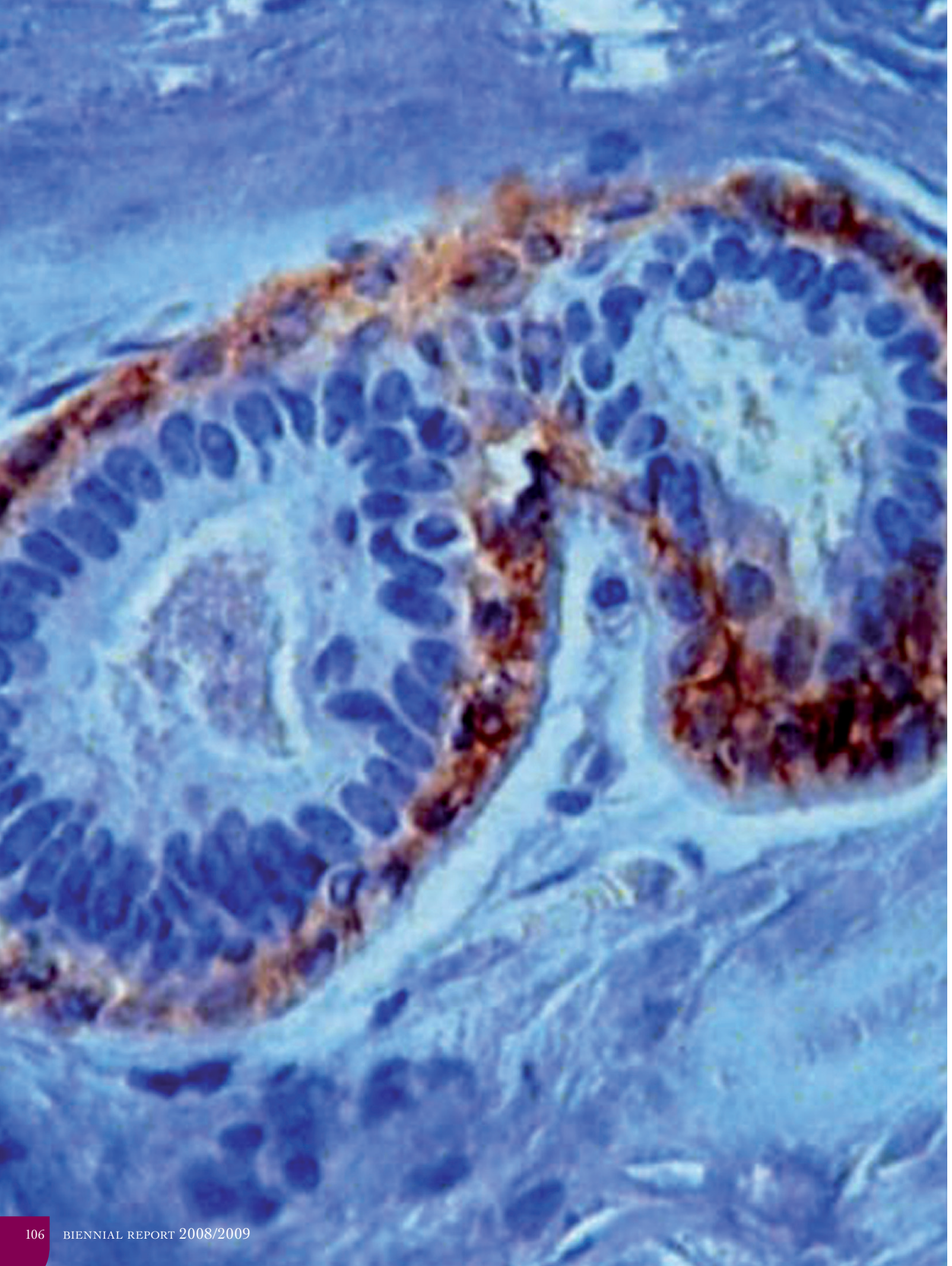
# Section of Early Detection & Prevention (EDP)

**Section Head**
Dr Rengaswamy Sankaranarayanan

The Section of Early Detection and Prevention comprises three Groups: the Prevention Group (PRE), the Quality Assurance Group (QAS) and the Screening Group (SCR).

