An unconventional cancer treatment lacking clinical efficacy remains available to Italian cancer patients

Domenico Franco Merlo¹, Monica Beccaro², Massimo Costantini², and the Italian Survey of the Dying of Cancer Study Group*

¹Epidemiology and Biostatistics and Clinical Trials and Bioethics, ²Regional Palliative Care Network, National Cancer Research Institute, Genoa, Italy

ABSTRACT

Aims and background. An unconventional cancer treatment known as "Di Bella multitherapy" gained popularity among Italian cancer patients during the 90's. In 1999, it was shown to lack any detectable antitumor activity. Access to the multitherapy was investigated three years later within the post-bereavement Italian Survey of the Dying of Cancer (ISDOC), whose broader aim was to investigate the end-of-life care experiences of terminal cancer patients.

Methods. ISDOC was carried out in a two-stage probability sample of 2,000 out of 160,000 Italian cancer patients deceased between March 2002 and June 2003. For each cancer patient, a non-professional caregiver, i.e., the closest and the best-informed person about her/his last three months of life, was identified. A specific question concerning the "Di Bella multitherapy" was included in a semi-structured questionnaire that was administered face-to-face to the caregivers by trained interviewers. Weighted estimates of the frequency of patients receiving the multitherapy in the target population and their 95% confidence intervals were computed by taking into account stratification and clustering of observations.

Results. During their last three months of life, 0.7% (95% CI, 0.3-1.6) of terminal cancer patients, corresponding to some 1,100 subjects (range, 480-2,560), received the multitherapy. No statistically significant difference was observed for age at death, cancer type, gender, education, marital status, or residence.

Conclusions. The finding indicates that an unconventional cancer treatment proven to lack clinical efficacy remained accessible to Italian cancer patients. Ethical, deontologic, and economic implications call for a routine monitoring of provision of and access to unproven cancer treatments. **Key words:** ethics, fraud, survey, terminal cancer patients, unconventional cancer treatment.

*The Italian Survey of the Dying of Cancer study group: Massimo Costantini, Monica Beccaro, Silvia Di Leo (Regional Palliative Care Network, National Cancer Research Institute, Genoa): Maria Pia Sormani, Paolo Bruzzi (Unit of Clinical Epidemiology, National Cancer Research Institute, Genoa); Domenico Franco Merlo (Unit of Epidemiology and Biostatistics, National Cancer Research Institute, Genoa): Gabriella Morasso (Psychology Service, National Cancer Research Institute, Genoa); Paolo Giorgi Rossi, Piero Borgia (Agency for Public Health, Lazio Region, Rome); Maurizio Montella, Maria Grimaldi (Department of Epidemiology, National Cancer Institute, G. Pascale Foundation, Naples); Eugenio Paci, Nicoletta Susini, Riccardo Cecioni, Guido Miccinesi (Clinical Epidemiology, Centre for the Study and Prevention of Cancer, Florence); Renato Pisanti (Labos Foundation, Rome).

Acknowledgments: The study was funded by the Italian Ministry of Health (Progetti di Ricerca Finalizzata 2001-2003).

Correspondence to: Domenico Franco Merlo, Epidemiology and Biostatistics, National Cancer Research Institute, Largo R Benzi 10, 16132 Genoa, Italy. Tel +39-010-5600966; fax +39-010-5600501; e-mail franco.merlo@istge.it

Received January 17, 2008; accepted February 8, 2008.