Final Report

of the

Network of Breast Cancer Screening Projects

in the

"Europe against Cancer" Programme

with financial support from grant agreement

SI2.307923 (2000CVG2-031)

A report to the European Commission
on the activities of the Network
from 1 August 2000 to 15 December 2001

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1 Summary

The European Breast Cancer Screening Network was initiated by the Europe Against Cancer Programme to support achievement of the long-term aim and commitment of the Cancer Programme, i.e., to reduce the number of cancer deaths. As breast cancer accounts for approximately 25% of all female cancer and since well organised breast cancer screening programmes can substantially reduce breast cancer mortality, improvement and promotion of such programmes has played a key role in Community health policy to date. Due to the substantial success of the network in developing and implementing methodologies promoting best practice in the area of breast care, network achievements have triggered fundamental improvements in health care systems throughout the Community. This has lead to numerous governmental decisions and legislative actions. A prominent example is the recent decision of the Health Committee of the German Parliament which unanimously recommended introduction of a national breast cancer screening programme according to the European Guidelines for the Quality Assurance of Mammography Screening developed in the network. The breast cancer screening network currently involves scientists, managers, health care professionals and dedicated co-workers in over 70 institutions in all of the member states of the European Union as well as in two EFTA countries and three preaccession countries. The present report covers the activities and achievements of the 23 projects supported by the grant agreement SI2.307923 (2000CVG2-031) during the contract period 1 August 2000 to 15 December 2001. These projects have been structured into 5 groups, co-ordinated by group leaders. Each project in the Network may carry out more than one of the activities mentioned below.

1.1 Aims and activities

In the past the main interest of the network has not been to investigate the benefits to be gained from high quality breast screening - this has already been demonstrated in several large scale population screening studies - but to enhance skills, effectiveness, and to provide support and experience for those countries lacking breast screening, explore methods of implementation and evaluation of breast screening in the national health system and to establish contact for exchange of information and experience between member states. During the past 10 years, the network has focused on all aspects in the chain of activities related to breast cancer screening, for example, identifying of target population, performance of high quality mammography screening examinations and film reading, setting quality assurance standards in epidemiology, quality control in physics and pathology, publishing quality assurance guidelines suitable for European use, controlling quality by visiting projects on-site, and encouraging studies on evaluation of the activities, both in terms of quality and in terms of the effect on mortality. In light of the comprehensive scope of network activities bridging disciplines and sectors of health care heretofore unaccustomed to intensive cooperation and in view of the international scope of network activities, coordination of the network projects and financial administration are activities essential to the effective performance of the network and therefore also receive special attention.

1.2 Methods

Numerous methods have been applied in the various projects, particularly: (1) data collection and analysis, (2) specialized training, (3) meetings, seminars, (4) expert consultation; (5) site visits and inspections, (6) equipment testing, development of technical protocols, (7) IT system design and analysis, (8) computer programming, (9) development of applications for internet surveys and (10) review of scientific literature and document search.
1.3 Results

The European Breast Cancer Screening Network of the Europe Against Cancer Programme made a long-term commitment to introduce high quality mammography screening services for women, in all member states of the European Community. A major achievement of the network during the contract period has been the publication of the third, revised edition of the European Guidelines for the Quality Assurance of Mammography Screening in the Fall of 2001. The third revised edition (360 pages) was prepared and edited by the EUREF\(^1\) network project and includes separate chapters on epidemiology, physico-technical aspects, radiography, radiology, histopathology and cytology, surgical management of screen-detected lesions, result monitoring and training. Draft EUREF certification protocols (working documents) and a document on breast centres from EUSOMA\(^2\) illustrate how improvements in quality assurance of breast cancer screening stimulate quality improvement in breast services in general, i.e., in routine non-screening services. The European Guidelines have been central in discussions with the network members to identify the strong and weak points of the screening service, and they have been used as the basis for government-approved policies. A prominent example is the recent decision of the Health Committee of the German Parliament which unanimously recommended introduction of a national breast cancer screening programme according to the European Guidelines. The fact that nearly all screening programmes represented in the network now have political and financial support within their member states is a reflection of a long-term commitment from their respective governments.

In addition to the above achievement, all of the planned objectives of the network have been fully or partially fulfilled during the contract period:

1. Initial results of a network survey show the contribution the network has made to implementation of high quality mammography screening programmes throughout the Community. Further documentation of the network achievements will be forthcoming from current network projects (see section 3.1).

2. Progress has been made toward certification of network projects to become reference centres in their countries allowing a diffusion of expertise from a regional to a nation-wide level. Toward this end certification protocols have been developed. Preliminary testing of the certification process has taken place in Italy, Ireland and Portugal. In Germany the Ministry of Health and the Health Committee of the Parliament have approved plans to develop currently network-supported pilot projects to become reference and training centres (see section 3.4).

3. Various models for evaluation of the quality and the effect of screening have been developed and employed in studies in several member states. These activities have played as essential role in the recent international discussion which has ended with confirmation of the validity of the population-based studies on the effectiveness of mammography screening (see section 3.2).

4. The European Guidelines for Quality Assurance in Mammography Screening have been updated and progress on practical implementation has been achieved in projects in several states (see sections 3.3 - 3.5).

\(^1\) EUREF: European Organization for Quality-Assured Breast Screening and Diagnostic Services

\(^2\) EUSOMA: European Society of Mastology
1.4 Dissemination and utilisation of results

Dissemination and utilisation of results of the network projects has taken place as planned:

1. within the European Network of Breast Cancer Screening projects at annual meetings in Belgium and Spain
2. in scientific workshops and symposia (in France, Italy and Germany)
3. through publication in peer-reviewed scientific journals (see Annex)
4. through the revision of the European Guidelines for Quality Assurance in Mammography Screening by EUREF and through the distribution of the newly revised third edition by the Commission (second printing in progress).

1.5 Network coordination

At the beginning of the contract period in August 2000 the administrative burdens on the network coordination and the individual projects had increased substantially and at the same time there was a delay in processing reports and claims through the Commission. Thus, funding for planned activities was considerably delayed. Furthermore, the contract of the previous coordinator, Dr. Sven Törnberg of the Swedish Cancer Society had expired with the conclusion of the previous contract period. When the new coordination team lead by Dr. Lawrence von Karsa assumed the task of the network coordination under the contractual umbrella of the National Association of Artisans and Crafts Health Insurance Funds (Bundesverband der Innungskrankenkassen, Germany) a substantial increase in the effort devoted to project and financial management and development of more sophisticated internal network structures was imminent, not least to ensure that in the future the network improve the effectiveness of fund allocation within and between individual network projects. A major improvement in managerial support has been achieved through continuous development of the financial management and coordination by J&AB Associates. This improvement has facilitated the smooth transition of the network structure and objectives and has helped to clear the backlog of applications and claim processing of previous years. The direct financial reporting of individual projects within the various groups to J&AB Associates and the correct and strict follow-up of the financial documentation has permitted more effective use of resources.

The transition in the network coordination at the beginning of the contract period was also used as an opportunity to expand the scope of the network beyond screening to encompass all aspects of quality assurance and best practice in breast health care.

1.6 Conclusions and implications for the future

The activities of the former European Breast Cancer Network have substantially contributed to improvement in and maintenance of high standards in breast health care in Europe. The success of these activities is evident in the widespread implementation in Europe of the quality standards developed and continuously improved in the network. The expansion of the scope of the network to cover all aspects of breast care in the framework of the new European Breast Cancer Network should enable the millions of women in the Community not attending screening programmes to benefit from advances developed to date in screening.

During the contract period, the former European Breast Cancer Screening Network has undergone a profound and fundamental transition affecting not only the essential nature of the public health and scientific activities but also the management structure and democratic processes by which all the member states and a number of applicant and associated countries are involved in the continuous quest for improvement of best practice and the quality of breast
services in Europe. The European Breast Cancer Network is currently in a favourable position to continue highly successful previous activities and to promote related new activities which have the greatest promise of promoting community added value in the future and which will provide essential support toward achieving the goals of Community health policy stipulated in the Treaty of Amsterdam. These achievements would not have been possible without the untiring support of the members of the network, particularly those volunteering to serve as group leaders, project leaders and partners and members of the advisory board.

The current third edition of the European Guidelines shows the necessity for constant revision of quality assurance guidelines. Furthermore, closer cooperation between the EUREF project coordinating guideline updating and certification development, on the one hand, and scientific societies and professional associations involved in breast care, on the other hand, can promote transfer of advancements in the quality assurance of screening to the nonscreening diagnostic and treatment setting.

The sophisticated and effective management structures implemented in the network and the excellent results in an area of health care requiring the highest professional standards and the most sophisticated levels of interdisciplinary and intersectoral cooperation demonstrate the unique and significant contribution the network has made in the past and could make in the future to improving health care in the member states. In light of this unique achievement it is essential that the quality assurance guidelines developed in the past continue to be revised in the future. Furthermore, future priority should be given to continuing and expanding efforts toward certification to identify and assist providers delivering services fulfilling the European standards.