The Section seeks to provide evidence as to which primary and secondary prevention interventions are appropriate, effective and cost-effective in lowering the global burden of breast, cervical, oral, colorectal, skin and prostate cancers. This approach includes studying the means to implement integrated and quality-assured interventions in routine settings in different parts of the world. These research topics are in tune with the overall mission of the Agency in that they aim to reduce cancer burden by prevention.



# Prevention Group (PRE)

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The overall goal of the Prevention Group is to evaluate the impact of prevention activities.

## Exposure to ultraviolet radiation (UV) and skin cancer

The Prevention Group has international expertise on skin cancer and ultraviolet radiation, and regularly publishes on these topics. PRE staff are active members of international societies on skin cancer such as Euroskin and the EORTC Melanoma Group.

The main project in this domain in 2008–2009 is the Quantification of Sun Exposure in Europe and its Effects on Health (the Eurosun Project), a three-year project designed to monitor ultraviolet exposure in the European union and its effects on the incidence of skin cancers and cataracts. Meteorological satellite data will be used to calculate exposure to various UV wavelengths for European populations; these data will be used to produce an atlas of UV exposure in Europe, which will contain maps similar to the one displayed in Figure 1. These data will also serve to predict the global EU burden of UV-related diseases in the future. Concurrent with this project is a similar one, limited to France, funded by AFSSET (Agence Française de Sécurité Sanitaire de l'Environnement et du Travail, Paris).

The Prevention Group has a broad agenda on indoor tanning issues, and participated in the 2009 IARC Monographs Volume 100-D meeting on radiation that classified this exposure as a Group I carcinogen. Ongoing collaborations with the WHO aim to translate into public health terms the most recent scientific evidence on the deleterious effects of exposure to artificial UV radiation.

## Vitamin D and cancer

An international IARC Working Group was established in 2007–2008 to investigate the current status of knowledge about the potential cause-effect relationship between an individual's vitamin D status and cancer and to determine if any anti-cancer benefit may be gained from increasing vitamin D status. Systematic reviews were undertaken, with meta-analyses, and the results are available in a downloadable report:

http://www.iarc.fr/en/content/download/10701/74064/file/Report_VitD.pdf

In brief, increasing vitamin D status was associated with a reduced risk of colorectal cancer, and not of breast or prostate cancer. Other studies show no evidence for an association with ovarian or pancreatic cancer. Randomised trials testing vitamin D supplements did not show a protective effect against colorectal cancer, but our meta-analysis published in 2007 showed a reduction in all-cause mortality associated with taking these supplements (*Autier and Gandini, 2007). The key issue now is to sort out whether vitamin D status is simply a marker or is causally associated with cancer and other chronic diseases.

## Eurocadet project
(www.eurocadet.org)

The objective of this project is to estimate the effect of the successful implementation of prevention strategies on the incidence of cancer. Data were gathered in 30 European countries on key exogenous determinants of cancer: smoking, alcohol consumption, overweight and obesity, physical activity, use of post-menopause hormonal treatment, and fruit and vegetable consumption. The future burden of cancer incidence in Europe was also calculated. These exposure data and incidence prediction will serve as a basis for developing scenarios of public health interventions and their likely impact on the cancer burden in Europe.

## Evaluation of impact of screening activities on cancer mortality

In mid-2007 the Prevention Group began conducting evaluations of the impact of screening activities on the incidence of advanced cancer at diagnosis. Normally, if screening works and is widespread, the incidence of advanced cancer should decrease. Such a decrease is independent of the effects of treatments and can provide information on the contribution of screening to changes in mortality. If this concept is largely accepted by the scientific community so far, it has only been correctly ascertained for cervical cancer screening. The Group hopes to have finished its evaluation of breast cancer screening by the end of 2009, and the first articles are already published or in press (*Autier *et al.*, 2009). This first article shows that in randomised trials on mammography screening, the decreases in breast cancer mortality were preceded by similar decreases in the incidence of advanced breast cancer. The next cancer we will examine is colorectal cancer.

## Tyrol study on prostate cancer

Prostate cancer screening activities have existed for the past 20 years in Tyrol, Austria. A large database has been put together by the Department for Urology at Innsbruck Medical University (Innsbruck, Austria) collecting the full pre-clinical and clinical history of men who were tested for prostate cancer. Analysis of this data will provide invaluable information on the natural course of this cancer.

