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Titolo tesi: Development and validation of a patient-reported outcome tool to assess cancer-related financial toxicity in Italy

ABSTRACT

Financial problems related to cancer care are a matter of global attention, and are being increasingly examined under the term "financial toxicity." The earliest studies coming from North America have reported that financial toxicity is associated with lower patient satisfaction, worse quality of life (QOL), increased chance of bankruptcy and poorer survival. The phenomenon of financial toxicity in Italy is scarcely investigated. The initial objective of this project was to explore whether financial difficulties, present at baseline or that develop during cancer treatment, are associated with survival, QOL and toxicity outcomes in adult oncology patients in Italy.

A secondary analysis of data from 16 pooled adult oncology cancer trials that had utilized the EORTC QOL C30 questionnaire (items 28-30) was conducted. Multivariable analyses were performed using logistic regression models or the Cox model adjusting for trial, gender, age, region and period of enrolment, baseline global QOL, financial burden and global QOL. At baseline 26% of the 3670 study patients had some level of financial burden (FB) that was associated with a higher chance of worsening global QOL (OR 1.35, 95%CI 1.08 to 1.70, $p=0.009$). During treatment, of the 2735 patients who completed subsequent questionnaires, 616 (22.5%) developed financial toxicity, and developing or worsening financial toxicity during treatment was associated with a higher risk of death (HR 1.20; 95% CI 1.05 to 1.37, $p=0.007$).

The second overall objective, sequential to the results of the initial study was to develop a patient-reported outcome tool to assess cancer-related financial toxicity in Italy, taking into account the relevant sociocultural context and health care system. A multidisciplinary Steering Committee was formed and a



many-phased research protocol was written for the development and validation of a patient-reported outcome tool to assess cancer-related financial toxicity in Italy. The first task objective was concept elicitation and coding into a thematic library. Sources were a literature review, focus groups of 34 patients and caregivers, and individual interviews of 32 patients and caregivers, conducted in north, central and southern Italy, and survey responses from 97 Italian oncologists. Initially 156 concepts were identified and organized in 10 thematic libraries (bureaucracy, medical access issues, domestic economy, emotion, family, job, health workers, welfare state, free time, and transportation. After controlling for redundancy, 55 items were generated. These items were tested through importance analysis (45 patients) and cognitive debriefing (45 patients) for relevance and comprehension. At the conclusion of this phase 30 items remained, and a further 6 were removed due to high inter-item correlation. Further instrument refinement and internal validation was performed with exploratory factor analysis and reliability analyses with 184 patients participating. The final proposed instrument has 16 items.

Themes related to the lived experience of financial toxicity also emerged in the qualitative interviews. Keeping a balance between cost and time, how financial toxicity enters a household and remains, and the new normal of constant negotiation between needs and resources were ways patients described living with financial toxicity.