Allocation of public sources in oncology: which role can ethics play?

By 2008, anticancer drugs will be the leading therapeutic area in term of sales. This appraisal has been done by the Intercontinental Marketing Services (IMS) Health [1], a provider of business intelligence and strategic consulting services for the pharmaceutical and ‘health care’ industries. Oncology, considered a niche sector just a few years ago, will reach a business volume of 41 billion dollars in 2008 compared with 24 billion dollars in 2004. The economic aspects will increasingly restrict access to new and expensive oncological drugs (e.g. Targeted therapy as monoclonal antibodies and angiogenesis inhibitors) in different health care realities.

A report by the Karolinska Institutet [2], in conjunction with the Stockholm School of Economics, exposes current stark inequalities in patient access to cancer treatment across Europe. The report found that patients across Europe do not have equality of access to new cancer drugs and the speed at which patients can benefit from them depends to a great extent upon the country in which they live. The report also argues that while new therapies generally increase health expenditure, they also contribute to survival and treatment of cancer patients.

Besides, as reported in the previously cited study, it should be considered that the share of health care expenditure allocated to cancer (5%–7%) is now significantly lower than the share of the burden of the disease (accounting for 17% of all Disability-Adjusted Life Years). Health care costs for cancer are dominated by costs for inpatient care, with drug costs accounting for <10% of total health care expenditure for cancer. A matter of concern is that the introduction of new innovative cancer drugs will result in an increase in the costs of cancer drugs, both in absolute terms and as a share of total health care costs.

This out of hand boost and a lot of other social and economic factors (such as getting older, having fewer children and working without a fixed income) impose an ‘expenditure rethinking’ which, however, cannot be only a saving cost instrument but should take into account results and consequences of future allocative choices and should respect a complex value system. In fact, more than any other branch of medicine, Oncology involves life and death decisions and many possible treatments have an amount of uncertainty. In this perspective, important questions emerge: how to face change? Should economic evaluation be integrated with ethical evaluation? Is this achievable?

Since ~75% of pharmaceutical expenditure is publicly reimbursed in Europe, pharmaceuticals have been subjected to a wide range of pricing policies. Ess et al. [3] have recognized the following three types of pricing policies as important strategies: direct control of product price, indirect control of product price and profit control. The direct control usually combines several criteria: the therapeutic value of the drug, the references to existing products or to international comparisons and the contribution of the pharmaceuticals to the economy. The indirect control consists in reference pricing (to adopt a ceiling reimbursed price) and generic substitution (to encourage the use of cheaper drugs because without patent). In the profit control, companies must provide accounting and economic information to justify the price proposed. Notwithstanding, all these strategies could not slow down public expenditure on pharmaceutical products.

Another potential strategy for cost savings could be to minimize inefficient use of pharmaceuticals. However, Schwartz and Mendelson [4], already in 1994, estimated that potential savings from the reduction of inefficiencies in the acute care sector fall short of administration’s cost containment. On the one hand we can assume, therefore, that pricing policies and attempts to eliminate waste and inefficiency can do little to contain costs.

On the other hand, as Zweifel et al. [5] illustrated, an initial decision to allocate more resources to health may be like ‘Sisyphus’s work’ (in Greek mythology, he forever repeats the same meaningless task of pushing a rock up a mountain, only to see it roll down again). Similarly in health care, the likely consequence of source increase is an additional number of survivors, who will exert new demands for health care. With more resources allocated to health, the cycle starts over again. Nevertheless, a regulatory approach, in terms of pricing regulation and efficiency adjustment, should be still adopted but joined with a different perspective that is the rationing approach.

In the next paragraphs, we will try to discuss the ethical dimension of health care rationing and to illustrate other ethical instruments to face allocation of public sources in Oncology.

Each allocative choice can be made at three levels: macro-, meso- and microlevel. Macroallocation includes the amount of resources a nation devotes to health care. Mesoallocation refers to strategic choices, for instance the way a hospital budgets its spending. Microallocation (the so-called bedside rationing), instead, focuses on treatment decisions regarding particular patients [6].

Generally speaking, rationing is the controlled distribution of scarce goods or services in order to provide all consumers with a certain quantity of the goods and services by meeting the most important needs and avoid price increase but the meaning of rationing varies considerably in the literature. In
particular, there has already been much debate on health care rationing definition and meaning. For our purpose we have decided to use Ubel and Goold [7] definition of health care rationing, whereby rationing encompasses any explicit or implicit measures that allow people to go without beneficial health care services.