## Methodological issues

The Prevention Group has developed methodological expertise in the area of meta-analysis, mainly for observational studies, for which little guidance is available in the specialised literature. This has allowed us to produce original meta-analytic work for vitamin D and cancer and for mobile phones and cancer. These studies will be published as articles or reports in late 2009 and in 2010.

The Group is also involved in the methodological issues inherent in what exactly is meant by "cancer incidence" when a cancer can be screen-detected. The first result of this work was an article on the limitations of using cancer survival data in public health (*Autier *et al.*, 2007).

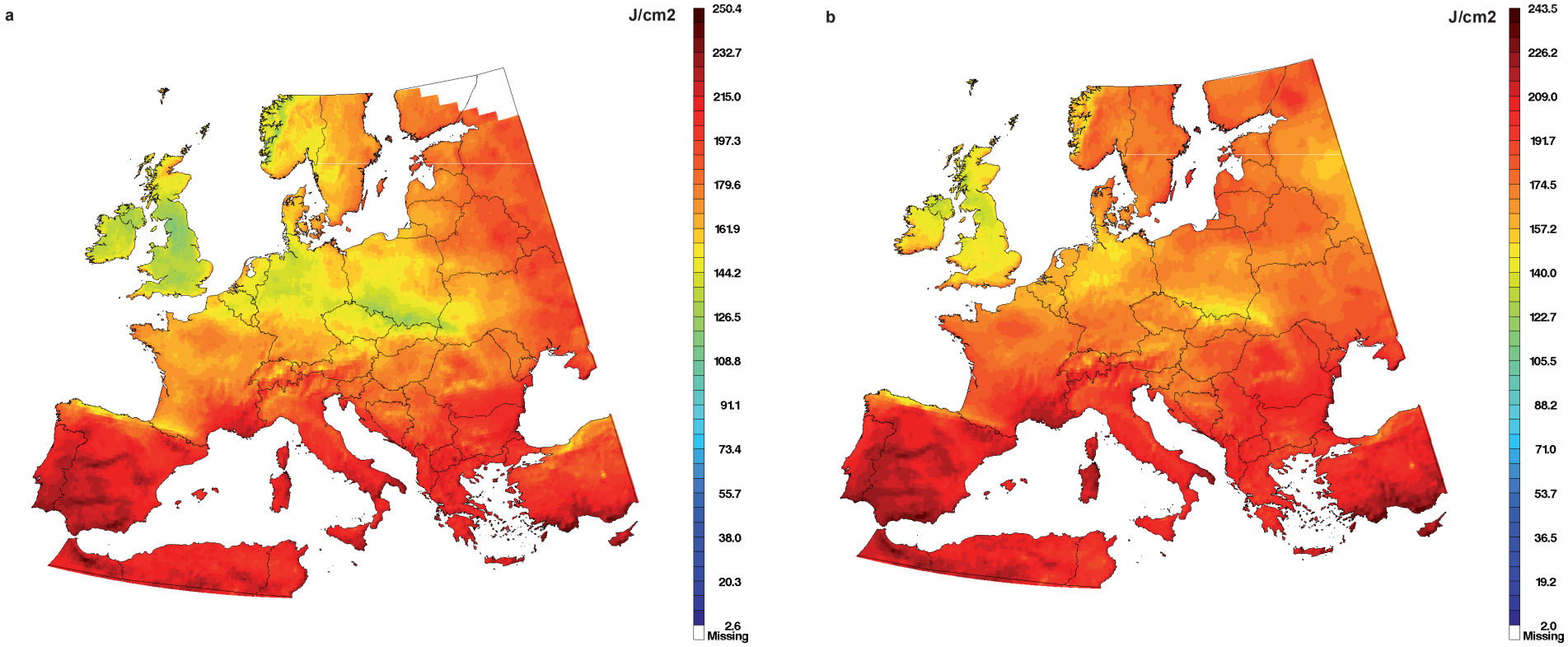


**Figure 1. Daily mean of total UV irradiation averaged over 5-year periods in Europe during the month of June for the period 1998–2002 (a) and for the period 2003–2007 (b)**

## European Cancer Observatory (ECO)

The ECO is an IARC-hosted website designed to present the number of cases and deaths by cancer in European countries in a user-friendly manner (http://eu-cancer.iarc.fr). The ECO site, launched on 5 May 2009, was developed by Philippe Autier (PRE group) and Jacques Ferlay (DEP group). Data presented on the site are those made publicly available by cancer registries and by national statistics agencies. The data on cancer cases are derived from data used for volumes I to VIII of the IARC Cancer Incidence in Five Continents Series. Data on mortality by cancer are derived from World Health Organization (WHO) data.