Since quality assurance in similar areas of health care, particularly involving colorectal, cervical and skin cancer are increasingly urgent in the member states, substantial benefits can be expected from integration of these areas into future network activities. The urgency of such efforts is demonstrated by recent decisions to implement endoscopic screening programmes for colorectal cancer in northern Italy and nationwide in Germany as well as a decision to perform a large skin cancer trial in Germany. Providing access of these efforts to the expertise in the European Breast Cancer Network could have a profound positive impact on the results and the quality of services provided in these programmes.

The future priorities of network management should include assistance to the network to finish ongoing projects and to present the achievements of the network in the final phase of the Action Programme on Cancer. Furthermore, the network should develop a strategy which will permit those activities essential to maintenance and improvement of quality and best practice in breast care to continue in the future, to be expanded to related fields in which similar needs are most urgent, and to be transferred to those countries which will become new members of the European Union.
2 Introduction

2.1 Scope of report

The present report covers the summaries, activity and scientific documents of all the projects in the European Breast Cancer Network demonstrating the activities and scientific work which have been undertaken towards achieving the objectives set down in the above grant agreement for the time period 1 August 2000 to 15 December 2001. The report contains a summary spreadsheet giving details of the actual costs incurred by the individual projects and also showing consolidated totals across the Network. The Network budget identifies funding by project, but for scientific purposes the projects are grouped into six categories (see also 2.3). The achievements in each area of activity are presented in separate chapters and summarized for the network as a whole.

2.2 Network aims

The European Breast Cancer Screening Network, initiated by the Europe Against Cancer Programme supports the long-term aim and commitment of the Cancer Programme, i.e., to reduce the number of cancer deaths. Well-organised breast cancer screening programmes can significantly reduce breast cancer mortality. During the past 10 years, the network has focused on all aspects in the chain of activities related to breast cancer screening, e.g.:

1. Identification of the target population; performance of high quality screening mammograms and film reading
2. Quality control in physics and pathology
3. Establishment of quality assurance standards in epidemiology
4. Publishing quality assurance guidelines suitable for European use
5. Quality control through on-site visitation of projects
6. Promotion of studies on evaluation of the screening activities, both in terms of quality and in terms of the effect on mortality.

The main purpose of the breast cancer screening network is to improve the quality and effectiveness of breast cancer screening services in Europe. The basis for these activities at the outset of the project was described in the European Guidelines for Quality Assurance in Mammography Screening (2nd edition) of which over 2,500 copies were distributed. A projected endpoint for the members of the network is the establishment of a reference centre having the expertise in building up the respective national breast cancer screening programme. Special attention is given to training of all personnel involved in the screening process. Network members representing countries with nation-wide screening are engaged in:

1. Helping and guiding countries with new projects
2. Providing expert input to the guidelines
3. Developing study models for evaluation.

With the prospect of the approaching completion of the current Programme of Action on Cancer, the initial grant proposal for the current project activities focussed on:

1. Completion of ongoing projects
2. Summarising the network achievements to date
3. Surveying the present breast cancer screening services in the member states.
During a lengthy application review process, the Commission addressed the need to promote those activities in the network conducive to further development of best practice in breast services, particularly in light of the advent of a new framework for Community health policy. Thus, a fourth central aim of network activities was covered during the current contract phase, namely:

4. Extending the scope of the network beyond breast cancer screening towards the full range of breast services

In this manner, advances in quality assurance and best practice developed with substantial success in the former breast cancer screening network may be extended to activities affecting millions of women who do not attend screening programmes.

2.3 **Major network activities**

The activities pursued to date within the network can be broadly summarized as follows:

1. Activities directly related to the quality of the screening process: i.e. improvement of participation rates, double reading of mammograms, documentation of activities, including optimising cancer registries, monitoring physical quality control, adequacy of the assessment process, surgical management of screen detected lesions, and monitoring of surgical and other end point data.

2. Supportive activities: i.e. training, site visits, external physico-technical control and national development of guidelines and protocols.

3. Feasibility studies related to breast cancer screening: i.e., cost effectiveness evaluation, harmonisation of cyto-pathology classification, psychological aspects of screening.

4. Development and testing of models for evaluation of the impact on mortality by screening.

The above activities are pursued within 23 projects. Each project in the Network may carry out more than one of the activities mentioned above. These projects have been structured into 5 groups, co-ordinated by *group leaders* (see below):

(1) Present status of screening within the European Community (a survey), centralised, vs. decentralised health care in screening - (all member states, previous pilot projects, *Mr. Lennarth Nyström, Mrs. Mireille Broeders, Dr. Frank Buntinx and Beatrice Gairard*)

(2) Evaluation of breast cancer mortality – Denmark, Finland, Sweden, Italy, France (*Dr. Lennarth Nyström*)

(3) Practical application of QA criteria - (15 projects, *Mrs. Mireille Broeders, Prof Roland Holland, Mr. Johan Schouten*)

(4) Training co-ordination and certification (EUREF, *Mrs. Mireille Broeders, Prof Roland Holland, Mr. Johan Schouten*)

(5) Pathology Quality Assurance Programme (involves all member states, *Dr. Clive Wells*)

(6) Coordination (*Dr. Lawrence von Karsa*)

2.4 **Projects participating in the network**

During the contract period, the 23 projects of the Breast Cancer Screening Network were lead by 21 participating centers, institutes or organizations and one coordination office. Madeira, Lisbon, and Coimbra represent one Portuguese project.
2.5 Important developments within the network during the contract period

The 2000 contract started with a restructuring of the network organization. The simple internal structure of a coordinator selected by the Commission and approved by the network members was replaced by a more sophisticated structure reflecting the diverse activities and wide geographic representation in the network and adhering to the deep-rooted democratic tradition of international and interdisciplinary cooperation within the network. The framework for the new structure was decided at the annual meeting in September in Knokke 2000. One of the first achievements was to install a network assembly, a temporary executive committee and the agreement to draft a network constitution and bylaws. The temporary executive committee met several times during the contract period (Amsterdam, Luxembourg, Santiago) and prepared the requested documents. At the annual meeting held in Santiago de Compostela in June 2001 the network constitution and bylaws have been adopted and the new advisory board members have been elected. This advisory board met in September 2001 to review the applications for the 2002 proposal and to determine the strategy for further development of the network.

Another major development entailed a basic transition in the scope of network activities. The activities specified in the 2001 application submitted in January 2001 have been extended beyond screening to include the entire range of breast cancer care, including management of breast cancer lesions. This has been accomplished by building on the achievements in the past in developing and implementing quality assurance of mammography screening. The new European Breast Cancer Network will also improve breast cancer care for women in Europe not covered by quality-assured screening programmes. The expanded scope of the network is reflected in new projects added in the current contract and the 2001 and 2002 applications addressing:

1. Genetics
2. Evaluation of breast cancer survival
3. New diagnostic technologies
4. Best practice in management of breast lesions

Furthermore, the following key European institutions and organizations involved in promotion and development of best practice and evaluation of breast services have been integrated into network projects:

1. the International Agency for Research on Cancer
2. Europa Donna
3. the European Association of Mastology

A major improvement in managerial support has been achieved through continuous development of the financial management and coordination by J & AB Associates. This improvement has facilitated the smooth transition of the network structure and objectives. The direct financial reporting of individual projects within the various groups to J & AB Associates and the correct and strict follow-up of the financial documentation has introduced a higher level of management among the projects (and within network coordination control) which permits more effective use of resources. The financial reporting is standardised and now payments to projects are directly related to performance of expenditure against the plan. This has resulted in avoiding the difficulties in earlier years in retrieving unjustified payments.

In 2001 the Greek project directed by Prof. Garas (Athens) indicated that it no longer requires further financial support of the Commission but would like to remain part of the scientific activities of the network. The initial payment (30%) to Athens has been reclaimed and can be taken into account (along with the 40% payment) within the calculations for the final contract payment. The withdrawal of Athens from receiving EC financial support has implications on the network totals and we believe that the final calculations will need to be based on a consolidated position and not just a network percentage with a pro rata reduction.
3 Group Activities and Results

Group activities were supervised by leaders nominated at the annual meeting in Knokke in Belgium in September, 2000. Reports on activities and results of each project were submitted to the respective group leaders and the network coordinator. The following reports of group activities and results were prepared by the group leaders and edited by the network coordinator.

3.1 Present status of screening within the European Community (Group 1)
(authors: M. Broeders, A. Scharpantgen)

Part I. Present status of breast cancer screening within the European Community
Part II. Summarising screening outcomes and performance parameters on the basis of aggregated data

The objectives of these two projects were:
• To summarise the achievements in the early phases of implementation and quality improvement of screening programmes using a standardised questionnaire,
• To summarise aggregated data of the screening programmes and compare their screening outcomes and performance parameters whilst taking into account their organisational differences,

Due to the important delay of the final signature of the present contract, the project team decided to set its priority to finalise the document on the survey” Present status of breast cancer screening within the European Community” under the 2000 contract.
For Part II, the dataset on summarising screening outcomes and performance parameters on the basis of aggregated data has been developed and sent out to the project leaders. The data analysis will be done under the next contract, 2001-2002.

Part I. Summarising implementation and quality assurance
Co-ordination: A. Scharpantgen, N. Ascunce, M. Broeders, B. Gairard, L. Nyström

In October 2000 and January 2001, 2 meetings took place in Amsterdam to design and develop the survey questionnaire. The objective of this survey was to explore the position of the screening programmes within European Breast Cancer Screening Network (EBSN) against the original aims of a decade ago.

