Published in final edited form as:

Gynecol Oncol. 2020 February ; 156(2): 263–264. doi:10.1016/j.ygyno.2020.01.016.

Financial toxicity: An adverse effect worthy of a black box warning?

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Cancer care in the United States is costly, and the field of gynecologic oncology is no exception [1]. Gynecologic oncology patients may receive multiple types of treatment with a single diagnosis, including surgery, radiation, and systemic therapies, including conventional cytotoxic chemotherapies and increasingly expensive novel therapeutics. With the current lack of a formal relationship between drug efficacy and pricing, and the inability for Medicare to negotiate pricing, cancer drug prices are set at whatever the market will bear [2]. However, beyond drug pricing and its effect on the US healthcare system, the financial impact of cancer care has significant patient-level implications. An estimated 40% to 50% of US patients experience either material or psychologic stressors related to the cost of cancer therapy [3]. For gynecologic cancer patients, a new diagnosis may impart significant financial burden, resulting in significant patient out of pocket costs [4]. The term financial toxicity describes the financial hardship placed on patients that is associated with medical treatment, including direct and indirect costs as well as the related psychological distress [5]. The impact of financial hardship is myriad, and includes inability to pay for medical care, taking on of debt, bankruptcy, and negative health effects including treatment nonadherence, decreased quality of life and psychosocial sequelae [6–9].

One of the first and largest studies of financial hardship in gynecologic oncology patients was recently published in this journal by Boubherhan and colleagues [10]. Patients seen in a gynecology oncology practice were surveyed using the Comprehensive Score for Financial Toxicity (COST) instrument [11]. One third of the patients surveyed had a COST score of <23 (indicating higher financial toxicity), and higher financial toxicity was significantly associated with all cost-coping strategies, including being seven times more likely to report delaying or avoiding medical care due to finances. Notably, this study was conducted in a patient population with near universal insurance coverage, over a third had reported annual income >\$100,000, 50% of patients were treated with only surgery, and 20% had benign disease.

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Disclosure of Interests: The authors report no conflict of interest.

In this issue of *Gynecologic Oncology*, Liang and colleagues report the results of their single-institution prospective study of financial hardship at a tertiary care NCI Comprehensive Cancer Center, again using the COST instrument [11]. This work should be commended for considerably increasing our understanding of the prevalence and scope of financial hardship among gynecologic cancer patients. By examining the complexities of financial hardship through the framework of psychological response, impact on material conditions, and coping behaviors, their findings are sobering. Financial distress was common, with 54% participants screening positive. Financial distress was associated with losing wages, not paying bills on time, and borrowing money due to their cancer diagnosis. While they did not find financial hardship to be associated with not taking or refilling medications, other coping strategies including delay in treatment were not specifically examined.

The magnitude of effect in this study, as compared to the Boubberhan study, likely reflects several important differences in this patient population that should be noted. In the current study, all patients included were gynecologic oncology patients, and all were screened within 8 weeks of starting a new line of systemic therapy for primary or recurrent disease. This population included uninsured patients (7% of participants) and was an overall lower income population, with half having an annual household income of <\$40,000. Interestingly, insured participants experienced as much financial distress as those who were uninsured or who only had public insurance, although uninsured status was associated with a higher frequency of moderate or severe distress as measured by lower COST scores. Additionally, younger age and lower income remained significant risk factors for financial distress in a multivariate analysis, and may represent a higher-risk population for targeting screening. Of note, the vast majority of patients included were treated with chemotherapy alone, thus these results may not be generalizable and may underestimate the impact of maintenance strategies, and targeted or novel agent treatments. Furthermore, the results were measured at a single time point, thus we eagerly await the results of a planned future analysis of follow up in this cohort, which will provide data on the trajectory of financial distress over the course of treatment.

As cost sharing increasingly impacts out of pocket costs for the patient, this study provides evidence to inform future investigators on who to screen (arguably, all gynecologic oncology patients) and how to screen (the validated COST measure appears both feasible and applicable to our patients). Of course, the obvious and important questions remain: when to screen and how to optimally intervene when financial hardship is identified [12].

Additionally, compared to a decade ago, our patients are more likely to receive treatment with expensive novel targeted therapeutics and immunotherapies either alone or in combination with cytotoxic chemotherapy. Increasing use of maintenance therapy introduces the potential for prolonged treatment durations and increased time on treatment. Therefore, the impact of these treatments on financial toxicity is also a key remaining gap in knowledge and further investigation is warranted to capture treatment strategies with highest adverse financial effect. Identification of populations at greater risk may help to identify populations to target interventions, but additional evidence is needed on the effectiveness of interventions aimed at reducing financial toxicity [5].

As the landscape of therapeutics continues to change, the evolving financial impact on our patients needs to be critically considered. There may be a compelling argument for incorporation of estimates of potential financial toxicity in both future trial design and drug approvals. Or, at the very least, increased awareness of this “black box warning”.

Acknowledgments

Funding: The National Institute of Health’s National Cancer Institute Grants K08CA234333; P30 CA016672.

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