**Figure 2. European Cancer Observatory website. http://eu-cancer.iarc.fr**


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The Epidemiology and Biostatistics Division of the European Institute of Oncology, Milan, Italy

Icelandic Cancer Society, Reykjavik, Iceland

Northern Ireland Cancer Registry, Belfast, UK

The University of Innsbruck, Austria

West Midlands Cancer Intelligence Unit, The University of Birmingham, Birmingham, UK

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## Publications


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# Screening Group (SCR)

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(SCR); July 2009–September 2009
(SCR+ QAS))
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**Technical Officers**
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(from April 2009)
Ms Krittika Guinot
Mr Eric Lucas
Dr Richard Muwonge
(from July 2009)

The objective of Screening Group projects is to guide the development of evidence-based public health policies in implementing cancer screening and early diagnosis in a range of healthcare settings, particularly in low- and medium-resource countries, leading to rational utilisation of healthcare resources and to improving quality of life. To meet this requirement, our studies address the accuracy, reproducibility, efficacy, benefits, harmful effects and cost-effectiveness of different screening interventions for breast, cervical, oral and other cancers, and development of quality assurance standards for screening in different settings, in collaboration with national institutions in different countries.

## 1. Cervical cancer screening

*Cluster-randomised controlled trial on the effectiveness of a single round of HPV testing, cytology testing or visual inspection with acetic acid in Osmanabad*

The efficacy and cost-effectiveness of a single round of screening using HPV testing or cervical cytology or visual inspection with acetic acid (VIA) in preventing cervical cancer cases and deaths as compared to a control group receiving routine care plus health education on cervical cancer prevention is being assessed in a cluster randomized trial in the Osmanabad district, India (*Sankaranarayanan, Nene *et al*., 2009). Screen-positive women had colposcopy and directed biopsies. Women with CIN were treated with cryotherapy by nurses, or loop excision by doctors. About 79% of the eligible women in the different groups were screened. About 60% of the patients in the HPV and cytology groups and 42% in the VIA group were diagnosed in stage I, as compared to 28% in the control group. There was a significant 53% reduction in the incidence rate of stage II or worse stages of invasive cervical cancer, and a significant 48% reduction in cervical cancer mortality in the HPV group as compared to the control group (Table 1). The significant reduction in the incidence of advanced cancers and cervical cancer deaths associated with HPV testing is quite likely to be due to the fact that HPV testing detects more precancerous lesions, with a high potential for malignant transformation, as compared to VIA or cytology, and that HPV testing is more sensitive than the other two tests for true premalignant lesions, resulting in fewer subsequent cancers diagnosed among the HPV-negative women.

*Cryotherapy and loop electrosurgical excision procedure for treatment of cervical precancerous lesions*

The effectiveness, safety and acceptability of treatment of cervical intraepithelial neoplasia (CIN) using cryotherapy provided by midwives and using loop electrosurgical excision procedure (LEEP) by new trained physicians were assessed in three studies in rural India (Table 2) (*Nene *et al*., 2008; *Rema *et al*., 2008; *Sankaranarayanan, Keshkar *et al*., 2009). We reported 94% cure rates for CIN by cryotherapy and 87%–94% rates for LEEP. Similar results are observed in developed countries. Minor side effects and complications were reported in less than 10% of women; these treatments are judged to be effective, safe and acceptable to women.

**Table 1. Incidence rates of stage II or worse and mortality rate in the cervical cancer screening trial in Osmanabad District, India**

| Variable | HPV testing | Cytology | VIA | Control |
|---|---|---|---|---|
| Incidence of stage II or worse cervical cancer (N) | 39 | 58 | 86 | 82 |
| Rate per 100 000 person-years | 14.9 | 23.8 | 21.7 | 34.6 |
| Hazard ratio (95% CI) | 0.49 (0.33–0.72) | 0.78 (0.52–1.17) | 1.09 (0.76–1.58) | 1.00 |
| Deaths from cervical cancer (N) | 34 | 54 | 56 | 64 |
| Rate per 100 000 person-years | 13.0 | 22.1 | 21.7 | 27.0 |
| Hazard ratio (95% CI) | 0.53 (0.33–0.86) | 0.91 (0.63–1.30) | 0.90 (0.63–1.28) | 1.00 |
| HPV: Human papilomavirus; VIA: visual inspection with acetic acid; CI: confidence interval | | | | |

