Wednesday, 16 April 2008 10:30–12:30

KEYNOTE SYMPOSIUM

Can we walk away from economics?

1 Invited

Can we afford the future: effectiveness or cost-effectiveness as the criterion for introducing new therapies for breast cancer?

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Most European countries (and Canada) have socialized health care that uses a form of cost effectiveness in organizing and paying for hospitals, health professionals and diagnostic procedures; the goal is to encourage appropriate distribution of health-care resources to their populations. In contrast, market forces largely control the cost of drugs. The approval of new therapies is based on demonstration of improved outcome (of undefined amount) to regulatory authorities, and in some countries on demonstration of cost-effectiveness; however pricing is based mainly on maximizing profit, especially for the USA where approval does not consider cost. The decision to assign a high price for a limited market versus a lower price to allow broader access is not based on maximizing clinical benefit – quite contrary to the philosophy behind funding of public health services in European countries.

Arguments for approving drugs based only on effectiveness include: (i) the profit motive is a powerful incentive to encourage investment in the development of new therapies; (ii) individual patients and/or physicians, insurance companies, public health providers, and even countries can make their own judgments about benefit relative to cost; (ii) cost is not stable and an expensive drug today will become more affordable; (iii) drug pricing is driven by the US market and attempts to control pricing might lead to non-availability of a drug in a particular country or region.

The argument in favour of using cost-effectiveness is that it allows limited health care resources to be distributed more equitably: new therapies which lead to small improvements in clinical outcome will be priced more cheaply than those that cause dramatic improvements. With the caveat that "cost effectiveness" must allow for the increasing costs of drug research and development, I favour cost effectiveness for approval of new agents. With a cohesive policy, wealthy countries with publicly funded health care systems (such as most of Europe) have sufficient impact on the market to ensure fair pricing of new treatments. Also, enforceable guidelines for proper use of new therapies can lead to equitable cost savings without harm, and these large cost savings would readily support many other interventions in the same country. I will review examples of how this might have influenced pricing of recent new therapies for breast cancer including aromatase inhibitors, trastuzumab, bevacizumab and lapatinib.

Regardless of which method is used to introduce new therapies we (meaning at least selected women in wealthy countries) will afford the future, because no company wants to develop a product that is too expensive to sell. However requirement for cost effectiveness as a basis of approval will ensure wider availability of new therapies.

A related question is "Can we afford the present?" While most women in Western Europe and North America have access to treatments that have a substantive influence on duration and quality of survival, this is not true for women in developing countries. If a goal of ESMO and EBCC is to promote optimal treatment for all women with breast cancer then one strategy would be to link the approval process and pricing for new therapies in wealthy countries to the provision of such therapies to patients in countries that cannot afford them.

2 Invited

The company's view

Abstract not received.

3 Invited

Coping with expensive drugs around the world

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Background: Breast cancer (BC) treatment is the most drug intensive area in oncology. There is a high cost of illness linked to BC and the prevalent population of BC patients has increased substantially over the last decades, closely linked to improved early detection and adjuvant treatment. Adjuvant medical therapy plays an important role in the curative treatment of early BC, EBC. The same drugs are also corner stones in the treatment of metastatic BC, MBC. Over the last decade several new drugs have been introduced. These include the 3rd generation aromatase inhibitors, AIs (anastrozole, exemestane and letrozole) as well as the monoclonal antibody trastuzumab, T. Both AIs and T now have regulatory approval for both MBC and EBC. There are also a number of cost effectiveness studies published, documenting the cost-effectiveness, particular for EBC. This report focuses on the introduction and level of use of AIs and T on a global level.

Materials and Methods: We have used sales data from IMS Health, epidemiological data from IARC and local cancer registries as sources for our analyses to describe up-take and use in relation to epidemiological factors. We have also performed extensive desk research in order to evaluated regulatory procedures, Health Technology Assessment procedures (HTA), reimbursement processes, as well as central and local factors that may influence introduction and up-take.

Results: Our studies have so far included 35 countries on all continents with the exemption of South America. This presentation is focused on data from Australia, Canada, Denmark, France, Germany, New Zealand, Norway, Sweden and the UK. In these countries there are large differences in rate of uptake and level of use of these drugs over time despite similar economic and social conditions. Differences in the rate of uptake and level of use are in the range of factor 4−5 with respect to use per capita or per case of MBC. None of the drugs has yet reached a plateau level with respect to use. In most of these countries, but not all, there has been a distinct increase of the level of use in relation to approval for EBC, both for AIs and T. The rate of uptake and level of use is closely linked to central authority evaluations in many countries (Australia, Canada, New Zealand and the UK). The impact of these decisions seems to influence the rate of uptake and levels of use, but do only explain part of the variation. Economic factors are important for the rate of uptake and level of use, specifically the presence of specific funding mechanisms, but we cannot see any systematic relation between evidence of cost-effectiveness and uptake as well as level of use.

Conclusions: Medical evaluation, time point and process (local vs central) of regulatory approval, HTA procedures, and reimbursement decisions, as well as central and local funding impact uptake and over all use of aromatase inhibitors and trastuzumab. However, the major part of the observed variations is unexplained, indicating that we still lack a rational approach how to cope with new expensive drugs.

4 Invited

The society's view

Abstract not received.

5 Invited

The patient advocate's view

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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, screening, and treatment of breast cancer. A main objective of Europa Donna-The European Breast Cancer Coalition, has been to establish advocacy groups in all the countries of Europe to ensure that up to date, factual information and education concerning breast health and services are provided to women everywhere. Advocating for guidelines for screening and best practice, including provision of breast services in specialist breast units, has been our priority in recent years, and in 2006 the EU published "European Guidelines for quality assurance in breast cancer screening and diagnosis". 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.

Health care systems use various methods for evaluating the effectiveness of treatments. However, the idea that paying for a new breast cancer treatment means cutting funds to provide treatments to patients with other diseases is an argument that is raised continually and needs to be fought by all patient advocacy groups. The concept that financial resources will get distributed differently thus creating competition among disease groups for funds is unacceptable; if a therapy is effective it should be made available to patients. Society, the public at large, which includes patients and their families, has a right to the best health services possible. Health economic analyses using QALY (quality-adjusted life year) represent important tools for analysis and comparison of treatments available, but patients need to understand to what degree decisions are dependent on these parameters. Industry should be transparent concerning pricing structures and should