

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

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

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: 01/20/2023

To: "Emily M Godfrey"

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

Subject: Your Submission ONG-22-2154

RE: Manuscript Number ONG-22-2154

"I definitely felt at greater ease": Patient perspectives of telemedicine versus in-clinic abortion

Dear Dr. Godfrey:

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, and STATISTICAL EDITOR COMMENTS (if applicable) below.

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 21 days from the date of this letter. If we have not heard from you by 02/10/2023, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

Dear Dr. Godfrey and co-authors:

Thank you for your submission.

Your paper has gone through our review and editorial review process.

We would like to give your paper additional consideration if you are able and willing to address our reviewers' comments. One suggestion included revising the title of your paper to remove the section in quotations.

Thank you for your submission and we look forward to receiving your revised paper.

- * Help us reduce the number of queries we add to your manuscript after it is revised by reading the Revision Checklist at https://journals.lww.com/greenjournal/Documents/RevisionChecklist_Authors.pdf and making the applicable edits to your manuscript.
- * Figure 1: Is this original to the manuscript or does a source need to be credited? Please upload as a figure file on Editorial Manager.
- * Figure 2: Please upload as a figure file on Editorial Manager.

REVIEWER COMMENTS:

Reviewer #1:

Thank you for the opportunity to participate in peer review. Below are my comments and questions.

Subject matter

Relevant, timely, clear gap that needs to be addressed

2. Study design

Qualitative, appropriate for the subject matter

3. Question/Purpose: clearly stated

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- 4. The theoretical framework clearly stated, figure 1 helpful
- 5. Research team: clearly stated, described, and appropriate, and data collection and analysis are clear to understand position and perspectives.
- 6. Sampling strategies: appropriate for the study
- 7. Reflexivity: Researchers reflected on how their unique position, preconceptions, and biases influenced the findings.
- 8. I could not find an explanation as to why the telemed group had 20 and in person 10 patients. Was that because there were more sequential telemed visits in that time period? How did this imbalance influence thematic saturation?
- 9. From what I recall in interview studies, the sample size is usually estimated or calculated based on theme saturation. Lines 280-281 in the discussion mention sampling to saturation but I could not find that in the methods/results section other than line 129 which did not go into detail.
- 10. Table 2 setting/efficiency of services/in-clinic comment about cattle herding and being told the same thing multiple times. I am sure any can relate to this. Very difficult to make in-person abortion services personal like telemed. I was wondering if the authors would want to explore that more. Maybe telemedicine should be the standard of care because it is more patient-centered and in-person is like a last resort?
- 11. Table 2 setting/perception of space/in-clinic comment about forced birth protestors at the clinic. I am wondering if authors can expand more on this, and also explore the possibility that telemedicine should be the standard of care because it is safer for patients and clinicians (given the current climate of violence against women and forced birthers running around unchecked hurting people)? It is like the underground railway family planning community is talking about.
- 12. The issue of pain control was not the main area of study but was one of the clinically significant findings. I often wonder why we do not tell med-abortion patients that they can narcotics or another type of ERAS meds let's say Tylenol and NSAID combo is not working. As a reader, I would have liked to hear what authors think we need to do about it. I know med ab pain is unpredictable, and the best way to avoid is to have a surgical abortion but this feels like an unsettled area.
- 13. Table 3 is very helpful. Would authors consider creating guides/materials to share for others to use based on their findings?
- 14. Line 65-I think is a mistake, and "Fellow" was meant to be "fellowship-trained"

Reviewer #2:

The authors present a convenience sample in-depth interview of 30 women who had received a medication abortion in the prior month at a mean gestational age of ~7 weeks. Twenty of the women had an abortion via telemedicine and 10 had an in-clinic experience.

Medication abortion is a mainstay of abortion care in the United States for individuals requesting abortion up to 10 weeks' gestation.

Telemedicine is a valuable adjunct that has been shown in prior peer-reviewed studies to be an effective surrogate for in-clinic medication abortion.

Medical eligibility for abortion consisted of a positive pregnancy test; no pelvic exam or ultrasonography were used to validate or date the pregnancies.

The interviews were voluntary and modestly incentivized with \$50 gift cards.

Fifty-five percent of participants via telemedicine were rural compared to 40% of in-clinic participants.

Medical outcomes, including hospitalizations, transfusion, continuous pregnancy, need for curettage or need for uterotonic agents were not presented, consistent with the genre of qualitative studies.

In all, the authors noted that there were no obvious differences in the telemedicine versus in-clinic experience apart from the greater privacy afforded by telemedicine and extra inconvenience involving time off from work, child care, travel times and lengthier in-clinic processing at the clinic compared to telemedicine.

The analyses were thoroughgoing and the structure of the interviews and evaluation of outcomes employed a known schema (Miller's definition of indicators).

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Comments:

- 1. As is true of all qualitative studies, the patient remarks chosen for inclusion were selected presumably because they were representative of other patients' experiences.
- Nonetheless, the choice of comments for inclusion is a highly subjective one and a selection bas may have been at work that highlighted the superiority of the telemedicine experience and placed the clinic and staff in the best light.
- 2. There were several aspects of care at the index site, self-described as "a high-volume independent reproductive healthcare clinic organization in Washington State" that deserve mention:

Several study participants and the authors made mention of the chaotic and time-consuming process during in-clinic medication abortions. It is possible that this clinic is now experiencing higher volumes due to restrictions in neighboring states (e.g., Idaho), but the authors do not allude to recent higher volumes as a reason for the seeming disorganization at the clinic.

One commentator noted that she was advised (p. 19) that the in-clinic procedure would take "up to six hours." The high-volume Midwestern clinic where I am medical director advises patients that the same medication abortion experience in our clinic will take 1-2 hours. This discrepancy indicates the magnitude of the disorganization at the index clinic where this study was conducted.

The advisory to women who call in that the in-clinic experience may take up to 6 hours could bias potential clients to choose telemedicine abortion.

On p. 24, one participant in each group (telemedicine, in-clinic) reported that naproxen was inadequate to achieve acceptable pain control. We know that the index clinic prescribed Plan B by phone at pharmacies where telemedicine patients resided, so it is natural to wonder why prescriptions for narcotics could not have been telephonically prescribed to patients using the 24-hour on-call line for whom naproxen was inadequate.

These issues indicate a degree of disorganization that is unsettling and requires further explanation to allay this concern.

Conclusion

This study is interesting and well-conducted. Medication abortion is increasingly a critical mainstay of induced abortion provision in the United States and telemedicine has an important role in helping individuals for whom travel is especially burdensome in the various states that do not forbid its use.

The virtue of a small qualitative study is the ability to see the excerpted personal comments of abortion patients who are willing to volunteer it.

The value of such a study is heavily dependent on the health facility where in-clinic and telemedicine procedures are offered, hopefully in an unbiased way.

The issues described above in the Comments section cause me to question whether this facility meets the criteria of efficiency and typicality that could allow the reader to accept their outcomes as representative of abortion facilities nationwide.

Sincerely,
[EDITOR NAME AND DEGREES]
[EDITOR POSITION]

The Editors of Obstetrics & Gynecology

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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February 16, 2023

Jason D. Wright, MD
Editor in Chief
Department of Obstetrics and Gynecology
Columbia University Irving Medical Center
161 Fort Washington Avenue
New York, NY 10032

RE: Manuscript Number ONG-22-2154

Dear Dr. Wright,

Thank you for your consideration of our manuscript. We appreciate your input as well as the reviewers and are very pleased with the favorable review. Per the journal's request, we have responded to each point raised by the reviewers. Any changes made to the manuscript have been completed with "track changes" feature.

The authors listed in this manuscript provided substantial intellectual contributions to the research, data analysis and publication development. All authors had access to relevant aggregated study data and the research protocol, required to understand and report the findings. Each author takes responsibility for the research findings and is willing to take public responsibility for all aspects of the work.

We adhere to the GPP3 guideline of disclosing information regarding entities that funded this study. This study was supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1 TR002319 and by the Society of Family Planning Research Fund (SFPRF15-MSD2). The funders were not involved in the writing or review of this manuscript. The information presented in this manuscript is solely the responsibility of the author(s) and does not necessarily represent the views of the NIH or SFPRF.



Emily M. Godfrey and Ian M Bennett receive honoraria from Organon as Nexplanon trainers, unrelated to the submitted work. None of the other authors has any conflicts of interest related to the submitted work.

All persons who contributed to the work but not sufficiently to be authors are listed in the acknowledgments. We have obtained written permission from the persons listed in the acknowledgments. We have obtained permission from the administrative leaders of the clinic from which we recruited participants to disclose its name in the manuscript.

This study is not under review nor has been published elsewhere. This study was presented in abstract form at the American Anthropological Association Annual Meeting, September 2022, Seattle WA and the NACRG Conference, November 2022, Phoenix, AZ.

Sincerely yours,

Emily M. Godfrey

EDITOR COMMENTS:

Dear Dr. Godfrey and co-authors:

Thank you for your submission.

Your paper has gone through our review and editorial review process.

We would like to give your paper additional consideration if you are able and willing to address our reviewers' comments.

One suggestion included revising the title of your paper to remove the section in quotations.

<u>Author response:</u> Per the Editor's request, we have removed the section in quotations from the title. However, to better clarify our objective of our study, we clarified the title to state: "Patient perspectives regarding provider communication during telemedicine versus in-clinic abortion"

Thank you for your submission and we look forward to receiving your revised paper.

* Figure 1: Is this original to the manuscript or does a source need to be credited? Please upload as a figure file on Editorial Manager.

<u>Author response:</u> This figure is original to the manuscript. We have uploaded this figure as a figure file in the Editorial Manager system.

* Figure 2: Please upload as a figure file on Editorial Manager.

<u>Author response:</u> We have uploaded this figure as a figure file in the Editorial Manager system.

REVIEWER COMMENTS:

Reviewer #1:

Thank you for the opportunity to participate in peer review.

Below are my comments and questions.

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Relevant, timely, clear gap that needs to be addressed <u>Author response:</u> thank you for your comments.

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Qualitative, appropriate for the subject matter *Author response: thank you.*

3. Question/Purpose: clearly stated Author response: thank you for your comments.

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- 6. Sampling strategies: appropriate for the study Author response: thank you for your comments.
- 7. Reflexivity: Researchers reflected on how their unique position, preconceptions, and biases influenced the findings.

Author response: thank you for your comments.

8. I could not find an explanation as to why the telemed group had 20 and in person 10 patients. Was that because there were more sequential telemed visits in that time period? How did this imbalance influence thematic saturation?

<u>Author response</u>: We added an explanation regarding why there were more telemedicine participants than in-clinic participants. See under "Participant selection" (In 146-148) in which we state: "Because we were most interested in evaluating patient-provider communication with novel telehealth abortion services, we purposively enrolled more telemedicine than in-clinic abortion participants."

9. From what I recall in interview studies, the sample size is usually estimated or calculated based on theme saturation. Lines 280-281 in the discussion mention sampling to saturation but I could not find that in the methods/results section other than line 129 which did not go into detail.

<u>Author response:</u> We agree with the reviewer that we did not provide an adequate explanation regarding how we defined meeting saturation. We added a sentence and reference under "Data analysis" (In 179-180) that states: "We defined data saturation as the point at which no relevant new themes related to the areas of focus were identified."

10. Table 2 setting/efficiency of services/in-clinic comment about cattle herding and being told the same thing multiple times. I am sure any can relate to this. Very difficult to make inperson abortion services personal like telemed. I was wondering if the authors would want to explore that more. Maybe telemedicine should be the standard of care because it is more patient-centered and in-person is like a last resort?

Author response: We appreciate the reviewer's comment about the difference between in-clinic and telemedicine. The authors feel that since the objective of the study was to assess patient-provider communication, we feel it is too far-reaching to suggest that telemedicine should be the standard of care with this particular study. Such a recommendation of standard of care would be better met with a systematic review of multiple studies, rather than a single study. Because the objective of the study may have been unclear by the reviewer, we revised the title of this study to state "Patient perspectives regarding provider communication during telemedicine versus in-clinic abortion."

11. Table 2 setting/perception of space/in-clinic comment about forced birth protestors at the clinic. I am wondering if authors can expand more on this, and also explore the possibility that telemedicine should be the standard of care because it is safer for patients and clinicians (given the current climate of violence against women and forced birthers running around unchecked hurting people)? It is like the underground railway family planning community is talking about.

<u>Author response:</u> The authors appreciate the reviewer's comment about making telemedicine the standard of care. As we stated in #10 above, we believe it would be too farreaching to suggest that telemedicine should be the standard of care based on our study alone. Our study was conducted at a single clinic and thus not necessarily generalizable to other settings. We hope this article contributes to a body of evidence conducted in multiple different settings that will be able to potentially assess that telemedicine be the standard of care in our new political climate with abortion care.

12. The issue of pain control was not the main area of study but was one of the clinically significant findings. I often wonder why we do not tell med-abortion patients that they can narcotics or another type of ERAS meds let's say Tylenol and NSAID combo is not working. As a reader, I would have liked to hear what authors think we need to do about it. I know med ab pain is unpredictable, and the best way to avoid is to have a surgical abortion but this feels like an unsettled area.

<u>Author response:</u> We agree with the reviewer regarding the pain control issue and were surprised to hear this comment made by a number of participants, regardless of whether care was by telemed or in-person. We added a reference from a recent Cochrane systematic review that suggests limited high-quality evidence surrounding adequate pain control with medication abortion to the Discussion section (In 309-318) stating: "Both telemedicine and in-clinic participants had less favorable views about the clinic's pain control regimen, with several expressing they felt unprepared for the pain associated with medication abortion. This is unsurprising given the limited high-quality evidence regarding adequate pain management during medication abortion.²¹ While participants stated they knew about the 24/7 nurse line, for reasons we did not thoroughly explore, participants who felt unprepared about the pain asserted they wish they had more pain medications at the moment of their abortion. This suggests that even if they had phoned the 24/7 line, they would have had to wait for a prescription to be called into a pharmacy for pick up, which may not have met their needs. Future studies should define patient characteristics associated with the need for additional pain medication to better inform clinic protocols."

13. Table 3 is very helpful. Would authors consider creating guides/materials to share for others to use based on their findings?

<u>Author response:</u> Thank you for this comment. The authors will certainly consider making guides to assist with patient-centered communication for medication abortion.

14. Line 65-I think this is a mistake, and "Fellow" was meant to be "fellowship-trained" *Author response: The authors agree and have corrected this mistake.*

Reviewer #2:

The authors present a convenience sample in-depth interview of 30 women who had received a medication abortion in the prior month at a mean gestational age of ~7 weeks. Twenty of the women had an abortion via telemedicine and 10 had an in-clinic experience.

Medication abortion is a mainstay of abortion care in the United States for individuals requesting abortion up to 10 weeks' gestation.

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Medical outcomes, including hospitalizations, transfusion, continuous pregnancy, need for curettage or need for uterotonic agents were not presented, consistent with the genre of qualitative studies.

In all, the authors noted that there were no obvious differences in the telemedicine versus inclinic experience apart from the greater privacy afforded by telemedicine and extra inconvenience involving time off from work, child care, travel times and lengthier in-clinic processing at the clinic compared to telemedicine.

The analyses were thoroughgoing and the structure of the interviews and evaluation of outcomes employed a known schema (Miller's definition of indicators).

Comments:

1. As is true of all qualitative studies, the patient remarks chosen for inclusion were selected presumably because they were representative of other patients' experiences.

