Author's response to reviews

Title: The Brustkrebs-Studien.de website for breast cancer patients: User acceptance of a German internet portal offering information on the disease and treatment options, and a clinical trials matching service

Authors:

Markus Wallwiener (markus.wallwiener@googlemail.com)
Christian W Wallwiener (cwallwiener@googlemail.com)
Sara Y Brucker (sara.brucker@med.uni-tuebingen.de)
Andreas D Hartkopf (andreas.hartkopf@med.uni-tuebingen.de)
Tanja N Fehm (tanja.fehm@med.uni-tuebingen.de)
Julia K Kansy (kansykatinka@gmail.com)

Version: 2 Date: 4 November 2010

Author's response to reviews: see over
Melissa Norton, M.D.
Editor-in-Chief, BMC Cancer
c/o BioMed Central
Middlesex House
34-42 Cleveland Street
London W1T 4LB

4 November 2010

BMC Cancer manuscript 1138047131285530, Revision 1:
Wallwiener et al. The Brustkrebs-Studien.de website for breast cancer patients: User acceptance of a German internet portal offering information on the disease and treatment options, and a clinical trials matching service

Dear Doctor Norton,

On behalf of my co-authors, I am pleased to submit our revised manuscript for publication in BMC Cancer.

We are grateful to the reviewers for their time, careful assessment of our manuscript, and valuable comments on our work. Below please find, in tabular format, our point-by-point responses to the reviewers’ comments and suggestions for improvements to the manuscript.

As far as possible, we have incorporated the reviewers’ suggestions in the revised manuscript. All changes have been high-lighted in yellow so they can be readily identified.

Dr Andreas Hartkopf has been added as an additional author as he participated in the early phases of the project, data collection and data analysis and was involved in reviewing early drafts of the manuscript.

We hope that our responses and the changes we have made to the manuscript will be considered satisfactory and that our manuscript will now be acceptable for publication in BMC Cancer.

Please do not hesitate to contact us with any queries you may have.

We greatly look forward to your reply.

Yours sincerely,

Markus Wallwiener, M.D.
<table>
<thead>
<tr>
<th>Page</th>
<th>Comment to be addressed</th>
<th>Done</th>
<th>Comment/Changes by M Wallwiener/Co-authors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Editor's Comments to Author:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>–</td>
<td></td>
<td>No specific comment or suggestion to be addressed.</td>
</tr>
<tr>
<td></td>
<td>Reviewer 1: Erich-Franz Solomayer (<a href="http://www.biomedcentral.com/imedia/3703715344501584_comment.pdf">http://www.biomedcentral.com/imedia/3703715344501584_comment.pdf</a>)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Thank you for inviting me to review this interesting paper reporting the first results on user acceptance of a German internet portal for, primarily, breast cancer patients seeking information on the disease and its treatment and considering participation in a clinical trial.

I consider this work as relevant research into current efforts to utilise online channels to provide expert-written information on breast cancer and its treatment and up-to-date information on ongoing and planned trials as well as offering patients the possibility to contact breast specialists and clinical investigators and interact with them. The Brustkrebs-Studien.de initiative as such is to be applauded, and the findings reported in this manuscript will interest many readers.

Thus this article addresses a topic that is relevant and newsworthy to the readership of BMC Cancer, not least because the BKS portal can serve as a model for similar websites tailored to patients with other cancers.

In my opinion, the authors have addressed their objectives and laid the groundwork for a national registry for ongoing and completed clinical breast cancer trials with important implications for both research and health professionals, and they also point to the next phase of work in this area.

The manuscript is well written, but there are some issues, outlined below, that the authors need to address. I have also made a few suggestions on how to improve manuscript readability, provide the non-specialist readers with additional context and highlight the important contributions of this work.

Overall, I recommend publication of this manuscript in BMC Cancer once these issues have been addressed and the necessary revisions made. I see no significant deficiencies. These comments are intended as constructive criticism and I hope they will be received positively.