**Table 2. Follow-up details of histologically-proven CIN treated with cryotherapy of LEEP in 3 different studies in India**

| | Study author (treatment offered) | | |
|---|---|---|---|
| | Nene et al., 2008 (Cryotherapy) | Rema et al., 2008 (LEEP) | Sankaranarayanan, Keshkar et al., 2009 |
| Number treated | 728 | 311 | 634 |
| Number followed up (%) | 574 (78.8) | 283 (91.0) | 489 (77.1) |
| Number disease-free (%) | 538 (93.7) | 248 (87.6) | 459 (93.9) |
| Number with minor side effects and complications (%) | 40 (5.5) | 39 (12.5) | 39 (6.2) |
| LEEP: loop electrosurgical excision procedure | | | |

*The Screening Technologies to Advance Rapid Testing (START) project for cervical cancer prevention*

The START project for cervical cancer prevention aims to develop, evaluate and make available affordable and accurate biochemical tests for the early detection of CIN in public health and clinical practice in developing countries. This project is in collaboration with the Nargis Dutt Memorial Cancer Hospital (NDMCH), Barshi and the Tata Memorial Centre (TMC), Mumbai, contributing to the development, validation and future commercial availability of the new test formats. From September 2005 to August 2007 we screened 10 593 women and collected 35 900 cervical and vaginal samples for test development and validation. A total of 407 biopsy specimens pertaining to all CIN cases and invasive cancer, as well as a sample of normal cases, were brought to Lyon for HPV genotyping and p16 immunostaining. We are currently analysing the data and investigating why the performance of fast HPV test in the Indian START component was inconsistent with that in China. In addition, results from HPV genotyping and p16 immunostaining will be used to reinforce the validity of histology diagnosis of CIN in our study.

*Multicentre HPV vaccine project*

This is a major randomised clinical trial in collaboration with 8 centres in India (Tata Memorial Centre, Mumbai; Nargis Dutt Memorial Cancer Hospital, Barshi; Jehangir Clinical Development Centre, Pune; Christian Fellowship Community Health Centre, Ambillikai; Gujarat Cancer Research Institute, Ahmedabad; All India Institute of Medical Sciences, New Delhi; MNJ Cancer Institute, Hyderabad and Cancer Foundation of India, Kolkata) to generate scientific evidence on the clinical efficacy of two-dose HPV vaccination as compared the current standard three-dose to prevent persistent HPV infection and cervical neoplasia in order to guide public health policies for planning and implementing wide-scale, sustained HPV vaccination delivery to pre- and early adolescent girls. This study will involve around 20 000 girls aged 10–18 years, and is funded by the Bill & Melinda Gates Foundation. The study protocol received clearance from the Ethics committees

of IARC and our Indian collaborative centres, and from the Ministry of Health and the Drugs Controller General of India, and the vaccination process is underway.

*Training*

The Group conducted six training courses in cervical cancer screening and prevention (1 in China, 2 in India, 1 in Tanzania, 1 in Gabon, and 1 in Morocco), training around 100 doctors and nurses from Asian and African countries. The group also published digital training manuals for cervical screening and treatment of CIN. Our collaborative cervical cancer prevention training schools in India, Angola, Guinea, Tanzania, Brazil and Peru are active in training human resources in their respective regions.

