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EDITORIAL

Health technology assessment: for whom the bell tolls?

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One of the oldest definitions of Health Technology Assessment (HTA) was given in 1985 by the Institute of Medicine in USA: "*Any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences whether intended or unintended*" [1].

It is worth noting that the term health technology does not refer only to drugs, medical devices, and equipment, but involves any intervention related to prevention, diagnosis, therapy, and management of disorders [2, 3]. A recent, even more comprehensive definition has been developed by the International Network of Agencies of HTA: "*HTA is a multidisciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion, and use of health technology*" [4]. This clearly states that the primary objective of HTA is to provide policy makers with reliable, documented information on the effectiveness, consequences, and costs of health-care technologies [5]. Therefore, a vital component of HTA is documented, internationally recognized competence in economic evaluation.

In general, HTA can be considered a "melting pot" of different disciplines dealing with various and somewhat contrasting needs [6]. Experts may include epidemiologists, economists, physicians, pharmacists, and health-care managers, brought together under the umbrella of public administration guidance. Since HTA activities often tend to be untargeted, uncoordinated, and without priorities [7], each country should appoint one organization of reference according to European directives [8].

The expected outcomes are recommendations bridging evidence-based medicine, economic evaluation, the experience of professionals, patients' expectations, and the capabilities of national health-care systems [3, 9, 10].

It is not clear whether HTA has developed so fast "because of" or "despite" its multidisciplinary approach. However, it does appear nowadays to be an internationally recognized process. In 2004, the European Commission and Council of Ministers targeted HTA as "*a political priority*," recognizing "*…an urgent need for establishing a sustainable European network on HTA*." That led to the establishment of EunetHTA [11], a network of 35 organizations throughout Europe that aims at developing practical tools to transform HTA into useful policy advice for the EU and its Member States. Results are expected to be disclosed in December 2008, i.e., in the next few months.

HTA is becoming more and more fashionable in Italy, too. Past experts and newcomers in health economics are actively following the HTA trend. A Google search on "health technology assessment" limited to Italian web sites resulted in about 10,600 references, despite the English wording. After checking only the first references, it is clear that there are many proponents, including industrial associations, pharmaceutical companies, scientific societies, and education providers. This calls for some considerations.

The Italian National Health Service (INHS) is required to provide qualified health care, but also to keep costs under tight control. If the key task of HTA is to support public authorities in deciding on INHS coverage of a new technology, it could play a major role in selecting the new expensive technologies that are most likely to have real

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social value. HTA could extend the current INHS focus from drugs and hospital services to comprise medical equipment and devices, clinical procedures and screening, offering qualified recommendations to public decision-makers. To meet this ambitious goal, two main criteria are essential: competence and transparency. From experience, we think that transparency can be achieved only if HTA is funded and managed by public authorities or highly reputed independent non-profit institutions. In fact, in this "melting pot," it is vital to avoid any confounding and biasing factors by clearly distinguishing the assessors from the manufacturers and marketers of any new technology.

It is worth noting that the statutes of the newly borne Italian Society of Health Technology Assessment (SIHTA) establish that firms can support the Society directly or indirectly through related foundations by "tangible and significant support activities and donations" [12]. The chairman of the SIHTA technical and scientific committee very recently co-signed a HTA report with six employees of the pharmaceutical company manufacturing the bivalent HPV vaccine, comparing it with the quadrivalent HPV rival [13]. We wonder if this is consistent with HTA's mission to be an assessment conducted from the public authorities' perspective.

In conclusion, we think it is vital for the development of HTA in Italy that public authorities indicate which national agency, among the several public health organizations, is responsible for supporting the INHS in this field. The Agency for Regional Healthcare Services (ASSR) might be entitled to do so [14], but its leading role must be clearly endorsed. If the INHS believes that HTA is worthwhile, it is time to "toll the HTA bell." The worst—to be avoided—is letting everybody toll it, which could turn it into a "tolling of the knell" for HTA in Italy if expectations are unfulfilled.

References

1. Institute of Medicine, Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy Press, Washington (2001)
2. http://www.ncchta.org/about/whatishta.shtml
3. Henshall, C., Oortwijn, W., Stevens, A., Granados, A., Banta, D.: Priority setting for health technology assessment. Int. J. Technol. Assess. Health Care **13**, 144–185 (1997)
4. http://www.inahta.org/
5. Banta, H.D., Andreasen, P.B.: The political dimension in health care technology assessment programs. Int. J. Technol. Assess. Health Care **6**, 115–123 (1990)
6. Fattore, G.: Health technology assessment: per chi suona la campana? Quaderni di Farmacoeconomia **6**, 5–6 (2008)
7. France, G.: Health technology assessment in Italy. Int. J. Technol. Assess. Health Care **16**, 459–474 (2000)
8. Report from the EUR-ASSESS Project. Introduction to the EUR-ASSESS Report. Int J Technol Assess Health Care. **13**, 133–143 (1997)
9. Nio Ong, B.: The lay perspective in health technology assessment. Int. J. Technol. Assess. Health Care **12**, 511–517 (1996)
10. Rotstein, D., Laupacis, A.: Differences between systematic reviews and health technology assessments: a trade-off between the ideals of scientific rigor and the realities of policy making. Int. J. Technol. Assess. Health Care **20**, 177–183 (2004)
11. http://www.eunethta.net/
12. Statuto della "Società Italiana di Health Technology Assessment" in sigla "SIHTA". January 25, 2007. Article #3. http://www.sihta.it/Statuto_SIHTA.pdf
13. La Torre, G., Chiaradia, G., Mannocci, de Waure, C., Ricciardi, W., Capri, S., Bamfi, F., Bianchi, C., Lapinet-Vera, J., Marocco, A., Patarnello, F., Recchia, G.: Health Technology Assessment della vaccinazione HPV. IJPH. **4**(2 Suppl. 1) (2007)
14. Presidenza del Consiglio dei Ministri. Conferenza Unificata. 20/09/2007. http://www.assr.it/normativa%20di%20riferimento/Nuovi_indirizzi_ASSR_sett_07.pdf