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## News

### A Workshop Report

## Cancer Screening in the European Union

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### INTRODUCTION

THE PURPOSE of this report is to present an account of cancer screening in Europe.

Primary prevention should be given the highest priority in the fight against cancer; however, the reduction in the incidence of cancer that can be achieved by interventions, based on present scientific knowledge of risk factors, is limited. This is, unfortunately, particularly true for some common cancers, such as those of the colon, rectum, breast and prostate. Early detection and screening programmes must, therefore, be considered the best second choice for reducing mortality from certain cancers.

Early detection and screening programmes involve contacting, examining and possibly treating healthy, symptom-free people.

Society should, therefore, not use resources on cancer screening programmes unless there is sufficient scientific evidence to ensure that the population will benefit. Any scientific evaluation should cover reduction in the number of cases of late-stage disease and of death from the specific cancer (the aim of such programmes), any possible side-effects, such as unnecessary treatment, and an overall evaluation of the potential impact of the programme on the general health of the target population, for instance in years of life saved.

It is hoped that this report will provide useful background information for politicians, administrators and the public. There is an emphasis on different health care systems and recommendations are made not only for individuals but also for society.

## BELGIUM

In Belgium, there is no national or regional screening programme, although some pilot studies have been carried out. In 1964, the Minister of Public Health asked the university cancer centres to undertake early diagnosis of cancers. Between 1964 and 1983, detection centres and mobile services were set up in some municipalities, and, after a general information campaign, people were invited by letter to participate in early detection of cancers of the cervix uteri, breast, thyroid, skin and colorectum in women, and of the prostate, thyroid, skin and colorectum in men. In other municipalities, people were invited to ask their general practitioner (GP) to perform early detection.

Annual reports were sent regularly to the Ministry of Health, but no thorough evaluation was made. In 1983, the responsibility for preventive activities was transferred to the Flemish and the French communities, in which organisation and financing are very different.

A total of 924 000 smears were taken in Belgium in 1989 by GPs and gynaecologists. Inquiries made in May–June 1990 among women aged 30–59 years showed that 59% had had a smear within the previous 24 months. This percentage varied from 38% among women aged 50–59 years in the low socioeconomic class (primary school education only) to 79% in women aged 30–39 years in the high socioeconomic class. The percentage of women who had had a mammography increased considerably between 1987 and 1990.

### *French community*

In the French community, a convention is signed annually between the Ministry of Health and the cancer detection units, concerning (i) examinations for early detection and reporting of these activities; (ii) teaching general practitioners about early detection (Why? For which cancers? How?); (iii) research, including testing of new methods and pilot projects; and (iv) informing the public.

Research activities under way include (i) screening for breast cancer among women aged 50–69 years in a rural population,

involving general practitioners and radiologists; (ii) development of cervicography; (iii) a pilot project for breast cancer screening in the Brussels region; and (iv) three other projects on breast cancer screening which are in preparation, organised by provincial authorities. The l'Oeuvre Belge du Cancer is trying to coordinate these from the point of view of public information and epidemiological evaluation.

### *Flemish community*

The Flemish Advisory Committee on Cancer Prevention gives advice to the Minister of Health about the organisation of primary and secondary cancer prevention. Members are mainly from the cancer prevention centres in Flemish universities and GPs. The compliance to cervical screening performed by GPs and gynaecologists has been studied in women aged 20 years and over in four towns.

In 1984, the Flemish Advisory Committee published a monograph on cancer prevention, and on this basis a 'health card' was developed in 1986 by the Flemish Scientific Society of General Practitioners. The card represents a 'memory system' intended for both the doctor and the patient. Campaigns for early detection and prevention are organised by local associations of GPs in cooperation with municipalities and involve information campaigns and personal letters. Each year, a specific target is chosen locally. Approximately 100 local projects are running. Projects for screening for breast cancer and cervical cancer are under way in the provinces of Antwerp, Limburg and West Flanders. Smears are taken by GPs and gynaecologists, and a call-recall system is being evaluated by the State University of Ghent. A pilot project on breast cancer screening among women aged 50–69 years began in 1992, involving GPs, gynaecologists and radiologists. Further pilot projects are screening for prostatic cancer by ultrasonography, an investigation of the negative side-effects of breast cancer screening, and a study of the motivation of the population.

## DENMARK

The Danish National Board of Health issues guidelines for health care activities, including cancer screening. The responsibility for health care rests, however, with the counties, and the actual organisation of cancer screening, therefore, varies across the 16 Danish counties.

Cervical cancer is the only cancer for which extensive screening is undertaken in Denmark. The vast majority of smears are taken by GPs, and the remainder are taken in hospital departments and by private gynaecologists.

Organised screening was started in the small municipality of Frederiksberg in 1962; this was followed by larger programmes in Maribo county and København municipality in 1967, and in København county in 1968. Other organised programmes followed in the 1970s. The programmes were based on personal invitations to all women in selected age groups.

Unorganised screening started in 1969, when the public health insurance agreed to pay for smears taken by GPs at the request of individual women. The organised and unorganised smear-taking activities together led to an increase in the number of smears taken among women aged 20–59 years, from 0.08 per woman in 1968–1969 to 0.47 in 1983. All smears taken in organised programmes were analysed in hospital pathology departments, whereas a substantial number of those taken in unorganised programmes were analysed by private pathologists.

From the very beginning, the National Board of Health recommended the organisation of smear-taking activities. The

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following guidelines were published in 1986: (i) smears should be offered to women every third year, (ii) smears should be offered primarily to women aged 23–59 years, (iii) in the near future, smears should also be offered to women aged 60–75 years, (iv) smears should be taken by GPs, and (v) integrated programmes should be initiated in which data on all smears are computerised, so that women who did not have a smear taken within the previous 3 years are personally invited to do so. When implemented, these guidelines will require an annual number of 523 000 smears. Statistics from 1983 showed that 631 000 smears were taken that year.

In 1994, 15 out of the 16 counties have organised programmes. Four counties include women over 60 years of age, and in total, 72% of women aged 25–74 are covered by organised programmes.

The smear-taking activity during a 3.6-year period was analysed in one county with an organised screening programme and in one county with unorganised screening only. The numbers of smears per woman in the age range 15–75 years were almost identical: 0.8 and 0.9, respectively. The smears were, however, distributed very differently in the two counties. Forty-two per cent of the smears in the county with unorganised screening were used either for screening of women below the age of 23 years, or for rescreening of women above the age of 23 years with shorter intervals than 3 years.

Until 1 April 1991, mammography was used only for diagnostic purposes in Denmark. A national survey showed that 37 000 mammographic examinations were made in 1983 and 51 000 in 1990.

A working group under the National Board of Health reviewed the evidence for mammographic screening for breast cancer in 1989 and made the following recommendations: (i) all women aged 50–69 years should be offered screening, (ii) two-view mammography should be used at the first examination, (iii) women with dense breast tissue should be re-screened after 1.5 years by two-view mammography, (iv) all other women should be rescreened after 2 years by one-view mammography, and (v) an integrated collaboration between radiologists, pathologists and surgeons is a necessary precondition for the initiation of a screening programme. An organised screening programme based on these guidelines started in the municipality of København on 1 April 1991, and in the Fyn county in November 1993.

The human benefits and costs of screening by mammography have been discussed extensively in Denmark, and the National Board of Health has formed a committee to deal with this subject.

GPs invited their patients for discussion of breast cancer and instruction in breast self-examination during one week in 1989, and in one county, small-scale teaching programmes in breast self-examination have been undertaken.

