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

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.

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

Date: Aug 26, 2022

To: "L. Lewis Wall"

From: "The Green Journal" em@greenjournal.org

Subject: Your Submission ONG-22-1330

RE: Manuscript Number ONG-22-1330

The Ghost of Savita Halappanavar Comes to America

Dear Dr. Wall:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 10 days from the date of this letter. If we have not heard from you by Sep 06, 2022, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

Thank you for your submission to Obstetrics & Gynecology. Given the timeliness and importance of your article we are interested in fast tracking the submission that it will be rapidly available to our readers. As such, we would ask that you submit your responses to the Reviewer comments within the next 10 days if possible. Again, thank you for your work.

REVIEWER COMMENTS:

Reviewer #1: This is a review of Savita Halappanavar, a woman who died in Ireland from septic shock as a result of being denied an abortion after previable PPROM. The authors present a compelling narrative of this tragic outcome, outlining the devastating impact of legislative interference with medical care. I thank the authors for their work on commentary as we certainly will encounter similar cases in the US. I do have some recommendations to make the paper stronger and more accessible to the readership of the Green Journal.

Lines 5-22 and lines 66-71 are very similar/redundant. Please edit to avoid unnecessary repetition. I suspect that this is because there is an abstract and then the body of the paper, but I don't know that an abstract is necessary. I favor editing lines 66-71 and leaving the abstract as the first paragraph of the commentary.

The commentary would be more accessible if it were 200-300 words shorter. Some suggestions to short the paper:

In outlining the care that Dr. Halapana received, I would omit the day of the week (just October 21, not Sunday, October 21) or omit dates if timeframes are given (10 days later, etc.). Much of the description of the case is in the passive voice. I encourage the authors to use the active voice when possible. "The medical team followed her expectantly" rather than "she was told that she would be", etc. Recommend trimming unnecessary words whenever possible (ex. "She did not improve, so the team started IV metronidazole and sent a urine culture" for lines 123-124, etc)

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Lines 135-6: did she spontaneously labor following fetal demise? Did she ever get medications for induction? These details would be of interest to the reader.

There is considerable detail about the clinical care of Savita. It would be helpful to note generally how this information was obtained. Is all of the information public? If so, then summary statement before outlining the details of the case would be beneficial, such as "we collected information about Savita's care from publicly available sources and present the following account of her care". If the details were obtained with permission from her family, please share that information.

Lines 207-208 - while I agree with the authors sentiment to add "(ironically)" I feel that the facts of the case speak loudly enough that additional editorializing is unnecessary. I recommend removal of "ironically" and adjustment to "right to her own life". There are other areas where editorializing can be limited (ex. Remove line 209 "they could hardly do otherwise...", etc).

Lines 224-225 - recommend stating what "these cases" entails, such as "morbidity of expectant management in previable premature rupture of membranes is..."

Line 226: what is not negligible? Can a number be provided her instead?

Reviewer #2: The author submits a current commentary on the death of Savita Halappanavar, and how we can anticipate similar outcomes in the U.S. following the overturning of Roe v Wade. This is a timely and well-written commentary. I have the following comments for the author's consideration:

- 1. Line 46. The term "medical negligence" infers that the party at fault in this death was the healthcare practitioner caring for her. I would argue that the party at fault was the law that created uncertainty surrounding the ability to care for this patient. Perhaps "inappropriate medical care" would be a better term.
- 2. Line 51. Could you be more specific about "many other external observers"? Who are you trying to capture here? Even broad categories would be helpful.
- 3. Line 84-85. I am not sure that the comment that the WBC was largely ignored is useful here. The majority of the journal readers are clinicians and they will understand the clinical significance of the elevated white count.
- 4. Line 99. Are the details such as the patient and her husband being emotional at this point of the care part of public record?
- 5. Line 136. The word "finally" can be removed. The time course is evident from the description.
- 6. Line 141. Disseminated is spelled incorrectly.
- 7. Line 216. Would change this description simply to "previable prelabor rupture of membranes" here and throughout as previable infers that it was preterm.
- 8. Line 223. Would change "delivery" to "termination of pregnancy" as this could also be accomplished by D&E as you noted.

EDITORIAL OFFICE COMMENTS:

- 1. Please obtain written permission/consent from the spouse/family of the woman you are writing about in this submission to let them know you are potentially publishing about her case. Please specify that the manuscript is under consideration at Obstetrics & Gynecology. In your revision cover letter, please attest to having obtained written consent. It is also preferable to share a copy of the manuscript with them, including the photo you intend to use.
- 2. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.
- 3. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
- * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at

the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.

- * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.
- 4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."
- 5. The journal follows ACOG's Statement of Policy on Inclusive Language (https://www.acog.org/clinical-information /policy-and-position-statements/statements-of-policy/2022/inclusive-language). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."
- 6. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Current Commentary: 3,000 words

- 7. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:
- * 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 or indicate whether the meeting was held virtually).
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
- * Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.
- 8. Provide a short title of no more than 45 characters, including spaces, for use as a running foot. Do not start the running title with an abbreviation.
- 9. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Current Commentary: 250 words

- 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, except with ratios. 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 examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the formal reference list. Please cite them on the line in parentheses.

