

OBSTETRICS & GYNECOLOGY



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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)*

**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: Jul 02, 2020
To: "Abigail R.A. Aiken" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1799

RE: Manuscript Number ONG-20-1799

Demand for Self-Managed Online Telemedicine Abortion in the United States during COVID-19

Dear Dr. Aiken:

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 July 7, 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: The purpose of this manuscript was " 1) to assess the impact of the emergence of COVID-19 on US demand for self-managed medication abortion, by quantifying changes in requests relative to baseline trends; and 2) to examine variation in these changes at the state level, since there is considerable heterogeneity among states in both the burden of COVID-19 infection and the policy response." This was a retrospective, database(s) study.

1. How is the data on online requests for medical abortion services stored? Is each request stored in a database with patient identifying information, home location, consultation form, those who met criteria and received a prescription, and follow-up? Does the patient directly enter information in the database? How is the data managed? How valid and reliable is the data in this database?
2. The authors note that "SafeGraph infers a home location for each device based on its night-time location." Do the authors have a reference for this statement? How valid is this method of determining a person's home location?
3. Could the authors please move their discussion of Aid Access to the Introduction, instead of having it in the Method's Section (lines 93 to 104)? What are the clinical criteria that have to be met for dispensing a prescription of mifepristone and misoprostol to the patient? What dose of mifepristone and misoprostol are dispensed? When is the "real-time instruction and follow-up provided by email?
4. In the Methods section, could the authors please include in their exclusion criteria that states were excluded if they had less than ten expected requests in the "after" period?
5. The authors note that they considered the "after" period for each state as starting the day after the state issued state-wide business-closure orders, because almost all states implemented them. How many states did not implement the business-closure orders? Did all states with an increase or the one with a decrease in Aid Access requests have state-wide business-closure orders? Did the authors evaluate or consider evaluating their data using March 13th as the start of the "after" period given that it was when "the US declared COVID-19 a national emergency?
- 6, Line 119: "state-level restrictions on abortion" and line 126 "abortion restriction". Should this be COVID-19 associated state-level abortion restrictions? Or did they include restrictions that were in place before COVID-19?
7. The authors note " Between March 20th 2020 and April 11th 2020 (the "after" period) there was a 27% increase in requests across the US as a whole ($p < 0.001$) (Table 1)." How did they determine the "after" period for the US as a whole? Please include in the Methods section where they discuss how the "after" period was determined for a specific state.

8. Line 274: "One potential policy solution is to expand remote provision of medication abortion up to 10 weeks' gestation." In Line 94 they note that Aid Access provides medical abortion services in the US up to 10 weeks' gestation. Please clarify.
9. In table 2. Please give units of time for the last column "Difference in median time at home".
- 10, Line 163: "state business closures went into using" Should this be "state business closures went into effect using"?

Reviewer #2: The authors present data on the incidence of requests for self-managed abortion via tele-medicine during the start of the covid-19 pandemic. I have several questions for the authors:

1. line 105. how did the authors obtain these data? are they publicly available, did they make a request to the organization, or did one of the authors have "inside" access to these data? it is important to clarify this.
2. similarly, the authors should comment on how they are confident the data are accurate and that data collection methods did not change over the course of the study period?
3. was the state determined from the address of the patient, or another method? was this verified or simply self reported?
4. the authors showed an increase in requests for this service. as they correctly noted in the discussion, this could be due to several factors, including increased requests for all abortion services, as well as those done remotely specifically. however, the authors then make the conclusion that federal oversight should be reduced due to this increased demand. while this certainly makes sense, couldn't one come to the opposite conclusion from the same data? namely, that increased demand and usage require more oversight, not less?
5. figure 1 and 2 should also include the graphs for the entire cohort (ie all states combined).