Screening for colorectal cancer is being studied in a randomised trial in Fyn county, and screening for ovarian cancer is being evaluated in a randomised trial at Rigshospitalet in København.

## FRANCE

Screening for cancer in France before 1987 might be summarised as "many initiatives, little organisation and no evaluation". Apart from the so-called programmes conducted by various organisations (such as the CNAM, non-profit private insurance schemes and regional health structures), many spontaneous, uncontrolled screening procedures existed. Most of this opportunistic activity was paid for by the CNAM, because the

tests were codified as diagnostic procedures in the insurance nomenclature.

As a result, only 30% of the population was covered by screening for cervical and breast cancer, and 80% of the screened women were under 50 years of age [1]. In spite of the absence of definitive conclusions on the efficacy of screening for colorectal cancer, mass screening by haemoccult methods was tried in some regions, without success: participation rates never reached 20%.

Between 1987 and 1993, the situation changed. A few organised programmes were set up after publication of the recommendations of the National Cancer Committee [2], which specified that for only two cancer sites for mass screening are currently beneficial: breast and cervix. In order to be beneficial, it was recommended that the programmes fulfil the following conditions: (i) the targeted population must be defined according to geographical area, age range, minimal participation rates and, eventually, risk factors, (ii) the screening tests must be mammography for breast and smear for cervix and their performance, periodicity and reading must be standardised and controlled, (iii) positive results must be followed by either diagnostic or other actions, (iv) GPs and specialists must be trained, (v) the results of screening programmes must be evaluated, including rates of false-positive and false-negative results, effects on mortality and incidence and financial costs and benefits.

As a consequence, pilot studies must be carefully organised in geographically limited areas, in particular, in areas where cancer registries already exist. All relevant health structures must be involved in such studies. Isolated screening centres with only voluntary participation are not in a good position to perform and evaluate mass screening, but they must, nevertheless, participate in population-based programmes.

In January 1988, a national budget for prevention was provided and the CNAM was designated to manage it. In 1989, the French Breast Cancer Society recommended that screening for breast cancer using mammography should be organised for all women over the age of 50 years every 2–3 years, and that a double reading was necessary to decrease the risk of false-positive or false-negative results [3].

In May 1989, a budget was assigned by the CNAM to set up cancer screening programmes, and 11 administrative areas (departments) received money to organise screening for breast cancer (eight departments), breast and cervical cancer (two departments) and cervix cancer only (one department). The choice of pilot regions was not clearly documented, except for three in which programmes were already in place. The CNAM also took initiatives to screen for colorectal cancer. The organisation of a programme is the responsibility of regional health structures, and no specific directives were given, except with regard to the screening tests, which should be mammography and smear, and should be free of charge for the participants. A call-recall system could be organised using the national health insurance listing, but this was not obligatory. Evaluation is performed by independent, local staff.

The ADEMAs campaign for breast cancer screening [4,5] and the EVE campaign for cervical cancer screening [6] are two such programmes in the Bas-Rhin. These campaigns are based on the existing medical structure, and women are not personally invited to attend the screening. A decentralised system, in which women can choose their own doctor and where the administrative complications involved in managing a call-recall system are avoided, was chosen since it enabled consideration of certain specific aspects of the French health care system. The radio-

logists, cytopathology laboratories, gynaecologists, and GPs working in both the public and private sectors had not waited for the authorities to define a screening policy before starting to screen on a massive scale.

For breast cancer, spontaneous screening by liberal radiologists was already well under way. In 1988, 1 200 000 mammograms were performed for screening purposes using diagnostic methods, and more than 2000 mammographs were available.

For cervical cancer, almost 5 million smears were taken during opportunistic screening by gynaecologists and GPs. These smears were interpreted at more than 1000 mainly private laboratories.

The final reason for choosing a decentralised system was the lack of exhaustive, high quality population list, and the impossibility of using any such lists that do exist because of the regulations imposed by the National Commission on Data Processing and Freedom.

The objective of the ADEMAs and EVE campaigns was to test a screening model that integrates the health care structures, takes account of the code of ethics, and of the French health care system, and which attains the same degree of effectiveness and quality as those of the highly centralised programmes of the countries of northern Europe. In order to evaluate these campaigns a database network was established for the ADEMAs campaign for breast cancer screening and for the EVE campaign for cervical cancer screening.

The numbers of women in the target populations, all those aged 50–65 years in the ADEMAs campaign and all those aged 25–65 years in the EVE campaign, are known from the basis of the censuses, which take place every 7 years. Annual estimates are made between censuses. The participation rates are calculated by dividing the number of screened women by the number of women living in the département.

The ADEMAs network includes a number of databases [4, 5, 7]. (a) A database on screened women: the information is provided by the women, who fill out a questionnaire when they go for mammography. The completed questionnaire is sent to the ADEMAs Centre, together with the mammograms. It includes the identity and address of the woman and the identity of the radiologist and that of the doctor to whom the woman wishes the results to go. The database also has the date of the screen, the results of the first reading by the radiologist who carried out the mammography, the results of the second reading carried out at the ADEMAs Centre by specialised radiologists and those of the third reading should there be a divergence between the first and second readings; (b) a database on the results of the diagnostic examinations: these data are collected by following up all women for whom the result of the test is positive.

The remaining five databases are: (i) a cancer register, (ii) a mortality register with causes of death, (iii) the results of all cytological and histological examinations carried out on women resident in the département, (iv) the identities of women who have undergone mammographic examination outside the screening campaign, and (v) a database containing the results of quality assurance.

The EVE network includes six databases [6]: (i) a record of all smears taken from women in the Bas-Rhin. This file is established by centralising data from the records of all cytopathology laboratories at the EVE Centre. The information recorded includes the identity and address of the woman, the identity of the doctor who carried out the smear, the name of the laboratory and the date and results of the smear; (ii) a database containing

the results of diagnoses for women whose smears present anomalies; (iii) a cancer register; (iv) mortality data; (v) a record of all the histological examinations carried out on the cervix, whether the results were pathological or normal; and (vi) the results of quality assurance.

Unorganised screening is, however, not only still continuing but is increasing throughout France. A study by Lancry and Fagnani [1] showed that 100 million French francs could be gained if unorganised screening was replaced by organised programmes. In addition, considerable potential gains in terms of public health would be incurred by a shift from individual screening, characterised by a lack of adequate training, quality assurance and evaluation, to an organised global system.

In 1990, a consensus meeting on cervical screening recommended that all women aged 25–65 years should have a smear every 3 years, and screening more frequently should be discouraged [8]. A national committee on quality control for cervical smear cytology has been created by pathologists, who are now organising quality control within their own specialities at a national level. Radiologists are setting up a similar committee. In 1991, the National Cancer Committee reaffirmed the major screening principles and emphasised the importance of external quality control. The CNAM has evaluated 10 departments where a breast cancer screening programme is running.

At the end of 1993, a national committee for the coordination of breast cancer screening programmes was created by the Health Minister. Jointly with the CNAM this committee wrote directives to be fulfilled by all departments to obtain money for conducting breast cancer mass screening. These directives, although they followed the European recommendations for cancer screening, are based on a decentralised system enabling the participation of all public or private medical structures concerned by such a programme. The committee is also in charge of the national evaluation of the subsidised programmes.

