes at adequate intervals.

#### 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 equal access to screening taking due account of the possible need to target particular socioeconomic groups.

#### 6. Introduction of novel screening tests taking into account international research results

- (a) implement new cancer screening tests in routine healthcare only after they have been evaluated in randomised controlled trials;
- (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) assess level of evidence concerning effects of new methods by pooling of trial results from representative settings;
- (d) consider 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 and other relevant aspects, such as cost-effectiveness in the different healthcare systems, have been taken into account;
- (e) consider 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 other epidemiologically validated surrogate endpoints.

7. Implementation report and follow-up

report to the Commission on the implementation of this Recommendation within three 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 fourth 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 Member States in research and exchange of best practices as regards cancer screening with a view to developing and evaluating new screening methods or improving existing ones.
3. To support European research on cancer screening including the development of new guidelines and the updating of existing guidelines for cancer screening.

Done at Brussels, 2 December 2003.

*For the Council*

*The President*

R. MARONI

## ANNEX

## SCREENING TESTS WHICH FULFIL THE REQUIREMENTS OF THE RECOMMENDATION (\*):

- pap smear screening for cervical cancer precursors starting not before the age of 20 and not later than the age of 30;
  - mammography screening for breast cancer in women aged 50 to 69 in accordance with European guidelines on quality assurance in mammography;
  - faecal occult blood screening for colorectal cancer in men and women aged 50 to 74.
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(\*) The indicated age ranges are to be understood as maximum ranges; subject to national epidemiological evidence and prioritisation, smaller age ranges may be appropriate.