Reviewer #3: The authors have queried Aid Access - the sole telemedicine abortion service in the US - to determine patterns during the pandemic

Abstract

- 1 - Interesting findings reported here and highly relevant Conclusions

Intro

- 2 - Much of the beginning (lines 61-66) is old news & overall this section could be shortened considerably
- 3 - Intriguing that 'some' states included abortion services as non-essential healthcare services & really astounding, but not really surprising that Texas was an outlier here
- 4 - Powerful info presented in lines 73-79, again highly relevant

Methods

- 5 - Good description of how Aid Access works (lines 93-104)
- 6 - Interesting SafeGraph social distancing data is included (line 148+)

Results

- 7 - Table 2 and Figure 2 could be transferred to SDC. Figure 1 needs to be bigger as hard to see.
- 8 - It gets hard to keep things straight and sentences such as line 187-189 are particularly difficult to decipher

Discussion

- 9 - Line 251 why was Aid Access 'forced to pause service provision'?
- 10 - Powerful concluding paragraphs

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: The column "Percent Increase Over Baseline Trend" should be Percent change, since some had a decrease and one

had no change. Also many States had modest absolute counts (esp KS, or many States in No change in requests group, thus there was likely low power to discern a difference. Since the Authors provided an aggregate of actual vs expected requests for all States, should also provide an analysis of all States with increase, all States with "No change in Requests". The designation "increase", "decrease" or "no change" as indicated in the left hand column is misleading, since some of the "decrease" category did have an increase, albeit not a significant one, and overall, this group had a slightly (+) change, but not a significant one. So, the designations should not be based on absolute increase, no change or decrease, but rather, on whether the changes O/E were significantly different. Again, for many of the States (including, but no limited to those omitted from analysis), the counts were so small that either they were purposely omitted from the analysis or had such low stats power that the NS difference of O/E may not be generalizable.

Table 2: The Authors need to clarify the column title "Abortion restrictions". They are referring to additional or new abortion restrictions associated with Covid-19, these States were heterogeneous in their baseline degree of abortion restrictions. That is, the designation "None" could be misinterpreted by the reader.

EDITOR'S COMMENTS:

Please revise this paper as a "Research Letter." Much of the state-by-state data can be moved to supplemental digital content. See particularly the Statistical Editor's comments regarding this. Your current paper includes a lot of editorial content, particularly as it relates to REMS. While this is an important discussion, it takes away from the power of your paper and is tangential to your data—almost like you were looking for an opportunity to address it. Please remove this. Some of the criticism of your paper is that it is not surprising that demand for medical abortion telemedicine services increased during the pandemic as ALL telemedicine service demands increased. Were abortion services demand in excess of other? The differences at baseline in different states with respect to the degree of restrictive abortion laws, compounded by further restrictions in some states during the pandemic, is based on what becomes very small numbers. Can you address this?

None of the authors indicate an affiliation with Aid Access. How did you get this data? Is it publicly available? Does the leadership at Aid Access know this paper has been submitted? How were they involved in the study? This needs to be described clearly. Why was Aid Access forced to pause services?

In addition, 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.

EDITORIAL OFFICE COMMENTS:

1. The Editor has requested that you reformat this to a Research Letter. The guidelines for this article type are as follows:

The Research Letter is a concise, focused report of original research (including pre-clinical research, sub-analyses or updates of previously published research, small studies, or pilot studies). Length should not exceed 600 words (approximately 2 1/2 manuscript pages; see Table 1). Figures or tables are limited to two, total.

Research Letters should be organized using the following headings: Introduction, Methods, Results and Discussion. An abstract should not be included.

2. 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.

3. 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 check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the

manuscript's title page.

4. Please add this text to your Financial Disclosure: "Abigail R.A. Aiken was previously a consultant for Agile Therapeutics (2016-2018). Rebecca Gomperts is the Founder and Director of Aid Access."

5. Please note the following regarding nomenclature surrounding COVID-19 and SARS-CoV-2, which are based on WHO guidelines and journal style:

a. "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" is the name of the virus, and "coronavirus disease 2019 (COVID-19)" is the name of the disease it causes, similar to the differentiation between "HIV" and "AIDS." COVID-19 should be only when discussing patients with symptomatic disease.

b. "Infection" is not used with "COVID-19." Similar to the differentiation between HIV and AIDS, SARS-CoV-2 infection can, but does not always, cause COVID-19, just as HIV infection can, but does not always, cause AIDS. Please be sure your paper does not use "COVID-19 infection."

6. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

7. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

8. 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.

9. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters articles should not exceed 2.5 pages (600 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.

10. 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).

11. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

12. 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.

13. 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.

14. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

15. In your submission, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

16. 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.

17. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

18. Figures

Figure 1: The current file may be resubmitted as-is.