At the end of February 2001 the survey was sent out to all 16 project leaders in 10 European countries. During a meeting in April 2001 in Luxembourg the survey was revised after comments received from the project leaders and sent out again to all of them.
By the end of June all project leaders had responded to the questionnaire.
All responses were entered into a Word database and prepared for interpretation.
In June, a preliminary report was presented at the annual meeting of the European Breast Cancer Network in Santiago de Compostella.

Since August 2001, Axion, Associate, Luxembourg has been extracting information from the questionnaires and drafting a report for the European Breast Screening Network. In October a draft report was edited and submitted to the co-ordination team. During a last meeting held in November in Luxembourg the draft report was analysed, evaluated and editing changes were proposed. In December the revised draft report was sent out again to the co-ordination team for revision. The full report is included as an annex to the present group report. A separate copy will be sent to the Commission.
Major results and conclusions

The information resulting from the questionnaires in Part I summarised the achievements of the EBSN in the past decade in the context of the European Union. General recommendations were extracted from this summary for the policy document (Part IV) to assist new countries in setting up screening programmes for breast screening in the new millennium.

The projects of most Member States set out to study the feasibility of introducing screening on a regional basis in their different health care systems. Today, most are aiming for national coverage of the target population by mammographic screening. Four projects have made significant progress in this respect (Ireland, France, Belgium and Germany).

It is possible to establish mammographic screening programmes in various health care systems. The effort required for coordination and quality assurance is particularly pronounced in decentralized health care systems.

The European Guidelines for the Quality Assurance of Mammography Screening have been pivotal in introducing and implementing quality assurance programmes in projects in the network and in promoting improvements in diagnostic mammography services. These activities have also encouraged many projects to introduce specialized training activities.

Information and an international exchange of experience promoted by the network played an important role in bringing about changes in screening policies and in helping to bridge the gap between research and practice. International contacts also proved to be of importance in establishing contacts with local policy-making institutions and ministries of health.

The fact that nearly all screening programmes now have political and financial support within their member states is a reflection of a long-term commitment from their respective governments.

Part II: Summarising screening outcomes and performance parameters on the basis of aggregated data

Co-ordination: M. Broeders, N. Ascunce, B. Gairard, L. Nyström, A. Scharpantgen

During this contract for Part II, the objective was to decide on a dataset and to develop a database on Excel sheets. This has been done during two meetings in November, 2000 (Amsterdam) and in April, 2001 (Luxembourg). In September 2001, the datasheets were sent out to all 16 project leaders.

Until November, 8 projects provided us with data available in the format we asked for. After a first review of the data received from these projects, the team decided to change and adjust one of the tables in the dataset. These new, revised datasheets will be distributed end of January 2002.

Activities and methodology

A computerised database has been developed in order to store all the data to be obtained in a standardised way.

Achievement of the objective of screening, i.e. mortality reduction, is inevitably long-term. There are, however, important early performance indicators which can predict outcome and which therefore must be accurately documented and evaluated.
Background information
Breast cancer occurrence in the three-year period before screening started:
- Female population
- Incidence (number), excluding DCIS
- Incidence (number), including DCIS
- Mortality

Early performance indicators
Covering the ten-year period after the start of screening activities:
- Target population
- Women invited
- Women screened
- Participation rate
- Cancer detection rate (in screened population)
- Age-specific detection ratio
- In-situ cancers/Total cancers detected (%)
- Invasive cancers # 10 mm/Total invasive cancers detected (%)
- Total cancers detected (%)
- Node negative cancers
- Cancers with T unknown

Screening outcomes will be judged as to the availability and quality of the data collected.

Expected results
The results of Part II during the next contract 2001-2002 will provide an overview of the screening activities that have taken place within European Breast Screening Network during the past decade. It is possible that the co-ordination team will expand data collection to include other performance indicators based on analysis of the completed data sheets. Parts of this work will be submitted to peer-reviewed international journals. However, also within each country appropriate media will be identified to report on the outcomes of this project.

Part III: Summarising screening outcomes and performance parameters, meta-analysis on the basis of individual patient data
Co-ordination: F. Buntinx, K. Cortebeeck, K. vanhulle

1. Summarising screening outcomes and performance parameters, meta-analysis on the basis of individual patient data

Part B of the meta-analysis was intended to summarise knowledge with respect to the effect of invitational systems on breast cancer screening outcomes. A literature search was done in several abstract data bases to extract randomized controlled trials that tested the effect of features of the invitational system on the attendance rate. After the results were extracted from studies that met the pre-set inclusion criteria, software to fit random-effects models was written in SAS to analyse the pooled study results. Based on the pooled results, the report “A meta-analysis of interventions to increase mammography screening” was written and discussed by all authors and the acknowledged person.
2. Evaluation database: codebook minimal dataset

In preparation of the meta-analysis on individual data (Leuven) and the breast cancer screening evaluation database (Turin), a data merge pilot project was set up in order to define the minimal data needed, and to get an idea of problems that will emerge during these two upcoming studies (differences in variable definitions, format differences, lacking variables, European guideline ambiguities, etc.). Scripts were written to extract data from both the Leuven screening and follow-up database, and to convert them in a format comparable to the Turin minimal database. A code book of this joint database has been developed.

Part IV: Policy document
Co-ordination: expert team involved in Parts I, II and III

Reports from Part I, II and III will provide the necessary evidence as well as suggestions resulting from the evidence, needed for policy making with respect to the organisation and implementation of breast cancer screening in Europe during future years. General recommendations will be deduced from the results obtained so that other countries starting new programmes can benefit from the experiences reported within the setting of the European Breast Screening Network. Given the delay in the reports for part II and III, the policy document will be drafted and finalized during the next contract period 2001-2002.

3.2 Evaluation of Breast Cancer Mortality (Group 2)
(author: Lennarth Nyström)

The projects in this group are of different nature and at different stages. This summary has put more weight on those projects in the final stage. Projects on course are described but no (preliminary) results are mentioned.

3.2.1 Evaluation of the national service screening programme for breast cancer with mammography in Sweden

Aim

The aim of the present study was to develop methods for evaluation of the effects of the national program of screening for breast cancer with mammography on the breast cancer mortality in Sweden.

Material and methods

The problem in evaluating national screening programmes is that there is no generally accepted method due to lack of a natural comparison group. Several approaches have been applied to evaluate the effect on the breast cancer mortality, e.g. comparison of the breast cancer mortality:

- Over time (so called before-after study)
- By geographical area

Planned activities

The paper focusing on the age group 50-69 years has been published. The next focus will be to study the effects on women 70-74 years. Here the same approach as for the 40-49 year age group will be applied. Further, the nation-wide Cause of Death Registry have had a delay in coding cause of death certificates due to a change in the International Classification of Disease. The
present follow up is until December 31, 1996 but as soon as data for 1997-98 are available our cohorts will be updated. Finally the work on developing our models will continue to allow for more precise point estimates of the effect.

Here a combination of these methods was applied.

Due to lack of individual screening history data, information on screening activities on aggregated level were collected from each county, that is:
- Date for start of program
- Progress of screening activities within the area
- Invited age groups
- Screening interval

By record linkage between the nationwide Cancer and Cause of Death Register information was collected on:
- Date of breast cancer diagnosis
- Date and cause of death

Population data aggregated on 5-year age group was received from Statistics Sweden.

<table>
<thead>
<tr>
<th>Table 1. Study and reference cohorts</th>
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<tbody>
<tr>
<td><strong>Age group</strong></td>
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<tr>
<td>40-49 y</td>
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<tr>
<td>70-74 y</td>
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</table>

The study and reference cohorts are presented in table 1 and the results in the 40-49, 50-69 and 70-74 year age group in table 2. At this early stage of the intervention, a 12% reduction in the breast cancer mortality was seen in the 40-49 years age group. The corresponding figure for the 50-69 and 70-74 year age group was around 20%.

<table>
<thead>
<tr>
<th>Table 2. Results by age groups</th>
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<tbody>
<tr>
<td><strong>Model</strong></td>
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<tr>
<td>40-49 years:</td>
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<tr>
<td>Cumulative breast cancer mortality</td>
</tr>
<tr>
<td>Cumulative breast cancer mortality (≥10 y f-u)</td>
</tr>
<tr>
<td>Poisson model</td>
</tr>
<tr>
<td>50-69 years:</td>
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<tr>
<td>Cumulative excess mortality</td>
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<tr>
<td>Annual excess mortality, Poisson model</td>
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<tr>
<td>Cumulative underlying cause of death</td>
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<td>Annual underlying cause of death, Poisson model</td>
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<tr>
<td>70-74 years:</td>
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<tr>
<td>Cumulative excess mortality</td>
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<td>Annual excess mortality, Poisson model</td>
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<tr>
<td>Cumulative underlying cause of death</td>
</tr>
<tr>
<td>Annual underlying cause of death, Poisson model</td>
</tr>
</tbody>
</table>

*Adjusted for bias

The scientific results of the research have been published in the following international medical journals:
3.2.2 Evaluation of the breast-screening programme in Stockholm

Background

In Stockholm researchers are fortunate to be have access to screening history data for the whole cohort which simplifies the evaluation considerably.