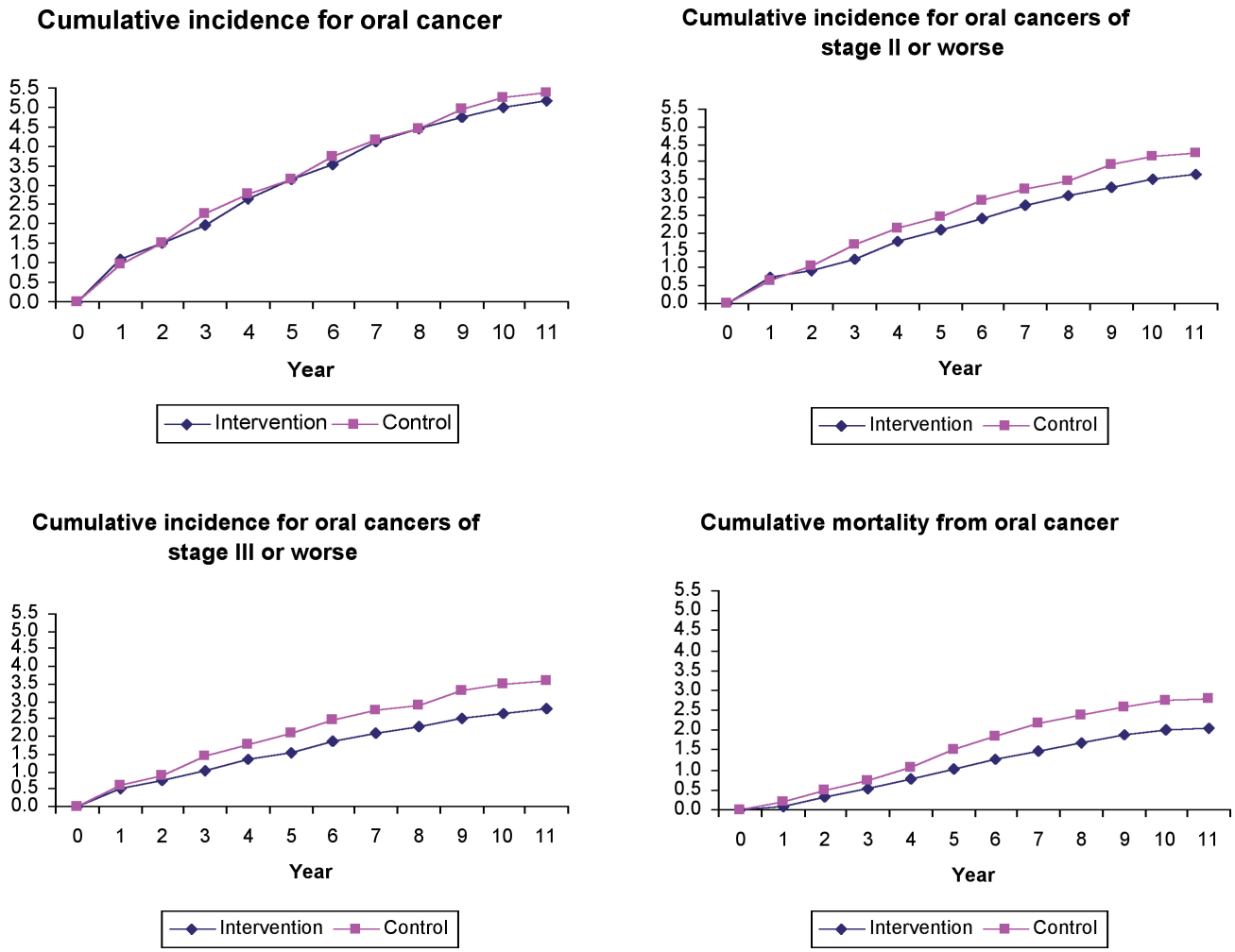
## 2. Oral cancer screening

Following a 34% reduction in oral cancer mortality among tobacco and/or alcohol users observed in a randomised controlled screening trial involving 200 000 subjects in Trivandrum district, Kerala, India, we have now completed a single round of oral screening for the 100 000 control subjects, as part of our ethical obligation (*Sankaranarayanan *et al*., 2005). A similar trend in reduction of cancer burden is still being observed after 13 years of follow-up. Figure 1 shows similar cumulative cancer incidence during follow-up between the intervention and the control groups. However, the difference between the two groups increased with increasing cancer stage and with mortality. A study of the cost-effectiveness of oral cancer screening reported that the most cost-effective approach was to focus on tobacco and/or alcohol users (*Subramanian *et al*., 2009). A clinical reference chart and web-based atlas to help in the detection of oral precancerous lesions and early diagnosis of oral cancer has been developed and will be validated.

## 3. Breast cancer screening

A cluster-randomised controlled trial was initiated in Kerala, India in collaboration with the Regional Cancer Centre (RCC), Trivandrum, India, to evaluate the effectiveness of a comprehensive intervention consisting of health education, opportunities for clinical early diagnosis and the provision of readily accessible diagnosis and treatment services in the clinical early detection and improved outcome of breast cancer. Around 56 000 women have been

**Figure 1. Cumulative incidence and mortality rate curves of oral cancer in the Trivandrum Oral Cancer Study**



recruited in the intervention arm to receive health education and clinical breast examination (CBE) by trained health workers, and 59 000 in the control arm to receive the currently existing health care in the region and health education on early detection and prevention of cervical cancer. Among the eligible women in the intervention arm, 90% received CBEs, of whom 6% were found to have abnormal breast symptoms and were referred for further investigations by physicians. Half of these women complied with the referral. During the first round, 74 breast cancer cases have been diagnosed in the intervention group (15% at stage I) and 61 in the control group (8% at stage I).