Figure 2: Please consider moving this to supplemental digital content, as this will not fit in print.

19. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

20. 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

2019 IMPACT FACTOR: 5.524

2019 IMPACT FACTOR RANKING: 6th out of 82 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.



POPULATION RESEARCH CENTER
THE UNIVERSITY OF TEXAS AT AUSTIN

[REDACTED]

July 3rd, 2020

Dear Dr. Chescheir,

We are pleased to resubmit our manuscript entitled “Demand for Self-Managed Online Telemedicine Abortion in the United States during COVID-19”. My co-authors have approved the manuscript. We have submitted the paper solely to *Obstetrics & Gynecology* and we will not publish, post, or submit the paper to any other venue while it is under consideration at the journal. A declaration of transparency appears at the end of this letter. The Institutional Review Board at the University of Texas at Austin approved the study.

As requested, we have reformatted the manuscript as a Research Letter. We have done our best to meet the quick turnaround time requested for this revision in order to allow timely publication. We endeavored to strike a balance between brevity and providing sufficient detail on our findings and their implications. As such, our manuscript is 655 words in length, with one table. We have also provided a comprehensive appendix that will allow interested readers a transparent and in-depth view of our findings and methods.

A detailed point-by-point response to the reviewer and Editor comments follows.

Many thanks for your further consideration of our work.

Sincerely,

A handwritten signature in black ink that reads "Abigail R.A. Aiken".

Abigail R.A. Aiken, MD, MPH, PhD

[REDACTED]

Declaration of Transparency:

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.

Signed by: Abigail R.A. Aiken*

*The manuscript's guarantor.

Response to reviewers

Please note that because the manuscript has been resubmitted as a Research Letter (as requested by the Editor), some of the line numbers in the following section refer to the online appendix, which now contains most of the details relevant to the reviewer comments. These are marked as “Appendix 1, line X”.

REVIEWER COMMENTS:

Reviewer #1: The purpose of this manuscript was " 1) to assess the impact of the emergence of COVID-19 on US demand for self-managed medication abortion, by quantifying changes in requests relative to baseline trends; and 2) to examine variation in these changes at the state level, since there is considerable heterogeneity among states in both the burden of COVID-19 infection and the policy response." This was a retrospective, database(s) study.

1. How is the data on online requests for medical abortion services stored? Is each request stored in a database with patient identifying information, home location, consultation form, those who met criteria and received a prescription, and follow-up? Does the patient directly enter information in the database? How is the data managed? How valid and reliable is the data in this database?

The data are stored by Aid Access in accordance with their security protocols. People making requests to the service enter information through online forms rather than entering it directly into a database. The online forms then automatically populate the service’s database with no manual intervention or data entry required. The information in the database is therefore self-reported by people who request medication abortion from the service and there is no way to clinically validate the information they provide since the service relies entirely on online telemedicine (so by definition, these abortions are taking place outside of the formal healthcare setting). However, since this analysis is only concerned with the number of requests received—rather than the information contained in the requests—we do not get into these details in the manuscript. The data are managed by the Aid Access helpdesk team. The researchers received only fully anonymized data from Aid Access and did not have access to the service’s database, which contains identifiable data. In the revised Research Letter, we have briefly explained that the data were provided to us in fully de-identified format by Aid Access (Manuscript line 50 and Appendix 1 lines 160-163).

2. The authors note that "SafeGraph infers a home location for each device based on its night-time location." Do the authors have a reference for this statement? How valid is this method of determining a person's home location?

Yes, the reference in the manuscript (reference #6) includes full details of all fields available in the SafeGraph data including the “Home dwell time” number. Further details about how SafeGraph works can be found in the supplemental appendix. Obviously this method is not perfect or comprehensive (since not everyone is able to spend night time at home). Here is how SafeGraph describes their process in the documentation:

“Home is defined as the common nighttime location for the device over a 6-week period where nighttime is 6 pm - 7 am... We require a sufficient amount of evidence (total data points and distinct days) to assign a home (common nighttime) location for the device.”

