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.

Version: 3 Date: 4 September 2012

Reviewer: Jackson Orem

Reviewer's report:

This is an informative article for those planning to increase access to new effective yet expensive cancer treatment to patients in poorer parts of the world. It is based on available data from an on going global program supported by pharmaceutical company and philanthropic organizations.

Under the background section the authors presupposes that there are inherent national and institutional factors that adversely affect outcome of patients on access programs beyond just provision of drugs. With this in mind the authors set out to identify these factors.

The first objective was to describe patients and institutions

The second objective was to assess enrollment at institutional levels and factor affecting it

Third objective was to identify institutional factors associated with patient survival

Issues

• Although the objectives of the study where very clear from the outset the authors stated in their abstract that they were actually looking at factors associated with enrollment efficiency and patient survival which is quite different from what they set out to do in the main text of the study.

• The authors also sated in their background that they were looking at both national factors and institutional factors affecting outcome. It is however very clear that they majored only on institutional factors. There is therefore need for clarification on how this can relate to the national factors adversely affecting outcome.

• It is rather mind stretching to understand the rational for categorising countries by WHO region, an elaboration on this would be important.

• It is very obvious that two countries have contributed most of the data hence skewing the findings, although the authors recognize this they don’t provide convincing reasons for the difference between these countries and the other. At best they should have stated why they consider these countries different from the rest of the countries. The most obvious explanation would be that there was a factor that favoured enrollment into the GIPAP programs in this countries that introduced bias which cannot be explained away statistically, this factors could possibly be explained by program factors or criteria for enrollment if not out right
bias.

- Despite the above the main draw back to this study is ethical. There was no ethical approval from the developing countries. The authors state in passing that they received authorization from Novatis and the max foundation and IRB exemption from Western IRB, this statement is rather naïve.

Summary of review

Although the paper had well stated and clear objective, these objectives were not systematically answered in a logical maner. The authors were selective in answering there own questions ignoring to alarged extent question regarding country level factors. It is not clear how WHO regions became an important variable for stratification and how this eventually was in line with the initial stated objectives.

The methods section is scanty on the how the issues of bias were handled especially considering most participants came from two countries. No attempts were made at defining the peculiar characteristics of these two countries. Perhaps the most disturbing methodical draw back is that of ethical approval in countries from where the data were collected.

Discretionary revision: None

Minor essential revision: Need to align the analysis and findings with the stated objective of the study

Major compulsory revision: Need to clear explain the ethical approval process for this study

Level of interest: An article of importance in its field

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I should declare that my site participates in the GIPAP program although I'm not related to this paper