Aim

The effect of mammography screening on the breast cancer mortality will be evaluated by
- Comparing the study county with counties that started their service screening programme at a later stage in time
- Comparing different levels of attendance rates, i.e., the participation in 0 to 5 screening rounds.
- Comparing the tumour stage distribution in the prevalence and incidence rounds with the stage distribution in the reference period 1979-1988.

Material

Excluding the screening unit at the South Hospital, where a randomised study had been performed, there are four units in Stockholm remaining that would be suitable for evaluation of screening effects in terms of a mortality reduction. At the start of the study, the cohort comprised approximately 130,000 women and 5% has been added, and 5% excluded for being invited, each year.

The database includes: personal identification number, address, screening round, reason for non-participation when relevant, result of screening examination, and for cases selected for further assessment, the results of the complete radiological examination, clinical examination, cytology, surgery, and histology.

Methods

A database exists with data on invitation and follow up for the Stockholm screening programme. All breast cancers in the cohort will be identified by record linkage with the Cancer register allowing classification whether the cancer was screening detected, interval cancer and cancer in the group of non-participants. A record linkage to the nationwide Cause of Death registry will give information of date and cause of death.

In the present study, a breast cancer case will be defined as a case of invasive breast cancer (ICD9=174, PAD=096 according to C24 code) reported to the cancer register during the study
period, i.e. after start of screening (or corresponding time for control counties). A breast cancer death will be defined as a breast cancer case reported to the Cause of death register with breast cancer as underlying cause of death (ICD8=174) not later than December 31, 1998.

The main goal of the present project was to evaluate - in terms of the identification of cancers, and the effect on breast cancer mortality - the quality of non-randomised, mammography screening.

Results

The group has proceeded with the aim to study models of evaluating the effect of mammography screening programmes as a general and population based health care service on breast cancer mortality.

The major statistical analyses have been made by Mr. Håkan Jonsson.

The study group has had 4 separate meetings and 9 telephone conferences during the contract period.

The scientific results of the research have been published in the following international medical journals:


3.2.3 An assessment of the clinical and epidemiological dimensions of the public health programme in Finland

Aim

The aim of the study group on breast cancer screening evaluation within the network was to develop methods in assessing the effectiveness of the service screening programmes. The main objectives of the Finnish study were to 1) assess the coverage, detection rates, interval cancer rates and other aspects, related to the implementation and quality assurance of the breast cancer screening programme in Finland; 2) follow-up effectiveness on breast cancer mortality rates among the whole nation-wide target population; and 3) follow-up effectiveness and sensitivity of breast cancer screening within given centres working with different screening settings.

Results

Evaluation of effectiveness

Data on three centres, each with a different policy in double reading, has been linked with the cancer registry; data on the screen-detected findings and on interval cancers have been obtained; the data analysis and reporting is on-going.

Data on the historical screening coverage and other process parameters and on routine breast cancer incidence and mortality rates during 1970-1998 in Finland have been collected, and entered into a Nordic study on breast cancer incidence and mortality. This study is financed by the Network and is co-ordinated by Lennarth Nyström, Sweden.
Data on screen-detected findings, and on overall cancer incidence and death cases in Helsinki, the capital of Finland with some 500,000 population, has been collected and analysed as to the

- Stability of screening findings over time,
- Proportion of screen-detected cancer vs. overall numbers of breast cancers,
- Stage-specific incidence rates after implementing the programme, looking particularly if there are reductions in the incidence of non-localised breast cancer
- Cumulative incidence, studying potential of over-diagnosis
- Incidence-based (refined) mortality since start of the programme in Helsinki; analysis by birth-cohort and calendar year.

The reference rates for incidence as well as refined mortality rates concerning screened age groups were drawn from age-cohort-period-components of non-screened cohorts. A scientific manuscript has been prepared from this study. Data on the historical screening coverages has been analysed together with incidence-based (refined) mortality rates within the population-based trends of breast cancer incidence and mortality. A manuscript has been sent for publication. A study on interval cancers from three screening centres, as well as their re-readings with various ways to obtain main determinants of mammography sensitivity has been published.

As to the epidemiological evaluation of the breast cancer screening programme as a public health policy, we have demonstrated earlier that there was a reduction of about 24% in the BC mortality among invited women as compared with non-invited controls (Hakama et al. 1997). Now we have been able to collect data on the whole programme, adding into the materials also those centres/municipalities which were not included in the first study (either with the mass screening registration information, or with age-municipality-specific matrices); and finding some basic tools for evaluating the effectiveness after 1992 (the end of the follow-up time of the randomised study) in a non-randomised analysis design. As the whole target population based coverage of the programme was only some tens of percents during the first few years (due to the randomisation), it is particularly important to include municipality & age group specific, or preferably individual-level, data in the estimation of the impacts of the programme (e.g. to include into the invited groups only those municipalities where the given age groups were really invited). Otherwise there would be tremendous misclassification bias in the screening indices. In the evaluation of the programme, data on the incidence and programme performance need also to be evaluated, along with data on mortality outcomes.

Because the systematic results on the Finnish programme will be available earlier than those from most of the other European countries, the results of the study will be important in contributing the evidence on the breast cancer screening policies in the European or world-wide level. In the future years there need to be more collaboration in the evaluation questions in a broad set of programme parameters on the European and other international level.

**Publications**


Dean P, Pamilo M, for the mammography working group, Radiological society of Finland. Screening mammography in Finland - 1.5 million examinations with 97 percent specificity. Acta Oncologica 1999; Suppl 13: 47-54.


3.2.4 Cancer mortality in Copenhagen following the introduction of mammography screening

Aim

To study the breast cancer mortality and the total mortality during the period April 1991 to March 2000 in the cohort of women offered breast cancer screening with mammography since April 1991 in the municipalities of Copenhagen and Frederiksberg, and identify tumour characteristics of interval cancers.

Methods

Mammography-screening data has been retrieved for the first four screening rounds of the Copenhagen programme (1991-1999). The registration of the fifth round was finished only recently. These data have been linked with information concerning cancer diagnoses and tumour characteristics in the Danish Cancer Register and in the files of the Danish Breast Cancer Cooperative Group. Data from the Central Population Register have been retrieved for the exact definition of the target group of the programme, and for information on deaths and movements in and out of the screening area. We are currently editing these data. They will be linked with the Cause of Death Register. We have included the county of Funen in the project, and are currently editing the mammography screening data for the first three rounds (1993-1999).

Results

Cancer identification

Screen-detected cancers in the fourth round have been identified, and final diagnoses have been established. Interval cancers have been identified between the second and third and between the third and fourth rounds. Final diagnoses are being established. Cancers in non-attenders in the second and third rounds have been identified. Final diagnoses are being established. Surrogate measures: Preliminary results concerning surrogate measures from the first four screening rounds have been calculated, discussed, and presented at the Network meeting in Santiago de Compostela.

Mortality analysis

In order to perform the mortality analyses, the editing of the population data to define the target population of the programme has to be finalized. Information on screening history of the women in all the first five rounds of the Copenhagen programme is also needed. The registration of the fifth round was finished recently, and data is currently being retrieved. Finally data on cause of death is needed. The Danish Cause of Death Register, administered by the Danish National Board of Health, is only updated including 1998. Thus, it will probably be necessary to develop a special procedure for obtaining causes of death for 1999, 2000, and 2001.
3.2.5 **Interval cancer group**

The section on Interval Cancer in the epidemiology chapter of the new “Guidelines for Quality Assurance in Breast Cancer Screening” by the Interval Cancer Group was finally published during the contract period of 2000.

**Aim**

The interval cancer study aims to identify the interval cancers in mammography screening programmes having different sources, accuracy and quality of the information, i.e., pathological reports, morphology registers, cancer registers, cause of death registers, for an ascertainment of the sensitivity of mammography in different settings, in different time periods and in different age-groups.

**Results**

In order to finish a manuscript of the earlier reported study to be submitted to an international medical journal, the group had a working meeting for two days in Santiago de Compostela in advance of the annual meeting. The draft is currently in its pre-final stage.

3.2.6 **Comparing breast cancer survival in Europe and the US**

**Aim**

The aim of the study was to compare systematically survival of breast cancer patients in Europe and USA, and to explain the lower survival in Europe found in previous studies.

**Materials and methods**

The study was divided in two parts:
In the first part, breast cancer cases diagnosed in 1975-89 and followed up for at least 5 years were included. For US, the cases included in the SEER public use database and for Europe, all breast cancer cases included in the EUROCARE database were used.

**Results**

The first part of work consisted in a descriptive analysis of the available data, aimed at comparing European and US data. The percentage distribution of quality indicators was considered (DCO, % of histological confirmation, % of lost at follow-up, completeness of information on the relevant study variables). A comparison of the distribution of age, stage and histological types was then performed, keeping in the analysis only those registries with a sufficient completeness of information.

The second part of work was focused on the survival analysis. For this part, the Eurocare high-resolution data was also included, which has detailed clinical data on stage, diagnostic examinations and therapy for patients diagnosed in 1990-91.

The differences in stage distribution, which emerged from the analyses carried out in the first part of the study, suggested that the criteria of stage definition were not uniform between Europe and USA. The definition of stage depends on the thoroughness of the diagnostic investigations performed for staging. Therefore, for a correct stage adjusted survival comparison, also the exams performed for staging must be taken into account, as a confounder of stage. Observed and relative survival was computed by the Hakulinen method. A multivariate survival analysis was performed by the by the Cox model, in order to compare the relative risk of death (RR) at 5 years after diagnosis in the SEER and in the Eurocare breast cancer cases, taking into account the contemporary effect of age, stage, and diagnostic examinations. The pattern of death hazard in the two data sets, was compared. The death hazard in each year following diagnosis was
calculated as the number of death occurred in the relevant one-year interval/ the total number of live subjects at the beginning of the interval. A detailed breakdown of the results of the descriptive analyses was reported in the first and second progress report.

Conclusions

The higher survival for breast cancer which emerged from the systematic comparison of the Eurocare and SEER data, for patients diagnosed during the eighties and the beginning of the nineties, was largely explained by differences in stage at diagnosis. In the US, breast cancer patients were diagnosed with earlier tumour stage than in Europe. However, different criteria of disease and stage definition made the comparison of survival difficult. In particular, the nodal status was investigated more deeply in the US than in Europe. More lymph-nodes were examined in the SEER cases during axillary lymphadenectomy, and this factor was taken into account in the multivariate survival comparison. This information is present in the SEER data base, but is available only in the Eurocare high resolution study, which included a sample of the general Eurocare data base. These high resolution data allowed us to classify stage with more detail than that of the standard cancer registry data, and to take into account the number of total examined nodes, which is the main determinant of nodal stage.

With proper stage and stage determinants adjustments in the multiple regression survival analyses, the differences in survival between SEER and Eurocare reduced importantly. The results of this analysis indicate there are no differences in breast cancer survival between SEER and Eurocare, for cases of the same age, stage and staging categories.

Further points of interest emerged during the development of the work, which could be the object of a new study project. For example, the comparison of the frequency and modalities of adjuvant chemo-radiotherapy. Also, the present study was carried out on patients diagnosed during the eighties and at the beginning of the nineties. It would be extremely interesting to consider the evolution of survival and care for breast cancer in a more recent study period.

3.2.7 European study of BRCA ½ gene carriers by IARC – LYON

Aim

The specific aims of the IBCCS study are to:

(1) more precisely estimate the age, sex, and site-specific cancer risks due to mutations in these genes;
(2) determine the importance of known reproductive risk factors in modifying these risks;
(3) examine the efficacy of prophylactic surgery and other screening/prevention options in high risk women;
(4) create an ongoing registry of gene carriers for potential use in future clinical trials.

Results

As of February 2002, a total of 1518 subjects have been enrolled in the IBCCS database. In an effort to bolster enrollment and increase statistical power for detecting associations between cancer incidence and some of the less frequent exposures, initial contacts have been made with a number of new centres who seem willing to join in the IBCCS study. These are: Athens, Greece (Dr. D. Yannoukakos), Szczecin, Poland (Prof. J. Lubinski), and Haifa, Israel (Dr. G. Rennert).
Retrospective Data Analysis

While data in the cohort accumulate, a retrospective analysis of the first 971 female carriers enrolled in the IBCCS is being conducted. The mean age at interview of these women is 47 years; 492 women are affected with breast cancer only, 107 have a previous diagnosis of ovarian cancer (56 breast/ovary), and 372 women are currently unaffected with cancer. A common data set has been distributed to members of the data analysis working group, and agreement has been reached on analysis strategies, definitions of censoring and exposure variables. The analyses will focus on the following groups of risk factors: reproductive, exogenous hormones (OC/HRT), radiation exposure, tobacco and alcohol consumption. In addition to analyses by standard survival analysis techniques, a matched case-control analysis will be performed using 207 breast cancer cases interviewed within 5 years of diagnosis and an unaffected woman matched for year of birth (+/- 2 years), age at censure (+/- 5 years) and responsible gene (BRCA1 or BRCA2).

Conclusions

It is difficult to assess the impact of the study on public health in Europe as any conclusions in this aspect must await adequate follow-up time (5-10 years) before there will be sufficient statistical power to draw conclusions. Although this project is focused on carriers of mutations in the BRCA1 and 2 mutations which are relatively rare in the European population (on the order of 1/600 individuals), there are implications as well for the female population as a whole. The study to date has identified a set of women who, because of their high risk, may be suitable for trials of chemoprevention or screening modalities which are impractical in normal-risk women. Thus this cohort could provide valuable evaluation of such agents which could be applicable to a much larger group of women. By enrolling women into the study from different parts of Europe, we will be able to address to some degree questions such as how variations in lifestyle across Europe are responsible for differences in incidence rates. Perhaps most importantly, an important resource for a variety of studies on hereditary breast and ovarian cancer has been created.

3.3 Practical application of Quality assurance criteria (Group 3)

(author: M. Broeders)

Scientific aims

The primary objective of the European Breast Screening Network (EBSN) as a whole is to improve the quality of breast cancer screening service in Europe. The European Guidelines for Quality Assurance in Mammography Screening have served as the main tool for supporting the standardised implementation of QA in all mammography screening projects in EBSN.

The key operational objectives for a successful population screening programme as outlined in the third edition of the European Guidelines are listed below:

1. To identify and invite eligible women for mammography screening.
2. To maximise compliance in the eligible population.
3. To ensure that mammography of the highest possible standard is performed and that films are read by personnel with proper training and proven skills in this area.
4. To maximise the acceptability of the service.
5. To provide prompt and effective further investigations and treatment where indicated.
6. To minimise the adverse effects of screening while optimising cancer detection.
7. To monitor outcomes and continuously evaluate the entire screening process.
8. To perform regular audit of programme activities and to provide appropriate feedback to staff.
9. To provide a cost effective service.
10. To ensure that all staff undergo initial training with regular updating and continuing professional development.

To achieve these objectives requires a multi-faceted and multidisciplinary approach, a weak link anywhere will diminish the overall effectiveness of the programme. This is the reason why guidelines such as the European Guidelines are essential for all stages of the screening and diagnostic process and for all professional disciplines involved. The effectiveness of any screening programme is directly related to the quality of the individual parts of that programme.

Activities related to the aims

A summary of the activities in the thirteen projects belonging to Group III "Practical application of QA criteria" in relation to the operational objectives for a successful screening programme is presented in the table below. More detailed information on the nature of the activities in the various projects can be found in the scientific reports submitted by each of the projects directly to the network co-ordinator.

Conclusions / results

There are several reasons why the summary table presented below does not give a complete picture of the activities undertaken by the individual projects:

• some projects have been involved in more than one group under the 2000 contract. Thus activities may also have been reported in other parts of the final report on this contract.
• activities that were financed by sources other than the European Commission, will not be included in the scientific reports submitted by the projects.

However, even with the above limitations, a number of conclusions can be drawn from the information presented in appendix 1 and the individual scientific reports:

• Operational objectives 3, 7 and 10 are mentioned most frequently as areas of activity. This is not surprising since these objectives are focussed on improving and maintaining a high-quality screening programme. Since most projects have now been around for some time, the greatest challenge is keep up the high standards needed to successfully influence breast cancer mortality in the long term.
• Several projects have focussed on a limited number of objectives. It should be recognised that this may partially be due to delays in payment from the European Commission as a result of which some subprojects were never initiated.
• Training has become accepted as an integral part of a successful screening programme. This is a big step forward in the implementation of quality assurance in breast screening programmes.
• Evaluation is an emerging area of activity. Given the regrouping of activities under the next contract, the majority of the EBSN programmes should be able to contribute to the data collection for joint projects in this field. This is very encouraging and will hopefully enable EBSN to benefit from the experiences of all programmes involved.
• The areas of assessment, treatment, regular audit, feedback and cost-effectiveness are currently underrepresented. If indeed these areas are not covered by the projects in some other way, this may identify opportunities for future joint research projects.
Added value

The scientific reports of the individual projects clearly indicate that projects greatly value their involvement with the European Breast Cancer Network. This view is also confirmed in the report of Group I on the survey that was performed and analysed under the 2000 contract. Even though each health care environment requires a unique solution to a common problem, sharing experiences gives rise to new ideas and avoids 're-inventing the wheel'. All projects also acknowledge the influence of the European Guidelines for Quality Assurance in Mammography Screening on screening protocols for their country.

Implications for the future

The continued funding by the European Commission will allow Network members to meet each other on a regular basis. Areas for future research and co-operation can be readily identified and will allow for efficient research activities. It will also provide a basis for the next edition of the European Guidelines necessary to keep this document up-to-date.
Table: Summary of activities from Group III 'Practical application of QA criteria' in relation to the operational objectives for a successful screening programme as listed in the European Guidelines for Quality Assurance in Mammography Screening.