We feel that SafeGraph is the best available data we have for constructing useful measures of social distancing. It is used by many of the major research efforts that are trying to track the pandemic, including those reporting forecasts to the CDC. We have looked at other fields in the SafeGraph data, including frequency of visitations to common commercial points of interest (e.g. grocery stores), and they reflect broadly similar trends to the Home Dwell Time metric. Finally, we also looked at the Apple Maps mobility data, which measures social distancing by the frequency of requests for walking, driving, or biking directions to the Apple Maps app. Again, it shows quite similar trends to what we see in the SafeGraph data. At the high level of geographic aggregation that we are using (states), virtually all of the available data sources that measure social distancing tell very similar stories of change within a state over time, as well as differences across states.

3. Could the authors please move their discussion of Aid Access to the Introduction, instead of having it in the Method's Section (lines 93 to 104)? What are the clinical criteria that have to be met for dispensing a prescription of mifepristone and misoprostol to the patient? What dose of mifepristone and misoprostol are dispensed? When is the "real-time instruction and follow-up provided by email?

Since the manuscript has now been reformatted as a 600-word Research Letter, we are unfortunately not able to accommodate these details. We include a description of Aid Access as well as a reference to follow for further information on clinical criteria and medication dosage for those interested in more detail (Manuscript, reference #3, Appendix 1, lines 57-64 and reference #9).

4. In the Methods section, could the authors please include in their exclusion criteria that states were excluded if they had less than ten expected requests in the "after" period?

Since the manuscript has now been reformatted as a 600-word Research Letter, we are unfortunately not able to accommodate these details. In the appendix, we explain that states with less than ten expected requests in the "after" period were excluded from the analysis (Appendix 1, line 119-122). This information is also included as a footnote to Table 1 in the manuscript.

5. The authors note that they considered the "after" period for each state as starting the day after the state issued state-wide business-closure orders, because almost all states implemented them. How many states did not implement the business-closure orders? Did all states with an increase or the one with a decrease in Aid Access requests have state-wide business-closure orders? Did the authors evaluate or consider evaluating their data using March 13th as the start of the "after" period given that it was when "the US declared COVID-19 a national emergency?

Three states did not implement business closure orders (NE, SD, and ND), but none of these met the threshold number of requests to be included in the analysis. All of the states included in the analysis (including those that showed a significant increase or decrease in requests) enacted business closures, and the dates of these closures are included in Table 2 (now in Appendix 1). We decided not to use the March 13th date as a nationwide threshold and apply it to each state, because it is very clear that different states had very different perceptions of the risk of COVID when it first appeared in the US, as well as very different responses to the emergence of the pandemic. A specific objective of our paper is to evaluate how requests to the Aid Access service varied by state, and so we chose to give each state its own individual threshold date that best reflected the state-level response.

6, Line 119: "state-level restrictions on abortion" and line 126 "abortion restriction". Should this be COVID-19 associated state-level abortion restrictions? Or did they include restrictions that were in place before COVID-19?

Thank you for pointing out this omission, we have now clarified that these are COVID-19 related abortion restrictions (Appendix, lines 83 and 90). These lines have been edited in the manuscript during its reformatting into a research letter and so this comment is no longer relevant there.

7. The authors note " Between March 20th 2020 and April 11th 2020 (the "after" period) there was a 27% increase in requests across the US as a whole ($p < 0.001$) (Table 1)." How did they determine the "after" period for the US as a whole? Please include in the Methods section where they discuss how the "after" period was determined for a specific state.

In the model that examines the US as a whole, we allowed each state to have its own individual threshold date. We have included an explanation of this in Appendix 1, lines 111-1113.

8. Line 274: "One potential policy solution is to expand remote provision of medication abortion up to 10 weeks' gestation." In Line 94 they note that Aid Access provides medical abortion services in the US up to 10 weeks' gestation. Please clarify.

The two are not related. We say "one potential policy solution is to expand remote provision of medication abortion up to 10 weeks' gestation" because this is the gestational limit for medication abortion in any setting in the US, as stipulated by the FDA. A key point here is that while Aid Access provides medication abortion up to 10 weeks to people living in the US, it does so entirely outside the formal US healthcare setting, and so these are self-managed abortions. Due to the increased demand for the service in some states during the COVID pandemic, we are thus suggesting policies to expand access to medication abortion using telemedicine *within* the formal healthcare setting.