## GERMANY

The German comprehensive cancer screening programme came into operation in 1971. It reaches more than 90% of the population that is covered by statutory health insurance (Krankenkassen). The remainder of the population is given secondary preventive care along the same lines. Since reunification in 1989, the programme has also applied to the new federal states.

The programme has some lower age limits, but no upper age limit. For women, it comprises a targeted personal history, a pelvic examination, a smear, a digital rectal examination, a physical examination of the breast and training in breast self examination. In 1977, faecal occult blood testing was added to the programme. Doctors also enquire about changes in moles; a full inspection of the body surface is not (yet) part of the programme. Men are offered a similar range of methods.

Screening examinations are carried out free of charge by office-based physicians. Screening contacts are documented in a standard way by the physician. In suspicious cases, the outcome of follow-up examinations is collected and coded as 'negative', 'confirmed by surgery or biopsy' or 'insufficient information'. Submission of the data sheet is a condition for the doctor's fee claim.

Approximately 90% of the examinations in women are performed by gynaecologists, usually using colposcopy for the primary examination, although this is not required. Accreditation is required for smear reading: experienced gynaecologists may do their own cytology, and others send slides to special laboratories;

the numbers are not known officially. Mammography is recommended for high-risk groups (positive family history, previous abnormality) and in cases with clinical abnormality. The latter definition is open, so that mammography is essentially available on demand.

More than 7 million women and about 1.3 million men annually take part in the programme. The overall annual attendance rates are about 30% for women and 15% for men. Women in the age group 30–50 years have attendance rates of more than 40% annually and about 60% over a 2-year period. These figures underestimate the screening activity, as 'clinical' examinations are not included even if they are performed for 'worried but well' individuals. Furthermore, the population coverage beyond the period given above cannot be calculated as individual record linkage is prohibited by law. Self-reported attendance rates from a survey of the non-institutionalised Germans in 1984–86 are probably too high, but they indicate that the proportion of women who have never taken part in the programme is small. Assuming a relative protection as estimated in the IARC study [9], 74% of all invasive cervical cancers should be prevented.

The attendance pattern by region is very stable over time. The attendance of men is best in Berlin and worst in Bavaria (114 and 88% of the level in northern Germany, respectively); the attendance of women is best in Berlin and worst in Rheinland-Palatinate (108 versus 90%). An ecological analysis, however, revealed no significant association between regional attendance rates and regional mortality trends [10].

Detection rates are monitored annually and tabulated by sex, age, region and health insurance group. Detection rates are low. People who are found to have suspect lesions in the initial screening examination but are cleared in follow-up investigations continue to be at high risk [11].

Only circumstantial evidence is available on the effectiveness of screening. Successive birth cohorts have decreasing mortality from uterine cancer. The mortality from colorectal cancer began to decline in the late 1970s. A case-control study to evaluate screening for colorectal cancer is under way in Saarland.

The direct costs of the programme are about 400 million DM per year. The secondary costs, for follow-up examinations and treatment, are not known, nor are possible savings or indirect costs.

Guidelines for the programme are issued by a joint committee of representatives of sickness funds and office-based physicians after consideration of the scientific evidence. The Government has a limited supervisory role. There is no clear policy on programme monitoring and technology assessment. This is due in part to the fact that record linkage is not permitted. A second reason is that the committee's mandate for decision-making relates only to the office-based out-patient sector, and not for instance to in-patient management or cancer registration and mortality statistics. A third reason is lack of scientific resources in the out-patient sector.

Mammography services are highly decentralised: 1700 units are operating in the western part of the country; in the eastern part, there used to be about 100 units of an inferior technical standard. The number and quality are now increasing. A regional study has been set up to test quality assurance measures, to develop training materials and to evaluate economic issues of mammographic screening. Three-year results demonstrate an increase in detection rates and predictive values associated with a decline in follow-up examinations. A set of recommendations aimed at a national mammographic screening programme is now under consideration by a joint committee.

## GREECE

Unorganised screening, for individuals not necessarily at high risk and with no possibility of follow-up, has been carried out mainly for cervical and colon cancer. Such opportunistic cervical cancer screening is performed by gynaecologists both in hospitals and in private practice. The Society of Cytologists has estimated that 10% of the population is screened.

A pilot study to achieve the conditions necessary for systematic screening is supported by the Ministry of Health and the Europe Against Cancer programme. It is being carried out by the Hellenic Society of Oncology and began in Peloponnisos in 1991. Screening for cervical cancer is recommended for women aged 25–65 years, every 3 years, with smears free of charge. In 1990, 21 313 Pap tests were performed in the Alexandra Hospital in Athens, and 91% of these were negative (Efstratiadou, personal communication, 1991).

To screen for colon cancer, the Haemoccult test was used in certain instances. At the Metaxa Cancer Hospital in Piraeus, this test was used on 1046 individuals over 45 years of age who had non-specific gastrointestinal symptoms and no visible blood in the stools. The results were positive in 4.6% of cases, and further examination of those individuals revealed four carcinomas and nine polyps of the sigmoid [12].

The first well organised screening for breast cancer in Greece was set up by the Hellenic Oncology Society and financed by Europe against Cancer programme and the Greek Ministry of Health. A mobile unit was constructed and all necessary equipment (including mammography) installed. A team of surgeons, radiologists, epidemiologists, cytologists and pathologists was organised. The programme began in the state of Ilia, which is located in western Peloponnisos, in August 1989 [13].

All women aged 40–65 years in the state of Ilia were invited to participate in the programme. Attending women underwent a complete physical examination, their history was taken and they were given a smear and a two-view mammography. Women from rural areas were transported to the mobile unit in a minibus. A total of 21 459 invitations were sent, and 8511 women responded. This corresponds to an overall participation rate of 40%; the rate was higher in rural areas (51%) than in cities (23%).

Two radiologists evaluated the mammographies separately but agreed on 93% of the cases. Out of 8511 mammographies, 90% showed no malignancy and 10% were considered to be suspicious and required follow-up. When the women with suspicious mammographies were re-examined, 75 were considered to be candidates for biopsy; 59 of these accepted, whereas 16 refused. Cancer of the breast was detected by biopsy in 25 women. The ratio between benign and malignant disease was 1.4:1. One patient had carcinoma *in situ* and 24 had infiltrating tubular carcinoma. Twenty-one of the 25 women underwent modified radical mastectomy. The prevalence of breast cancer in the screen population was thus 0.3%, and 2.99% of women with suspicious mammographies were found to have cancer.

This programme has been extended to other states of Greece. The programmes in the other states will also include women aged 40–65 years. The reason for including women in the age group 40–49 years is that the incidence of breast cancer is, at present, the same in this age group as in the age group 50–59 years. The annual rate of increase of mortality from breast cancer in Greece is at present 4% (Kogevinas, personal communication, 1991).

## IRELAND

Screening activity for cervical cancer in Ireland is considerable. Two studies provided data on the volume of screening. One carried out for the Department of Health was a survey of cytology laboratories and community-based cervical smear clinics. The other was a detailed study of a cytology laboratory which reports on 25% of all smears.

The studies showed that approximately 165 000 smears are processed annually by 24 laboratories. Two laboratories process more than 20 000 smears/year, whereas 15 process less than 5000 smears/year.

Fifty-seven per cent of the smears were from women below the age of 35 years. The annual screening rates were 17% for women aged 35 years and below, 14% for women aged 35–44 years, and 7% for women aged 45 years and above. Approximately 60% of the screened women were in upper or middle income groups. Therefore, the pattern of unorganised screening described elsewhere prevailed: namely, younger, better educated women availed themselves of the service more readily than older women and women who are more socially deprived.