<table>
<thead>
<tr>
<th>Operational objectives</th>
<th>BRU</th>
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<th>STR</th>
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<th>COI</th>
<th>SAN</th>
<th>PAM</th>
<th>VAL</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>1. Identify/invite eligible women</td>
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<td>2. Maximise compliance</td>
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<td>X</td>
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<td>X</td>
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<td>3. High-quality mammography &amp; Trained personnel</td>
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<td>4. Maximise acceptability</td>
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<td>5. Assessment and treatment</td>
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<td>6. Balance adverse effects and cancer detection</td>
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<td>7. Monitor outcomes and evaluation</td>
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<td>8. Regular audit and feedback</td>
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<td>9. Cost-effective service</td>
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<td>10. Initial training and updates</td>
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</tbody>
</table>
3.4 Guidelines, certification and training (Group 4)

(authors: J. Schouten, E. Puthaar)

Aims

The aims of the EUREF-project are threefold and can be described under the following three headings:

- **Guidelines:**
  To enhance overall performance, EUREF has drawn up guidelines for all involved disciplines to establish criteria that must be met in order to perform high-quality breast cancer screening. EUREF’s aim is to keep these guidelines up-to-date with cooperation of representatives of all Member States involved in screening.

- **Certification:**
  The aim is to develop a European Programme for voluntary certification of high-quality mammography screening by granting certificates to those mammography units, assessment centres and screening programmes that operate according to the European Guidelines.

- **Training:**
  From its inception EUREF has been actively involved in the stimulation, documentation and organisation of training activities. The aim is to provide training to people who work or will be working in a screening programme.

Activities

- **Guidelines**
  Due to delays at the Office of Official Publications, EUREF has carried its Guidelines activities well into the 2000 contract period. EUREF was able to still have some additional items inserted into the third edition before it went into print. Next to this, much was done to promote the existence of this recently printed document. Brochures were made and distributed to people involved. Also copies were purchased and sent to the different authors of the guidelines.

- **Certification**
  In January and November 2001, The Certification Steering Group convened with a number of experts who have contributed to the pilot certification visits that took place under the previous contract. Much work was done during these meetings on the questionnaires and the requirements of the certification.

- **Training**
  The EUREF Office received several requests to provide training to personnel who work or will soon be working in different (national) programmes. Members of the EUREF-staff therefore gave training in Leuven, Bremen and Wiesbaden.

- **Other activities**
  A core group of the former EUREF Advisory Board convened to redefine EUREF’s tasks and functions. Since the European Breast Screening Network has evolved into a more independent, self supporting body, EUREF will now focus more on independent performance of its activities.
Results

**Guidelines**
During the contract period the most visible result of the EUREF activities have been the publication of third edition of the European Guidelines for Quality Assurance in Mammography Screening. Also a brochure was made to promote this document (annex I).

**Certification**
The Visitation Protocol and questionnaires (annex II) have been thoroughly reviewed point by point in order to determine what aspects still stand in the way of standardised reporting on the performance of a certain unit or centre. Also problem areas were defined. It became clear that much information could be obtained in advance as long as ample time is provided and moreover, that it is made very clear to the candidates what is expected from them. Also the quality assurance document of the Irish Screening Programme which recently started, was reviewed in order to check if the programme operates according to the European Guidelines and if a certificate may therefore be granted in the future.

**Training**
The EUREF Office received several requests to provide training to personnel who will soon begin to work in different (national) programmes. Members of the EUREF-staff gave trainings in Leuven, Bremen and Wiesbaden.

**Other activities**
EUREF’s tasks were redefined and written down in the new EUREF-protocol 2001 (annex III), which can be found in the third edition of the European Guidelines. The term EUREF was reconsidered and will from now on stand for “the European Reference Organization for Quality Assured Breast Screening and Diagnostic Services”. EUREF will remain active in certification, guidelines and training, but will operate in a new structure. Still, this new EUREF structure will be logistically supported by the administrative EUREF Office in Nijmegen.

What was the added value?

**Guidelines**
By realising the third edition of the Guidelines, an up-to-date document was created containing quality assurance standards written by well-known experts in the disciplines involved.

**Certification**
By granting a certificate to a unit, assessment centre or screening programme, the women can see that the respective service works according to the quality standards of the European Guidelines.

**Training**
By sharing the knowledge from experience of screening programmes of different member States, EUREF contributes to training personnel in screening programmes.

Implications for the future

**Guidelines**
Keeping the guidelines up-to-date. Making preparations for a fourth edition.

**Certification**
Creating a well-tested certification protocol ready for large-scale implementation.
Training
Continue to provide training to programmes and services in member states and to organise training courses.

3.5 Pathology (European Commission Working Group on Breast Screening Pathology - ECWGBSP (Group 5)
(authors: Dr. Clive Wells)

Scientific aims
During the contract period the following aims were pursued in the pathology project:

1. To produce a high quality electronic EQA and teaching system for breast pathology.
2. To evaluate its performance and uptake in comparison with conventional histology.
3. In the process of achieving 1) and 2) to disseminate further the ECWGBSP’s standardised breast pathology reporting system.

Activities related to the scientific aims

1. One meeting of the ECWGBSP was held on 20th and 21st July 2001 in Porto, Portugal. 18 members of the group were able to attend.

   The Porto meeting was the first meeting of the ECWGBSP under its new Chairman, Dr. Clive Wells (St. Bartholomew’s Hospital, London, UK). At this meeting a number of questions were discussed.

   Cases which formed an interesting case series for inclusion on the Break-IT virtual case repository had been sent round to all members and a consistency analysis performed on these was discussed. (annex 1). These cases were further discussed in detail and the consensus diagnosis determined. Cases on which there was no formal consensus were excluded from the teaching series and the rest were agreed to be digitised to form an addition to the Break-IT case repository.

   The distribution of Break-IT was also discussed. Due to the death of the previous chairman, it appears that money earmarked for the Giunti company for the Break-IT project in 1999 had not been invoiced for or paid. Due to this, Giunti were unwilling to release copies of the Break-IT project to the Group or for general distribution. Possible solutions to this dilemma were discussed and a strategy to allow the distribution of the Break-IT CD-ROM series was agreed.

   Slides from 15 cases had been circulated to 100 pathologists throughout Europe and responses from 85 pathologists had been obtained on these slides. A consistency analysis on these responses was discussed (Annex 2). It was agreed at the meeting that the CD-ROM with an electronic reporting form would also be circulated to the pathologists who had submitted answers to the slides. The format of this CD-ROM to be produced for the first European test of virtual QA was discussed and agreed.

   A previous circulation of oestrogen receptor slide tests had been reanalysed in accordance with the guidance for reporting. (Annex 3). These data were not published previously due to the variable methods of scoring oestrogen receptor tests which were used by different laboratories. The publication of a recommended scoring system now meant that
these results could be assessed according to the recommended scoring system and the CSEU performed an analysis based on the new scoring system. The results from this were discussed and a draft paper will be produced on the results.

The rest of the meeting centred around work for the next project due to start in December 2001 and suggestions for the Pathology Group activities in October 2002 – 2003

2. The Chairman of the Group attended the Annual Network Meeting and a number of Network Advisory Group meetings. These were:

   a. The Annual General Meeting in Santiago de Compostella with the members of the European Breast Cancer Network
   b. In Amsterdam 23rd – 24th October 2000 with the interim advisory committee of the European Breast Cancer Network
   c. In Luxembourg 16th November 2000 with the interim advisory committee and Dr. Freese of the European Commission
   d. In Leiden 21-23 .9.01 with the interim advisory committee of the European Breast Cancer Network

3. Preparation of CD-ROM circulation: The previous slide circulation of 15 cases, reported by members of the group to the Cancer Screening Evaluation Unit was further circulated to 100 pathologists throughout Europe. Eighty-five responses from this extension of the slide circulation were obtained giving an 85% response rate. The names of responding pathologists are given in ANNEX 4. Analysis of these responses was performed (ANNEX 2). The slides were then digitised with approximately 20 images per case and the first European Pathology Quality Assurance CD-ROM was produced and duplicated. This CD-ROM (ANNEX 5) contained an electronic reporting form which automatically sent back the pathologist’s answers to the analysis centre and also an electronic copy of the standard European Pathology QA form to be used if the electronic submission was unavailable to the participants. The CD-ROM was distributed to the 85 pathologists who responded to the slide circulation (Annex 4) and answers were received either by electronic means or by paper form. Answers are still being received by the co-ordinating centre and to date some 25 responses have been analysed by the Cancer Screening Evaluation Unit in Sutton. (Preliminary analysis attached as ANNEX 6). The content of the CD-ROM is also accessible on the Internet at: http://www.telepathology.qmul.ac.uk/euroqa/euroqa1/start.htm where any pathologist can submit a response to the cases not just those who have received the CD-ROM.

4. Break-IT update and distribution. The Break-IT educational multilingual CD-ROM series has been updated with 13 extra cases comprising images from the slides, multi-lingual text and commentary and video which were all produced for this update. A copy of the updated Break-IT CD-ROM series is included (ANNEX 7). Due to the Commission approval of the change to the pathology budget to allow the distribution of the Break-IT CD-ROM series throughout Europe, 300 copies of the CD ROM series (900CD’s) have been ordered and on arrival in February 2002 will be sent to the members of the group for distribution to a group of pathologists reporting breast pathology in each member state. The distribution of this CD-ROM set is designed to complement the European Guidelines as a teaching resource and to further harmonise terminology across the European Union.
Results

1. The Break-IT CD-ROM set is now ready for distribution and 300 copies are being mastered to distribute throughout the European Union. The CD is now a 3 volume set incorporating 5 different languages. Extra cases have been added to the CD-ROM virtual case library comprising 13 particularly interesting cases of prime educational value.

2. Consistency analysis between 85 European pathologists has been investigated in a recent slide circulation showing excellent agreement with Kappa statistics of 0.8 for 4 categories and 0.88 in the important distinction of benign and malignant lesions. As previously seen in the 1999 series estimating consistency of the Working Group on these cases, there were some problems in estimating the true size of tumours, related to the presence of satellite areas of tumour but generally the consistency between observers was good. Grading and typing of individual tumours was generally good with an excellent result in grading of tumours of no special type (ANNEX 2).

3. The CD-ROM circulation is the first time that QA on histological sections has been attempted in the EU by virtual means. The results so far from this circulation indicate that there is a slower uptake than expected but so far 30% of pathologists who received the CD and answered the slides have responded. The results of consistency on this first innovative circulation are given in annex 6.

4. The contents of the CD-ROM are also published on the web with a submission form at http://www.telepathology.qmul.ac.uk/euroqa/euroqa1/start.htm so that any pathologist in the EU wishing to participate in a virtual EQA scheme can do so.

Added value resulting from EU funding

Harmonisation of guidelines and terminology throughout Europe would be impossible without European funding. This can be applied to symptomatic practice as well as breast screening.

A major teaching resource has been created in the Break-IT project. This multimedia CD-ROM is a major achievement and will undoubtedly be a potent factor in further harmonising standards across the EU. Its production in 5 languages (English, French, Italian, German and Spanish) will enhance the use of the CD in the various member states and represents a major common teaching resource for Europe which cuts across National boundaries. Distribution of 300 copies of this throughout the European Union thanks to the budget amendment agreed by the Commission will undoubtedly help to make European Pathologists familiar with the standardised terminology and can only increase the standard of pathological reporting across Europe. This would have been impossible without European funding.

An increasing number of pathologists now taking part in slide exchange schemes for quality assurance throughout Europe will protect women and help to avoid over and under-diagnosis of breast lesions and the first testing of a pan-european virtual quality assurance circulation is a major step in creating a virtual scheme which could replace the old limited slide exchange schemes and extend the principle of quality assurance throughout Europe.

The measures above, comprising education, refinement of criteria and quality assurance will benefit the women of Europe in that it is expected that a reduction in over and under-diagnosis by pathologists will lead to better and more equitable healthcare with consequent reduction in...
inappropriate treatment throughout Europe. This also helps to reduce the costs of inappropriate treatment for all member states.

Implications for the future

In order to be effective a quality assurance programme should give guidance on diagnosis, set targets for acceptable performance, measure the performance against the targets and review the guidelines based on the evidence obtained from the QA programme itself and from related studies. The Break-IT CD-ROM has a number of self assessment cases which have been increased in number this year but would benefit from the inclusion of full virtual slides of core biopsy with major benefit as the non-operative diagnosis of breast lesions is the major means of reducing the number of unnecessary benign operations and hence cost both within screening and symptomatic practice. The maintenance of quality depends on a degree of continuous slide circulation and extension of the circulation to other pathologists, while refining the criteria for diagnosis and disseminating this information.

The large National circulations at present operating within the UK, France and Belgium especially are extremely cumbersome with large numbers of pathologists wishing to participate in the circulations. Because of this, slide circulation, although useful, is limited in the number of pathologists it can reasonably reach in a given time. Quality Assurance in Pathology therefore could reasonably be enhanced by the development of virtual slide systems so that virtual slides can be distributed on CD to all participants at once. The EWGFBSP foresees that a pan-European circulation of CD-ROM based quality assurance of virtual slides would be a major improvement on the current virtual circulation which was limited by the number of images which could be reasonably digitised from each case. In addition lesions such as atypical hyperplasia and specimens such as core biopsy which are not amenable to circulation by slide exchange could be targetted with CD-ROM based methods.

3.6 Network Coordination

(author: Lawrence von Karsa)

Background to transition in network coordination

At the beginning of the contract period in August 2000 the European Breast Cancer Screening Network embarked on a phase of transition from which the European Breast Cancer Network emerged in the Fall of 2000. The situation of the network at the time was precarious, not least because the revisions to the 2000 network application requested by the Commission had not yet been completed and the impending enactment of a new framework for public health in the European Union did not show a perspective for continuing network activities in the future. Furthermore, there was a widely perceived need within the network for a more sophisticated formal structure of democratic representation of network membership within the administrative activities of the network. Finally, the strain of administrative burdens on the network coordination and the individual projects had increased substantially and at the same time there was a considerable delay in processing reports and claims through the Commission, thus, funding for planned activities was considerably delayed, which, in some cases, inhibited performance of planned activities.

When the Cologne office took over the coordination activities from the Stockholm office in the Fall of 2000 work had not yet begun on the 2001 network application. Thus, a substantial backlog of application activities existed. Furthermore, the perceived need for restructuring of the network and the need to communicate with the Commission and the European Parliament on the
perspective for future network activities substantially increased the workload on the coordination office compared to past years. Furthermore, a substantial increase in the effort devoted to financial management was imminent, not least to ensure that in the future the network improve the effectiveness of fund allocation within and between different projects in the network.

The transition in the network coordination at the beginning of the contract period was accomplished under constant time pressure. With the untiring support of the previous coordinator Sven Törnberg, J&AB Associates and the Cologne coordination team a consensus was reached in the network on the above issues. The cooperative and supportive role of the host project lead by Dr. Erik van Limbergen, at the annual network meeting in Knokke, Belgium in September 2000 played a substantial role in reaching this consensus. Whereas the main purpose of the network in the past had been to improve the quality and effectiveness of breast cancer screening services in Europe. The new breast cancer network builds on those elements of previous network activities such as data collection and analysis, development and implementation of guidelines of best practice and quality assurance that proved effective and are relevant to the concerns and challenges that the Community will be confronting over the next years. Improvements in health information and knowledge will be depending, among other things, on the availability of population-based data such as data collected in the population-based screening projects evaluated in the breast cancer network. Further development, dissemination and evaluation of the certification protocols for both clinical and screening diagnostic services will also contribute to improvements in health information and knowledge. Quality assurance activities in breast diagnosis and management will continue to contribute to health care services improvement in member states and will also be a source of assistance to applicant countries to the European Union seeking expertise and infrastructure necessary to ensure high standards of breast care for their own country.

Aims and objectives

During the contract period the central co-ordination office of the European Breast Cancer Network in Cologne had the primary formal task of supporting the network members to fulfil the obligations of the 2000 network contract, stimulate networking and coordinate the management of EBCN network applications and projects. The later task is supported by a service contract to J&AB Associates for the financial and monitoring aspects and a public health consultant contract for all related coordination and administrative tasks. The specific objectives mentioned in the 2000 network contract are listed below.

1. Co-ordination of the network contract (collecting scientific & financial information) which includes:
   2. Collection and collation of all breast cancer screening applications
   3. Drafting a comprehensive proposal covering all aspects of the tasks of the network,
   4. Collecting all estimated budgets and supporting information for the financial justification.
   5. Assisting new applicants in complying with the EC and network rules.
   6. Reporting related to the existing contract (interim & final report, financial reports) with the help of group leaders
   7. Follow-up of the requests made by the Commission for information on each project, i.e., monitoring the performance of the projects in each group, and advise, where needed, on improvements related to quality assurance and quality control.
   8. Presenting the achievements of the network and the importance of QA at other international conferences

Activities and results

The coordination activities and achieved results during the contract period 1 August 2000 to 15 December 2001 are presented below:

1. Beginning in August 2000 the Cologne coordination team was established: (Network Coordinator: Dr. Lawrence von Karsa, German Mammography Screening Coordination Office; Financial Management: J & AB Associates, UK; Public Health Consultation: Dr. C. de Wolf, Revolux, Luxemburg; Object. 1-9)

2. Transfer of documents and files from previous coordination office, discussion with previous network coordinator (Dr. S. Törnberg) at meeting with Cologne coordination team in Stockholm, Sept 2000 (Object. 1-9).

3. Revisions of the 2000 contract and integration of new projects (deadline: 1 November 2000; Object. 2-3;)

4. Collection and collation of all 2001 individual breast cancer screening applications into a comprehensive network application including new aspects and tasks of the network (deadline 31 January 2001, Object. 2-3).

5. Collecting all estimated budgets and supporting information for the financial justification of the accepted 2000 contract and the initial budgets for the 2001 application. (J&AB). Financial systems have been introduced to identify potential project underspending and to stimulate corrective action. A standard form for budget changes has been agreed and used in management of the 2000 contract (Object. 4-7).

6. Follow-up of the requests made by the Commission for information on each project, i.e., monitoring the performance of the projects in each group, and advise, where needed, on improvements related to quality assurance and quality control. Financial systems have been introduced to identify potential project underspending and thus to provide the opportunity of the network as a whole being able to move money to deserving projects subject to Commission approval (Object. 6-7).

7. Transfer to all network applicants of the first and second received payment on the 2000 contract after projects have provided cost evidence to appropriate levels (Object. 1).

