# PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

# **ARTICLE DETAILS**

TITLE (PROVISIONAL)	The proliferation of gynaecological scientific societies and their financial transparency: an Italian survey
AUTHORS	Vercellini, Paolo; Viganò, Paola; Frattaruolo, Maria; Somigliana, Edgardo

# **VERSION 1 - REVIEW**

REVIEWER	Bonati, Maurizio IRCCS- istituto di ricerche farmacologiche "Mario Negri", Public Health
REVIEW RETURNED	29-May-2015

GENERAL COMMENTS	The theme of the paper is interesting and the Authors' aim shared. The compliance of ethical principles should be guaranteed and proved by a scientific and professional society. Thus, transparency, independency, and autonomy should be part of the "identity card" of all scientific and professional societies. The "problem" is well-known, it is widely discussed for years, it is not exclusive of a country, society, or medical discipline. However, it continues to be present and continuous monitoring is need. These considerations should be reported and documented with examples and references in introduction section, then discussed at the end. A lot of papers were published, and the three references cited in the introduction make a wrong to what available.  Abstract. It should be reviewed (rewritten) to give greater prominence to the work done.  The text of the whole manuscript should be edited by a native English researcher.  Strengths and limitations of the study. This section has to be rewritten with appropriate sentences.  Introduction. As reported above, the work must be contextualized at national and international level, as well as concerning the different scientific fields.  Methods. The use of websites as main information source is questionable taking into account their role, aim, format, etc. and Authors intents. Websites can be useful to identify and retrieve the societies, but are scantly appropriate and accurate to collect specific information. Authors would have to apply directly to identified societies submitting a questionnaire or interviewing the president, or  However, using a website as font of information the evaluation of its quality is mandatory. Reference criteria and tools for quality evaluations were available, and should be used.  Line 145. "the headquarters was independent" this should be a result, if not it should be justified.  The chi-square test is not justified taking into account the reported results. A trend analysis was not adequately reported, and Fig. 1 is
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not correct: is not a plot of data, it is an interpolation and estimate of values not reported.  Results. The report of findings probably benefits starting from the two main Italian societies, following with the affiliated, recognized, etc. evaluating common strengths and weaknesses.  CME is source of income for the provider, thus without an evaluation of CME "products" (i.e. scientific quality, compliance with society mandate) any comment is free.  Table 2 should be commented and discussed, citing duplications, replications, networks, etc.  Discussion. Widely rewritten according to (new) methods and results.  Line 248. "PubMed for" for sustaining the sentence other retrieval approach must be applied.
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REVIEWER	Contro Elena, MD, PhD
	University of Bologna, Italy
	Dept Obstetrics and Gynecology
	Fetal Medicine Unit
REVIEW RETURNED	30-May-2015

GENERAL COMMENTS	The paper is original, well designed and well written.
	However I do not think it is suitable for publication on this journal
	because of the limited international interest. The Italian setting is
	peculiar and completely different compared to other countries.

REVIEWER	Federico Prefumo Department of Obstetrics and Gynaecology, Spedali Civili di Brescia and University of Brescia, Italy
	I am a member of the Italian Society of Gynecology and Obstetrics (SIGO) and the Italian Society for Ultrasound in Obstetrics and Gynecology (SIEOG).  I have been Vice-President of SIEOG in 2010-13, and I have been elected again as Vice-President of SIEOG for 2015-17.
REVIEW RETURNED	30-May-2015

GENERAL COMMENTS	This manuscript attempts to analyze the level of financial transparency of Italian obstetrical and gynaecological societies.
	The issue is a very important one, and the Authors should be congratulated for devising an original systematic approach to information finding in this subject: I am not aware of similar attempts having been published previously.
	The results of this study raise important issues on the financial transparency of Italian obstetrical and gynaecological societies. If published, this paper may make an important contribution to the ongoing debate on the conflicts of interest in the Italian healthcare system. Such results are of interest also for other countries.
	The study also has significant limitations, but most of them have been adequately addressed in the Discussion. I only have a few changes to suggest:
	1) I would replace the term "overspecialized" with "subspecialty".

- 2) Discussion, lines 247-50: this kind of approach to bibliographic analysis is too simplistic. As this is not crucial to the Authors' argumentation, I would delete this sentence.
- 3) one significant limitation which is not addressed by the Authors, is that they attempted to retrieve information on annual financial balances, declaration of competing interests of board members and executive personnel, etc. only from websites. It seems that they did not make any attempt to retrieve such information through direct contact with the individual societies. Although transparency would require an easy public access to such information, which is nowadays obtained through official websites, this limitation should be stated.
- 4) Finally, the Authors should make a comment on whether they think that their findings and comments only apply to ob/gyn societies, or also to other medical societies in Italy or out of Italy

### **VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1

Reviewer Name Bonati, Maurizio Institution and Country IRCCS- Istituto di Ricerche Farmacologiche "Mario Negri", Public Health

1. The theme of the paper is interesting and the Authors' aim shared. The compliance of ethical principles should be guaranteed and proved by a scientific and professional society. Thus, transparency, independency, and autonomy should be part of the "identity card" of all scientific and professional societies.

