EBCC: Driving up standards in breast care

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The European Breast Cancer Conference set up by researchers, clinicians and advocates who wanted to co-ordinate their work and widen the fight against cancer to include the public and politicians. This year it took place under the shadow of the Clinical Trials Directive.

In 1998, three of Europe's leading organisations representing researchers, clinicians and women cancer advocates launched the biennial European Breast Cancer Conference (EBCC) to co-ordinate breast cancer research, educate primary care providers about breast cancer and sensitise politicians and women to the potential for progress.

These conferences are unusual in that they bring together, on an equal footing, researchers, clinical practitioners and women activists, and are oriented as much towards the public and politicians as towards professionals. Each EBCC issues a closing statement, which makes demands on national politicians, the EU and on clinicians and researchers.

They press for measures to improve the legal framework for research and treatment, the interchange between research and clinical practice and the management of services. They push ethical issues up the agenda, and introduce the patient view into debates.

The statements emanating from the biennial conferences carry great weight because of the authority of its three organising bodies:

- The Breast Cancer Co-operative Group of the European Organisation for Research and Treatment of Cancer (EORTC) – an important driver of laboratory and clinical research in Europe.
- EUSOMA (the European Society of Mastology) – the organisation that sets standards in the management of breast diseases, and helps clinicians and centres to meet the standards to become specialist breast units.
- Europa Donna – the coalition of breast cancer groups throughout Europe that represents the concerns and interests of women.

Both EORTC and EUSOMA promote translational research, seeking to move laboratory discoveries quickly into clinical trials and to minimise the delay between the development of effective anti-cancer therapies and their use in patient treatment.

Europa Donna has proved a powerful lobby, pressing authorities and governments for improvements. It played a key role in securing a strong resolution in the European Parliament, in June 2003, aimed at reducing cancer mortality by 25% across Europe – the first policy ever passed by that body on a specific disease.

The EBCC formula emerged from lengthy discussions in the early 1990s around the possibility of

extending the former EORTC Breast Cancer Working Conference.
The plans were finalised in June 1995, at a meeting hosted by Umberto Veronesi and attended by representatives of the three organising groups and the Federation of European Cancer Societies. It was a success from the first and has since grown in size and diversity. In 1998, Florence attracted more than 3,000 delegates from 74 countries. The fourth EBCC in Hamburg this year welcomed 3,599 delegates from 82 countries.

Focus on optimal care

Florence focused on the quality of treatment, demanding that all women should have access to multidisciplinary and multi-professional breast clinics. It also drew attention to the need for research to feed more quickly into clinical trials and treatments. By the time of the second EBCC in Brussels in 2000, the three societies had agreed guidelines defining the requirements for these dedicated breast units. The Brussels Statement called for all breast units to develop quality assurance programmes and to contribute to a common European database. It also called for mammogram screening to be implemented throughout Europe for women aged between 50 and 75, free at the point of delivery. The statement expressed early concerns about the future of European research projects. The Brussels Statement called for informed consent to be routinely obtained from all breast cancer patients for the use of frozen tumour specimens. However, the EU, driven in part by public disquiet about medical abuses, was pursuing a different agenda.

Research concerns top the agenda

Fast forward two years to Barcelona in 2002, and the third EBCC recognised "pan-European concern about the future of clinical and translational research for cancer in general and breast cancer in particular". The conference was presented with data about the steep increase in age-specific mortality from breast cancer between the war and the mid 1980s, followed by a significant fall in mortality between 1987 and 2000.
There was a consensus that around two-thirds of the reduction in breast cancer mortality could be attributed to improvements in treatment since the first trials of tamoxifen in older women and cytotoxic chemotherapy for pre-menopausal women.
The Barcelona Statement feared that European multi-centre trials, which were largely responsible for continuous incremental improvements in treatment, were under threat by "well meaning, but

Since its founding conference in Florence, 1998, the EBCC has gone from strength to strength. This year's gathering in Hamburg was attended by more than 3500 delegates from 82 countries

The 4th EBCC, in Hamburg, was chaired by Jacek Jassem, the dynamic head of Oncology and Radiotherapy at the Medical University of Gdansk. He is pictured here at the opening ceremony

misguided, bureaucratic challenges". Indeed, what the EU called 'good clinical practice' as applied to clinical trials, patient confidentiality and ethical issues would make trials difficult to conduct and prohibitively expensive.

Ethics Committees were tightening their interpretation of the Helsinki Declaration on ethical research to the point of threatening the recruitment of patients into trials. The statement said that unless Ethics Committees encouraged cancer research they would become obstacles to progress, "carrying equal responsibility for unnecessary loss of life in the future, as those clinical scientists who have abused the trust of the public in the past".

