

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Family Planning and Pregnancy Issues for Women with Systemic Inflammatory Diseases: Patient and Physician Perspectives
AUTHORS	Chakravarty, Eliza; Clowse, Megan; Pushparajah, Daphnee; Mertens, Sarah; Gordon, Caroline

VERSION 1 - REVIEW

REVIEWER	Des Toomey Clinical Fellow in Colorectal Surgery Castlehill Hospital Hull UK
REVIEW RETURNED	21-Oct-2013

GENERAL COMMENTS	<p>Figure 1 b) and c) are difficult to read and interpret. Perhaps this data could be presented in a different format.</p> <p>Overall a good paper highlighting that this problem, which has previously been demonstrated in specific populations, is widespread across several countries and diseases.</p> <p>The issue of ongoing education for physicians so that they can confidently advise their patients is touched on. Do the authors have any further results on this? Previous studies have shown a knowledge gap both a physician and patient level that needs to be bridged. This could be further dealt with in the discussion with more robust suggestions on how it could be achieved.</p>
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REVIEWER	Monika Østensen National Center of Pregnancy and Rheumatic disease, Department of Rheumatology, University Hospital of Trondheim, Trondheim, Norway
REVIEW RETURNED	03-Nov-2013

GENERAL COMMENTS	<p>Ethics approval: In 'methods' no explicit mention of ethics approval is made, however, in the physicians' questionnaire a reference to 'code of conduct' is made. Does this imply ethics approval was given in all countries that participated in the study?</p> <p>There is a certain abundance in the presentation of the results given both as text and figures. The figures are excellent and present the result at a glance. Perhaps the text could be somewhat shortened?</p> <p>The citation (ref. 9) for paragraph 2, line 6 on page 6 is not adequate: this paper deals with the increased risk of preterm birth in</p>
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	IBD, not a decreased chance of conceiving caused by the disease state.
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REVIEWER	<p>Zuzana Zelinkova Department of Gastroenterology&Hepatology Erasmus MC Rotterdam The Netherlands</p> <p>Department of Gastroenterology, 5th Department of Internal Medicine University Hospital Bratislava Slovakia</p>
REVIEW RETURNED	04-Nov-2013

GENERAL COMMENTS	<p>There are, methodological issues that need clarification.</p> <p>Selection criteria for participating physicians: - 3 to 30 years of experience cover a large range – differences in attitudes between the generations are likely and may influence the variation in results. For instance, there are no data shown of the physicians` age distribution per geographical region, neither are the results age-stratified. - Why were the physicians participating last month in medical research excluded? - A minimum of 8 patients with CD per month with a minimum of 2 patients on biologics per month is rather low. How were these limits determined? This may lead to biased results in the group of gastroenterologists as only physicians with rather limited experience with IBD (and therefore likely to be less inclined to discuss these very specific issues with the patients) were allowed to participate.</p> <p>Patients` recruitment procedure: - This part is unclear. It only states that a professional agency recruited the patients. How exactly were the patients approached? What was the drop-out rate during recruitment? It is known that patients willing to participate in surveys differ significantly from overall patients` population. Therefore, before making any general conclusions, the recruitment procedure with its possible bias must be clearly described in details.</p> <p>The study by Chakravarty et al. entitled 'Family Planning and Pregnancy Issues for Women with Systemic Inflammatory Diseases: Patient and Physician Perspectives' deals with an important issue frequently encountered in the clinical practice of diverse specialists who care for chronically ill patients with immune-mediated inflammatory disease. The insights into the current practice as well as patients` perception of the quality of information delivered by this practice are important. In this regard, the study certainly offers valuable information to be used for improvement of clinical practice of every concerned specialist. There are, however, some concerns about the study methodology that need to be clarified as stated here above.</p>
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VERSION 1 – AUTHOR RESPONSE

Des Toomey

Comment 1: Figure 1 b) and c) are difficult to read and interpret. Perhaps this data could be presented in a different format.

Author Response: We have changed the titles for Figures 1B and 1C to reflect the specific question asked of physicians to gauge the frequency of their discussions with their pregnant patient's GP and gynaecologist to clarify the data presented. This change should improve interpretation as the question asked (ie. To what extent did you discuss these questions, issues...with the patient's GP/gynaecologist? [see Question 20/21 of the Physician Survey, Appendix 1]) more clearly relates directly to the categorized responses presented (ie. Always/Very often/Sometimes/Rarely/Never).

We also considered that the results presented in these stacked bar charts could alternatively be presented as pie charts, however given the number of groups presented (5 per graph) we felt the current format was the most space-efficient and that there was insufficient space for the required number of pie charts.