The survey showed that there were 656 public open-access clinics throughout Ireland. Many smears were also taken in maternity hospitals and by GPs. Smear reports are sent to the woman's GP. In only one health board area—the Western Health Board—was a computerised recall system used to invite women for subsequent smears. No population register is available, and women are recruited to screening through health education given to women's groups and via the local media. In the Western Health Board, women with abnormal smears are reminded to visit their own doctor.

A pilot study of cervical cancer screening, subsidised by the Europe Against Cancer programme, began in August 1991. The study population consists of 16 000 women aged 25–59 years who are entitled to totally free medical care and are resident in a defined geographical area in central Dublin. A computerised register exists for this group in the lower income category, which comprises approximately 40% of the total population of Ireland, but there is no register for the remaining 60% of the population.

The aim of the study was to examine the logistics of setting up a computerised call-recall system for cervical cancer screening including: (i) to establish a computerised population register, (ii) to establish a call-recall invitation system based on GPs, (iii) to create a central computerised record at the health board level for each woman, with linkage of data from GPs, cytology laboratories and gynaecological services, (iv) to establish a fail-safe method for follow-up of women with abnormal smears, and (v) to provide data on cooperation from GPs in providing a cervical smear service, response rate to invitations and reasons for non-response, detection rate of abnormal smears, follow-up of women with abnormal smear, and the costs of the programme.

The pilot study will run for 2 years and will be reported fully in 1994–1995.

Fifteen public hospitals and at least two large private hospitals offer mammography services. It is not possible, however, from the data available to distinguish between screening and diagnostic mammography.

A randomised controlled trial of breast cancer screening by mammography, subsidised by the Europe against Cancer programme, was started in Dublin in 1989. The study population was 35 000 women aged 50–64 years, equally divided between urban and rural areas, and the control population consisted of 34 000 women in the same age group, resident in the Southern Tumour Registry area. The objectives of the study were: (i)

to compare breast cancer mortality in the study and control populations, (ii) to document compliance with screening, and (iii) to compare the sensitivity, specificity and predictive value of the mammography screening programme with that reported in other studies.

Screening is undertaken by a specially trained team, and it includes a computerised record system with call-recall facilities. The response rate in the first year of the trial was 60–70%.

## ITALY

Cytological screening for cervical cancer is not organised on a national basis in Italy. No recommendation for screening is available from the Ministry of Health or from regional health authorities. Recommendations for cancer screening [14] and detailed guidelines for cervical screening [15] that have been agreed upon by most national experts have been published by the Italian League against Cancer.

Smears are available almost everywhere in Italy, but organised screening exists in only a few districts (e.g. Florence, Bologna, Turin, Varese), mostly in the northern part of the country. In most cases, organisation is limited to smear reading; there is no invitation activity, and assessment and treatment are carried out through the normal health care system. The only programme organised according to the recommended guidelines (call-recall system, centralised reading of at least 25 000 smears/year, centralised assessment of cases found to be positive at screening, centralisation of out-patient treatment, active follow-up of treated cases) and which undergoes routine, periodic quality control of all phases is that in the district of Florence [16,17]. Evidence for the efficacy of screening has been reported from only two Italian studies [17–19].

In most of the country, smears are performed on a self-referred basis at family planning consultancies or at gynaecologists' offices. Most recommendations for screening frequency from laboratories, gynaecologists and local health authorities (95% recommend every 6 months to every 2 years) are in contrast with the national guidelines (every 3 years) [20]. Reliable data on the coverage of the population are available only in the few centres in which screening and residence files can be matched. For other areas, the estimates of coverage are unreliable: the total number of smears performed is known in some areas, but no information about the proportion of repeat smears is available. An estimate of coverage was attempted by interviewing a random sample of women throughout the country [21]. According to this survey, 17% of women aged 20–79 years reported having had a smear in the previous year. Compliance was greater in the 30–49 year age group than in women over 50 years, greater in the north (22%) compared to central (16%) and southern (11%) Italy, and greater in high than in low educational and social classes. As the women who come for a smear tend to be the same each year [22], coverage of the population is low and is concentrated in subgroups at lower risk.

Even when a smear is taken, the recommended technique of smear sampling (Ayre spatula plus cytobrush) is seldom used. Smears are interpreted in local laboratories, most of which (95% [20]) undergo no quality control and process fewer than the recommended 25 000 smears/year. Assessment of cases found to be positive at screening is not organised: colposcopy is not available everywhere and is often performed by people with limited experience. Lesions detected at screening are not treated according to homogeneous guidelines, and under- or overtreatment is common.

A major effort will be needed to organise cervical cancer

screening properly, according to official guidelines, on a national basis, and it will take many years before an efficient programme is implemented.

The first European breast cancer screening programme was implemented in the district of Florence in 1970, following the preliminary results of the Health Insurance Plan (HIP) study [23]. Women aged 40–70 years and resident in 24 municipalities of the district were invited by mail (call-recall) to undergo a two-view mammography in a mobile unit every 30 months on average. After 1983, the interval was reduced to 24 months, and only one oblique view was taken at the repeat screening test.

A case-control study was carried out to evaluate the efficacy of the programme by comparing the probability of dying from breast cancer among the screened and unscreened women [24]. In a further analysis, the results were studied in relation to time interval since the last test [25]. The study showed an overall 40% reduction in mortality; no significant effect was shown in women aged 40–49 years.

Attendance increased from 54 to 61% in the period 1970–1989, and it was somewhat higher in the younger than in the older age groups. The recall rates decreased from 20.3% in 1979–1981 to 1.4% in 1987–1989, while the recall for biopsy decreased from 0.9 to 0.3% [26]. This improvement in screening accuracy was due to the increasing quality of mammography and the availability of new diagnostic devices, such as the stereotaxic technique introduced in 1986. Today, 1.8% of women are recalled for mammographic assessment, and 92% of those biopsied have a breast cancer.

An analysis of early indicators of efficacy in the period 1975–1986 showed that the detection rates, the prevalence and incidence ratios and the proportion of interval cancers out of the total number of cancers expected in the absence of screening were comparable to those observed in other European studies [27].

Guidelines for breast cancer screening in Italy were issued by the Italian League against Cancer in 1988 and by the Italian National Task Force for Breast Cancer in 1990: biennial mammographic screening of women over age 49 years was recommended as a routine public health policy, although limited to those areas in which proper technical and organisational resources are available.

Twelve population-based screening programmes have been implemented in Italy, in addition to that in the Florence district. Some of these programmes do not follow the national and European guidelines, and efficient quality control is not fully assured.

In many other regions, the number of asymptomatic women who undergo mammographic examinations (spontaneous screening) is increasing rapidly. In the main cities, mammographic coverage (at least one mammographic examination within the past 3 years) outside of screening programmes is reaching 20–30% of women aged 40–49 years; these examinations are performed in diagnostic centres, with no quality control [28].

A national group for the implementation and quality control of population-based breast cancer screening programmes has now been organised in Italy. The group has issued a document on the feasibility of a national programme on the basis of available knowledge on Italian needs and the quality of care for breast cancer [29]. Incidence rates in each region of Italy have been calculated from the specific mortality rates (Micheli, personal communication, 1991). The estimated incidence is highest in northern Italy and follows a decreasing gradient from the north to the south, which is in agreement with observations

from cancer registries, which now monitor about 10% of the Italian population.