If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document. In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

Please make sure your references are numbered in order of appearance in the text.

- 13. Figure 1 may be resubmitted as-is.
- 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 https://wkauthorservices.editage.com/open-access/hybrid.html.

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 as a Microsoft Word document. Your revision's cover letter should include a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Sincerely,

Jason D. Wright, MD Editor-in-Chief

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.

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Jason Wright, MD, Editor Obstetrics & Gynecology

August 27, 2022

Dear Jason:

Thank you for your comments and for the review of my paper, "The Ghost of Savita Halappanavar Comes to America." I am pleased to submit the revised version of the manuscript, and I address the reviewers' comments in this letter.

EDITOR COMMENTS:

Thank you for your submission to Obstetrics & Gynecology. Given the timeliness and importance of your article we are interested in fast tracking the submission that it will be rapidly available to our readers. As such, we would ask that you submit your responses to the Reviewer comments within the next 10 days if possible. Again, thank you for your work.

 I appreciate your interest and I am responding as quickly as possible to expedite the "fast track" process. I have previously sent you an e-mail (August 26, 2022) in relation to some of the issues noted in your comments

REVIEWER COMMENTS:

Reviewer #1: This is a review of Savita Halappanavar, a woman who died in Ireland from septic shock as a result of being denied an abortion after previable PPROM. The authors present a compelling narrative of this tragic outcome, outlining the devastating impact of legislative interference with medical care. I thank the authors for their work on commentary as we certainly will encounter similar cases in the US. I do have some recommendations to make the paper stronger and more accessible to the readership of the Green Journal.

Lines 5-22 and lines 66-71 are very similar/redundant. Please edit to avoid unnecessary repetition. I suspect that this is because there is an abstract and then the body of the paper, but I don't know that an abstract is necessary. I favor editing lines 66-71 and leaving the abstract as the first paragraph of the commentary.

• I have some revisions, including revisions to the abstract. My understanding from the attached Editor's comments is that an abstract is required, therefore I have retained the abstract while simultaneously trying to address the reviewer's comments.

The commentary would be more accessible if it were 200-300 words shorter. Some suggestions to short the paper:

• I have gone through the manuscript again with an eye to being more parsimonious.

In outlining the care that Dr. Halapana received, I would omit the day of the week (just October 21, not Sunday, October 21) or omit dates if timeframes are given (10 days later, etc.). Much of the description of the case is in the passive voice. I encourage the authors to use the active voice when possible. "The medical team followed her expectantly" rather than "she was told that she would be", etc. Recommend trimming unnecessary words whenever possible (ex. "She did not improve, so the team started IV metronidazole and sent a urine culture" for lines 123-124, etc)

 See previous comments. In this case, she was told she would be followed expectantly. She and her husband were not given any other choice. I think the wording here is actually important and I have largely left it intact.

Lines 135-6: did she spontaneously labor following fetal demise? Did she ever get medications for induction? These details would be of interest to the reader.

• She did not receive medications for induction (although she clearly should have). Labor was spontaneous. I have amended the article to clarify.

There is considerable detail about the clinical care of Savita. It would be helpful to note generally how this information was obtained. Is all of the information public? If so, then summary statement before outlining the details of the case would be beneficial, such as "we collected information about Savita's care from publicly available sources and present the following account of her care". If the details were obtained with permission from her family, please share that information.

• I have clarified this information, although it is clear from the references that this is all in the public domain. Each paragraph actually cites the inquest report from which this information is taken. Surely readers can look at the references. The article specifically cites these sources in line 59 [references 15-20]. Kitty Holland published a detailed account of the case (working closely with Savita's husband, Praveen) in 2013 entitled Savita: The Tragedy that Shook a Nation. Savita's picture was provided by her husband to The Irish Times and was used on the book cover as well as on posters during the campaign to overturn the Irish abortion laws. Two Irish government inquests into the case were published and are available online, also in the public domain. It should be obvious to any reader where the information was obtained.

Lines 207-208 - while I agree with the authors sentiment to add "(ironically)" I feel that the facts of the case speak loudly enough that additional editorializing is unnecessary. I recommend removal of "ironically" and adjustment to "right to her own life". There are other areas where editorializing can be limited (ex. Remove line 209 "they could hardly do otherwise...", etc).

 I have been through the case to minimize editorializing. I would note in overview that the entire case became a massive "editorial" on reproductive health care in Ireland that lasted for years until the Irish abortion referendum in 2018. Lines 224-225 - recommend stating what "these cases" entails, such as "morbidity of expectant management in previable premature rupture of membranes is..."

Noted and attended to.

Line 226: what is not negligible? Can a number be provided her instead?

NEED TO ADDRESS HERE

Reviewer #2: The author submits a current commentary on the death of Savita Halappanavar, and how we can anticipate similar outcomes in the U.S. following the overturning of Roe v Wade. This is a timely and well-written commentary. I have the following comments for the author's consideration:

Line 46. The term "medical negligence" infers that the party at fault in this death was the healthcare practitioner caring for her. I would argue that the party at fault was the law that created uncertainty surrounding the ability to care for this patient. Perhaps "inappropriate medical care" would be a better term.