8. Network restructuring; Installation of network assembly and temporary executive board, drafting EBCN Network bylaws. Several meetings were held to reach the current structure (Annual meeting Knokke, Sept. 2000, Meeting of project leaders in Amsterdam in October 2000, Meeting of the executive board in Luxembourig, November 2000, Group leader meeting in Amsterdam, January 2001; Object. 1).


10. Presenting the achievements of the network and the importance of Quality Assurance at other international conferences and meetings. (Meeting Vienna Oct 2000; Object. 8)

11. Organisational support and scientific planning for the Annual Meeting of the Network members in Knokke Belgium (23-24 Sept 2000; Object. 9)
12. Organisational support and scientific planning for the Annual Meeting of the Network members in Santiago de Compostela, Spain, 25-27 June 2001 (Object.9)

13. Preparing network application 2002 - 2003 (Object. 2-3)

14. Coordination meetings with the European Commission in Luxembourg in May and November 2001 (Object. 1, 3, 9)

15. Presentation of the European Guidelines on Quality Assurance in Mammography Screening at the “Journée de la mammographie” in Strasbourg, November 2001 (Object. 8)

16. Presentation of the European Guidelines on Quality Assurance in Mammography Screening at the EUROPA DONNA conference December 2001 in Milan (Object. 8)

17. Drafting and circulating of draft Network Constitution and Bylaws (meeting Turin, May 2001; Object. 8)

18. Instructions on EBCN website and providing information on the current applications (Object. 2, 3, 5).

19. Networking activities and information source related to the discussion on the effectiveness on mammography screening as being questioned by Götzsche and Olsen (Object. 1).

20. Preparation of an international workshop on evaluation of mammography screening in Wiesbaden (workshop held in January 2002, preparations began at EBCN annual meeting in June 2001; Object. 8).

21. Liaison with EUREF and EUSOMA on further development of the European Guidelines and certification protocols, taking into account the essential differences between diagnostics for patients and screening for clients (meeting in Amsterdam in November 2001; Object. 1, 9).

Conclusions

The activities of the former European Breast Cancer Network have substantially contributed to improvement in and maintenance of high standards in breast health care in Europe. At the outset of the contract period the network faced a grave threat to continuation of activities which have been successful in the past and to application of advances in quality management of screening developed in the network to areas of breast care previously beyond the reach of the network - due to substantially increased administrative demands and the need to expand and further develop the internal network structures. The threat to the existence of the network was transformed into an opportunity for further development through a coordinated effort involving close cooperation with the previous network coordinator and the members of the network as well as with the Commission representatives, expansion and further development of financial management procedures, a dedicated team approach to network coordination and last, but not least, continued voluntary assistance of numerous professionals involved in the network projects. During the 13 months from the beginning of November 2000 to the end of November 2001 three network applications with a total volume of ca. 13 million € were completed and submitted to the Commission. Thus, the contract period became a transition phase from which the current
European Breast Cancer Network has emerged in which the advances formerly achieved in the area of breast cancer screening are now being applied to the full range of breast cancer care including management of breast lesions. New projects in the areas of quality assurance, evaluation and development and promotion of best practice have been added and the network now includes professionals associated with over 70 institutions in all of the member states of the European Union as well as in two EFTA countries and three preaccession countries actively participating in 24 projects.

**Implications for the future**

The availability of European Guidelines for the Quality Assurance of Mammography Screening has in the past enabled national governments in various member states to improve the secondary prevention of breast cancer. The recent extension of the scope of the network to include the entire field of breast cancer care will give national governments throughout the Community a similar opportunity to improve the quality of diagnosis and management of breast lesions detected in routine practice outside of a screening programme.

The currently planned quality assurance, certification and training in best practice of diagnosis and interdisciplinary management of breast lesions has the potential to open the benefits of systematic quality assurance established in the screening programmes to all women seeking and receiving breast care in the European Union.

The future priorities of network management are three-fold:

1. to continue to improve internal management procedures in order to better assist the projects in achievement of planned aims and objectives.

2. to help the network to finish ongoing projects and to present the achievements of the network in the final phase of the Action Programme on Cancer.

3. to assist the network in developing a strategy which will permit those activities essential to maintenance and improvement of quality and best practice in breast care to continue in the future and to include fields in urgent need of similar development as well as to those countries which will become new members of the European Union.
4 Network Financial Report

Attached are summary spreadsheets for each project and a 3 page network summary spreadsheet showing actual costs in each budget heading against budgets agreed by the Commission for the time period 1 August 2000 to 15 December 2001. In agreement with the responsible persons handling financial management of the contract at the Commission we enclose only summaries for the time being on the understanding that evidence for costs will be requested on a random basis within some of the projects. Supporting evidence is being held by J&AB Associates on behalf of the Coordinator and requests can be made directly to J&AB Associates. Please note that the third page of the Network Summary demonstrates that it is important that the final claim part needs to be calculated on each project and then consolidated. It can be seen from the bold line just under the last four lines that the withdrawal of Athens makes a difference as the final claim on a historic basis would be 342,399.78 when the correct figure should be 381,118.75. We would appreciate your careful consideration on this matter.
Summary spreadsheet
Summary spreadsheet, cnt'd
Summary spreadsheet, cnt'd
5 Partner list 2000 Contract

Group 1: Present status of breast cancer screening within the European Community

1. Mireille Broeders, Nijmegen, the Netherlands
2. Astrid Scharpantgen, Luxembourg, Luxembourg
3. Beatrice Gairard, Strasbourg, France
4. Nieves Ascunce
5. Lennarth Nyström, Umeå, Sweden,
6. Frank Buntinx, Leuven, Belgium
7. Kaat Cortebeeck, Leuven, Belgium

Group 2

Sub 1 Evaluation of the national service screening programme for breast cancer with mammography in Sweden
1. Häkan Jonsson, biostatistician, Umeå
2. Lennarth Nyström, epidemiologist/biostatistician, Umeå
3. Per Lenner Oncologist, Umeå
4. Sven Törnberg, Oncologist, Stockholm

Sub 2 Evaluation of the breast screening programme in Stockholm
1. Häkan Jonsson, biostatistician, Umeå
2. Lennarth Nyström, epidemiologist/biostatistician, Umeå
3. Per Lenner Oncologist, Umeå
4. Sven Törnberg, Oncologist, Stockholm

Sub 3 An assessment of the clinical and epidemiological dimensions of the public health programme in Finland
1. Ahti Anttila, project manager, Helsinki, Finland.
2. Matti Hakama supervisor Tampere, Finland.
3. Tiina Salminen, Researcher (Epidemiologist): Tampere, Finland
4. Dr Eero Pukkala, ADP manager Helsinki, Finland.
5. Helvi Brugnoli, and Minna Heikkilä; both from the Mass Screening Registry.
7. Irma Saarenmaa, consultant radiologist Pirkanmaa Cancer Society.

Sub 4 Breast cancer mortality in Copenhagen following the introduction of mammography screening
1. Elsebeth Lynge, University of Copenhagen
2. Mogens Blichert-Toft, Rigshospitalet H:S, Dept of Surgery
3. Maj-Britt Jensen, Danish Breast Cancer Cooperative Group
4. Fritz Rank, Rigshospitalet H:S, Dept of Pathology
5. Ilse Vejborg, Rigshospitalet H:S, Dept of Radiology

Sub 5 Comparing Breast Cancer survival in Europe and USA, MILAN
1. Milena Sant
2. Emily Taussig
Sub 6  European study of BRCA ½ gene carriers by IARC – LYON

1. David Goldgar

**Group 3: Practical application of QA criteria**

**BELGIUM**

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1. Dr. A Grivegnee, co-ordinator
2. Dr. C Bourdon, co-ordinator
3. Dr. J.-C Brombart; Radiologist
4. Dr. A De Guchteneer; Radiologist
5. Dr. D Faverly, Pathologist
6. Dr. F Renard, epidemiologist
7. Dr. A Rimulo, epidemiologist
8. Pr. R van Loon, physicist
9. Mrs. D Dierckx, physicist
10. Dr. M Provoost, General Practitioner
11. Mrs. K Cannoodt, Secretary, data-manager

Leuven
12. Erik van limbergen
13. Andre van Steen
14. Karla Vanhulle
15. Kaat Cortebeeck
16. Hilde Bosmans
17. Frank Buntinx

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2. Béatrice Gairard

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3. Fritz Hansen

Bremen
4. Hans Junkermann

Wiesbaden
5. Margrit Reichel

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  2. E. Paci
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  3. Dr. Segnan
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  3. Monserrat Quinteiro
Valencia
  4. Dolores Cuevas
  5. Isidro Vizcaino

**Group 4:** Training Coordination and Certification
  1. Roland Holland,
  2. Johan Schouten,
  3. Mireille Broeders

**Group 5:** Pathology quality assurance (QA) programme
  1. Clive Wells (coordinator)

**Group 6:** Coordination
  1. Lawrence von Karsa
  2. Chris de Wolf
  3. J & AB Associates
6 Annexes to Final Report

The following Annexes to the present report are available on request from the coordination office:

1. Group Summaries and scientific and activity reports from each project
2. Annexes to group reports in Chapter 3
3. List of publications resulting from network activities

Separate project spreadsheet summaries of the financial report have been sent separately to the Commission by J&AB Associates and may be commuted to the report here.
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