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Assessing Financial Toxicity in Cancer Patients: Moving Away from a One Size Fits All Approach

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To the Editor

We would like to comment on the review by Rotter et al on financial toxicity (FT) in advanced cancer, highlighting that this is a critical problem also outside the United States, and that context-specific tools are required to expand on this neglected research topic.¹

In a large pooled analysis of 16 different prospective clinical trials including overall 3670 Italian cancer patients, we recently found that those with greater baseline financial difficulties also reported worse quality of life (QoL) treatment outcomes. We also showed that worsening of financial difficulties during treatment, identified a subgroup of patients who had a higher death risk over time.² Notably, however, financial difficulties in our study were only assessed by one question from the well validated EORTC QLQ-C30 questionnaire, which is not devised to capture the multiple challenges associated with the patient's experience of financial problems.³

Based on these findings, and cognizant that such results were obtained by using only one item of a generic QoL cancer measure, we embarked in a large national project to develop an Italian-based FT measure. The development of this measure, funded by an Italian Charity (Fondazione AIRC), is ongoing and broadly follows the working methodology codified by ISPOR,^{4,5} and used by de Souza et al for the recently developed COST instrument, validated in the US cancer population.^{6,7}

In line with the call for action by Rotter et al to fully consider the socio-cultural context when discussing and measuring FT, we a priori did not attempt any cultural or linguistic validation of already available FT measures, such as the COST instrument. Healthcare and social welfare systems greatly vary by country to country (and this is also true within European countries) and, therefore, they do impact on how financial problems may affect patient's life when facing cancer.

According to the three domains proposed by Altice et al to conceptualize financial burden (material hardship, psychological burden and behavioral changes),⁸ it is interesting to see, for example, that the 11 items of the COST instrument pertain to psychological (8 items out of 11) and material hardship (3/11) but do not include coping behavior measures.

Because of differences in health care systems between US and Italy we hypothesized that developing an instrument in the Italian context would produce different results, and, although still limited to early phases of the development process, our expectations seem to be confirmed. Indeed, the 30 candidate items, after concept elicitation (that reduced the initial 156 concepts to 55 items) and importance analysis done by Italian cancer patients, prevalently fall within the material hardship category (23/30), eliciting the role of patient reported experience in FT assessment.⁹ Further, differences in health care systems and cultural attitudes toward financial sustainability could strongly limit generalizability of measurement instruments to other countries. Since heterogeneity of tools is expected, plea for consistency of measures should be first addressed to development process, eventually assessing the agreement between tools in a subsequent step.

Careful consideration should be also given to the temporal frame of FT's evaluation of material and behavioral items. From our initial evidence it seems that the wide patient experience along the whole treatment process should be taken into account.

Hopefully, such a tool might be useful to identify strategies for contrasting causes of financial toxicity in the specific context where it was generated. For this reason, we are going to name the Italian instrument PROFFIT (patient reported outcome for Fighting Financial Toxicity).

To conclude, Rotter et al should be applauded for having pointed out the importance of making major efforts to better understand how financial toxicity impact on patients' life (also in patients with metastatic disease) and, hopefully, their review will also stimulate the development of country-specific tools to be used in future studies.

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