The "problem" is well-known, it is widely discussed for years, it is not exclusive of a country, society, or medical discipline. However, it continues to be present and continuous monitoring is need. These considerations should be reported and documented with examples and references in introduction section, then discussed at the end. A lot of papers were published, and the three references cited in the introduction make a wrong to what available.

The reviewer's considerations have been included in both the Introduction and Discussion sections as suggested (lines 75-90; 92-103; 120-122; 364-389; 416-436). Moreover, several publications have bee added to the reference list and cited in the above sections of the manuscript.

- 2. Abstract. It should be reviewed (rewritten) to give greater prominence to the work done. The Abstract has been modified, taking into account the word limit (lines 50-53).
- 3. The text of the whole manuscript should be edited by a native English researcher. The manuscript has now been reviewed by a native English medical translator.
- 4. Strengths and limitations of the study. This section has to be rewritten with appropriate sentences. Introduction. As reported above, the work must be contextualized at national and international level, as well as concerning the different scientific fields.

See response to point 1.

- 5. Methods. The use of websites as main information source is questionable taking into account their role, aim, format, etc. and Authors intents. Websites can be useful to identify and retrieve the societies, but are scantly appropriate and accurate to collect specific information. Authors would have to apply directly to identified societies submitting a questionnaire or interviewing the president, or... This study limitation has been addressed and the reviewer's comment included in the Discussion section (lines 316-326)
- 6. However, using a website as font of information the evaluation of its quality is mandatory. Reference criteria and tools for quality evaluations were available, and should be used.

Verifying the reliability and credibility of health information provided by obstetrical and gynaecological societies in their websites was not among our pre-planned aims. However, according to the reviewer's recommendation, we have used the HONcode instrument to evaluate the transparency of the medical information provided in the websites of the two major Italian obstetrical and gynaecological societies, Società Italiana di Ginecologia e Ostetricia (SIGO) and Associazione Ostetrici e Ginecologi Ospedalieri Italiani (AOGOI). This is explained in the Methods section (lines 172-177) and the results are included at lines 264-278.

- 7. Line 145. "the headquarters was independent..." this should be a result, if not it should be justified. Whether the headquarters were independent or located in the offices of a professional congress organiser was one of the general PMAs' characteristics retrieved from individual websites. This is included in the Methods section (lines 154-156). The headquarters of the associations were independent in 26/41 instances, and located in the offices of a professional congress organiser in the remaining 15. This is included in the Results section (lines 242-244), and commented in the Discussion section (lines 340-344).
- 8. The chi-square test is not justified taking into account the reported results. A trend analysis was not adequately reported, and Fig. 1 is not correct: is not a plot of data, it is an interpolation and estimate of values not reported.

Our statistical advisor maintains that in this particular case we may not make inferences for the general situation of obstetrical and gynaecological scientific societies based on our particular sample. Therefore, we have now chosen to disregard statistical testing. Moreover, we have changed Figure 1, which is now a simple bar graph.

9. Results. The report of findings probably benefits starting from the two main Italian societies, following with the affiliated, recognized, etc. evaluating common strengths and weaknesses. We have specifically addressed the transparency of the medical information provided by the two main Italian obstetrical and gynaecological societies in their websites using the HONcode questionnaire (see reply to point 6). With regard to transparency on COIs and commercial support, the situation is so systematically poor (disclosures and information are practically non-existent) that we do not know how we could distinguish the condition of the two main societies from that of affiliated or non-affiliated ones.

However, in order to comply with the reviewer's request, we analysed again each society's website and read all bylaws to verify whether the issue of COIs was discussed, a policy for interactions with industry was available, and sponsored sessions/symposia were included in the last PMA's annual meeting program. The information retrieved on these further items was added and used to define two domains, i) the general characteristics of the society and its website (year of establishment; whether the headquarters were independent or located in the offices of a professional congress organiser; online availability of society's bylaws; provision of CME activity; inclusion of sponsored sessions or symposia in the last society's annual meeting program; presence in society's website of industry advertisement or links to industries' websites), and ii) the financial transparency of the association (discussion of COIs in society's bylaws; adoption of a policy for interaction with industry; availability of COI disclosures of presidential trio, board members and executive staff; online availability of annual financial statement; disclosure of restricted and unrestricted industry grants and individual donations; indication of industry sponsorship in the last annual meeting program based on informative printed text in addition to mere logo inclusion). This is now included in the Methods (lines 152-164), Results (lines 242-263), and Discussion sections (lines 304-315). Table 2 has been modified accordingly. We hope that in this way the results of the survey are more informative and better organised in order to facilitate readability and comprehension.