No specific comment or suggestion to be addressed.
<table>
<thead>
<tr>
<th>Page</th>
<th>Comment to be addressed</th>
<th>Done</th>
<th>Comment/Changes by M Wallwiener/Co-authors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Major Compulsory Revisions</strong></td>
<td></td>
<td>None required.</td>
</tr>
<tr>
<td></td>
<td><strong>Minor Essential Revisions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Accuracy and currency of entries:</strong> How is it ensured that the entries are accurate and up-to-date?</td>
<td>✓</td>
<td>Automated reminders were sent out to the investigators, who additionally received personal encouragement through the German Society of Senology (DGS). Automated notification is mentioned in the last paragraph on page 9. The wording has been modified accordingly to make a clearer statement.</td>
</tr>
<tr>
<td></td>
<td><strong>Number of recruited patients:</strong> The authors mention the impact on trial recruiting via the website. The user online survey confirmed overall acceptance of this service. However, it would have been interesting to analyse the subsets of patients currently/actually included in trials based on inquiries from the registry. This would definitely be worth pursuing in follow-up studies.</td>
<td>✓</td>
<td>We agree. This is exactly what we are planning for future trials. The conceptual framework for monitoring real-life trial inclusion has already been established. In the next phase of our project, principal investigators will be asked to provide feedback on trial outcomes. This will be part of the BCRM breast cancer trial matching tool, an algorithm for eligibility screening.</td>
</tr>
<tr>
<td></td>
<td><strong>Data and statistics:</strong> The authors did a nice job of outlining the growing demand for the service. The figures and tables are well presented and help to better illustrate user access and demand. However, it would add to the value of this work to have more recent data, especially on the demand for this service.</td>
<td>✓</td>
<td>In the revised manuscript we have included very recent data up to 30 June 2010. Figure 3 has been updated accordingly.</td>
</tr>
</tbody>
</table>
### Inclusion and exclusion criteria (Page 3)

In addition, the inclusion and exclusion criteria for trials can vary to such an extent that physicians may not have sufficient knowledge to identify eligible patients. The authors might also consider discussing the nature of these criteria, which appear to be inhomogeneous, and whether it would be possible to add more sophisticated algorithms to make appropriate suggestions to patients.

Given the progress (and response) achieved in establishing an initial clinical trials database, we absolutely agree that the next step is to make it easier for both patients and attending physicians to identify suitable trials. However, having patients screened for trial eligibility by their physicians is complex and time consuming in clinical routine. Therefore we need screening tools. Nonetheless, in our opinion the final decision on inclusion or exclusion requires a hospital setting. However, online services such as Brustkrebs-Studien.de could enable preselection of suitable trials open for recruitment, based on histology, hormone receptor status and clinical history.

Successful matching of patients to clinical trials requires parameterisation of the inclusion/exclusion criteria, this being the next challenge for the Brustkrebs-Studien.de portal. Our group has done some work in this area and we plan to publish the data soon.

### Discretionary Revisions

In the Introduction (in the last three paragraphs on page 4-5), Methods (page 6) and Discussion (page 16) sections, there is some repetition of goals/aims, which may not be necessary.

We feel that a certain amount of redundancy is inevitable when discussing certain points in different contexts. In our opinion the manuscript parts in question are not excessively redundant.
### General comments

This report by Wallwiener et al. is a well-written report on a German internet study. [Summary of the study follows.]

- No specific comment or suggestion to be addressed.

### Comments and suggested changes

- **The English language should be improved; the manuscript might be read by a native speaker.**
  - The manuscript has been carefully revised and a number of stylistic changes and improvements have been made. All changes to the original manuscript have been highlighted in yellow in the revised manuscript.

- **How were the studies selected? Please describe. Is there a bias in the selection?**
  - Studies were selected by a committee of the Deutsche Krebgesellschaft and DGS. We cannot completely exclude the presence of a selection bias. However, for a proof-of-concept study, the bias problem could be considered to be of minor importance.
<table>
<thead>
<tr>
<th>Page</th>
<th>Comment to be addressed</th>
<th>Comment/Changes by M Wallwiener/Co-authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>8ff.</td>
<td>Parts of the results, describing the website, should be part of the method section.</td>
<td>✔ Our objective was 1) to design and develop a website and 2) to investigate its use and acceptance by the targeted user groups. Therefore the portal and its components are, in our view, to be considered results of the study, as much as the user statistics. We would agree with the Reviewer if the website had existed before study initiation and been used to investigate user behaviour. We hope the reviewer will agree. The manuscript has not been changed in this respect.</td>
</tr>
<tr>
<td></td>
<td>Do you have figures on the nature of the website visits? How long? What was searched?</td>
<td>✔ Average website visit duration was 3.2 minutes. The terms and topics typically searched for included drugs, e.g. herceptin, and treatments, e.g. sentinel lymph node biopsy. Table 1 lists the most frequently visited trial protocols for 08–12/2008.</td>
</tr>
<tr>
<td>12ff.</td>
<td>Discussion: do you have any figures on the issues of elderly pts access? Please compare literature.</td>
<td>✔ The two-week survey showed that the users who completed the questionnaire had a mean age of 61 years (range: 41–74 years). On the whole BKS users tend to be younger than the usual age distribution (see “Krebs in Deutschland 2005/2006 – Häufigkeiten und Trends”, 7th ed. 2010, p. 57. <a href="http://tinyurl.com/399x7nz">http://tinyurl.com/399x7nz</a>)</td>
</tr>
<tr>
<td>Page</td>
<td>Additional changes made during revision</td>
<td>Done</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>