

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Jun 15, 2020
To: "Mariam Naqvi" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1586

RE: Manuscript Number ONG-20-1586

Tocilizumab and Remdesivir in a Pregnant Patient with COVID-19

Dear Dr. Naqvi:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors are interested in potentially publishing your revised manuscript in a timely manner. In order to have this considered quickly, we need to have your revision documents submitted to us as soon as you are able. I am tentatively setting your due date to June 17, 2020, but please let me know if you need additional time.

The standard revision letter text follows.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

REVIEWER COMMENTS:

Reviewer #1: Clearly this is interesting and important. I think the value of this report is limited by

- 1) The inability to infer causality;
- 2) The inability to establish safety.

Most pregnant patients with COVID-19 get better with supportive care. If clinical trials establish the effectiveness and guide the role of the drugs you used outside of pregnancy, this report might be of more value.

Reviewer #2: the authors have submitted a case of a woman in 2nd trimester with declining respiratory status who was managed with IL-6 block and compassionate use remdesivir with subsequent improvement.

1 - Causal language should be removed as this is a single case. Did the patient improve because of tocilizumab, or remdesivir, the combination, or did she just improve on her own unrelated to these meds? There is no way to know for sure - it is all speculation.

2 - The Intro runs a bit long & specifically lines 79-82 where the reader is told what to expect is unnecessary

3 - What is the value of pointing out that the patient is Filipino or a dialysis technician? line 84, 88

4 - Table 1 and Figure 1 can both be sent to supplementary data

5 - Line 97 what is the value of pointing out that FHR was obtained by 'hand-held doppler device'?

6 - Could the authors better describe 'modified prone positioning' line 99?

7 - Discussion begins by unnecessarily repeating the Intro lines 76-77

8 - Stating the obvious in line 123-124 also unnecessary

9 - Lines 128-132 it would be helpful to better understand why the authors chose tocil and rem, but not any of the others listed

10 - Line 134 unnecessary to yet again point out what tocil is - this will be mentioned again in line 149

11 - What is the internal criteria for using IL-6 blockade at their hospital? line 147

12 - Line 176 unnecessary to reiterate who the patient was

13 - Concluding paragraph line 186-190 can be deleted without loss of content

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

36. Please use past tense in the precis.

59. Please consider using the term "Cytokine release syndrome" or "Cytokine storm" in the teaching point. Would you consider having 1 of your 3 teaching points specifically about remdisivir, similar to point 3 about Tocilizumab?

70. Would you consider instead of "leads to high rates"....instead "has resulted in" or "has led to...". As the rates of preterm birth and CS may not be entirely evidence based and seem largely to be iatrogenic and fueled in part by base line differences in OB Care in the primary reporting countries, it would seem appropriate to not imply otherwise.

77. Could you mention here the role of cytokines in the pathophysiology of severe COVID 19 disease as an explanation as to why an IL-6 inhibitor may be important?

84. I agree w/ the reviewer that the race and occupation of the patient don't seem relevant

98. At 22 weeks, do you think "fetal heart rate was documented" or "fetal heart rate was in the normal range" is more accurate? What is normal FHR at 22 weeks?

95. On the table could you please indicate that dates that the tocilizumab and remdisivir were started?

127. This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

134. Why did you choose Tocilizumab over other IL 6 inhibitors?

143. Please edit out the "to our knowledge" or similar wording. As the readers cannot gauge the depth and breadth of your knowledge, this phrase does not add significant meaning. You can either reference your literature search details (database searched and search terms used) that informed your knowledge, or you could say something noting that your cited references provide limited information about this point.

176. Equivalent in what way? Same serum levels? Same response?

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.

B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please ask Sarah Smithson to complete our Copyright Transfer Agreement. A link to it was sent to her today from our Editorial Manager email account.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. You mention in the acknowledgment that Gilead Sciences provided the remdesivir. Would you describe (on the title page) whether they were involved in the case otherwise?

5. Provided a retrieved date for reference 12.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Case Reports should not exceed 8 typed, double-spaced pages (2,000 words); . Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.

* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.

* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.

* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Case Reports is 125 words. Please provide a word count.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

13. Figure 1 may be resubmitted with the revision.

14. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

If you choose to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

- * A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and
- * A point-by-point response to each of the received comments in this letter.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.

June 15, 2020

Re: Manuscript # ONG-20-1586 [Revisions]

Dear Editor,

Thank you for your interest in our case report entitled “Tocilizumab and Remdesivir in a Pregnant Patient with Coronavirus Disease 2019 (COVID-19)” for consideration by *Obstetrics & Gynecology*.

