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Editorial

State-of-the-art breast units — a possibility or a fantasy? A comment from the US

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In this issue of the *European Journal of Cancer* pp. 2288–2293, EUSOMA (the European Society of Mastology) provides a detailed protocol for the development and operation of a multidisciplinary breast unit [1], an idea they would like to see propagated throughout Europe. The breast centres would be audited and required to meet high standards in order to be certified.

At first, I questioned the wisdom of asking a non-European to comment on an idea conceived in Europe for Europeans. While I visit Europe often and participate in numerous international breast conferences, I do not live or work in Europe and I certainly do not understand the medical politics unique to each country and to Europe as a whole. If my words are offensive to any, they can be dismissed as the comments of a foreigner who simply does not understand the European system.

However, I may be a very rational choice to comment on this document. I started the first multidisciplinary breast clinic at the University of California in Los Angeles (UCLA) in 1973 [2]. In 1979, I designed and developed the first free-standing breast centre in the United States (The Van Nuys Breast Center, Van Nuys, CA) and served as its Medical Director until it closed in 1998 [3,4]. Following this, I was responsible for the establishment of the Harold E. and Henrietta C. Lee Breast Center at the Norris Comprehensive Cancer Center at the University of Southern California (USC) in Los Angeles and I am currently the Medical Director of this facility. So I have nearly 30 years of experience in the design, development, and operation of both academic and private breast care facilities.

The requirement of a Breast Unit is a quality assurance (QA) plan with the overall goal of improving breast care for women with both benign and malignant disease. The document lays out a plan for the design of state-of-the-art, multidisciplinary breast care units. The implementation of these units should result in an increase in *in situ* lesions along with a decrease in both the number and size of invasive cancers. There should be an accompanying decrease in nodal positivity, lower staging overall, more breast preserving surgery, and a marked reduction of more radical procedures, such as mastectomy or complete axillary dissection for patients in whom there will be no additional benefit. All of this should translate into more cures and less morbidity. The EUSOMA model forces doctors to work together, to talk with one another, to meet minimum training requirements, to perform a minimum number of procedures yearly (mammograms, surgeries, etc.), and to stay current by participating in continuing medical education. It covers all of the important components required to build a multidisciplinary breast unit and it sets minimum requirements for each. It guarantees that patients will be treated well and humanely. These goals are noble and admirable. The question is whether they can be achieved throughout Europe and is the EUSOMA plan the best way to go about it?

The protocol is quite rigid in structure and by intention, weak on methodology, with many details having been left to specific working parties in EUSOMA. In other words, the document focuses on the individual parts required to build a breast unit and the training required for those who work there. It does not deal with specific disease management problems; for example, when an axillary dissection is required, should it be one, two or three levels, or what to do about atypical ductal hyperplasia, or microinvasive breast cancer, etc? We are promised future documents which will detail the specifics.

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I showed the EUSOMA protocol to two of my colleagues here in the United States, both more 'liberal' than I. Each felt that the document was too rigid and could certainly not be implemented in the USA. They felt that it did not allow for individual judgement or legitimate differences of opinion and that it assumed absolute proof of all aspects of management. I did not see the document in exactly the same way. Rather, I saw it as a blueprint for what could be an ideal facility, but I saw its structure and requirements as simply too inflexible.

Obtaining consensus on structure, as difficult as that maybe, may be easier than getting consensus on therapy for difficult issues, such as ductal carcinoma *in situ* (DCIS), choice of chemotherapy, sentinel node technique, etc. I am concerned that the next step for EUSOMA will be a series of position papers that spell out exactly how to evaluate and manage every aspect of breast cancer. As these algorithms are developed, physician input will be less important and more of the management could actually be done by physician assistants and other non-physician personnel.

A word about the minimum requirements set out in this document: they are certainly not minimal. If the authors of this document were to site visit my own breast unit, at the USC/Norris Comprehensive Cancer Center, they would be impressed by an ultramodern, state-of the-art, privately endowed, physically beautiful facility that meets most but not all of the criteria set out in the protocol.

As an example, the protocol suggests that all screening be carried out as part of the breast unit. When we designed the Lee Breast Center at the USC/Norris Cancer Center, we did not have the space to screen large volumes of asymptomatic women nor did we see that as our mission as a cancer centre. Rather, the USC/Norris Cancer Center has historically acted as a tertiary referral centre for our community with the majority of patients with breast cancer first seen and generally diagnosed at other medical facilities before being referred to Norris for therapy and ongoing oncological care. So my current centre 'fails' because we have no formal organised screening programme. This in turn leads to the qualifications of our three radiologists, who do not read 5000 films each per year.