Comment 2: The issue of ongoing education for physicians so that they can confidently advise their patients is touched on. Do the authors have any further results on this? Previous studies have shown a knowledge gap both a physician and patient level that needs to be bridged. This could be further dealt with in the discussion with more robust suggestions on how it could be achieved.

Author Response: We have included further suggestions related to improving education of physicians and co-ordinating cross-specialty care in several paragraphs within the Discussion (see paragraphs 2 and 3). In addition, suggestions for improving patient education and support can be found in several paragraphs within the Discussion, including paragraphs 4, 5 and 6.

Monika Østensen

Comment 1: Ethics approval: In 'methods' no explicit mention of ethics approval is made, however, in the physicians' questionnaire a reference to 'code of conduct' is made. Does this imply ethics approval was given in all countries that participated in the study?

Author Response: Formal ethical review and approval was not undertaken for these survey-based studies, however the research did comply with the ICC/ESOMAR, EphMRA, ABPI, MRS and BHBIA market research codes of conduct. An additional sentence has been added to the start of the Methods section (page 8 of the manuscript) to clarify this point.

Comment 2: There is a certain abundance in the presentation of the results given both as text and figures. The figures are excellent and present the result at a glance. Perhaps the text could be somewhat shortened?

Author Response: Where data are presented in Figures any duplication in the Results text has been removed and the reader directed to the appropriate figure in which to find the data (pages 11 to 15). Where data are presented in text only this has been retained as the authors feel that this information is pertinent to the key messages and also likely of interest to many readers.

Comment 3: The citation (ref. 9) for paragraph 2, line 6 on page 6 is not adequate: this paper deals with the increased risk of preterm birth in IBD, not a decreased chance of conceiving caused by the disease state.

Author Response: This section of the Introduction has been reworked to more accurately reflect the message of the literature cited, and additional references have been included where appropriate as

requested; see paragraph 2 of the Introduction (page 6).

Zuzana Zelinkova

Comment 1: There are, methodological issues that need clarification.

Selection criteria for participating physicians:

- 3 to 30 years of experience cover a large range – differences in attitudes between the generations are likely and may influence the variation in results. For instance, there are no data shown of the physicians' age distribution per geographical region, neither are the results age-stratified.

Author Response: This is a very good point and it would certainly be interesting to stratify the results in this way. Unfortunately, however, the physician survey did not collect information on responding physician's age, therefore this information is not currently available. We have, however, included an additional statement in paragraph 7 of the Discussion (page 20) to highlight this potential issue.

- Why were the physicians participating last month in medical research excluded?

Author Response: This type of restriction is standard practice in market research to exclude those frequently involved in market research in order to avoid inclusion of 'professional' responders motivated only by receipt of the nominal payment. This has been clarified in the second paragraph of the Methods section on page 9. Furthermore, an additional sentence has been included in the first paragraph of the Methods to clarify that respondents received nominal payment to compensate for their participation in the surveys.

- A minimum of 8 patients with CD per month with a minimum of 2 patients on biologics per month is rather low. How were these limits determined? This may lead to biased results in the group of gastroenterologists as only physicians with rather limited experience with IBD (and therefore likely to be less inclined to discuss these very specific issues with the patients) were allowed to participate.

Author Response: These exclusion criteria were applied to ensure that physicians had regular experience treating CD patients with biologics, by excluding those who treated fewer than 8 CD patients per month and those who treated fewer than 2 of their CD patients with biologics. These criteria were applied to ensure that physicians with sufficient expertise were involved in the study. In addition, the thresholds were not set too high in order to avoid only including physicians with a great deal of experience, the intention was to survey physicians with a range of experience who regularly treat women of child-bearing age living with systemic inflammatory conditions. An additional sentence has been added to paragraph 3 of the Methods (page 9) to clarify this issue.

Comment 2: Patients' recruitment procedure:

- This part is unclear. It only states that a professional agency recruited the patients. How exactly were the patients approached? What was the drop-out rate during recruitment? It is known that patients willing to participate in surveys differ significantly from overall patients' population. Therefore, before making any general conclusions, the recruitment procedure with its possible bias must be clearly described in details.

Author Response: Further information regarding patient recruitment and the process used to filter respondents has been provided in paragraph 4 of the Methods (page 9-10) in order to clarify these points. Drop-out rate was not specifically calculated however for Phase 1 23,321 patients were contacted, with 2,387 subsequently failing the initial screening questions (see patient survey questions 1-3 in Appendix 2); for Phase 2 20,318 patients were contacted, with 2,160 subsequently failing the screening questions.

In addition, we have included a sentence in paragraph 7 (page 20) of the Discussion to highlight the possible bias introduced by only including data from patients who are willing and motivated to complete the questionnaire.