10. CME is source of income for the provider, thus without an evaluation of CME "products" (i.e. scientific quality, compliance with society mandate) any comment is free.

The reviewer's comment has been included in the Discussion section (lines 344-346)

11. Table 2 should be commented and discussed, citing duplications, replications, networks, etc. Table 2, now Supplementary table 1, has been commented in more detail, and duplications/replications are pointed out both in the Results and the Discussion sections (lines 231-

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233 and 283-288).

12. Discussion. Widely rewritten according to (new) methods and results.

The Discussion has been amply rewritten and additional text on COIs, CME activity, policy for interactions with industry, and proposals of some medical organisations has been included (lines 364-389 and 416-436).

13. Line 248. "PubMed for..." for sustaining the sentence other retrieval approach must be applied. The sentence has been deleted.

Reviewer: 2

Reviewer Name Contro Elena, MD, PhD Institution and Country University of Bologna, Italy

The paper is original, well designed and well written.

However I do not think it is suitable for publication on this journal because of the limited international interest. The Italian setting is peculiar and completely different compared to other countries. We are not sure to have clearly understood what the reviewer means with "the Italian setting is completely different compared to other countries", therefore we are unfortunately unable to respond to this comment. We understand that the generalizability of findings of a study aimed at assessing the transparency of scientific societies within a specific specialty area and within a single country may be limited. We have addressed this in the Discussion section (lines 357-360), but believe that our methodological approach could be adopted in other countries (lines 360-363).

Although much has been written on the general concerns regarding COIs of professional medical associations and need for divestment or COIs management strategies, we are not aware of formal studies conducted to scrutinise societies' actions to put ethical principles into practice. We hope that our study could represent a model for conducting similar surveys also in other medical specialty areas.

Reviewer: 3

Reviewer Name Federico Prefumo

Institution and Country Department of Obstetrics and Gynaecology, Spedali Civili di Brescia and University of Brescia

This manuscript attempts to analyze the level of financial transparency of Italian obstetrical and gynaecological societies.

The issue is a very important one, and the Authors should be congratulated for devising an original systematic approach to information finding in this subject: I am not aware of similar attempts having been published previously.

The results of this study raise important issues on the financial transparency of Italian obstetrical and gynaecological societies. If published, this paper may make an important contribution to the ongoing debate on the conflicts of interest in the Italian healthcare system. Such results are of interest also for other countries.

The study also has significant limitations, but most of them have been adequately addressed in the Discussion. I only have a few changes to suggest:

1) I would replace the term "overspecialized" with "subspecialty". In most instances the term "overspecialised" has been replaced with "subspecialty" throughout the manuscript.

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- 2) Discussion, lines 247-50: this kind of approach to bibliographic analysis is too simplistic. As this is not crucial to the Authors' argumentation, I would delete this sentence.

  The sentence has been deleted.
- 3) One significant limitation which is not addressed by the Authors, is that they attempted to retrieve information on annual financial balances, declaration of competing interests of board members and executive personnel, etc. only from websites. It seems that they did not make any attempt to retrieve such information through direct contact with the individual societies. Although transparency would require an easy public access to such information, which is nowadays obtained through official websites, this limitation should be stated.

This limitation has been addressed and the reviewer's comment included in the Discussion section (lines 316-326).

4) Finally, the Authors should make a comment on whether they think that their findings and comments only apply to ob/gyn societies, or also to other medical societies in Italy or out of Italy The comment suggested by the reviewers is now included in the Discussion section (lines 357-363).

### **VERSION 2 – REVIEW**

REVIEWER	Maurizio Bonati, MD
	Laboratory for Mother and Child Health, Public Health Department,
	IRCCS - Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy
REVIEW RETURNED	05-Aug-2015
GENERAL COMMENTS	Authors addressed reviewers' suggestions mainly and adequately.
	The manuscript is improved.
REVIEWER	Federico Prefumo
	Department of Obstetrics and Gynaecology, Spedali Civili di Brescia and University of Brescia, Italy
	I am currently a member of SIGO and SIGO, and Vice-President of SIEOG for years 2015-17
REVIEW RETURNED	30-Jul-2015
GENERAL COMMENTS	I think that the Authors have successfully addressed the issues raised by reviewers.