9. In table 2. Please give units of time for the last column "Difference in median time at home". **Thanks for catching this omission. The unit of time is minutes and we have added this information to Table 2 in Appendix 1.**

10, Line 163: "state business closures went into using" Should this be "state business closures went into effect using"?

Thanks for catching this typo: we have now corrected it (Appendix 1, line 157).

Reviewer #2: The authors present data on the incidence of requests for self-managed abortion via telemedicine during the start of the covid-19 pandemic. I have several questions for the authors:

1. line 105. how did the authors obtain these data? are they publicly available, did they make a request to the organization, or did one of the authors have "inside" access to these data? it is important to clarify this.

Aid Access provided us with the de-identified data (Manuscript line 50 and Appendix 1 lines 160-163). Additionally, one of our authors is the Founder and Director of Aid Access, as is listed in her disclosures. We have now also included Aid Access in this co-author's affiliation information on the title page of the Research Letter.

2. similarly, the authors should comment on how they are confident the data are accurate and that data collection methods did not change over the course of the study period?

As explained the response to Reviewer 1 above, these data represent requests to the Aid Access service, and people make these requests using the online consultation form on the Aid Access website. This process did not change during the study period. We feel confident that the data are accurate since the only way that a request makes it into the database is if a person fills out the consultation form online.

3. was the state determined from the address of the patient, or another method? was this verified or simply self reported?

The state was determined by the information the person accessing the service provided at the time of consultation. There is no way to verify that a person actually lives in the state they provided, but since the medications are to be shipped to their home, it would be counter-productive for a person to give an incorrect state.

4. the authors showed an increase in requests for this service. as they correctly noted in the discussion, this could be due to several factors, including increased requests for all abortion services, as well as those done remotely specifically. however, the authors then make the conclusion that federal oversight should be reduced due to this increased demand. while this certainly makes sense, couldn't one come to the opposite conclusion from the same data? namely, that increased demand and usage require more oversight, not less?

While we see what the reviewer is saying, the point about federal oversight as it relates to medication abortion is that it is currently a major reason why such abortions cannot be provided through a remote telemedicine model within the formal healthcare setting. The fact the more people are turning to self-managed abortions through Aid Access strongly suggests that barriers to in-clinic care have gotten worse during the pandemic. Moreover, we did not see a blanket increase in requests to Aid Access: the biggest increases in requests were seen in states with high burdens of COVID infection or which put in place additional severe restrictions on in-clinic care during the pandemic. Without a change to FDA policy on mifepristone, it is not possible to provide a fully remote telemedicine medication abortion service in the US. As we note in the paper, other countries, including the UK, have already implemented such fully remote services to reduce the risks to patients of coming in person to a clinic. If more people are turning to self-management during COVID either because they cannot or do not want to access in-clinic care, it is not clear what good additional federal restrictions on medication abortion would do, especially when they currently serve as a major barrier to providing care by telemedicine.

5. figure 1 and 2 should also include the graphs for the entire cohort (i.e. all states combined).

Figures showing the results for all of the states are included in Appendix 1 (Figures 1 and 2) since space limitations prevent us from including a graph for every state in the Research Letter.

Reviewer #3: The authors have queried Aid Access - the sole telemedicine abortion service in the US - to determine patterns during the pandemic

Abstract

1 - Interesting findings reported here and highly relevant Conclusions

Many thanks for this positive feedback

Intro

2 - Much of the beginning (lines 61-66) is old news & overall this section could be shortened considerably

This point is well taken. We have now considerably streamlined the introduction since the manuscript has been reformatted as a Research Letter.

3 - Intriguing that 'some' states included abortion services as non-essential healthcare services & really astounding, but not really surprising that Texas was an outlier here

4 - Powerful info presented in lines 73-79, again highly relevant

Thank you for this positive feedback!

Methods

5 - Good description of how Aid Access works (lines 93-104)

6 - Interesting SafeGraph social distancing data is included (line 148+)

Many thanks for this encouragement!

Results

7 - Table 2 and Figure 2 could be transferred to SDC. Figure 1 needs to be bigger as hard to see.

These Tables and Figures have now all been moved to Appendix 1.

8 - It gets hard to keep things straight and sentences such as line 187-189 are particularly difficult to decipher

We have now considerably pared down and streamlined our description of the results since the paper has been reformatted as a Research Letter.

