Reviewer’s report

Title: Increased financial burden among patients with chronic myelogenous leukaemia receiving imatinib in Japan: A retrospective survey study

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Reviewer: Anne Mason

Reviewer’s report:

The paper reports findings from a questionnaire survey of Japanese patients who have been or are being treated with imatinib for Chronic Myelogenous Leukaemia (CML). The authors have clearly invested a great deal of time, effort and care in composing the manuscript and the findings are interesting and have important policy implications. The background information on the Japanese copayment system is particularly helpful and interesting. However, it is quite difficult to ‘see the wood for the trees’ and there is considerable scope to improve the presentation of the findings. In addition, some of the methodology is unclear.

Major Compulsory Revisions

1. Presentation of the findings: key findings should be clearly highlighted and some of the statistics could be presented graphically rather than in tables.
   a. My understanding is that the key objective of the study is to establish the relationship between patient income, the financial burden of treatment, and patients’ consequent willingness to continue treatment (p. 6, para 2), using imatinib for CML as a case study. The findings relating to this are summarised in a single sentence (p.11, top) in the results section. The abstract contains mainly descriptive statistics on the population, but does not clearly report these key findings: that whilst around 75% of patients feel financially burdened by treatment costs, only 31% considered discontinuing treatment because of the financial burden, and a tiny percentage (2.6%) actually did discontinue treatment for this reason (albeit temporarily). This information needs to be more prominent: it should appear in the abstract, be positioned earlier in the results and its policy implications considered in the discussion (it’s mentioned on p14, but no policy implications are drawn out).
   b. The current manuscript reports lists of descriptive statistics and is quite difficult to follow. Some of the findings would have a greater impact on readers if they were presented graphically – for instance, the data in Table 4 could be presented as a bar chart (perhaps with error bars). These findings are some very striking, showing that the financial burden on patients – despite the ‘ceiling’ for final copayment imposed by the government – is highly regressive. This is mentioned in the discussion (p14) which then considered the option of 3-monthly prescriptions/hospital visits. Other specific policy recommendations are warranted – e.g. should the ratio of out-of-pocket expenses to medical costs depend not only on age but also on income?
2. Lack of clarity on methodology.
   a. The authors undertook a questionnaire survey, but asked patients for retrospective data on income, medical insurance, out of pocket costs and final copayments. There are very few responders for the data from 2000, and it is not clear why this is: was the question directed only to those diagnosed before 2000, or does this simply reflect a lack of response? The authors inaccurately describe the retrospective data as coming from ‘patients who were followed through the study’ which implies a prospective approach. This is misleading and needs to be corrected. Given the very small numbers of respondents (n=41) who provided data on income in 2000, the finding that income fell by US$13k over the period (p 13) should be interpreted with caution. The authors discuss possible reasons for the drop in income that are related to CML, but these patients could have retired during that period.

   b. The odds ratios (p. 11, bottom) need to be explained for those without a statistical background – talk through one as an example (upper confidence interval below 1 etc). Also, are these ‘conditional’ odds ratios (i.e. the odds ratio for family residence is conditional upon the other factors being held constant)?

Minor Essential Revisions

1. Background: p5, para 1. “To lower medical expenses,….” How do the authors know this is the reason for reducing government subsidies? I am not sure cost cutting is the key factor, rather the aim is to curb the rate of increase in medical expenditure. The authors cite our paper from the JCO, but we only discuss increased copayments by private health plans.

2. Methods and procedures (p 6): surely ‘Methods’ is sufficient?

3. Methods: p 7, para 2. ‘Payment of medical costs in Japan’: this section is important but doesn’t fit under Methods – it is background. The statement that the ratio of patient payments to medical cost depends on age needs to be explained: what is the nature of this relationship?

4. Language: the paper is generally well written, but needs to be proof-read by a native speaker.

Discretionary Revisions

None

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests