**Date:** Feb 15, 2019
**To:** "Kendall Harcourt" [redacted]
**From:** "The Green Journal" em@greenjournal.org
**Subject:** Your Submission ONG-19-99

RE: Manuscript Number ONG-19-99

Engaging Obstetric and Gynecology Patients in Safety and Quality through Shared Visit Notes

Dear Dr. Harcourt:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

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).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Mar 08, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1) This is a compilation of the results of a quality improvement initiative designed to assess the impact of patients having access to their own ambulatory visit notes.

2) The report suggests that "Ob-Gyn patients readily use patient portals" (Line 77) but only 37% of your total patient population had active patient portal accounts (Line 174) at the time of the analysis. This is a discrepancy between what was stated and what was observed in your patient population. Please comment on this in the results section as a limitation.

3) The results indicate that 69% of patients (6594/9550) with online access to their medical records read at least one ambulatory note (Line 47) but only a small percentage (3.2%) that read at least one note responded to the query via the patient reporting tool (Lines 47-48). These findings question how applicable the results are to the entire patient population.

4) Over 80% of the patients that accessed at least one note and used the online reporting tool had a college or graduate degree (TABLE 1). The study would be strengthened by providing information about the educational demographics of the entire patient population for comparative purposes. This information would be beneficial both to assess its effect on the use (or lack thereof) of the online reporting tool as well as the study's overall applicability to other demographic populations. For example, how does this study apply to populations who have limited to no understanding of written English and/or have limited health literacy?

5) There were few comments suggesting bothersome phrasing in the notes. One of the key issues regarding transparency is how open access to ambulatory notes may affect the physician/patient relationship. Could open access to ambulatory notes negatively impact the physician/patient relationship? How might it also impact provider to provider communication? Please comment on this in the discussion section of the paper.

6) The manuscript had no discussion of how physician documentation may have been affected by the knowledge that their notes may be reviewed by the patient. Please include this in the discussion section of the paper.

Reviewer #2: This is a QI initiative using OpenNotes with three aims: to assess ob/gyn patients interest in reading their

notes, explore whether patients find errors in their notes and what types, and identify patient perceived sensitive language in notes. The authors do meet their aims showing 69% of patients read at least one note, about 25% of patients who provided comments found errors in notes, with a high percentage potentially posing patient safety problems, and very few patients identified sensitive language. Paper demonstrates ob/gyn patients will read notes with positive experiences. Another value is this process can uncover patients who do not totally understand what their provider said at the time of the visit. One drawback to process some patients mentioned was not understanding medical terminology. Authors do acknowledge reasons why their findings may not be generalizable to other patient populations. Conclusion can be stronger

Line 35-38 - please rephrase as this is not written as an objective. Objective stated clearly in lines 85-88

Line 79-81 - the first part of this sentence is unclear, please rephrase

Line 115-122 - were patients consented and advised their comments would be part of a published paper? Or did patients think their information was only being used by the health system to improve the quality of the notes?

Line 147 -how often were patient responses reviewed? What was the time frame for determining urgent issues?

Line 232-233 - what are examples of suggestions for improvement by patients?

Line236-238 - what were the rates of patients opening at least one note in primary care and all-comer patients?

Reviewer #3:
This is a report of a limited number of patients who completed a questionnaire about having read OpenNotes. The response rate was very low but most of the respondents liked the option of reading their outpatient notes and found them helpful. Patients identified errors in about a quarter of notes, the majority of which were considered important. Giving patients the opportunity to read their office notes is becoming increasingly common, thus the topic is interesting and important. Involving patients in assessing accuracy is a growing need with HER errors from copy/paste propagation of misinformation, "smart phrase" draw-ins of extraneous data, and signing of lengthy notes much of which the signer may not themselves actually have written (or proof-read).
Comments are as follows:

1. My biggest concern is the low response rate of 212/6594 = 3.2%. Adequate sampling and response rate are crucial in survey research, and convincing conclusions are difficult to draw from this small a proportion of respondents. It does appear that many patients are interested in reading their notes, but because so few completed the questionnaire, one cannot conclude that many of the total number of patients who used OpenNote had positive experiences. True, many of a tiny subset that responded reported positive experiences, but extending this to the entire population of note-readers is speculative.

2. I don't see any mention of IRB approval for this study. Even if it was begun as a quality improvement project, it should have some form of post hoc institutional review to be published as research. There is no mention of consenting patients who completed the questionnaire, or that they knew their answers would be part of a research project.

3. The statement in the 3rd Methods paragraph that those who read their notes "were invited to use a reporting tool" is vague. Did most patients actively decline to complete it, or did they not see it, or what? Were there differences between patients who completed it and those who did not?

4. Why was Family Planning not part of the project? The 1st paragraph of the Methods states that all clinicians and departments were expected to participate unless they explicitly presented a reason for not doing so. What was Family Planning's reason?

5. It's not clear why MFM was grouped with generalists, whereas all the GYN subspecialties were put in a separate group. MFMs are subspecialists too, and often address different problems than do generalists.

6. The title seems at odds with the results: based on the poor response rate, engagement with Safety and Quality actually was extremely low, but the authors' discussion implies that OpenNote did engage patients. The survey did identify a number of charting errors, but what impact OpenNote had on actual patient safety (i.e., outcomes) was not assessed.

7. Some of the Methods are unclear, e.g., various groups "collaborated for about a year to create and online tool to proactively report..."(could the authors be more specific?) "Responses...were incorporated into routine QI operations for real-time responses" (borders on jargon) " "Did you find tests or results that concerned you?" (concerned in what way? Were unaware of them? Concerned because they were serious? Because they didn't understand them?).

8. The authors state that they "avoided focusing on statistical comparisons" and do not describe any statistical methods, but Table 2 includes p-values (chi-square? Fishers?).

9. Patient examples of "bothersome words" seem quite subjective, and some appear to be misinterpretations. It isn't clear how a clinician would know for a given patient what words or medical terminology she might find bothersome or objectionable. Also, although I understand that patients would like to understand notes written about them, medicine can be a highly technical field and has its own language. Medical notes are supposed to document what was said, done, thought, and planned so facilitate understanding of the interaction, thought process, and management. Complex medical diagnoses and treatments may not lend themselves to simple prose, and writing notes at the level of patients with widely varying degrees of medical literacy would be nearly impossible. Fortunately, the number of patients reporting bothersome words was fairly small.

10. In the Discussion, the authors state "chart review was beyond the scope of this project," but 212 reviews would not be an insurmountable obstacle and review would have been valuable by allowing comparison of the what was written and the patient's interpretation of it. In fact, chart review WAS done when patients raised questions about errors.

11. The authors do a good job acknowledging the limitations of the study. Documenting the number of errors and inaccuracies in the EHR is an important contribution in itself. Patients have a large potential role in keeping documentation accurate and honest, and in discouraging physicians from drawing in information and exams they did not actually review or do.

Reviewer #4: Thank you for the opportunity to review this interesting and well written manuscript. It explores an area not sufficiently studied in obstetrics and gynecology and would be read with interest by members of our specialty. The study looks at the uptake and patient reactions to the use of a feature in the authors electronic medical record system that allows patients to review their outpatient visit notes.

I do have some comments and queries for the authors:

1. Line 110: Why was the Family Planning practice not included in the implementation of OpenNotes?

2. Line 174: Among patients with open portal accounts--how many notes were generated and what number (percent) of notes were opened by a patient? It might be interesting to see how many patients opened one note and how many opened several notes (provided that there were several notes to review).

3. Line 191: What does this mean that there were concerning reports? Is it that the patients' were concerned about the test--or that the test was abnormal?

4. Line 205: Among reports identifying a possible inaccuracy, who noted that it was important? The reviewer or the patient?

5. Line 243: Sometimes the discrepancies between what the patient believes should be in the note and what the provider wants to record--are different and not inaccuracies. For example, a patient who is viewed by the provider to be an unreliable historian or difficult. There is an implication here that these inaccuracies identified by patients were correct. Maybe in some, the provider's documentation is exactly what the provider felt should be in the record.

6. Line 259: The authors seem to imply that giving patients access to their notes may be responding to a need that patients have and because they are not getting it from the providers they are turning to other sources. But what they seek online may be explanations of conditions and guidance as to the appropriate management. Things they may not find in the note. They may be double checking what their providers told them or seeking a deeper understanding of their condition or treatment (information that would not typically be in a note).

7. Line 281: The authors correctly note that while a large number of the notes were opened, patient participation in reporting on their reactions to being able to read the note was quite limited. This is the biggest limitation of this study. This whole part of the study is based on only 232 responses. Thus, limiting the strength of the conclusions significantly.

8. One other question that I have for the authors is whether they have any provider feedback on the OpenNote initiative. Did providers feel burdened by the initiative? Did they change how they wrote their notes and what the content was? Were they more frequently or less frequently contacted by patients after the initiative started? How did they respond to the inaccuracies that were pointed out to them? A companion survey of providers about the initiative would be very interesting.

STATISTICAL EDITOR:

lines 173-177: Need to expand this analysis to address potential selection bias. That is, only 37% had active patient portals, among that subset, 69% used the portal opening at least once, while some patients had multiple visits, with >84 k visits among 6594 patients. In turn, how did the 212 respondents in this series who were volunteers relate to those figures? Were they representative of the entire group?

Table 1: How did these demographic profiles relate to the overall patient profile?

Table 2: Two issues with this analysis. First, there were 20 more responses than individuals, so the counts of patient perceptions are not independent events. Should either have corrected for that, or provided analysis using only a randomly chosen response from any individual with > 1 response. Under the heading "Did you find inaccuracies?" the comparison of "Yes" (18.1 % vs 30.2%) is significantly different , the comparison of "I am not sure" response rates was NS and if those were aggregated, then difference has p value = .06. Also, how does this Table relate to lines 166-167 where the Authors stated that "We avoided statistical comparisons and use descriptive tools given the low expected response rate ..."

Table 3: Some of these reported inaccuracies could be checked, e.g., when the Mirena was inserted, or how Grave's disease was treated whether an HPV vaccine was given. Were those checked vs a medical or surgical record?

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

***The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.***

- As this is a QI project, please reformat it to be a "clinical practice and quality " submission. Please see the Instructions for Authors for the formatting specifications for that article type.

- we don't use abbreviations in the precis

- Make sure you read the Instructions for Authors regarding the Clinical Practice and Quality article type. There is specific guidance there for abstract, word counts, etc

- It seems from your paper that this project was throughout your organization, not just Ob GYN, but that you carved out the Ob GYN data. That needs to be made clear in your methods.

- Is this denominator for your whole medical center, or just ob gyn?

- The first paragraph of your introduction does not really seem to relate to patients reading clinical notes, but rather to their seeking additional information about their health care outside of the clinical visit. Please either make a stronger link between the content of the first paragraph OR replace it with some background information form other areas of medicine about patients reading their notes and then introduce the gap about reproductive health and what your are studying.

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell the words out throughout the manuscript. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper.

- Their website describes this as an international initiative. In the introduction, it would be important to explicate Open Notes a bit more. Perhaps including the URL, their mission statement or some part of it. . OpenNotes is an international movement advocating fundamental change in the way visit notes are managed. We're committed to spreading the availability of open visit notes and studying the effects. We believe that providing ready access to notes can empower patients, families, and caregivers to feel more in control of their healthcare decisions, and improve the quality and safety of care.

- is the department "chief" the person in charge of a service line or is it the same as a department chair?

- Do your generalists provide any GYN care or only OB?

- one reviewer wants to know why FP is not included. I'm agnostic about whether you decide to include that information, although it may be interesting in case others are considering joining the open notes movement.

- This is after the publication of the use of the reporting tool you reference below. Why did you select this time frame, rather than extending it?

- This is after the publication of the use of the reporting tool you reference below. Why did you select this time frame?

- was this reporting tool something that preexisted your QI project or was it new for this?

- not sure what this means? How did the clinicians participate or do you mean, that all of the notes of the all of the clinicians were included?

- how would a patient then know that the reporting tool exists?

- OK, so here is this information about the development of the tool. Again, was this for the whole medical center or just Ob GYN?

- how is it presented to the patient in the portal? When was it first available to patients and was it advertised or promoted at that time?

- The Journal style doesn't not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

- Is the process only for Ob GYn or was it throughout the mediical center?

- ob gyns?

- This is where you need to be clearer. Please state your primary and secondary outcomes. On lines 85-88 you listed 3 aims: the first is apparently open rates and thereafter, its results from the reporting tool. You don't provide any methods about open rates (read rates) and how you got that data.

- This seems like a large number of discrete Ob GYN patients in 16 months, although certainly possible. Could you provide the use for the entire medical center during ths same time period (# of discrete patients, % with active accounts, # opening at least one note, # hidden...etc)

- as noted by the statistical editor, and even though this is a descriptive study, you need to do something about repeat reports by the same person. The same person may always report problems with tests, etc.

- since you are noting a difference in these findings between groups, please provide OR and CI's. That will need to be included in your methods as well--how you made those statistical comparisons.

- As patients sometimes misremember things, was there any effort to look in the EMR to verify what was true?

- This is called a primacy claim (your paper is the first or biggest) and must either be deleted or supported by providing the search terms used, dates, and data bases searched (Medline, Ovid, Pubmed, Google Scholar, etc) in order to substantiate your claim.

- this is one place to highlight whether your open rate is higher than that of other programs at BIDMC

- reporting tool. This will need to be included in the discussion of the limits of your study (with respect to any sort of conclusions or generalizations you can make about the results of the reporting tool) but its also a finding of your study. the third comment here is not really supported by your data: Among the few who read their notes and used the reporting tool, patients reported positive..... Same true for the 4th point.

- see note above...most do not report anything.

- what about sexual activity?

- not sure what an "activated patient" is. Does that refer to activation of their portal registration or do you mean motivated?

- here is your explanation of sexual activity. You may want to say something in text that a patient was bothered by a description of her sexual activity.

- This is particularly important I think and should probably be mentioned. Billing language is necessary but I can sure see how a patient would misinterpret it. If opennotes becomes more universal CMS may need to allow some flexibility in the way billing phrases are used.

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, as well as subsequent author queries. 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:
1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

3. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Materials and Methods section, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Materials and Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

5. 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Clinical Practice and Quality articles should not exceed 26 typed, double-spaced pages (6,500 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.

7. 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).

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

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Clinical Practice and Quality, 300 words. Please provide a word count.

9. 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.

10. The commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using

"and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

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

13. 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/ifauth.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.

14. If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Mar 08, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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3.15.19

**Re: An Opportunity to Engage Obstetrics and Gynecology Patients through Shared Visit Notes**

Dear Dr. Chescheir,

We appreciate the thoughtful review of our manuscript, “An Opportunity to Engage Obstetrics and Gynecology Patients in Safety and Quality through Shared Visit Notes (revised title).” We have revised the paper to integrate the reviewers’ suggestions, and we believe the revised manuscript is substantially improved.

There were multiple requests for additional information, new analyses, and expanded discussions. After revision, we are well below the total word count maximum. However, in order to address all the questions and comments from reviewers - requiring expansion of the introduction and discussion- the distribution of word count may not fall precisely into section limits. Nonetheless, the paper as a whole is 1300 words shorter than the overall limit.

We are submitting the revised manuscript for consideration for publication in *American College of Obstetricians and Gynecologists’ Green Journal,* and hope it will stimulate discussion among your readership. Please let us know if you have further questions or suggestions. We look forward to hearing from you.

**Reviewers’ Comments and Author Responses:**

**Reviewer #1:**

This is a compilation of the results of a quality improvement initiative designed to assess the impact of patients having access to their own ambulatory visit notes.

1) The report suggests that "Ob-Gyn patients readily use patient portals" (Line 77) but only 37% of your total patient population had active patient portal accounts (Line 174) at the time of the analysis. This is a discrepancy between what was stated and what was observed in your patient population. Please comment on this in the results section as a limitation.

**Response:** Line 77 (introduction) was intended to reflect the literature on positive attitudes regarding use of patient portals among Ob-Gyn patients, not our own experience. We have revised the sentence in the introduction to clarify this, as background information regarding Ob-Gyn patient willingness to use the portal. We agree that actual portal registration requires additional focus to barriers and facilitators. Thank you for pointing this out.

2) The results indicate that 69% of patients (6594/9550) with online access to their medical records read at least one ambulatory note (Line 47) but only a small percentage (3.2%) that read at least one note responded to the query via the patient reporting tool (Lines 47-48). These findings question how applicable the results are to the entire patient population.