And so to the fourth conference in Hamburg in March this year, barely a month before the European Directive on Clinical Trials came into force. The Hamburg Statement – published in full on these pages – issued a clear warning: "Excessively rigid legislation, unjustifiable administrative restrictions and government budget cuts are threatening cancer research in general, and breast cancer research in particular." The EU directive was said to be especially damaging to research into surgery, imaging, radiation therapy and tailoring treatments.

There were calls for action. Karin Jöns, the European Parliament's standing rapporteur for breast cancer, who is herself a breast cancer survivor and President of the German Forum of Europa Donna, criticised the fact that only eight European countries currently offer nationwide mammography screening, and many of these are not in line with EU guidelines.

The need for screening was underlined by a controversy over self-examination. Professor Lars Holmberg, from the Uppsala Regional Oncologic Centre, Sweden, said that self-examination raised anxiety levels to no good effect and could be positively harmful.

He based his remarks on a Russian study, which found that women were reporting more benign lesions to their doctors without any reduction in cancer deaths.

Focus on age

Age-related issues were a recurring theme. The Institut Gustave Roussy in Villejuif, France, reported that women who carry the highly aggressive BRCA breast cancer gene are at no greater risk of relapse after treatment. The gene is associated with cancer in young women, who are prone to recurrence. However, the risk factor appears to be age, rather than genetics.

Dr Suzette Delaloge, assistant professor at the Institut, called for more research into why younger women relapse. Younger women who survive breast cancer can suffer long-term physical and psychologi-

cal after-effects. Dr Lonneke van de Poll-Franse from the Comprehensive Cancer Centre South in Eindhoven, in The Netherlands, said that 22% of younger women were having problems with unusual tiredness even ten years later, compared with only 4% of older women.

In general, follow-up care is not reassuring. Ingrid Kössler, President of the Swedish Association of Breast Cancer Societies, reported on a questionnaire returned by 600 women following treatment for breast cancer, which revealed that follow-up examinations were often hurried, with no opportunity to ask questions, express emotional concerns or talk about a woman's social situation.

She called for research into follow-up by specialist nurses.

It is not only young women who need special attention, but also the elderly. Professor Holmberg said that doctors were not trying hard enough to find suitable treatments for women aged 75 or older, who make up a quarter of breast cancer patients and who have a worse prognosis than younger patients.

The consensus session, chaired by Alberto Costa, where delegates vote on which issues to prioritise in the closing statement

"We don't know enough about attitudes among physicians; we don't ask elderly patients what they want; and we don't do enough specific trials for them."

Professor Silvio Monfardini, from the Division of Medical Oncology, Padova, Italy, agreed on the need for trials. "If this is not done we will discriminate against an already vulnerable group and deny us information on a very relevant part of the breast cancer population in Europe."

Targeting treatment on specific age groups is a step towards individual packages of care, which is the direction signposted by research. Dr Alane Koki, Chief Scientific Officer of the French biotechnology company, Ipsogen, said that significant progress was being made towards identifying the genetic make-up of individual tumours, allowing treatment choices that are based on personalised information.

Ipsogen has developed a breast cancer profile chip for use in local pathology laboratories.

Widening the fight

The next EBCC, in Nice in 2006, will be chaired by Alberto Costa, a breast surgeon from Pavia, Italy, and Director of the Milan-based European School of Oncology. At previous EBCCs he moderated the drafting sessions that developed the influential conference statements.

Dr Costa has a number of plans for Nice. He will invite experienced breast care nurses, to spread the concept of specialist breast care nursing beyond Northern Europe.

Dr Costa also hopes that some of the big cancer charities in Europe will attend, creating a forum for discussion on how to fund multi-centre, multi-national trials on breast cancer at a European level.

He said: "If we can include some of the major cancer charities in the Nice EBCC, it will strengthen links between those who raise money and the researchers and clinicians who need the funding to target treatment more precisely. If this led towards some national cancer charities combining resources to fund a major European cancer trial, that would be a fantastic step forward."

The Florence, Brussels and Barcelona Statements can be found on the Eusoma web site at www.eusoma.org
(go to Guidelines and Publications, EUSOMA Statements)

The Hamburg Statement

The partnership driving the European agenda on breast cancer

Breast cancer is the commonest cancer and the most frequent cause of cancer death in women throughout Europe. However, mortality from breast cancer is decreasing as a result of concerted action by all parties involved (women at risk, doctors, nurses, researchers, patients, journalists etc.). Partnership is paying off. Increasing numbers of breast cancer patients may nowadays achieve a normal life expectancy.