Discussion

9 - Line 251 why was Aid Access 'forced to pause service provision'?

This was due to the suspension of flights to the US from the country where the medications ship from. International flights were grounded temporarily due to the COVID pandemic. We now explain this in Appendix 1 (lines 249-250).

10 - Powerful concluding paragraphs

Many thanks!

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: The column "Percent Increase Over Baseline Trend" should be Percent change, since some had a decrease and one had no change. Also many States had modest absolute counts (esp KS, or many States in No change in requests group, thus there was likely low power to discern a difference. Since the Authors provided an aggregate of actual vs expected requests for all States, should also provide an analysis of all States with increase, all States with "No change in Requests". The designation "increase", "decrease" or "no change" as indicated in the left hand column is misleading, since some of the "decrease" category did have an increase, albeit not a significant one, and overall, this group had a slightly (+) change, but not a significant one. So, the designations should not be based on absolute increase, no change or decrease, but rather, on whether the changes O/E were significantly different. Again, for many of the States (including, but no limited to those omitted from analysis), the counts were so small that either they were purposely omitted from the analysis or had such low stats power that the NS difference of O/E may not be generalizable.

We have changed the table to use “Percent Change” rather than “Percent Increase.”

We have also included as a limitation that our study may have a lack of power to detect changes in states with smaller numbers of requests (Manuscript lines 90-91). We have also changed Table 1 to reflect the fact that there were four states where we did estimate relative changes of at least 20% in magnitude, but where the results were not statistically significant. These four states are classified as “Changes of at least 20%, but not significant.” The remaining states without significant findings were labeled as “Changes of less than 20% and not significant.” We think that this table now appropriately conveys a message both about practical significance (the estimated effect size) as well as statistical significance. We chose 20% change as a reasonable because all the states with statistically significant changes all have an effect size of 20% or more.

Table 2: The Authors need to clarify the column title "Abortion restrictions". They are referring to additional or new abortion restrictions associated with Covid-19, these States were heterogeneous in their baseline degree of abortion restrictions. That is, the designation "None" could be misinterpreted by the reader.

Many thanks for pointing out this omission: we have now made this change in Table 2 (now in Appendix 1).

EDITOR'S COMMENTS:

Please revise this paper as a “Research Letter.” Much of the state-by-state data can be moved to supplemental digital content. See particularly the Statistical Editor’s comments regarding this.

As requested, we have reformatted the paper as a Research Letter.

Your current paper includes a lot of editorial content, particularly as it relates to REMS. While this is an important discussion, it takes away from the power of your paper and is tangential to your data—almost like you were looking for an opportunity to address it. Please remove this.

We have considerably pared down the Discussion section of the manuscript in its revised version as a Research Letter. We have removed any editorializing and provide only the facts, particularly with respect to the REMS (which is mentioned only once in the context of the change that would be necessary to allow no-touch telemedicine provision of medication abortion within the formal US healthcare system). We feel that it is important to include this aspect in our discussion since the implication of our results is that people are turning to abortion telemedicine models that operate *outside* of the formal healthcare setting during the pandemic. Manuscript lines 95-97.

Some of the criticism of your paper is that it is not surprising that demand for medical abortion telemedicine services increased during the pandemic as ALL telemedicine service demands increased. Were abortion services demand in excess of other? The differences at baseline in different states with respect to the degree of restrictive abortion laws, compounded by further restrictions in some states during the pandemic, is based on what becomes very small numbers. Can you address this?

We are not aware of any current method of quantifying demand for other telemedicine services in the US. However, we think that the point here is not whether demand for telemedicine abortion services increased more than demand for any other kind of telemedicine service, but rather that other kinds of medical services can be provided by telemedicine *within* the formal US healthcare system, whereas medication abortion cannot. People making requests to Aid Access are looking for self-managed abortions (i.e. abortions that take place entirely *outside* of the formal US healthcare setting). While these abortions involve input from a doctor, who reviews the consultation form, and a helpdesk, which provides information and support via email, they do not involve a real-time video or phone consultation and they are not without legal risk. Our results are important because they are showing not just an increased demand for medication abortion by telemedicine during the COVID pandemic, but also an increased demand that is unfulfilled by our healthcare system. Moreover, rather than a blanket increase in requests, we are seeing the largest and most significant increases in states worst hit by COVID or which enacted additional abortion restrictions during the pandemic. This fact suggests that people are struggling to access care in the clinical setting both due to the extra policy barriers placed in their way and due to the fear of going to a clinic and risking infection. These issues could indeed be dealt with by increasing telemedicine abortion services that provide fully remote care within the formal healthcare setting. But, without a change to the REMS, such services cannot be set up (hence the importance of our very brief discussion of the REMS in the Discussion).

