Health & Consumer Protection
Directorate-General

INFORMATION NOTE

EUROPEAN GUIDELINES FOR QUALITY ASSURANCE OF BREAST CANCER SCREENING AND DIAGNOSIS, 4th edition

Background

The European guidelines for quality assurance in breast cancer screening and diagnosis are based on over 20 years of experience in the EU Member States in implementation of regional and national breast cancer screening programmes based on mammography. They have been developed in the European Breast Cancer Network (EBCN) which was co-financed under the Europe against Cancer Programme. In the framework of the EBCN, scientists, programme administrators and other professionals from most of the EU Member States cooperate in exchanging experience on implementation and continuous improvement of breast screening programmes. In recent years, this cooperation has been extended to include quality assurance and best practice in diagnosis and treatment of breast cancer outside of screening programmes. Breast cancer advocates from EUROPA DONNA, the European Breast Cancer Coalition, have taken an active role in the network.

The first edition of the EU guidelines appeared in 1993, followed by updated and expanded editions in 1996, 2001 and now in 2005. New chapters in the current (fourth) edition deal with communication in screening, the physico-technical aspects of digital mammography, certification of diagnostic and screening units, multidisciplinary diagnosis, and specialist breast units. Production of the revised and expanded fourth edition was coordinated by the EUREF project in the EBCN network. The United Kingdom National Guidelines and EUSOMA documents provided the basis for some of the chapters. A total of over 200 professionals and client and patient advocates from 18 Member States of the European Union as well as Norway, Switzerland, Israel, Canada and the United States contributed to the new edition of the EU guidelines. The new chapters and other major changes were discussed and approved by the European Breast Cancer Network (EBCN) at its annual meeting held 23-25 September 2005 in Budapest.

The standards of technical quality control set in the first and second editions had a profound impact on the quality of mammography equipment and imaging throughout the European Union. Manufacturers and responsible authorities responded by raising standards to meet the European levels. Millions of women across Europe have benefited from this development, including women obtaining mammograms outside of screening programmes. Similar benefits are expected from the introduction of the new EU guidelines on digital mammography and the guidelines for specialist breast units in which women with a diagnosis of breast cancer should receive optimal treatment.

Breast cancer is the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe. The number of women diagnosed with breast cancer in Europe will rise continuously over the coming decades due to the increasing age of the female population. Mammography screening has the potential to substantially reduce the number of breast cancer deaths by detecting breast cancer 3 to 4 years before symptoms would be noticed by the patient. Treatment undertaken at this time is often more effective.

Since the appearance of the first EU guidelines a number of Member States have implemented or expanded regional or national mammography screening programmes based on the quality standards and recommendations in the guidelines. Due to the substantial impact of the previous editions, the new edition is also expected to raise the level of breast cancer care across the EU, particularly in diagnosis and treatment of breast lesions. Discussion of implementation and further development of the guidelines will take place in the EBCN under the umbrella of the new European Cancer Network (ECN) which is co-financed by the European Commission under the current public health action plan. This discussion should stimulate further pan-European cooperation to improve the quality of breast cancer care in Europe.

The new edition of the guidelines will be published in the 1st quarter of 2006 by the Office of Publications of the European Commission.

Key aspects of EU guidelines

Key general elements of the quality assurance and best practice recommendations in the Guidelines include:

- population-based invitation to screening
- training of all staff, particularly: radiographers, radiologists, pathologists and surgeons
- specialisation of personnel
- observance of volume levels
- multidisciplinary team working, including above staff as well as breast care nurses or psychologically professionally trained persons and medical oncologist/radiotherapists
- targets, performance indicators and regular audit
- organization of preoperative and post-operative multidisciplinary conferences
- avoidance of mixing of screening and symptomatic women
- complete and accurate recording of all relevant data for evaluation
- accreditation of units meeting quality standards

The following must be applied to all steps in the screening process (not just screening test):

- invitation
- performance of the screening test (mammography)
- reading of mammograms
- further diagnostic work-up of women with suspicious results
- treatment of women with screen-detected lesions

More specific requirements for quality assurance of breast cancer screening include:

- adequate information presented in an appropriate and unbiased manner in order to allow a fully informed choice as to whether to attend
- extensive quality assurance protocols for equipment and technical performance in conventional and digital mammography
- interpretation of screening mammograms by two independent readers
- standardization of pathology procedures and reporting
- standardization of data collection and monitoring
- comprehensive protocols for non-technical quality assurance
- nomination of a given professional responsible for overall unit performance and with the authority to maintain standards and outcomes by suspending inadequate elements if necessary

Further substantial improvement in breast cancer care can be expected from delivery of breast surgery in specialist units because the majority of breast cancer cases are diagnosed in women not attending screening programmes. Thus, high quality standards apply regardless of whether cancer is diagnosed in a screening programme or in a symptomatic setting, For example:

- Breast surgery should be performed by specially trained surgeons in specialist units providing a minimum of 150 primary breast cancer operations annually.
- Each breast surgeon should perform a minimum of 50 primary breast cancer operations per year.
- Clinical, imaging and pathology findings of all women requiring breast surgery should be discussed and documented in regular pre-operative and post-operative meetings of the full multi-disciplinary team (radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist)
- Patient support must be provided by specialist breast care nurses or appropriately psychologically professionally trained persons with expertise in breast cancer
- Continuous monitoring of outcomes and regular audit are essential for maintaining high quality

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