We greatly appreciate the thoughtful comments from the reviewers and have edited our manuscript to reflect this feedback. Please see our point-by-point responses attached with this letter, and do not hesitate to reach out to us if any other modifications or revisions are needed.

We again confirm that this work is original and has not been published, nor it is under consideration for publication elsewhere. As the lead author, I confirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. The patient described in our report provided written consent to this manuscript.

Thank you for allowing us to submit our research and for considering it for publication. We look forward to hearing your thoughts.

Sincerely,



Mariam Naqvi, MD
Division of Maternal Fetal Medicine,
Department of Obstetrics & Gynecology
Cedars-Sinai Medical Center



Responses to reviewer comments are in blue.

REVIEWER COMMENTS:

Reviewer #1: Clearly this is interesting and important. I think the value of this report is limited by

- 1) The inability to infer causality;
- 2) The inability to establish safety.

Most pregnant patients with COVID-19 get better with supportive care. If clinical trials establish the effectiveness and guide the role of the drugs you used outside of pregnancy, this report might be of more value.

We thank Reviewer #1 for this input, and we agree that a case report is limited by its inability to establish causality and safety. We have added a statement to our discussion to highlight this limitation.

There are currently data from a randomized controlled trial demonstrating shorter time to recover with remdesivir compared to placebo, and this was cited in the report (Beigel et al, NEJM March 2020). More limited data on tocilizumab for patients with COVID-19 have been published in smaller series; however, a randomized controlled trial is ongoing and also cited in the report. We look forward to the results of ongoing clinical trials investigating both of these medications, as randomized and controlled data is essential for their continued use.

Reviewer #2: the authors have submitted a case of a woman in 2nd trimester with declining respiratory status who was managed with IL-6 block and compassionate use remdesivir with subsequent improvement.

- 1 - Causal language should be removed as this is a single case. Did the patient improve because of tocilizumab, or remdesivir, the combination, or did she just improve on her own unrelated to these meds? There is no way to know for sure - it is all speculation.

We thank Reviewer #2 for the thoughtful feedback on our report. We agree that a case report is limited by its inability to establish causality and safety. We have added a statement to our discussion to highlight this limitation. Please also see comments in response to Reviewer #1 addressing similar concerns.

- 2 - The Intro runs a bit long & specifically lines 79-82 where the reader is told what to expect is unnecessary

We agree and have shortened this part of the introduction.

- 3 - What is the value of pointing out that the patient is Filipino or a dialysis technician? line 84, 88

We removed these descriptors.

- 4 - Table 1 and Figure 1 can both be sent to supplementary data

We appreciate this feedback. If space is available, we would prefer having both the Table and the Figure available with the primary text, as this would ensure access to many readers of the Green Journal who receive the paper version directly to their office or home.

If space is limited, however, we favor including the Figure with the primary text as we found the trends in CRP and IL-6 to be a clinically interesting aspect of this case.

5 - Line 97 what is the value of pointing out that FHR was obtained by 'hand-held doppler device'?

We changed this verbiage to state that the FHR was normal.

6 - Could the authors better describe 'modified prone positioning' line 99?

We provided more details regarding the patient's positioning in the text. The modifications included use of support pillows under the gravid uterus, and a slight tilt toward the left lateral decubitus position (as opposed to directly horizontal) per guidelines from SMFM.

7 - Discussion begins by unnecessarily repeating the Intro lines 76-77

We agree this is redundant, and we shortened this sentence to remove the descriptions of remdesivir and tocilizumab, which have already been explained briefly in the Introduction.

8 - Stating the obvious in line 123-124 also unnecessary

We deleted this line.

9 - Lines 128-132 it would be helpful to better understand why the authors chose tocil and rem, but not any of the others listed

We agree that data regarding effective medications for COVID-19 are needed and are evolving. Currently, the NIH COVID-19 Treatment Guidelines Panel recommends against the use of hydroxychloroquine, hydroxychloroquine +/- azithromycin, and lopinavir/ritonavir for treatment of COVID-19 except in a clinical trial. The Panel also recommends against the use of corticosteroids for the treatment of COVID-19 in non-critically ill hospitalized patients.

We requested remdesivir as available data at that time had been overall favorable with regard to treatment of COVID-19 in non-pregnant patients, including a randomized placebo-controlled trial. The above Panel also recommends remdesivir for treatment of COVID-19 in hospitalized patients with $\text{SpO}_2 \leq 94\%$ on ambient air or those who require supplemental oxygen – both of which apply to our case.