None of the authors indicate an affiliation with Aid Access. How did you get this data? Is it publicly available? Does the leadership at Aid Access know this paper has been submitted? How were they involved in the study? This needs to be described clearly. Why was Aid Access forced to pause services?

These data are not publicly available and were provided to us in fully anonymized format by Aid Access (as described in the manuscript lines 49-50). As stated in her author disclosures, our co-author Dr. Gomperts is Founder and Director of Aid Access. While her primary affiliation with Women on Web, we have now also included her Aid Access affiliation in the author information on the title page.

Aid Access was forced to pause services due to the suspension of flights to the US from the country where the abortion medications ship from. This temporary suspension is due to the COVID pandemic. We have now included this information in Appendix 1 (lines 249-250).

EDITORIAL OFFICE COMMENTS:

1. The Editor has requested that you reformat this to a Research Letter. The guidelines for this article type are as follows:

The Research Letter is a concise, focused report of original research (including pre-clinical research, sub-analyses or updates of previously published research, small studies, or pilot studies). Length should not exceed 600 words (approximately 2 1/2 manuscript pages; see Table 1). Figures or tables are limited to two, total.

Research Letters should be organized using the following headings: Introduction, Methods, Results and Discussion. An abstract should not be included.

We have reformatted the manuscript as a Research Letter.

2. 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.

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

All confirmed correct.

4. Please add this text to your Financial Disclosure: "Abigail R.A. Aiken was previously a consultant for Agile Therapeutics (2016-2018). Rebecca Gomperts is the Founder and Director of Aid Access."

We have now disclosed this information on the manuscript's title page.

5. Please note the following regarding nomenclature surrounding COVID-19 and SARS-CoV-2, which are based on WHO guidelines and journal style:

a. "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" is the name of the virus, and "coronavirus disease 2019 (COVID-19)" is the name of the disease it causes, similar to the differentiation

between “HIV” and “AIDS.” COVID-19 should be only when discussing patients with symptomatic disease.

b. “Infection” is not used with “COVID-19.” Similar to the differentiation between HIV and AIDS, SARS-CoV-2 infection can, but does not always, cause COVID-19, just as HIV infection can, but does not always, cause AIDS. Please be sure your paper does not use “COVID-19 infection.”

We have now made sure to avoid using the terms COVID-19 infection or transmission in the manuscript. We do, however, refer to COVID-19 throughout the piece because this is disease burden measured in the data we use in our analysis, as well as the disease state governments are enacting policies in relation to, and the disease that people are afraid of when they fear coming in person to abortion clinics.

6. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

We have now included this information on the title page of the Research Letter.

7. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

We have included the STROBE checklist for our Research Letter. Please note that some of the information appears in the Appendix out of necessity due to the tight word limit on Research Letters (these pages as marked as A1, A2, etc.).

8. 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.

We use “medication abortion” throughout our manuscript, as specified in the reVITALize definitions.

9. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters articles should not exceed 2.5 pages (600 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.

Our Research Letter is 655 words in length. We had a very short requested turn-around on this revision and we did our very best to make the piece as brief as possible while still including all important details.

10. 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).

We have provided these in the manuscript as appropriate.

11. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

We have included this short title on the title page.

12. 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 conformed to this requirement.

13. 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.

We have not used this symbol in the manuscript.

14. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout

your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

The word “provider” does not appear in our manuscript.

15. In your submission, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

We have conformed to all of these guidelines.

16. 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.

We have conformed to all of these guidelines.

17. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

We have checked that our citations reflect the most recent ACOG documents.

18. Figures

Figure 1: The current file may be resubmitted as-is.

Figure 2: Please consider moving this to supplemental digital content, as this will not fit in print.

Both figures have now been moved to the appendix.

19. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in

the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

We have conformed to all of these guidelines.

20. 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.

Noted, thank you.