Viewpoints and debate

Health economic decision making in Europe – a new priority for breast cancer advocacy

Susan Knox*

Europa Donna – The European Breast Cancer Coalition, Piazza Amendola, 3, Milan 20148, Italy

A R T I C L E  I N F O

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A B S T R A C T

The lay public, patients and advocates are not usually aware of how decisions are made by health systems, insurers, or governments concerning the availability of medicines provided through national health systems. Today a variety of health economic analyses are undertaken to determine if a particular therapy is cost effective and meets specific criteria to be covered under the national health service programmes. This decision making process is complicated, and in some countries the methodology used is not transparent; these decisions are not adopted in the same way in all countries and often there is no communication or approval required by the public or patient representatives. This is not acceptable from the patient’s perspective as effectiveness must remain the criteria and these decisions must be understood and shared in such a way that all stakeholders agree on guidelines for the approval and delivery of new medicines. Other solutions that impact cost need to be explored – new methods of raising funds for research, public health prevention programmes to reduce the burden in future years and increasing health budgets by taxing items that contribute to the cancer burden such as tobacco and alcohol.

The overriding mission of European breast cancer advocacy is to ensure that all European women have information on and access to state-of-the-art early detection, diagnosis, and treatment of breast cancer. Europa Donna – The European Breast Cancer Coalition is advocating to see that all European women gain access to services carried out according to the “European Guidelines for quality assurance in breast cancer screening and diagnosis” and that these should be provided by the national health systems of each country. This of course includes immediate access to new treatments and medicines that are developed and proven effective in treating breast cancer.

Current debate and discussions about new breast cancer therapies are focusing on health economic and cost effectiveness concerns with regard to breast cancer treatment. Advocates need to be aware of these aspects and understand them, as they potentially pose a serious threat to ensuring that women receive the best and most effective treatment available. Equal access to best practice is what all women should have a right to, but it is not a reality across Europe today.

Efficacy and cost effectiveness are being evaluated today by health economists, health systems and insurers using various criteria. How much may be spent or even the decision to introduce a new treatment today to extend a patient’s life or save it varies greatly from country to country. Governments and health care systems use various methods for evaluating whether or not to introduce and pay for a new treatment such as cost effectiveness analyses (CEAs) and rationing; quality adjusted life years (QALYs) are used in cost utility analyses to calculate the ratio of cost to QALYs gained for a particular health care intervention. Acceptable thresholds of cost effectiveness are then established, varying from country to country.¹ Health technology assessment (HTA) units have been established in many EU countries to evaluate new treatments and health technologies; however, they have not been set up or configured in the same manner as there are no European wide standards for their development or conduct. While there are several models reflecting best practice, for the most part there is little transparency concerning their activities, and few involve the public or patient advocate stakeholders in the process.² The consumer must beware; these exercises may be valuable, but their design and how they will be used needs to be carefully monitored and studied. Design and interpretation of the data can vary greatly; various models, sensitivity analyses and quality of life adjustments may be employed in different ways resulting in different outcomes when done by different entities, i.e. industry, insurers, health systems or non-profit organisations.³

Health economic models provide important tools for analysis and comparison of treatments available, but patients need to

* Tel: +39 2 3659 2280; fax: +39 2 3659 2284.
E-mail address: susan.knox@europadonna.org

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understand to what degree decisions are dependent on these parameters. While the European Medicines Evaluation Agency (EMEA) has a centralised procedure for market authorisation, each country then negotiates its own price to offer a given therapy and decides whether or not to provide it. The methodology used and the negotiation taking place in each government cannot be easily scrutinised by the public. The rationale behind these decisions is not always transparent or clear and the amount paid for a particular therapy is not the same from country to country. The public rarely understands how these decisions are reached and who makes them.

Pharmaceutical company profits, income forecasts and budgets are impacted by these decisions; this is a reality that must be considered for industry investment to continue in drug development. These areas are problematical and complex but need to be understood and discussed openly. Industry should be transparent concerning pricing structures and should be pro-active in price adjustment and negotiating prices so that new therapies introduced are economically viable for the health systems that must pay for them.

Furthermore, there is growing concern that paying for a new breast cancer treatment means cutting funds to provide treatments to patients with other diseases or other types of cancer. The concept that financial resources will get distributed differently thus creating competition among disease groups or professions for funds is unacceptable. It is essential that when a therapy has been proven effective it is made available to patients. This may mean that more funds for healthcare have to be allocated from national budgets by reducing spending in other areas or increasing taxes on such items as tobacco and alcohol. Citizens and voters, which include patients and their families, certainly want and have a right to the best health services possible. They are key stakeholders who should be involved in the decision-making process that will have a direct impact on their lives and their health.

The challenge is before us: as people live longer and as care and treatments become more complex and expensive, who will pay for them? Patient advocates need to begin addressing these issues and make this a key priority: they need to become informed, and involved in these debates; they need to understand how decisions are being made concerning drug pricing, and what the determining factors are in making a new therapy available. They need to explore why one country pays more than another even in the EU and why some countries will cover the cost of some drugs while others will not. These decisions have significant ethical implications and consequences. If a drug is too expensive will only the rich be able to afford it? How should physicians react when faced with knowledge of an effective therapy, not available in his or her country or his or her region of a country?

Looking toward the future: given increasing life expectancy, the cancer burden is estimated to increase dramatically in 20 or 30 years. How will the health budgets cover the increased expense of providing all the treatments that are proven efficacious? The outlook for the future may not be as negative as currently projected. As more is understood about prevention and early detection, it may be possible to contain or lower the cancer burden in future years through appropriate education, particularly educating the public and girls and women at young ages concerning risk factors and the importance of attendance at screening. They need to be aware of the impact that lifestyle choices concerning nutrition, obesity, physical exercise, and environmental factors have on breast cancer incidence and health generally. Investments need to be made now in major public health education programmes as well as dedicated health services for high-risk women.

New diagnostic techniques, research findings and increased coverage and uptake in screening, will result in fewer people needing costly treatment. The MINDACT trial is an example of a research project that is attempting to identify people who will not require chemotherapy. Independent academic research, particularly collaborative preventive research, is needed to ensure that more studies are undertaken in areas that might result in savings but might not be of interest to the pharmaceutical industry. Current estimates indicate that it costs 1 billion dollars to bring a new drug to market; methods must be sought to contain this upward spiral. As public funding is stretched to its limit new joint endeavours including academic institutions, industry, and major philanthropic organisations may need to forge new partnerships to share cost.

Only through the ongoing collaboration and partnership of all the groups involved will a satisfactory solution emerge. Researchers, medical professionals, politicians, health ministers, health economists, industry and advocates will need to join together to seek the best solution for the patients of Europe with regard to health economic issues. Just as the concerted effort of numerous European organisations produced the European Guidelines for quality assurance in breast cancer screening and diagnosis, these partners along with others, should work together on this issue and incorporate their views into the EU guidelines.

The human dimension must remain central; there is a face to each and every diagnosis of breast cancer, an individual with a family – a life that needs to be lived and a life that needs to be saved using every means available to us. The value of this is incalculable and cannot be reduced to a statistic or a formula; there is no adjusted quality of life year that can measure what a life is worth to the individual, to a family, or to society.

Breast cancer advocates need to keep a close watch on the health economic decision-making process utilised in each country setting and become a part of this important process which ultimately will have an impact not just on patients, not just on women, but on all citizens.

References
5. TransBig Project Summary September 2004.