Several surveys carried out at a population or hospital level have made it possible to estimate the distribution of stage of breast cancer in different regions. Surveys of the quality of care for breast cancer are available [30]. Attitudes to conservative treatment and the availability of radiotherapy facilities will be followed. Using a Dutch simulation programme (MISCAN) [31], the impact of screening services on mortality and clinical stage has been estimated on the basis of a model using assumptions derived from the experience of the Florence district programme. In summary, the results support screening for women aged 50–70 years.

## LUXEMBOURG

Luxembourg has 380 000 inhabitants, of whom 25% are foreigners. The social insurance system covers almost the entire population. Health care is provided mainly by private medical care (private medical consulting rooms, centres, hospitals), and fees of medical practitioners are refunded by social insurance. The costs of preventive medicine are normally borne by the Ministry of Health; but this is not the case for the breast cancer screening programme.

Screening exists at present only for cancers of the cervix and breast. No well-structured screening system for cervical cancer exists at present in Luxembourg. Nevertheless, the majority of women are regularly followed up by gynaecologists, resulting in a significant reduction in the incidence of this type of cancer. At present, about six women per year die from cervical cancer, most of them aged 70 and over.

The Ministry of Health recommends a smear test after first sexual intercourse. No age limit has been recommended, and no invitation system exists. Smears are taken during gynaecological check-ups by gynaecologists or GPs. An attempt to establish a screening centre for cervical cancer failed, as women preferred to be seen by their own doctors. The National Health Laboratory provides the necessary kits and makes cytological and histological diagnoses, free of charge. Cytology may be performed in private laboratories, but it is then not refunded by social insurance. The smear test itself is not officially refunded by the social insurance, which, in general, does not refund preventive examinations. In actual practice, gynaecologists charge a consultation fee and a fee for colposcopy, which are refunded. The Ministry of Health provides an incentive to the physicians to use this type of screening widely, by paying them a small premium (50 FLux).

A proper evaluation of the effectiveness is not possible at present because of the existence of private laboratories, to which the Ministry of Health has no access.

From 1 May 1992, the Ministry of Health, together with the Union of Social Insurance and the Luxembourg League Against Cancer, started a programme of screening for breast cancer by mammography. The target population is all women aged 50–65 years, giving a total of 34 000 women. The Union of Social Insurance sends a personal invitation and a voucher to each woman, offering her the possibility of undergoing early detection by mammography, free of charge. A large multi-media sensibilisation campaign will precede the programme.

One mammography every 2 years is foreseen. Mammography will be performed according to the norms of the European Community by accredited radiologists and gynaecologists. All mammograms will be read twice. In case of disagreement a third reading will take place. The result of the mammography



will be transmitted to the physician of the woman's choice (GP, gynaecologist or internist). The physicians will inform their patients of the result and provide a general preventive check-up. Medical technical assistants in radiology will participate in re-training courses, and radiologists will attend lectures. An initial visit to each centre was organised by the Ministry of Health for information purposes and technical inspection.

The sensitisation campaign will be carried out and financed by the Luxembourg League against Cancer. Mammographies and preventive check-ups will be refunded by the Union of Social Insurance. The management, organisation and evaluation of the programme will be performed by the Division for Preventive and Social Health Care, Direction for Health, Ministry of Health. The total annual cost of the programme will be approximately 30 million FLux.

A cancer registry was started in 1992 under the auspices of the National Health Laboratory. The Ministry of Health will ensure statistical evaluation, quality assessment, follow-up, etc.

### THE NETHERLANDS

Screening for cervical cancer had a slow start in the Netherlands. Screening began opportunistically among gynaecological patients in teaching hospitals in about 1960. Pilot projects in general practices followed in the 1960s and early 1970s. The costs of examination of smears taken by general practitioners have been refunded since 1974.

Two years later, in 1976, an organised, population-based screening programme was started in three pilot regions, covering a quarter of the Dutch population. The remainder of the population was intended to be the control group in this state-aided experiment. Under pressure from women's organisations and the Second Chamber, the Health Secretary was obliged to subsidise service screening in the control areas also, in addition to the screening project in the three pilot regions. Every 3 years, all women in the age group 35–54 years were invited for screening, and the smears were taken by trained women in mobile vans.

An increasing number of smears was taken outside the screening programme, however. In 1981, about 1 million smears were taken, one-third within the programmes, one-third by general practitioners and one-third by gynaecologists. The Minister of Health decided to terminate the screening programmes by 1985, and recommended that the taking of smears for screening purposes should be carried out by general practitioners. As the general practitioners had not been consulted before this decision was taken, the National Association of General Practitioners pointed out that population screening was a new kind of activity for them and that they should be paid a fee for this service. In 1988, an agreement was reached with the National Association, and a fee of 12.50 Dutch guilders (5.5 ECU) was introduced for each smear taken in response to an invitation for screening.

This new-style screening programme made a hesitant start. Women aged 35–54 years are invited by letter to make an appointment with their general practitioner for a smear. Only 40–50% currently do so: some 40% do not make an appointment because they have recently had a smear or a hysterectomy or for other medical reasons; about 15% of women are not covered. Not all municipalities are willing to cooperate by making available the names and addresses of women to be invited.

In 1990, the Health Secretary initiated an enquiry into the reasons for failure to attend screening. The main conclusion was that the organisation and financing of the screening programme should be improved. The Health Secretary endorsed the re-

commendation, and asked the Health Insurance Executive Board to take measures to improve the organisation and to advise him on financing the programme from one financial source. The improved organisation should not involve increased overall costs, as the costs of the improvements should be compensated for by a substantial decrease in opportunistic screening.

Some important developments are: (i) issuance of guidelines for the management of abnormal smears (1987, 1988); (ii) the development and implementation of an information system for the performance and evaluation of the screening programme (1988–1992); (iii) analyses of cost-effectiveness (1988, 1991); (iv) a cohort study of women aged 45–54 years who had negative results after screening, which showed that the incidence of *in situ* and invasive cancers was very low after a negative smear (1991).

An adjusted screening strategy can be anticipated soon, involving a screening interval of 5 years and women aged 30–60 years as the target group.

Two non-randomised studies of breast cancer screening were started in Utrecht and Nijmegen in 1974–1975. The results of a case-control study to evaluate these projects were published in 1984. On this basis, the Health Secretary decided to continue the screening projects and to make preparations for a national screening programme. In 1987, the Health Insurance Executive Board was requested to proceed with the preparations and set up a national coordinating committee. Guidelines for quality assurance were endorsed by the colleges of general practitioners, radiologists, histopathologists, surgeons and radiotherapists and issued in 1988. A national reference centre was established in Nijmegen in 1989, which is responsible for training the radiographers, radiologists and histopathologists who are involved in the screening process and the diagnostic work-up of 'positive' screens. The reference centre is also responsible for quality assurance of the physical aspects of screening mammography. At the request of the Department of Health, a cost-effectiveness analysis was also performed. The final report for 1990 showed that well-organised screening may prevent the deaths from breast cancer of 700 women per year. The cost-effectiveness ratio is about 8000 Dutch guilders (3500 ECU) per year of life saved.

In April 1991, the Health Secretary led a debate in Parliament on breast cancer screening. Two small political parties raised doubts about its efficacy, but the majority of Parliament remained in favour of the policy to prepare a national screening service. The Health Secretary announced a mid-term review of his policy, which confirmed his position on population screening for breast cancer.

