

LETTER TO THE EDITOR

The economic crisis and cancer chemotherapy: the role of the oncologist

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The world economy is experiencing the worst crisis since the Great Depression of the 1930s, and many countries have difficulty resolving problems such as poverty, hunger and disease. The costs of healthcare, and in particular cancer care, place an enormous burden on patients, their families and governments both in the United States and Europe, where the national expenditure for the treatment of cancer is steadily increasing. The annual costs of cancer care in the United States are expected to rise from \$ 104 billion in 2006 to over \$ 173 billion in 2020¹. Sales of drugs against cancer are second only to those of drugs for heart disease. Seventy percent of these sales come from products introduced in the last 10 years and most of the new molecules are priced at \$ 5,000 per month or more, with cost-effectiveness ratios in some cases far exceeding commonly accepted thresholds; this trend is not sustainable¹. In Europe the trend of rising costs is similar: the estimated proportion of healthcare costs associated with cancer is 6.5%, which is consistent with the estimated 5% in the United States².

Public resources in oncology are distributed at 3 levels: macroallocation, mesoallocation and microallocation. Macroallocation refers to the resources a nation devotes to healthcare; mesoallocation refers to strategic choices, such as the way in which a hospital budgets its spending; microallocation focuses on treatment decisions regarding particular patients³.

In Italy the National Health Service provides healthcare to all citizens. The Italian public health system is structured as follows: the governments of the 21 regions are responsible for the management of services, while the national government through the Ministry of Health provides financial resources to the regions and for health policy planning. The financial management of Italian healthcare has deteriorated over the last decade because the regional healthcare expenditures have not always been controlled. This has resulted in a cumulative deficit of over 38 billion euros, about 4.2% of the total expenditure for the period⁴, despite the repayment plans of the national government. At this point, given the severe economic crisis of the national government (macrolevel) and the resulting reduction of resources available to the regions (mesolevel), the role of hospi-

tals, and thus of oncologists (microlevel), is increasingly important. It is evident that the role of the oncologist becomes decisive when financial resources are contracted. The only way of action is to pursue therapeutic appropriateness, ideally with strong support of a hospital ethics committee that adheres to the same philosophy and keeps in mind the necessity of cost savings.

There are few experiences that quantify the foregoing, but we believe it is crucial to respect patients' right to demand care and at the same time their dignity. It is well known that the results obtained in pivotal clinical trials are often not reproducible in the general patient population^{5,6}. With regard to an intervention at the local microlevel we suggest another role for the hospital ethics committee. With the introduction of a new drug, regardless of the verdict of the EMA (European Medicines Agency) or AIFA (Agenzia Italiana del Farmaco), assessment by local mini-HTA (Health Technology Assessment) is necessary. This may give the oncologist indications as to which subgroups of patients gained the most effect from the drug in the pivotal study. The oncologist can then select those patients who are most likely to benefit, so that the proposed treatment will be as appropriate as possible. An example where this approach might be useful is the extensive discussion about the cost-effectiveness of ipilimumab in metastatic melanoma⁷, where the hospital ethics committee may indicate to the oncologist the patient subgroups in which the drug was demonstrated to be most effective. Another type of intervention at the microlevel is exemplified by our experience at the Istituto Oncologico Veneto. We have examined new drugs included in the AIFA register and found that a considerable number of patients stopped treatment within 3 months (38.1% of 856 patients received only few drug administrations and their treatment was stopped within 4 or 12 weeks)⁸. This analysis has been brought to the attention of those in charge, so that greater attention is now being paid to the inclusion of patients with characteristics similar to those of the pivotal studies. With these type of interventions, where the oncologist does not decide alone but is supported by guidelines defined by local ethics committees or specific HTA, the appropriateness of therapy can be improved and consequently the costs reduced.

We hope that, if there is awareness that the microlevel decision-making is strategic in the allocation of resources and good practice, at the macrolevel decisions such as "raise the bar of efficacy for drug approval"⁹ will not be taken and therefore there will not be any reduction of new drugs available to the oncologist.

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