Explicit rationing defines the criteria for exclusion of services and the standards of care. Intuitively, pros of this approach are transparency, consistency, less conflict of interest for physicians, less strain on physician–patient relationship, simultaneous control of quality and cost of care and definition of priority setting (e.g. urgent needs). Cons are the loss of discretion for physician, political obstacles and influence of interest groups.

Implicit approach uses budgets and financial incentives, often creating situation of unsustainable conflict of interests. On the whole, the implicit approach is simpler to apply but it is strongly influenced by emotional and political pressures.

From the ethical point of view, explicit rationing should be preferred because of prevalent ethical reasons but, mainly for pragmatic motives, implicit rationing is unavoidable. On the other hand, health care cost containment, especially in Oncology, is perceived as a concrete moral issue which evokes fundamental values [8], such as justice, fairness, the priceless dignity of each individual patient and the therapeutic covenant [9, 10].

A European survey [11] has shown that, while doing bedside rationing to forgo medical interventions, physicians apply personal criteria which are essentially based on ethical values (e.g. concerns for the quality of life).

Therefore, giving the prevalence of rationing in public health care service, the bedside approach seems to be insufficient to control cost increase but individuating a just allocation of sources appears a common need. Besides, even if the rationing process shows an ethical dimension, it seems to require some additional instruments in order to adequately face the scarcity of public health care funds.

The role of bioethics can be performed at the following several levels: microlevel, mesolevel, integration between micro- and mesolevel.

At microlevel, an important instrument can be the ethics consultation, that is a process by which trained consultants or a Hospital Ethics Committee respond to requests for help to solve ethical conflicts, issues or questions involving patient care. An ethics consultation is advisory. Patients, family members and health care providers remain responsible for their own decisions.

Hurst et al. [12] have shown that, in solving ethical difficulties in medical practice, physicians entertained competing goals that they did not always successfully achieve and additionally the means employed were not always the most likely to achieve those aims or to avoid moral problems along the way (valuation of the behavior of general internists, oncologists and intensive care specialists; n = 344, response rate: 64%). Besides, the survey cannot demonstrate the ethical appropriateness of the actions that respondents took because they could present only a single point of view regarding the described dilemma.

These results indicate that ethical dilemmas in the clinical practice are often unsolved because of the lack of appropriate skills to be applied in case of controversy. Physicians tend to avoid ethics consultation, which is often an unknown possibility or it is perceived as the last resort rather than a primary source in cases of ethical difficulty.

Instead, considering that the bedside rationing is an unavoidable process, a bioethical sensibility should be improved also by taking into account that the use of ethics consultations has been associated with reductions in hospital days and treatment costs among patients who had not survived after hospital discharge. On the other hand, consultations can resolve conflicts that would have inappropriately prolonged nonbeneficial or unwanted treatments instead of focusing on more appropriate comfort care [13].

Nevertheless, some questions arise: can ethics foster a fair and inclusive decision-making process that honors patients/proxy preferences and individual and cultural value differences among all the parties in the consultation? Are ethics consultations worthwhile? The answer can be positive if the following three conditions are respected: (i) ethics consultants should have competence both in medicine and ethics; (ii) they should be influential persons for the medical team and (iii) they should be easily available [14–16].

On the whole, ethics consultation could be a concrete instrument to join essential values and economic issues, especially when the process of consultation is performed by Hospital Ethics Committees which can fulfill better the previously cited conditions because of their multidisciplinary character.

At mesolevel, the Hospital Ethics Committees can help the Hospital Health care Management Department (the mission-oriented Department concerned with improving the health care system in the hospital by taking strategic decisions as regard to health policies and the allocation of funds), using their competences to indicate working indications in the course of rationing and allocation process. Besides, using the concept of organizational ethics proposed by Thurber [17] (that is to enhance the overall ethics of an organization with the goal of changing the climate and then the culture of the organization), bioethics can also reach a broader and lasting mesolevel.

Besides, attention should also be devoted to integrate microlevel with mesolevel. In fact, the mesolevel can guarantee an explicit rationing, which, as previously illustrated, is ethically justifiable. The challenge for the future could be to improve the development of internal guidelines, shared with the Hospital Health care Management Department, in order to achieve common clinical practice. The Hospital Ethics Committee should support this activity, drafting ethical guidelines on critical aspects, for example end of life decisions, and coordinating multidisciplinary groups. In this way, the rationing process can become a collaborative process which could be useful to emphasize the positive dimension of rationing.

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