The number of screening units currently in operation is 40. The target is a total of 44 units by the end of 1995, backed up by about 20 central units where dual reading of films can be performed by the radiologists responsible for quality control. Screening is offered at 2-yearly intervals to women aged 50–69 years, who numbered 1.5 million by 1993. Screening is used by about 80% of women at the first round, and 1.25% of screened women are referred for a follow-up examination.

The organisation of the programme is uniform throughout the nine regional comprehensive cancer centres. These centres and the municipal public health departments are jointly responsible for the implementation of the screening process. An information system, linked to the regional cancer registries, has been developed to ensure the performance, quality assurance and evaluation of the programme. The programme is financed from one source (Exceptional Medical Expenses Act). The cost will



amount to about 50 million guilders (23 million ECU) in 1995, when the national programme should be fully implemented.

'Wild' initiatives for breast cancer screening, on a profit or a non-profit basis, have been limited in both number and scale. Unorganised screening for breast cancer, within normal health care, is hard to quantify. The number of clinical mammographies performed in 1988 was estimated to have been between 186 500 and 285 000. Only some were carried out for preventive purposes: general practitioners refer an estimated 80 000 women per year for mammography. These include 24 000 women aged 50–69 years, but about 70% of the referred women are under 50 years of age, and most belong to the category of 'well but worried'.

A pilot project on screening for colorectal cancer was carried out among 15 000 inhabitants of the city of Zoetermeer aged 40 years or over and was repeated 1 year later. The participation rate declined from about 50% in 1979 to 35% in 1980, the decline corresponding to increasing age. The predictive value of a positive haemoccult test was found to be 4–12%. These results discouraged continuation of the programme or the development of new programmes.

In 1986, the Health Secretary decided that screening programmes for cancer of the prostate could not be recommended other than for evaluation of the validity of new screening tests. The value of transrectal ultrasonography appears to be limited to the diagnosis of prostatic carcinoma. In an investigation among urological patients in Nijmegen University, the specificity of ultrasound was only 56%.

In 1982, the Minister of Health rejected a proposal for a randomised trial on screening for lung cancer. A proposal for a feasibility study was rejected in 1988.

Since 1988, several screening activities have existed in this field, including free clinics organised by departments of dermatology and the so-called 'Freckle Bus', an adapted trailer which visited four seaside resorts and several factories. The Health Department does not support these screening activities, but by mutual arrangement, a professional and public education programme is being prepared in order to reduce both patient delay and doctor delay in the diagnosis of melanoma.

The Government has had an active policy on population screening for many years, supporting only programmes of proven efficacy and studies of screening which may be beneficial. In 1992, the Population Screening Act was introduced which states that population screening that may damage health is subject to a system of permits.

## PORTUGAL

Portugal, a member state of the EC since 1986, has a population of 10 million, distributed mainly along the west coast, where the socioeconomic level is highest. According to the Portuguese Constitution, a free, universal national health system is available, supported by hospitals and GPs. This system co-exists with a total of about 27 000 private doctors, most of whom have agreement with the national health system. A GP career system was created in 1980, and about 7000 GPs are distributed throughout Portugal, at a ratio of 1:1500 inhabitants. They cover the whole country and represent a crucial pillar of the Portuguese national health system. Sub-systems cover the health of, e.g. civil servants, bank clerks and workers in large enterprises.

Portugal has one oncological institute, with three regional branches (in Porto, Coimbra and Lisbon), in which only cancer patients are treated. The main district hospitals provide several diagnostic and treatment protocols. A campaign to educate the general public and school children about cancer ongoing since

1972 in central Portugal. Emphasis was placed on breast cancer (breast self examination, physical examinations and periodic mammography where possible) and cervical cancer (periodic cervical smears and gynaecological examinations). General practitioners attended lectures, meetings and courses on cervical and breast cancer.

In the 1980s, the Government took a special interest in the cancer problem, defining the political and scientific guidelines for oncology in Portugal (research, prevention, diagnostic and treatment activities)—the National Oncological Plan, 1990–1994. This is coordinated at the national level by the National Oncological Council and at the regional level by the regional oncological institutes. Among other activities, three regional population-based cancer registries have been set up, and guidelines have been elaborated for popular education, early diagnosis and screening activities. The plan also gives priority to the implementation of screening programmes for cancers of the cervix (among women aged 20–55 years) and breast (women aged 45–65 years).

The history of early detection and screening, mainly for cancers of the stomach, cervix and breast, goes back several years in Portugal. One of the first screening activities was for stomach cancer. Mortality from this cancer is high all over the country (standardised mortality rate 26.1, in relation to the 1989 European population), especially in the central interior. It was there that some screening activities were undertaken in the 1970s, using X-ray and gastrocamera.

Cervical cancer (standardised mortality rate 3.2) has always been a major concern of Portuguese gynaecologists. Regular, early diagnostic examinations by means of smears have been carried out, especially by gynaecologists who received their medical training at the Medical Faculty of Coimbra. With regard to cervical cancer, unorganised programmes have developed steadily since 1978, when family planning clinics were created at which women beginning their sexual activity have a smear once a year. Several pilot programmes on screening were set up in small, localised geographical areas, mostly in the central part of Portugal, to assess different screening methods. As electronic demographic lists and population-based cancer registries do not exist in Portugal, a more extensive programme could not be envisaged.

The guidelines are currently being implemented. The Oncological Institute of Coimbra is running a cervical cancer screening programme, with centralised organisation and cytological reading, in collaboration with the regional health administrations and with the support of the central branch of the Portuguese League Against Cancer for popular education and sensitisation. Gynaecological examinations and cervical smears are carried out by general practitioners at health centres.

In 1986, the central branch of the Portuguese League Against Cancer started a screening programme for breast cancer (standardised mortality rate 24.1), using a mobile mammographic unit. In 1986–1990, 18 500 women were screened, with a single oblique view at a 2-year interval. Since July 1990, a second breast cancer screening programme has been under way in the central region under the auspices of the central branch of the Portuguese League Against Cancer, involving mobile mammography units. This project is part of the European breast cancer screening pilot projects. The assessment unit is based at the Oncological Institute of Coimbra, where most of the cancer cases are treated.

The organisation and implementation of early diagnosis and screening activities in Portugal met with some difficulties, mostly

due to: (i) incomplete demographic information (census data from 1991 will, however, become available in May 1994) and frequent migration; (ii) the non-existence or unavailability of electronic demographic registries, which makes it difficult to issue personal invitations to target groups of women; (iii) the newness of the population-based cancer registries, which have only been in operation since the middle of 1989; (iv) the fact that only recently has there been complete coverage of the country by general practitioners; and (v) the absence of specific legislation that would make it possible to trace mortality and morbidity.

### SPAIN

The overall cancer mortality rates for Spain are 157.5 per 100 000 (World Standard Population) for men and 78.3 for women. These figures place Spain among the European countries with the lowest rates. In men, lung is the most frequent cancer site, followed by stomach, prostate and colon and rectal cancers. Among women, breast cancer takes first place, followed by stomach, genital organs and colon and rectal cancers. Stomach is the only cancer site that shows a downward trend.

In 1988, the Ministry of Health and Consumer Affairs initiated a national cancer prevention and control plan, with the aim of laying down national guidelines in the areas of prevention, health care and research. Throughout the period 1988–1990, in parallel with activities in various regional autonomous communities, a wide variety of cancer programmes and plans for health care have been under way. These programmes have not been coordinated.

Cervical and breast tumours are treated regularly and continuously throughout the population. Colon and rectal cancer has been monitored only in limited programmes set up by primary health care teams and some hospitals.

