Reviewer's report

**Title:** Improving access to care in low and middle-income countries: institutional factors related to enrollment efficiency and patient outcome in a cancer drug access program.

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**Reviewer:** Raul R Ribeiro

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**General**

Tekinturhan and colleagues analyzed follow up data of almost 5,000 patients who were enrolled on the Glivec International Patient Assistance Program (GIPAP). The objective of their work was to identify institutional factors associated with enrollment efficiency and survival on GIPAP. The presence of >1 hematologist or oncologist and private status were institutional factors associated with increased patient enrollment. Treatment at a public institution was associated with decreased survival while increased survival was found in institutions with research capabilities and those with enrollment of >3 patients/year into GIPAP combined with the presence of >1 hematologist or oncologist. They concluded that the selection of institutions that participate in GIPAP might help to optimize care and outcomes for CML and GIST patients in the developing world. They also speculated that the results of the study might also be applicable to the treatment of patients with other forms of cancer, due to the overlap of infrastructure and staff resources used to treat a variety of cancer indications. Finally, they concluded that a multi-sector approach is required to address these barriers.

Although this study attempted to address a very important issue—the evaluation of interventions to improve cancer care in developing countries—a statistical analytic approach chosen may not be appropriate to account for the vast heterogeneity among countries. Data analysis of individual national programs could have produced more information. It is likely the authors knew the successful factors a priori and attempted to build a statistical model to reflect that. In this process two countries had to be removed from the analysis (based on the fact that they were “different” from the other 42 countries!). In fact, that seven Sudanese physicians registered and followed-up 971 patients (it is not clear if the patients were entered in institutions in South or North Sudan) during a difficult sociopolitical period is a case study in itself! Why were Sudan and Uzbekistan separated from the other countries? Do they have similarities between them other than enrolling a large number of patients?

**Specific**

1) The authors noted “the program has been implemented in 81 developing countries, including 49 low-income countries, and 50,395 patients in these
regions, 4,300 of which are in low-income countries, have received Glivec through GIPAP free of charge.” This statement is not consistent with the numbers presented in the current manuscript. The current manuscript includes 4,946 patients from 47 institutions in 44 countries (Table 1 only listed 43 countries!). How is this subset of patients related to the 50,395 patients from 81 countries and to the 4,300 patients in low-income countries? What were the criteria utilized to classify 81 countries as developing and 49 as low-income countries?

2) The authors noted “GIPAP helps patients who are properly diagnosed with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) and patients with c-Kit (CD117)-positive inoperable and/or metastatic malignant gastrointestinal stromal tumors (GISTs) and (b) GIPAP provides assistance to patients who are not insured or reimbursed, cannot pay for treatment privately, and live in countries that have minimal reimbursement capabilities for their condition.” What does “helps” and “provides assistance” mean? Does the program finance other aspects of patients care?

3) The authors noted that “data from institutions participating in GIPAP have been collected in several databases. Axios maintains an Access to Treatment Online Management System (ATOMS) database, which captures detailed information on institutions and countries where Axios programs operate. The Max Foundation also maintains an institution, physician, and a Patient Assistance Tracking System (PATS). All data analyses were conducted under the authorization from Novartis and the Max Foundation and an Institutional Review Board (IRB) exemption was received from the Western IRB.” Who collected the data? Trained data managers, physicians or others? Is the quality of the data monitored? Did the local IRBs approve the project?

4) The authors noted that “Sudan and Uzbekistan comprised 30% of the patients included in this study and the profiles of these two countries were different from the other 42.” How are these two countries different? Please elaborate on the reasons Sudan, Uzbekistan, Nepal, Azerbaijan, Ethiopia, Kenya, Congo, Nigeria, Georgia registered more than 200 patients each? Why did countries with limited resources from Latin America not participate? What were the factors associated with the high enrollment in Sudan?

**Level of interest:** An article of limited interest

**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.