Accurate Measurement of Financial Toxicity Is a Prerequisite to Finding a Remedy

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Discussions about the affordability of cancer treatments tend to focus on balancing the potential to save and extend lives against the imperative to minimise costs to health care providers [1]. This is for good reasons that are well described in the health economics literature regarding the efficient use of a fixed healthcare budget [2]. Standard guidance on health economic evaluation in most developed nations therefore recommends that only costs incurred by healthcare systems or third-party payers are considered in cost-effectiveness analyses [3]. But it does mean that, to date, less consideration has been given to the broader costs of cancer treatment, including costs borne by individual patients, their family and carers, along with implications to society.

These out-of-pocket (OOP) expenses, which patients deem essential for accessing healthcare or maintaining health and well-being, are potentially wide ranging in any setting. They may, however, be especially pertinent in less developed countries or jurisdictions without universal healthcare coverage. In the US, for example, one study estimated that cancer patients were about 2.5 times more likely to become bankrupt than people without cancer [4]. For those who went bankrupt, mortality increased to a degree that outweighed the benefits of many cancer treatments [5].

For breast cancer patients, OOP costs may include (i) direct medical costs such as prosthesis, rehabilitation or additional therapies not subject to national coverage or requiring co-payment, (ii) non-medical direct costs of accessing healthcare, such as transportation and overnight stays, (iii) other non-medical direct costs outside of the healthcare setting that patients and their families consider essential, e.g. new clothes, extra heating, household alterations or even taking a long-desired trip to visit friends or family [6–8]. Further costs may also arise relating to employment or earnings potential which have financial implications for both the patient and wider society. These include the opportunity cost of time spent using healthcare (e.g. lost earnings or lack of sleep) and those periods where poor health has curtailed usual activities, such as work [9] or other productive activities (e.g. housekeeping or volunteering).

Since more people are living for longer after a cancer diagnosis, it may be that these OOP expenses are becoming more significant as patients and their families face recurring and persistent costs over many years. However, few studies have examined the scope and magnitude of these OOP costs, or the characteristics of those patients and situations where the adverse impact is greatest.

A first stage in understanding this is to gather high-quality data. Yet the availability of instruments to examine OOP costs in cancer patients is limited (for breast cancer, one US review identified just 3 studies which had examined them) [7] and few have been validated in terms of showing they accurately capture the costs they were designed to measure [10].

Measuring OOP Costs in Prospective Research

The inclusion of patient questionnaires in clinical trials is now standard practice for the measurement of quality of life or other patient reported outcome measures (PROMS). Adding questions that attempt to measure OOP costs should be feasible if the correct balance of pertinence and brevity can be achieved.

An important factor to consider is the range of costs to include in the questionnaire [2]. Partly this depends on the perspective of the analysis and the purpose of the study. Researchers must consider the extent to which it is necessary to include short- and long-term costs, for example, or costs related to a patient's wider family (including informal carers) and society.

If the purpose of the study is to assess the cost-effectiveness of a specific intervention, then costs which are likely incurred by patients whether they are in the intervention or control group could be disregarded, regardless of their potential magnitude. Likewise, in some situations it might be vital to include long-term costs, even lifetime costs, if their inclusion would have a critical impact in terms of favouring one intervention over another. In other cases this may be considered unnecessarily onerous. However questions

are designed, researchers must be mindful of bias through the omission of costs that may be incurred unequally between comparator groups.

Other sources of potential bias exist in the capture of OOP costs [11]. The choice of recall period is important [12] because patients may be unlikely to remember costs incurred over long time periods and may give greater weight to costs they have recently incurred, regardless of their magnitude [13]. For these reasons, it appears to be common for studies to use a 3-month recall period [14–16]. When a longer-term perspective is required, the additional cost (to researchers) of using patient diaries or repeat questionnaires may be justified in order to minimise bias, but more evidence for their reliability as a research tool is needed [17]. There may also be a trade-off between specifying the costs that researchers expect patients will think important, in order to trigger their memory, versus allowing free space for patients to express other costs they feel are important but overlooked by researchers [18]. The complexity of the question is also relevant in terms of the extent to which the patient must mentally sum numerous and diverse costs in order to arrive at a total cost [10, 13].

Other considerations relate to the setting under consideration. Certain methods of administering the questionnaire may be better suited to particular populations. For example, younger people could be more amenable to an online questionnaire [19]. Knowledge of the health and social care system operating in the country or region is also critical. Whilst many existing surveys have been designed to assess OOP expenses in the US, these are unlikely to be readily transferrable to other countries where the magnitude and range of OOP costs are probably different.

Implications

The potential implications of OOP costs are wide ranging. So-called ‘financial toxicity’ and the resulting financial distress may be important in many situations not least through its own negative impact on health and wellbeing [1, 20]. From a distributional per-

spective, some patients might delay or forego healthcare opportunities due to excessive financial pressures [21], increasing the risk of health inequalities.

From a health policy perspective, the exclusion of OOP costs from health economic evaluations may lead to a larger financial burden on patients than would otherwise be the case. In some instances, historical technology adoption decisions would likely have been different if a broader cost perspective were taken. However, empirical study is required to examine this, including an assessment of the healthcare that would be displaced if a different choice of technology imposed higher costs on healthcare providers. Whilst it is unconventional to include OOP expenses in the reference (base) case of cost-effectiveness analyses, some would support doing so and, at the least, standard guidance nevertheless suggests reporting additional patient or societal costs (and benefits) separately. By highlighting OOP costs in this way, the extent of the financial burden placed on patients, their carers and society, by reimbursement decisions would at least be revealed. Decision makers may also consider funding interventions to help ease this burden (e.g. a welfare advisory service).

We suggest the development of standardised and reproducible methods for capturing OOP expenses in either generic or disease-specific contexts. In particular, we emphasise the importance of studying the extent of variation and causes of variation in OOP expenses, (for example, predicting which patients are at high risk of catastrophic costs) with a view to reducing inequalities. Other opportunities could involve the underused and potentially rich resource of population-level longitudinal household surveys (observational data) or census data [9]. Together, these approaches may support analysis of the wider, longer-term impact of cancer and other chronic diseases on the financial wellbeing of individuals, their families and society.

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