The public health service offers a permanent early diagnostic service for cervical cancer through family planning centres. The Spanish Association Against Cancer runs surgeries dedicated to this activity, in addition to frequent information and motivation campaigns. Private medicine also covers a relatively large segment of the population in this area.

Programmes for breast cancer are less widespread, as agreement on the technique to be used and on the criteria for inclusion has yet to be reached. In several autonomous communities and also through the Spanish Cancer Association, breast cancer screening programmes are being carried out on well-defined populations. Others are taking the first steps in initiating these programmes.

In March 1990, the Department of the Government of Navarra began a population programme with the aim to reduce mortality due to breast cancer and improve quality of life in affected women. The first round ended in June 1992 and the second round is now coming to the end.

All 60 000 women between 45 and 65 years of age resident in Navarra will be screened every 2 years by a half-side oblique mammography per breast. Coverage and accessibility are guaranteed by two screening units—a permanent one in Pamplona, serving the city and the surrounding area, and a mobile unit covering the rest of Navarra.

On the basis of the population census, women receive a letter inviting them to attend, giving the place, day and time of the mammography. The tests are free of charge. The same screening unit makes arrangements for hospitalisation in the centre corresponding to the patient's residence if further tests, diagnostic tests and/or treatment are required.

An extensive information campaign has been put in place to raise awareness in both the target population and all the social

and health sectors involved, with the aim of obtaining full acceptance of the programme. During the first round, 48 691 women were examined, 84.6% of the target population, and 283 tumours were diagnosed, resulting in a detection rate of 0.58%. Of these, 17% were intraductal.

This programme is supported by the Europe Against Cancer programme. It was also declared a pilot project for Spain by the Ministry of Health and Consumer Affairs and it is being used as a reference for the development of other programmes.

Regional health authorities are very interested in broaching the problem of breast cancer, and are allocating human and financial resources to the development of screening programmes.

The experience in Navarra has been very satisfactory as, acting in a totally integrated way, massive participation and a high detection rate, which includes small tumours, have been achieved, thus enabling conservative treatment in 70% of cases. This allows us to forecast that the proposed goal of reducing mortality due to breast cancer will be achieved.

### UNITED KINGDOM

Screening for cervical cancer by cytology was introduced formally into the National Health Service in the United Kingdom in 1965–1966, although it has been practised to a limited extent before then, chiefly as a method of diagnosis in symptomatic women. Its effectiveness in reducing the incidence of invasive cancer, and hence mortality, was at that time unproven, and unfortunately, the opportunity to set up a randomised controlled trial of screening was missed. Gynaecologists and pathologists were firmly convinced of its value and transmitted their enthusiasm to women in the general public, whereas some other doctors, notably epidemiologists, were highly sceptical. Both extremes of opinion could be found among GPs (who were intended to be the main source of smear-takers), but the majority were probably only mildly interested in either direction.

Recognising that there were far too few cytopathologists available in the country to read the hundreds of thousands of cervical smears that would be generated by a population screening programme, the Government funded a training programme for lay cyto-technicians to read cervical smears. Apart from this money, however, no additional resources were allocated for hospital boards or local health authorities (at that time they were funded separately) to provide the service.

A Department of Health committee on gynaecological cytology was established to advise on policy. Initially, they recommended that women between the ages of 35 and 65 should be offered routine screening every 5 years; subsequently, the age restriction was waived for women under 35 who had three or more children. The most recent recommendation is that women should be screened routinely between the ages of 20 and 64 at intervals no longer than 5 years.

Given the changes in underlying age-specific incidence of invasive cervical cancer over the past 25 years, these recommendations were eminently sensible. But neither the committee nor the Department of Health had any control over the extent to which the medical profession followed their policy recommendations. The only actions taken centrally were: (i) to offer a small incentive fee to general practitioners for screening women aged over 35 years who had not been screened in the previous 5 years, and (ii) to introduce a very cumbersome manual system of recalling women for rescreening 5 years after they had had a negative smear. Neither of these measures was successful: the first because very few general practitioners had age-sex registers that would enable them to identify women due for screening,

and the second because most women who were recalled had already had another screen within the 5-year period, and the response to recall was 20% or less.

The screening service, therefore, developed according to the whims of those doctors who took the smears—general practitioners, family planning medical officers and obstetricians/gynaecologists—and to a lesser extent to those of the well-educated, low-risk minority of women who requested screening. Even the cytopathology laboratories had very little control over the planning of the service, merely responding to the demands placed upon them. As a result, very large numbers of screening smears were taken at unnecessarily frequent intervals from young, generally low-risk women, many of whom were undergoing a vaginal examination for contraceptive or other purposes unrelated to their need for cervical screening. The older, high-risk women, who had few indications for vaginal examination after their reproductive life was over, were left out of the screening programme. There were some local exceptions to this pattern of screening, notably in Aberdeen and Dundee in Scotland, and some individual general practitioners ran efficient screening programmes, but the overall impression was of an unorganised service which was failing to meet its objectives. National registration and mortality data for carcinoma of the cervix showed no evidence that the screening programme was effective, although trends in underlying age-specific incidence suggested that screening probably contributed to avoidance of invasive cancer in some age groups.

In the first half of the 1980s, several independent factors contributed to a re-appraisal of the British screening programme and ultimately to its long-overdue reorganisation. Convincing evidence of the effectiveness of organised screening emerged from the Nordic countries, supported by the results of case-control studies which provided evidence of appropriate screening intervals. The general public became aware of the increasing incidence of cervical cancer and also of the fact that some women developed, and died from, invasive cervical cancer in spite of the screening programme. A number of research papers were published, which analysed the reasons why women with invasive cervical cancer had not been detected in the screening programme at a pre-invasive stage, thus highlighting the programme's inefficiencies.

All of these factors raised professional, public and governmental awareness that something had to be done about the cervical cancer screening service. But the factor that has contributed most to its reorganisation has been the rapid expansion in information technology. In 1985–1986, lists of people registered with general practitioners, which are held by Family Health Service authorities for the purpose of paying general practitioners, were computerised. The Department of Health instructed district health authorities to use these registers to set up a computerised system for inviting women to be screened at regular intervals. Standard software was then developed to add a summarised record of the outcome of each screening invitation to the woman's record, including a reminder of when her next screening invitation is due. Meanwhile, computerised cytopathology systems came into use (unfortunately not standardised across the country), which enabled electronic transfer of the result of each smear to the Family Health Service authority at which the woman is registered.

This screening information system has provided, for the first time, routine data on the participation of eligible women in the screening programme, and shows that population coverage is increasing, especially in older women. Figures for 1992–1993

show that 80% of eligible women between ages 20 and 64 years had been screened within the previous 5.5 years.

Others steps were taken to improve the screening programme. In 1990, the fees paid to general practitioners for screening women at risk were replaced by a different form of incentive payment: general practitioners who succeed in screening 50% of eligible women in their practice receive a fairly modest sum once a year but if they succeed in screening 80%, a much larger sum is paid. The effect of this incentive is to boost the acceptance rates achieved by computerised invitations. In one area of Scotland, the proportion of women screened increased from 78 to 85% during the first 6 months that the new incentive scheme was in operation, and the proportion of practices that achieved the 80% target increased from 62 to 85%.

