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LETTER TO THE EDITOR

Pitfalls and controversies of guidelines in oncology

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Over the last years research in oncology has generated a proliferation of information that has made it difficult to make clinical decisions on the basis of the available scientific findings[1]. Since the 1980s the extensive development of guidelines has aimed to supply recommendations useful for the clinical practice. This need became critical when the resources for oncology were found to be limited and evidence-based medicine was established[2]. On the other hand, the development of guidelines is essential on the basis of other considerations. The benefits resulting from the proper use of guidelines have improved the quality of health care and patients' health status. A pre-established diagnostic-therapeutic pattern removes useless or unnecessary procedures and reduces waiting times, mean hospital stay and, therefore, health care expenditure. Guidelines are a useful tool for the young resident oncologist who benefits from an ethical guide that complements his/her own experience and provides patients with the assurance of proper medical treatment. The patient feels more protected and safeguarded and not at the mercy of the physician's personal decisions. Uniformity of procedures allows the patient better to approach his/her discomfortable situation. Moreover, guidelines may be useful for the evaluation of the physician's responsibility: indeed, guidelines are drawn up by specialists selected by scientific societies or groups of oncologists and are based on an objective evaluation of the relevant literature. Guidelines are designed to evaluate objectively the conduct of the physician, even at the forensic medicine level[3].

The main characteristic of guidelines is their consistency: the recommendations should be consistent with the literature and aim at identifying interventions which ensure the best possible results. The development of guidelines involved an increasing number of multidisciplinary specialists who have supported their adoption in the various medical areas[4]. The need for applying a specific working methodology compelled the experts to justify their decisions on the basis of scientific data. The objective was to systematically mine the available clinical studies, preferably controlled and randomized, because the strength of the recommendations depends on the quality of the scientific evidence.

Guidelines are divided into two major classes: evidence-based and consensus-based. The former have more scientific strength because they are based on the level of evidence emerging from a systematic review of clinical studies. The latter have less strength because they don't depend so strictly on the level of evidence; instead, an authoritative team of experts considers different factors including the available professional figures and diagnostic/therapeutic tools as well as the level of experience of the operators who will adopt the guidelines[5].

The unavoidable globalization of the health care system has required clearer guidelines with a precise and simple terminology that can be easily consulted in the daily medical practice by referring to flowcharts or written statements. Evidence has shown that the recommendations are more likely to be adopted in the clinical practice when the strategy of their dissemination is more active and aggressive. Guidelines should not only be published in scientific journals but also be promoted through conferences, by arranging *ad hoc* workshops and information meetings for small groups, as well as by using information networks.

The final step of guideline development consists of the most modern evolution theories, i.e., it belongs to the earliest steps of modern science and Galileo Galilei should be systematically monitored to verify if their introduction has achieved the expected results. Concomitantly, periodic review should be carried out and it should be followed by such changes as new scientific findings or the development of new technologies may require.

However, guidelines have come to a standstill at the height of their success. The dogmatic behavior in some areas of oncology has converted these recommendations into rigid rules and made their practice similar to the initiation rituals of certain sects. As a result, the guidelines

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are kept and defended. Like in medieval congregations, they are considered the holders of truth having the right to defend the truth until it is concealed to the community[6]. The reasons for this attitude are the following. Firstly, the competition with the new rules of the business world, which necessarily affect decisions on cancer care, is experienced as a kind of intrusion by some scientists[7]. Secondly, extensive insurance coverage for malpractice has resulted in increasing litigation (the new goose that lays the golden eggs). This has led to the application of defensive medical practice, where guidelines represent a means of defence[8].

The guidelines' characteristics of flexibility and adjustability to different clinical practices should be coupled with the rigid and pre-established conduct schemes deriving from evidence-based medicine. This demonstrates the complexity and difficulty of generating and developing guidelines. However, since the benefits resulting from this activity improve the quality of health care and patients' health status, we hope that oncologists will be able to cope with this challenge.

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