- Noted and addressed.
- 2. Line 51. Could you be more specific about "many other external observers"? Who are you trying to capture here? Even broad categories would be helpful.
 - Noted. I think the details are contained in the 5 references cited in this paragraph, but I have revised this sentence to read "as well as by many other commentators and protestors."
- 3. Line 84-85. I am not sure that the comment that the WBC was largely ignored is useful here. The majority of the journal readers are clinicians and they will understand the clinical significance of the elevated white count.
 - I actually disagree here. My hope is that this article will receive wide publicity by the general public and this information is very helpful in that context. I do not doubt that clinical readers will understand this, but the general public reading this article might not. I have therefore opted to keep this information in. The clinical reader also needs to know that the team taking care of her neglected/ignored/overlooked the significance of this lab finding.
- 4. Line 99. Are the details such as the patient and her husband being emotional at this point of the care part of public record?
 - This is all fully documented in the public record.
- 5. Line 136. The word "finally" can be removed. The time course is evident from the description.
 - Noted.

- Line 141. Disseminated is spelled incorrectly.
 - Noted and corrected.
- 7. Line 216. Would change this description simply to "previable prelabor rupture of membranes" here and throughout as previable infers that it was preterm.
 - Noted and corrected.
- 8. Line 223. Would change "delivery" to "termination of pregnancy" as this could also be accomplished by D&E as you noted.
 - Noted and corrected.

EDITORIAL OFFICE COMMENTS:

- 1. Please obtain written permission/consent from the spouse/family of the woman you are writing about in this submission to let them know you are potentially publishing about her case. Please specify that the manuscript is under consideration at Obstetrics & Gynecology. In your revision cover letter, please attest to having obtained written consent. It is also preferable to share a copy of the manuscript with them, including the photo you intend to use.
 - I am not sure that this is possible under the "fast track" timeline suggested of 10 days.
 - I fully understand the desirability of doing this if possible, but I also do not think this is necessary. Considering what happened in Ireland, Savita Halappanavar is considered a "public figure" and should be treated as such. Her husband cooperated fully with the publicity of this case and personally provided the photograph that was published in *The Irish Times*. I have permission from *The Irish Times* to use this photograph and that documentation was submitted along with the manuscript. Savita's family in Ireland and in India were active participants in the campaign to amend the Irish constitution and to overturn the Irish abortion laws, and this is fully and copiously documented in the public record. They collaborated extensively with Kitty Holland on her book about the case and allowed Savita's photograph to be used on posters in the campaign for abortion law reform. I have attached a second figure, courtesy of *The Irish Times*, that can be used along with or instead of, the photograph of Savita.
 - Her husband, Praveen Halappanavar, worked for Boston Scientific in Dublin and later moved to the United States. I understand he is currently an engineer with Intuitive, also in the medical engineering field. I have tried to contact him through Linked-In, but have not yet had a response. I have no other contact information for him. In light of his extensive cooperation with the Irish abortion reform campaign and the fact that <u>ALL of this</u> information is widely available in the public domain, I do not think additional family permission is required here. It is an exceptional case.
 - I have offered to share the manuscript with him prior to publication, but I have not yet had a response from him in this regard.

- 2. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.
 - I have no objection to the revision letter being available.
- 3. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

Done

- * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
- * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.
 - None of this information is pertinent to this manuscript.
- 4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."
 - I have reviewed the manuscript with this in mind.
- 5. The journal follows ACOG's Statement of Policy on Inclusive Language (https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org %2Fclinical-information%2Fpolicy-and-position-statements%2Fstatements-of-policy%2F2022%2Finclusive-
- language&data=05%7C01%7Cwalll%40wustl.edu%7C8c3dcd07b2f04b071d8208d a879d4f9b%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637971407114 334571%7CUnknown%7CTWFpbGZsb3d8eyJWljoiMC4wLjAwMDAiLCJQljoiV2luMzliLCJBTil6lk1haWwiLCJXVCl6Mn0%3D%7C3000%7C%7C%7C&sdata=V15U9YHjaNkmG4kxex1%2FD2TnyL1LYuXGe%2FskzL%2Fecgw%3D&reserved=0). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."
 - I have reviewed this. I am writing a clinical biography of a pregnant woman. Noted.

6. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Current Commentary: 3,000 words

- The article is under the word limit.
- 7. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:
- * All financial support of the study must be acknowledged.
 - No financial support was given.
- * 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.
 - Not applicable.

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- * 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.
 - Not applicable.
- * 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 or indicate whether the meeting was held virtually).
 - Not applicable.
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
 - Not applicable.
- * Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.
 - Not applicable.

- 8. Provide a short title of no more than 45 characters, including spaces, for use as a running foot. Do not start the running title with an abbreviation.
 - Provided
- 9. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.
 - Noted.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Current Commentary: 250 words

 Although reviewer 1 suggested eliminating the abstract, I have kept the abstract in accord with the editorial policy stated here.

Respectfully submitted,

L. Lewis Wall, MD, DPhil.

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