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# Quality Assurance Group (QAS)

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Cancer screening aims to reduce the burden of disease by detecting and treating cancer, or in some cases precancerous lesions, before individuals seek treatment due to self-detected signs or symptoms. For a number of cancer sites, particularly breast, cervical and colorectal cancer, which account for approximately one of four cancer deaths worldwide, population-based screening is currently a component of cancer control implemented in many high-resource countries. Efforts are underway to develop screening strategies appropriate to medium- and low-resource countries.

The vast majority of the people invited to attend population-based screening programmes have low to medium risk of developing a target cancer. The screening process has to be optimised for individuals to adequately benefit from early detection and to avoid the potentially detrimental effects of unnecessary further examinations or treatment. Therefore, comprehensive quality assurance, encompassing all aspects of the process of cancer screening is of paramount importance (Perry et al. 2009; European Commission 2008; Arbyn et al., in press).

The screening process comprises complex activities extending from invitation of the eligible population to performance of a screening test, assessment of detected abnormalities and, if necessary, treatment. Even in countries with relatively small target populations, quality-assured introduction of nationwide screening programmes may take 10 years or more due to the need for feasibility testing and planning, piloting and quality-assured rollout of services across the regions served by a programme. International collaboration has therefore become a key factor for successful application and further development of the standards and procedures required to maintain the effectiveness and the cost-effectiveness of cancer screening programmes.

Achieving and maintaining high quality at every step in the screening process requires an integrated, population-based approach to programme implementation. The population-based approach is essential in order to adequately monitor, evaluate and continuously improve performance, and in order to give all eligible people an equal chance of benefiting from screening. Nationwide implementation of population-based screening programmes of appropriate quality generally makes services performing to high standards accessible to the entire population, not just those persons eligible to attend screening. Large numbers of professionals undertake further specialisation and training in order to meet the screening quality standards. Consequently, these nationwide efforts also contribute to widespread improvement in the diagnosis and management of cancers that are detected outside of screening programmes. Implementation of cancer screening programmes of appropriate quality therefore has the additional potential to improve the entire range of cancer care.

Figure 1

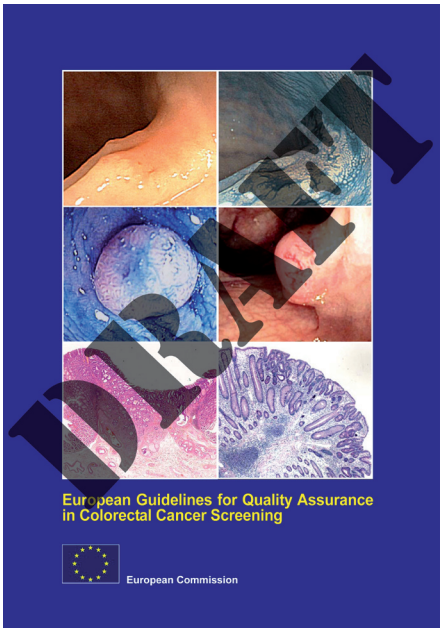


Figure 2

During the current biennium, the limited resources of the QAS group have been concentrated on further development and updating of European guidelines for quality assurance in breast, cervical and colorectal cancer screening (Figs. 1 and 2) and documentation of screening programme implementation in Europe (Fig. 3.)(Karsa et al. 2008; Anttila et al. 2009). [1] Due to the wide span of activities and the multidisciplinary scope of quality assurance guidelines for cancer screening, collaboration with experts from several IARC groups and the WHO are ongoing. The current status of cancer screening programmes reflects the substantial experience gained in Europe: 70 breast, cervical or colorectal cancer screening programmes, 50 of which follow the population-based approach, had been implemented in the