In this patient with *marked* elevation of IL-6 and CRP, we also elected to treat with IL-6 blockade based on our hospital's criteria for this approach in non-pregnant patients. In addition, this medication has specifically been used to treat rheumatoid arthritis in pregnant patients with a favorable safety profile. The NIH Panel does not make a recommendation for or against IL-6 blockade currently as data are evolving.

10 - Line 134 unnecessary to yet again point out what tocil is - this will be mentioned again in line 149

We agree and have shortened this sentence.

11 - What is the internal criteria for using IL-6 blockade at their hospital? line 147

We added this as a Supplemental Table.

12 - Line 176 unnecessary to reiterate who the patient was

We agree and removed the redundant portion.

13 - Concluding paragraph line 186-190 can be deleted without loss of content

We shortened and changed the verbiage of the last paragraph to address the concerns of Comment 1.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues and other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

36. Please use past tense in the precis. We have made this change.

59. Please consider using the term "Cytokine release syndrome" or "Cytokine storm" in the teaching point.

We have adjusted the text and teaching point to include the term "cytokine storm."

Would you consider having 1 of your 3 teaching points specifically about remdesivir, similar to point 3 about Tocilizumab?

We have changed Teaching Point #2 to address remdesivir.

70. Would you consider instead of "leads to high rates"....instead "has resulted in" or "has led to...". As the rates of preterm birth and CS may not be entirely evidence based and seem largely to be iatrogenic and fueled in part by base line differences in OB Care in the primary reporting countries, it would seem appropriate to not imply otherwise.

We appreciate this input and have made this change.

77. Could you mention here the role of cytokines in the pathophysiology of severe COVID 19 disease as an explanation as to why an IL-6 inhibitor may be important?

We added more discussion regarding the pathophysiology of IL-6 and cell damage to lines 165-167.

84. I agree w/ the reviewer that the race and occupation of the patient don't seem relevant

We removed both of these descriptors per both of your recommendations.

98. At 22 weeks, do you think "fetal heart rate was documented" or "fetal heart rate was in the normal range" is more accurate? What is normal FHR at 22 weeks?

We have made this change and agree.

95. On the table could you please indicate that dates that the tocilizumab and remdisivir were started?

We have added these fields to the table to make this more clear.

127. This is known as a primacy claim: yours is the first, biggest, best study of its kind. In order to make such a claim, please provide the data bases you have searched (PubMed, Google Scholar, EMBASE for example) and the search terms used. IF not done, please edit it out of the paper.

For simplification we have elected to edit this out of the paper. Thank you.

134. Why did you choose Tocilizumab over other IL 6 inhibitors?

We chose Tocilizumab as it is the only FDA-approved IL-6 inhibitor, and it is the IL-6 blocker with the most safety data in pregnancy.

143. Please edit out the "to our knowledge" or similar wording. As the readers cannot gauge the depth and breadth of your knowledge, this phrase does not add significant meaning. You can either reference your literature search details (database searched and search terms used) that informed your knowledge, or you could say something noting that your cited references provide limited information about this point.

We have edited out this wording. Thank you.

176. Equivalent in what way? Same serum levels? Same response?

We have clarified this in the text.

EDITORIAL OFFICE COMMENTS:

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review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

- A. OPT-IN: Yes, please publish my point-by-point response letter.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.

[We choose to opt-in.](#)

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Please ask Sarah Smithson to complete our Copyright Transfer Agreement. A link to it was sent to her today from our Editorial Manager email account.

[Dr. Smithson completed the eCTA today,](#)

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

[This statement is included in this cover letter.](#)

4. You mention in the acknowledgment that Gilead Sciences provided the remdesivir. Would you describe (on the title page) whether they were involved in the case otherwise?

[Gilead was not involved in this case beyond providing the medication. This has been added to the title page.](#)

5. Provided a retrieved date for reference 12. [Done.](#)

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics& Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data

definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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8. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Case Reports is 125 words. Please provide a word count.

[The abstract word count is 125 words exactly.](#)

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

[We have made removed abbreviations from the title and précis, and spelled out coronavirus disease 2019 in lieu of COVID-19.](#)

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

Have confirmed that / is only in sentences expressing measurements.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here:

http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

13. Figure 1 may be resubmitted with the revision.

14. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at

<http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.