All previous European Breast Cancer Conferences produced Statements that became important tools in communicating with politicians and the media and we want to continue building upon this successful approach. Previous statements (Florence, Brussels and Barcelona) addressed the importance of screening programmes, translational research, patient involvement, risk assessment and the need for breast cancer to be managed in multidisciplinary clinics (breast units) according to the guidelines recently approved by the European Parliament. The 4th European Breast Cancer Conference in Hamburg reached a consensus on key issues during the closing plenary session on the 20th March 2004. Clinicians, scientists, advocates and health care consumers representing 3,599 participants used a computerised voting system to formulate the Hamburg Statement.

The delegates of the 4th European Breast Cancer Conference wish to give priority to the following four areas:

Academic research

Excessively rigid legislation, unjustifiable administrative restrictions and government budget cuts are threatening cancer research in general, and breast cancer research in particular. In addition, the new European Directive on clinical trials might exacerbate this by leaving cancer research almost entirely to the initiative of the pharmaceutical industry. Whilst not denying the contribution of those pharmaceutical companies engaged in new drug development, the participants in the 4th European Breast Cancer Conference are concerned that this situation will lead to a decline of non-pharmacological research (in surgery, imaging, radiation therapy, treatment tailoring etc.). This negative effect on independent academic research will also encourage even more gifted European researchers to emigrate to the United States to complete their studies and projects.

Participants in the 4th European Breast Cancer Conference call for a more determined financial and structural support to academic research, facilitation of the free circulation of tissue and blood samples within the European Union for research purposes, and a greater involvement of patients and consumers in research planning and monitoring. They also propose that funds originating from the EU central budget (e.g. a percentage of the current annual tobacco subsidy) are re-allocated to transnational research on breast cancer and also that private donations to breast cancer research are encouraged through the raising of the tax deductibility level currently imposed on such contributions in all Member States.

Individual risk assessment

Women increasingly want to know about their individual risk of developing breast cancer. All breast units should put in place special clinics for the assessment of individual risk and develop research in the field. Counselling should include a discussion of all proven risk-reducing measures, their availability within the relevant healthcare system and assistance in privacy protection. As risk-reducing interventions are being developed the issue of their availability, at no cost to the patient, should be addressed.

For women with a serious family history of breast cancer full genetic counselling should be offered and be made freely available, without cost, to the patient. Genetic testing, when indicated, should also be provided at no cost to the patient.

Age limits

Most diagnostic and treatment protocols and procedures in breast cancer have age limits, but evidence is lacking for most of these limits. The 4th European Breast Cancer Conference wishes to draw attention to the growing size of the elderly population and their special needs, and proposes that participation in clinical trials is decided according to physiological status rather than age and that no upper age limit is laid down in the design of standard prevention and treatment plans.

Care after breast cancer

The 4th European Breast Cancer Conference recognises the need to redefine the concept of care for breast cancer patients after primary treatment. Routine continuous follow-up, as currently practised, does not serve women well. Care after breast cancer should not just aim at detecting local relapse and second primary tumours but should also include psychological support and the management of treatment side effects. On the other hand, no consensus seems to exist on the duration and frequency of follow-up, nor on the schedule of requested examinations. For those patients treated outside a research setting, care after primary breast cancer treatment should be planned by the multidisciplinary team and individually tailored following discussion with the patient.

Conclusion

Breast cancer incidence is increasing, and deserves priority.

The four aspects addressed in this document – academic research, assessment of individual risk, breast cancer in the elderly and care after breast cancer – represent major issues in breast cancer management.

Research is fuelling progress, and clinical trials and translational research must be supported. Increasing knowledge of risk assessment should be translated into comprehensive individualised approaches.

Better care should be provided to elderly patients and breast cancer survivors.

The Breast Cancer Group of the European Organisation for the Research and Treatment of Cancer (EORTC-BCG) and the European Society of Mastology (EUSOMA), together with Europa Donna, the European Breast Cancer Coalition, will work towards these goals by lobbying European Governments, the European Parliament and the European Commission and by mobilising health-service providers, the scientific community and the healthcare industry. You are invited to spread this statement, and the proposals put forward in it, in order to further advance the improvements already made in breast cancer research, treatment and policy in Europe. The measures called for by EBCC-4 delegates will be reviewed at EBCC-5 to be held in Nice, France in March 2006.

The Hamburg Statement was published in the European Journal of Cancer vol. 40, pp. 1810-1811, and is available online at www.eusoma.org and www.fecs.be