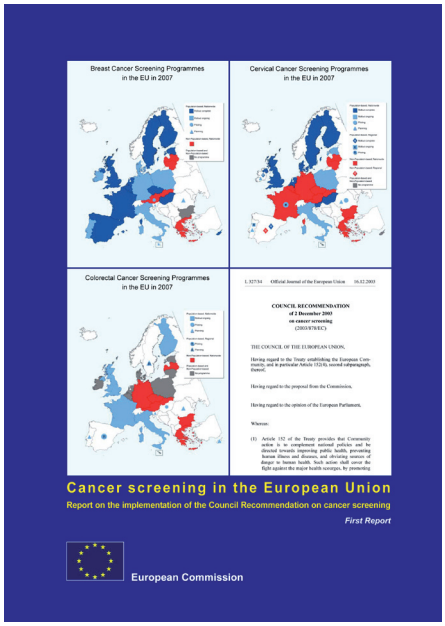


Figure 3

[1] These activities have been co-financed by the EU Health Programme through the projects: *European Cancer Network (ECN),* grant no. 2004309, *European Network for Information on Cancer (EUNICE)* grant no. 2004114, *Development of Guidelines for Quality Assurance of Colorectal Cancer Screening, grant no. 2005317, and European Cooperation for development and implementation of Cancer screening and prevention Guidelines (ECCG-ECN),* grant no. 2006322. Associated partners in the project for updating the EU Guidelines for Quality Assurance of Breast and Cervical Cancer Screening are: *ARCADES*, France; *EUROPA DONNA, The European Breast Cancer Coalition*, Italy; *Stichting Landelijk Referentie Centrum voor Bevolkingsonderzoek, (LRCB-EUREF),* The Netherlands; *Queen Mary & Westfield College,* United Kingdom; *Scientific Institute of Public Health, Belgium, Royal Surrey County Hospital NHS Trust,* United Kingdom. Associated partners in the project to develop quality assurance guidelines for colorectal cancer screening are: *University of Oxford*, United Kingdom; *Azienda Ospedalliera San Giovanni Battista and CPO,* Turin, Italy; *Public Association for Healthy People* (PROEMBER), Budapest, Hungary; *European Cancer Patient Coalition (ECPC),* Utrecht, The Netherlands.

EU by the end of 2007. At current levels, over 500 million screening tests will be performed in publicly mandated cancer screening programmes in the EU over the next 10 years. Due to the expansion of the current programmes, this volume is likely to double in the foreseeable future. Europe therefore offers a unique opportunity to deal with the challenges of implementation of population-based cancer screening programmes on a scale that is not likely to be encountered in other regions of the world until ten or more years from now. Colleagues from around the world have therefore been invited to collaborate with European experts in the efforts of the QAS group to further develop and to facilitate implementation of quality assurance guidelines for population-based programmes for cancer screening.

A truly integrated approach to quality assurance in implementation of secondary prevention should be based on comprehensive efforts to control cancer and other chronic disease. During the current biennium, an increasing amount of attention has been devoted to expanding the evidence base to improve implementation of primary prevention strategies that are complementary to cancer screening. These include, for example, vaccination against human papilloma virus infection to prevent cervical cancer, as well as strategies to effectively promote a healthy lifestyle by lowering risk factors such as smoking or lack of exercise. These activities have been co-financed through grants from the EU Health Programme to update cervical cancer screening and prevention guidelines and to update the European Code Against Cancer. [2] The EU project to develop guidelines on HPV vaccination will provide an important source of evidence and expertise for recently initiated efforts of the WHO, the French National Cancer Institute and IARC to collaborate in updating and expanding previous WHO guidelines on cervical cancer control.

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Anttila A, Karsa L v, Aasmaa A, Fender M, Patnick J, Rebolj M, Nicula F, Vass L, Valerianova Z, Voti L, Sauvaget C, Ronco G. Cervical cancer screening policies and coverage in Europe. Eur J Cancer 2009 45(15): 2649-2658

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### Books


European Commission (2008) European Guidelines for Quality Assurance in Cervical Cancer Screening – second edition. Arbyn M, Anttila A, Jordan J, Schenck U, Ronco G, Segnan N, Wiener H, Herbert A, Daniel J, von Karsa L (eds). Office for Official Publications of the European Communities, Luxembourg.

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Ronco G, von Karsa L, Anttila A (2008). Chapter 7. Key performance indicators. In: European guidelines for quality assurance on cervical cancer screening - Second edition (Arbyn M, Anttila A, Jordan J et al., eds). Office for Official Publications of the European Communities; Luxembourg.

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