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The need to assess financial adverse events

A new *Lancet Haematology* Commission¹ is dedicated to adverse event assessment for patients with haematological malignancies. It is important to recognise that the adverse effects of a cancer diagnosis and cancer therapy extend beyond the physical and psychological effects of the disease and treatment. The social and financial effects of cancer, cancer treatment, and supportive care can profoundly influence the lives of patients and families worldwide. The costs and benefits of cancer treatments have been extensively studied from the payer's perspective. Although some therapies are cost-effective, many treatments surpass cost-effectiveness thresholds used throughout European nations, and even drugs that produce remarkable benefits such as ibrutinib and imatinib are associated with substantial financial burden to patients and society.^{2,3} Although the financial burden associated with cancer treatment is more difficult to assess than treatment toxicity, it has substantial effects on patient wellbeing. Emerging tools such as the affordability index⁴ should be applied to quantify this effect.

The cost of cancer care has continued to increase despite marketplace competition.⁵ Surprisingly, although imatinib cost US\$26 000 per year in 2001, its price increased by 10–20% per year until it reached \$146 000 per year before becoming available as a generic.² One approach to curb price increase has been estimating a value-based price for a new drug. A value-based pricing model will be tested after approval of the first chimeric antigen receptor T-cell therapy (tisagenlecleucel), which has a list price of \$475 000 for children and young adults with acute leukaemia. Overcoming the increasing cost of cancer drugs might also require new payment systems.

Discussions about the costs of cancer care commonly focus on balancing the potential to save and extend lives against the costs to society or payers, but out-of-pocket expenses incurred by patients for cancer care can affect patients' financial wellbeing profoundly and are considered by some as an adverse event.⁶ More than a third of patients with multiple myeloma reported taking steps to help cover medical costs, including pharmaceutical assistance programmes, depleting savings accounts, or borrowing from retirement savings.⁷ 40–85% of patients with cancer are estimated to stop working during initial treatment, with absences

ranging from 45 days to 6 months, and cancer survivors could face long-term health concerns that limit their ability to work after treatment.⁸ Financial hardship resulting from cancer therapy disproportionately affects patients who are the primary or only household wage earner.

Many more individuals live longer after an initial diagnosis of haematological cancer, and some patients continue chronic oral therapy or serial treatments at relapse, so out-of-pocket expenses could become even more substantial for these survivors and their families. In one study examining the economic burden of oral therapies for the treatment of patients with chronic lymphocytic leukaemia, oral therapies such as ibrutinib, idelalisib, lenalidomide, and venetoclax had facilitated treatment administration, reduced toxicity, and improved outcomes, particularly for elderly patients, yet these regimens raised concerns about the financial burden to patients.² For some patients, the high costs of care could lead to non-adherence to recommended treatments and poor outcomes. Higher out-of-pocket costs have been linked with high rates of oral prescription abandonment and delayed cancer treatment initiation.⁹ At the extreme, financial hardship after a cancer diagnosis has been associated with increased risk of filing for bankruptcy,⁷ and bankruptcy after cancer diagnosis has been associated with increased mortality.¹⁰

The inclusion of patient questionnaires in clinical trials to measure quality of life or other patient-reported outcome measures is increasing. At the individual patient level, adding questionnaires to the evaluation of novel therapies in clinical trials and observational studies that measure out-of-pocket costs should be feasible if the correct balance of pertinence and brevity can be achieved. Future efforts should draw from expertise in pharmacoeconomics, survivorship, and haematological malignancies to tailor existing tools and design questionnaires that objectively measure factors that influence a patient's perception of financial burden. Further studies are also needed to examine the association between financial burden and patient outcomes. Such tools will enable the effect of costly therapies on treatment adherence, dose rationing to reduce the cost of refills, treatment toxicity, treatment



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response, and survival to be assessed. Ultimately, showing the effects of financial burden on outcomes might motivate efforts to curb the increasing costs of treatments for patients with haematological malignancies if, in actual practice, those treatments do not realise their expected benefits because of their financial burden.

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