Nonetheless, the choice of comments for inclusion is a highly subjective one and a selection bas may have been at work that highlighted the superiority of the telemedicine experience and placed the clinic and staff in the best light.

<u>Author response:</u> Our goal of the study was not to assess whether one type of service was superior to another, but rather to assess whether patient-provider communication practices during consultation need to change when using telemedicine, as opposed to the familiar, facility-based, in-clinic provider communication that has been used since the FDA's approval of mifepristone 2 decades ago. We respectfully disagree with the reviewer that our choice of comments were "highly subjective." We followed rigorous qualitative methods, employed

researchers experienced in qualitative methods, and reviewed quotations with our research team and community advisory board (see "Research team and reflexivity" (In 115-121), "Data collection" (In 169-170), and "Data analysis" (In 175-181): Additionally, we used a well established framework to measure patient-provider communication (see "Theoretical framework (In 126-130).

2. There were several aspects of care at the index site, self-described as "a high-volume independent reproductive healthcare clinic organization in Washington State" that deserve mention:

Several study participants and the authors made mention of the chaotic and time-consuming process during in-clinic medication abortions. It is possible that this clinic is now experiencing higher volumes due to restrictions in neighboring states (e.g., Idaho), but the authors do not allude to recent higher volumes as a reason for the seeming disorganization at the clinic.

Author response: The perspectives of this study were from the point of the view of patients, so they would not necessarily know whether other patients were coming from different states. We engaged a community advisory board throughout the study and had a representative from the clinic at meetings in which the research team presented findings in aggregate and asked for reflections. While our board members were not research subjects, and thus their responses were not formally analyzed (and thus not reported), the general input regarding inclinic operations had more to do with adhering to COVID-19 restrictions with social distancing for patients and frequent staff absences (since COVID-19) was still widespread in Sept, 2021-Jan 2022 and 10-day CDC quarantine/isolation restrictions were still in place. We added a sentence in the Discussion (In 301-308) that states: "Because this study occurred when COVID-19 infection was still widespread, we surmise that many of the in-clinic participant experiences were due to unpredictable staff absences and social distancing requirements limiting clinic capacity. These in-clinic constraints ultimately compromised overall patient-clinician communication." In response to the reviewer's comment, we added that the time-period in which this study was conducted as a limitation and that our findings may not be generalizable to a time-period when the nation/state is not under a public health emergency (see Discussion, In 332-334).

One commentator noted that she was advised (p. 19) that the in-clinic procedure would take "up to six hours." The high-volume Midwestern clinic where I am medical director advises patients that the same medication abortion experience in our clinic will take 1-2 hours. This discrepancy indicates the magnitude of the disorganization at the index clinic where this study was conducted.

Author response: As noted in the response above, our study took place when COVID-19 infections were still prevalent and CDC guidelines still recommended 10-day isolation/quarantine periods for those infected or exposed, which was very disruptive to most clinical operations in Washington state. The quotations related to waiting are likely more of a reflection of the pandemic and the United States Public Health Emergency, than the clinic itself. Many patients we interviewed went to this particular clinic because other abortion clinics had a 2-3 week wait, so for them, a 6-hour wait was less than ideal, but better than waiting several weeks. Since we utilized a framework that included clinical setting/clinical efficiency as part of patient-provider communication, our findings show that when clinics are at- or over-capacity, it adversely affects patient-provider communication.

The advisory to women who call in that the in-clinic experience may take up to 6 hours could bias potential clients to choose telemedicine abortion.

