Letter to the Editor

Dear Sir.

CBN recently published an excellent paper on the use of patient-reported outcomes (PROs) in clinical trials (2016;4(2):54-58). I would like to offer a future perspective based on recent findings regarding the role that financial problems may play in the outcomes for cancer patients.

The increasing cost of drugs and the organization of the health system have prompted a huge debate in the United States. Several and consistent data have been produced showing that (i) cancer patients have an increased risk of bankruptcy [1], (ii) financial strain is correlated with worse quality of life [2], and bankruptcy is associated with an increased risk of death [3].

To properly describe the phenomenon, US researchers have developed a PRO instrument, named COST (COmprehensive Score for financial Toxicity), that measures financial toxicity through 11 items [4]. In reality, in the US health system it is not possible for a patient to receive adequate cancer care without paying at least a portion of treatment cost out-of-pocket; therefore, the items selected during the production of COST pertain mainly to domains of psychological response and coping behaviours, rather than to the reporting of material conditions that cause financial distress [5].

Recently, in Italy, we have pooled data from 16 prospective multicenter trials involving 3,670 patients with either lung, breast or ovarian cancer, who completed the European Organization for Research and Treatment of Cancer (EORTC) quality of life C30 questionnaire. In this questionnaire, question 28 asks patients to rate financial difficulties related to their disease or treatment on a scale from 'not at all' to 'very much'. Our analysis showed that financial problems at baseline were present in 26% of patients, and were associated with a 35% greater risk of worsening global quality-of-life during subsequent treatment (p=0.009). Furthermore, financial toxicity, defined as a worsening of response to question 28 in subsequent questionnaires, was observed in 22.5% of patients and was associated with a 20% increase in the risk of death (p=0.007) [6].

We conclude that the issue of financial toxicity may also be relevant outside the US, and are now working to develop an Italian questionnaire for appropriately describing it. A European-wide cooperation on this matter might be valuable.

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