My previous facility, the Van Nuys Breast Center, which was truly a ground-breaking innovation, would also have 'failed'. The Van Nuys facility had virtually everything EUSOMA requires except for written protocols. We attempted this and found it impossible to achieve because of legitimate differences in clinical opinion. One of our reconstructive surgeons felt the transverse rectus myocutaneous free-flap with microvascular anastomosis was the reconstruction of choice, another did not; one of our medical oncologists had broader indications for chemotherapy than the other; one of our oncological surgeons believed in three-level axillary node dissection as routine practice, the others did not, some of our oncological surgeons were more aggressive breast savers than others some of our doctors routinely employed induction (neoadjuvant) chemotherapy and others did not, and so on. All aspects of every patient's care were discussed and reviewed at our patient care conferences, but the ultimate treatment decision was not mandated by the group. Rather, it was made by the patient in concert with her family and her doctors.

For the protocol that we are discussing to be successful, it will have to be accepted by all of the European countries that are members of EUSOMA and I think that is unlikely. The document does not take into account the differences in practice, from country to country. Applying these concepts all over Europe will prove difficult. While I think that it is a reasonable idea to set standards, an inflexible system may suppress competition and perhaps even innovation.

During my 19 year tenure at the Van Nuys Breast Center, which was a centre organised very similarly to the breast units described by EUSOMA, there were hundreds of visitors from just about every state in the USA and from more than 20 foreign countries. Most marvelled at the integrated multidisciplinary nature of the facility and left saying that they were going to create a similar breast centre at home. But whenever a visitor communicated with me a year or two later and I asked whether they had been able to set up a breast facility like the Van Nuys Breast Center, the answer was uniformly no. When I asked why, the answer was always the same: political and financial problems. Physicians who were not part of the new centre felt that they would lose their patients and they did all they could to block formation of a breast centre. If a centre was started and it included all physicians who wanted to participate, there were generally so many physicians involved that each individual physician saw very few patients with breast cancer. With a large number of physicians participating on a rotation, it was very difficult to control patient treatment in a standard fashion. In addition, the treatment might be different, depending on the physician on call. In the USA, it was and still is exceedingly difficult to develop a truly multidisciplinary breast centre and to mandate the way it operates. I suspect the same will be true in Europe.

The document as written calls for protocols for the management of all stages of disease. How will this be done? Consider DCIS as an example. In 1997, a consensus conference regarding the pathology of the disease was held in Philadelphia [5]. No agreement could be reached on a unified classification for the disease. Two years later, a second consensus conference was held, this time to discuss treatment. Again, no uniform agreement could be reached [6]. Because breast cancer is a heterogeneous group of lesions, as the current cliché goes,

written protocols for the management of all stages will be extremely challenging.

Who should tell the patient that she has breast cancer? I certainly do not think that it always has to be a surgeon. Relationships are important. Often the physician with the best relationship with the patient may be the most appropriate. In my own facility, a surgeon does it commonly, but often it may be the medical oncologist or perhaps the radiologist if he/she has developed a relationship during the stereotactic biopsy. Not uncommonly, the general physician, the doctor who has a longstanding relationship with the patient, has already told the patient that she has breast cancer prior to making an oncological referral. It is difficult to mandate, in a document, who should tell the patient. On this point, the document is clearly too unyielding. Common sense should apply.

Who should discuss and decide adjuvant therapy? Clearly the doctors who prescribe adjuvant chemotherapy therapy should do this. This may vary from centre to centre, and it will certainly vary from country to country.

There are many small items within the document that can be scrutinised. Must a radiologist do 5000 mammograms a year? Would 4000 be sufficient? Must a surgeon do 50 cases per year? What if he/she does 100 but does them all wrong? How will new technology, like sentinel node biopsy, be incorporated? Will it be mandated throughout the system? Will some centres use it and others not?

One of my colleagues stated that the major defect with this protocol was that it focused on the structure of a multidisciplinary breast service, but not on the goals. The structure proposed by this document is comprehensive, state-of-the-art, but inflexible. With an excellent structure, obvious goals like improvement in stage, more breast conservation, better breast cancer-specific and overall survival, etc. should follow naturally. Working toward those goals, though, may require a great deal more flexibility than this document currently permits.

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