Reviewer's report

Title: Influence of a Patient information program on adherence and persistence with an aromatase inhibitor in breast cancer treatment The COMPAS-Study

Version: 2 Date: 7 June 2013

Reviewer: Heather Becker

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Minor Essential Revisions:
This is a generally well-conducted study on an important topic. As the authors point out, patients cannot benefit from prescribed medication if they don’t take the medication, so this study addresses an important clinical question. However, the authors need to exercise caution in how they refer to the adherence issue. Clinicians (at least in the United States) are moving away from using the term “compliance”, which implies a passive patient role, and now use the term “adherence”. While the authors generally use that language, they occasionally refer to compliance (see for example Table 3).

The manuscript would benefit from editing to make it more understandable to an English speaking audience. For example, there is an incomplete sentence in the third paragraph on page 17.

The authors describe a number of controls that increased the rigor of this study, such as data collectors blinded to group assignment. Multiple measures of adherence were used. The participation rate among those eligible for the study was high and the sample size was sufficient to detect at least a moderate effect when it was present. However, the number of participants at the 12-month data collection should be shown in the Consort Table and also indicated in the text.

While I agree that the three groups look generally comparable on most of the variables listed on Table 1 (baseline characteristics), it does appear that the letter group had a higher percentage of patients who received chemotherapy. Since the letter group also had the highest adherence rate, it would be important to point out the possibility that differences in treatment experience could have contributed to observed adherence differences.

The definition of discontinuation is a little confusing to me. It seems to include discontinuation listed in the patient files, which I am assuming could be based on a provider’s decision as well as lack of adherence by patients. Since the point of the study is to increase patient adherence, then it seems that discontinuation should reflect only patient decisions, or the authors should clarify that the analysis of discontinuation included more than just patient non-adherence.

The authors’ conclusions are reasonable since only when both interventions were combined did they find statistically significant differences between intervention and control groups. However, it would be useful to provide more specific information such as the dfs, as well as the p value.
Note that the terms in the legend for Figure 4 refer to “written” and “oral”. Please make these terms consistent with the terminology used elsewhere.

While they report no statistical association between adherence and ratings of side effects, the authors do report that two-thirds of those who reported they were not adherent gave side effects as the reason for discontinuation. This finding would tend to suggest that interventions focused on helping patients deal with side–effects may be more effective at increasing adherence than interventions that emphasize educating patients about the importance of the medication. It would also be useful to explore in future studies why the letter intervention may be more effective than the phone call. Were all the patients reached by phone at the designated intervals? If not, then they would not have received the full “dose” of the intervention, which would be something to address in this article. Further exploration of patient reaction to the intervention should also be undertaken in future studies.

The abstract generally reports the study accurately. However, because closer to 155 patients actually provided outcome data, it would be more accurate to state in the Methods paragraph that 181 patients were originally randomly assigned to one of three groups. Also, the Discussion paragraph in the abstract should be rewritten to indicate that the pooled intervention effect was statistically significant.

**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.