Author response: There is no question that each of the 10 participants who decided to be seen in the clinic for their medication abortion mentioned some sort of wait during their inclinic experience. The authors reviewed other quotations and decided to replace this particular quotation with another in-clinic participant who reflected perhaps more gently the theme of "having to wait." We wish to respectfully remind this reviewer that the goal of this study was to evaluate patient-provider communication using a well-established patient-centered communication framework that also included clinic setting/efficiency, which was not ideal at a time when this nation was under a Public Health Emergency. This study's aim was not comparing telemedicine with in-clinic service operations, as the reviewer suggests. To resolve this misunderstanding, we clarify in our methods the following: "This study used convenience sampling of all patients who had been given the option to receive medication abortion either by telemedicine or in-clinic from a Washington State independent, high-volume reproductive healthcare clinic organization, Cedar River Clinics (CRC)." (see In 133-135).

On p. 24, one participant in each group (telemedicine, in-clinic) reported that naproxen was inadequate to achieve acceptable pain control. We know that the index clinic prescribed Plan B by phone at pharmacies where telemedicine patients resided, so it is natural to wonder why prescriptions for narcotics could not have been telephonically prescribed to patients using the 24-hour on-call line for whom naproxen was inadequate.

Author response: This reviewer makes a similar, valuable comment as Reviewer #1, in which we stated the following: "We agree with the reviewer regarding the pain control issue and were surprised to hear this comment made by a number of participants, regardless of whether care was by telemed or in-person. We added a reference from a recent Cochrane systematic review that suggests limited high-quality evidence surrounding adequate pain control with medication abortion to the Discussion section (In 309-318) stating: "Both telemedicine and inclinic participants had less favorable views about the clinic's pain control regimen, with several expressing they felt unprepared for the pain associated with medication abortion. This is unsurprising given the limited high-quality evidence regarding adequate pain management during medication abortion.²¹ While participants stated they knew about the 24/7 nurse line, for reasons we did not thoroughly explore, participants who felt unprepared about the pain asserted they wish they had more pain medications at the moment of their abortion. This suggests that even if they had phoned the 24/7 line, they would have had to wait for a prescription to be called into a pharmacy for pick up, which may not have met their needs. Future studies should define patient characteristics associated with the need for additional pain medication to better inform clinic protocols."

These issues indicate a degree of disorganization that is unsettling and requires further explanation to allay this concern.

Author response: As mentioned earlier, recruitment and data collection for this study took place during the COVID-19 pandemic, which undoubtedly would have affected the perceptions conveyed by study participants who sought in-clinic care. In response to the reviewer's comment, we added that the time-period in which this study was conducted as a limitation and that our findings may not be generalizable to a time-period when the nation/state is not under a public health emergency (see Discussion, In 332-334).

Conclusion:

This study is interesting and well-conducted. Medication abortion is increasingly a critical mainstay of induced abortion provision in the United States and telemedicine has an important role in helping individuals for whom travel is especially burdensome in the various states that do not forbid its use.

Author response: thank you for your comments.

The virtue of a small qualitative study is the ability to see the excerpted personal comments of abortion patients who are willing to volunteer it.

<u>Author response:</u> thank you for your comments.

The value of such a study is heavily dependent on the health facility where in-clinic and telemedicine procedures are offered, hopefully in an unbiased way.

<u>Author response:</u> thank you for your comments.

The issues described above in the Comments section cause me to question whether this facility meets the criteria of efficiency and typicality that could allow the reader to accept their outcomes as representative of abortion facilities nationwide.

Author response: Unfortunately, this study took place when the US was still under a Public Health Emergency due to COVID-19 and CDC isolation/quarantine guidelines were 10 days, which likely affected how participants experienced the clinical setting. We added a sentence in the Discussion (In 304-307) to reflect this. We believe in usual circumstances the clinic we partnered with meets criteria of efficiency. We partnered with Cedar River Clinics, which is a respected clinic in WA state, is certified by several networks, including the National Abortion Federation and is the only abortion facility in the State of Washington to have Accreditation Association for Ambulatory Health Care (AAAHC) certification. We added additional description about the clinic to the methods (In 135-136) to reassure readers that the facility we chose to work with is well-regarded. Additionally, we added that the time-period in which this study was conducted was a limitation and that our findings may not be generalizable to a time-period when the nation is not under a public health emergency (see Discussion In 332-334).