Other steps now being taken to improve the programme include training programmes in smear-taking technique for doctors and nurses in primary care, a compulsory external quality assurance test, which all cytopathology laboratories must undergo at least once a year, national guidelines on a fail-safe system to ensure follow-up of women with abnormal cytology, a requirement that every district health authority should have one person (normally a public health doctor) responsible for the screening programmes, and replacement of the previous advisory committee by a group of regional representatives with responsibility for the programme in the health districts of their own region. The main tasks of the last group are to feed back performance statistics to the providers of the service, share ideas on improving the quality of the service and involve providers in policy decisions. The Department of Health has recently announced that it is appointing a national co-ordinator of the cervical screening programme.

The effect of this more tightly organised system on the future incidence of invasive cervical cancer remains to be seen, but there is optimism that it will be able to achieve results comparable to those in Finland, Iceland and Sweden. Mortality rates have fallen more sharply in the late 1980s, and the previously rising mortality in women aged under 40 has now reversed.

Have the lessons learnt from this 25-year history of cervical cancer screening been applied to other cancer screening programmes? We hope that the answer is yes.

Firstly, no screening programme should be introduced as a service before it has been evaluated by research. This is well recognised, although within the United Kingdom the design of the evaluative breast screening trial left much to be desired. Fortunately, results from properly designed trials in the U.S.A and Sweden provide a reasonably clear view of the amount of benefit that can be achieved, and it was these that led the British government to judge that the level of reduction in mortality that could be achieved justified the cost of a national breast screening programme for women aged 50 and over.

Secondly, ear-marked resources should be set aside for implementation of a new screening programme in its development phase. This was carried out in the case of breast cancer screening: the government provided a special allocation from its reserve funds for the first 3 years of the programme. Moreover, the special allocation was decided on the basis of what was judged to be the optimal organisational structure—to offer screening every 3 years to women aged 50–64. Health authorities could choose to add additional resources if they wished, but the central allocation ensured that a standard minimal level of service was available everywhere.

Thirdly, training of all categories of staff involved in the screening programme should be mandatory. Again, this has

been carried out for breast cancer screening, and there is now a requirement that radiographers (technicians) and radiologists should have attended certificated courses on screening mammography.

Fourthly, regional health authorities were required to nominate a quality assurance manager for breast cancer screening with responsibility for monitoring all aspects of the programme, from population coverage, to measurements of radiation dosage, to incidence of interval cancers. Targets or performance indicators were set nationally, and if screening units do not meet these, the quality assurance manager must feed back this information to the screening staff and take steps to improve the situation. A series of national groups representing each discipline has been established to enable sharing of ideas on good practice as well as providing peer group support.

Fifthly, a standardised computerised information system was set up. There are plans to use this to link screening data, Family Health Service authority registers and regional cancer registers. This makes it possible to monitor the service continuously, and individual screening units can see how their performance compares with that of others.

A national breast screening programme was introduced in 1987, which is based firmly on the results of evaluative research trials and is tightly controlled. It is limited to women aged 50 and over, and mamography screening is offered every 3 years. Formal quality assurance mechanisms have been set up for all aspects of the programme, and a computerised information system ensures that progress towards achievable targets can be monitored. The development of this centrally directed, nationally standardised breast screening programme is thus very different from that of the cervical cancer screening programme. It appears to have been an expensive exercise, but this may merely be because the costs of its components are explicit whereas those of cervical cancer screening have been hidden. There is a sense of purpose and optimism that the breast screening programme will prove more efficient because of its structured control.

Until there is research-based evidence of the extent of the reduction in mortality from screening for cancers at other sites, no additional cancer screening programme will be provided in the National Health Service. Active research is being pursued, however, into the value of screening for colorectal cancer with faecal occult blood testing, and of screening for breast cancer from the age 40 with mammography. Pilot trials of screening for ovarian cancer and neuroblastoma are under way. Even though these studies may last 10 years or more, screening will not be introduced nationally until the reduction in mortality they may achieve has been quantified.

The current British attitude to cancer screening can be summarised as firstly, insisting on evidence of the size of benefit to be expected from any new programme, and where this does not exist, setting up appropriate research trials; and secondly, on monitoring existing screening programmes to ensure that their performance is as efficient as possible. This requirement may raise awkward political difficulties, as in the current situation regarding breast screening for women under 50. The public perception is that this age group is excluded because of constraints on resources rather than due to lack of scientific evidence, but a decision on the introduction of screening for this group will be postponed for 10 years, until the results of a newly started randomised controlled trial are available.

## ACTIVITIES OF THE EUROPE AGAINST CANCER PROGRAMME

The Europe Against Cancer programme aims to introduce systematic screening for breast cancer for women aged 50–69 years and for cervical cancer for women aged 25–69 years.

Pilot projects on breast cancer screening were initiated in several European countries in 1989–90. A network was formed including pilot projects in Spain, Ireland, Belgium, Greece, Portugal and France, and the national programme in the United Kingdom. Projects in Italy, Luxembourg and Denmark were added in 1992. In 1993, cooperation was established with the German study group on breast cancer screening [32].

An early aim was to determine the best methods within each country's health care system for ensuring an adequate participation rate (60% or over). The cooperation of GPs and a constant flow of public information proved essential; however, it also became clear that the methods used to encourage women to participate must take into account the national mentality and the national health care system.

The needs for high quality mammographies, including interpretation, rapid diagnosis for patients with suspect mammographies and appropriate and immediate treatment were also stressed from the beginning. It soon became clear that screening staff in most of the pilot projects required extra training. Training needed to be improved for both radiologists and technicians, and a few 2-weeks training course in reading mammographs were arranged for experienced radiologists.

In 1990, it was noted that there appeared to be inadequate quality assurance in many pilot projects. Issues such as participation rate, quality of mammography, accuracy of interpretation, frequency of screening, follow-up system, adequacy of diagnostic investigations and treatment, cost, safety and detrimental effects, incidence of interval cancers must be closely monitored. Quality control of mammographic equipment is also of great importance. European guidelines for quality assurance in mammographic screening were published in 1992 [33] and were well received.

Besides diagnostic methodology, another problem which emerged at the European level was the need to decide on appropriate treatment for small lesions detected by mammography in asymptomatic breasts (screening or early detection). There is general agreement on treatment for breast tumours between 1.5 and 4 cm, although there is still some question about the indications for adjuvant treatment. In contrast, experience from the pilot breast cancer screening programmes shows that discussion and information are needed regarding the treatment of small tumours (less than 1.5 cm) detected by mammography. In particular, care must be taken that women do not undergo unnecessary surgery, but it is also necessary to ensure that these nascent lesions and the auxilliary nodes receive adequate treatment. The indications for adjuvant treatment are particularly difficult to define for small tumours. The main criterion used for tumours of a diameter of 2 cm or more and auxilliary nodes involvement is no longer relevant, since a non-negligible proportion of such small tumours give rise to distant metastases without invasion of the nodes. Other criteria must, therefore, be used for prognosis. A European School of Oncology working partly on treatment of small breast lesions has recently written a report [34].

The Europe Against Cancer programme launched pilot projects in cervical cancer screening in 1993, and is organising them in a network. European guidelines for quality assurance in cervical cancer screening were published in 1993 [35] and were

well received. Implementation of quality assurance in cytology and terminology will be discussed in working parties.

With regard to screening of colorectal cancer, the current position is, firstly, to support the ongoing randomised studies on haemocult and to encourage meta-analyses whenever possible. Secondly, mass screening is not currently recommended. Thirdly, new types of screening should be investigated. Feasibility studies are ongoing for the screening of prostate cancer and oral cancers.

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