**Response:** We noted the high read rate among patients registered for the portal, signaling their interest in notes, an important outcome in and of itself. We agree with the reviewer that compared to this high

read rate, voluntary participation in the reporting tool was low. However, this is a known limitation of patient reporting tools and not dis-similar from other published accounts of patient reporting tools, as referenced in the methods and limitations. Indeed, we expected limited participation even before launching the project, based on the literature and prior reporting tool experiences, and because there was no advertisement as part of the project and the link to the reporting tool was at the bottom of the note, so patients would have to read their entire note to get to the tool. Nonetheless, in our prior experience with the patient safety reporting tool in primary care, although patient reporting rates were also low, they exceeded the use of the online clinician ambulatory adverse event reporting system several fold, and patient reports generated actionable issues that supported quality of care.[1] Most reporting systems do not focus on response rates but rather gathering information that can improve care and organizational systems. The purpose of this paper is to report on this novel intervention, and provide a framework for other organizations considering patient engagement through visit notes (not to generalize findings). We acknowledge that the population is biased, and that local adaptation and testing is needed in other organizations in the limitations section (results of the QI work are not intended to be generalizable). Experts urge patient engagement in safety but few tested methods exist. We hope that our QI process and our learning experience can help inform future use in larger, more diverse settings. We have repeatedly stated the explorative nature of work, the QI focus, and have further emphasized the non-generalizability in the revisions. We were not aware of the QI submission category at the time of our initial submission, but the paper has also now been reformatted into a QI article type, per the editor's request, further clarifying the intended goals.

3) Over 80% of the patients that accessed at least one note and used the online reporting tool had a college or graduate degree (TABLE 1). The study would be strengthened by providing information about the educational demographics of the entire patient population for comparative purposes. This information would be beneficial both to assess its effect on the use (or lack thereof) of the online reporting tool as well as the study's overall applicability to other demographic populations. For example, how does this study apply to populations who have limited to no understanding of written English and/or have limited health literacy?

**Response:** We agree that the population is biased, as described in the limitations. As access to the reporting tool not only required the patient to read their entire note, they also needed to have a portal account in the first place. We added a comparison of the reporting tool using population to the general population of Ob-Gyn patients at that time, as well as the overall demographic of our organization's patient population to the results section. Tool users were more white and more educated than these 2 comparator groups, although it should be noted that the overall population at our hospital is biased toward Caucasian and educated patients. In addition, the demographics of patients using the reporting tool are similar to other published studies on reading notes with traditional, cross-sectional surveys with higher response rates.[3] One interpretation is that responses reflect a likely bias in note-readers overall. We added this information to the results and to the limitations sections.

In addition, respondents may have been biased toward those that encountered note problems, and therefore the reported frequencies of patient-reported inaccuracies and "bothersome words" may be higher than in the general patient population. However, some patients experiencing care concerns may also experience unique barriers to reporting such as language barrier, low health literacy, or other known factors, making directionality of bias difficult to predict. Because prior studies suggest that less educated and non-white patients were more likely to report notes were extremely important to engage in care than more educated and white patients,[15] we can't estimate whether larger, more diverse

populations are more or less likely to benefit from open notes than the group responding to the voluntary reporting system.

4) There were few comments suggesting bothersome phrasing in the notes. One of the key issues regarding transparency is how open access to ambulatory notes may affect the physician/patient relationship. Could open access to ambulatory notes negatively impact the physician/patient relationship? How might it also impact provider to provider communication? Please comment on this in the discussion section of the paper.

**Response:** In a previous pilot of the patient reporting tool in primary care, the majority of patients felt that the relationship with their physician did not change, while 25% believed that their relationship improved.[1] Additionally, a study involving a cross-sectional survey of doctors and patients on their experiences with shared visit notes found that over half of doctors believed that patients trusted them more and their satisfaction increased after a year of open notes implementation.[3] Provider to provider communication has not been studied and is out of the scope for this project, but it would be a great future project. We have added information and questions for further consideration about the patient-doctor relationship to the discussion, thank you for pointing this out.

5) The manuscript had no discussion of how physician documentation may have been affected by the knowledge that their notes may be reviewed by the patient. Please include this in the discussion section of the paper.

**Response:** This QI project did not seek feedback from the Ob-Gyn providers, however, in the original reporting tool pilot done in primary care in 2014, among physicians who completed the intervention and completed user experience surveys, none reported worsening workflow.[1] Additionally, in the initial OpenNotes cross-sectional survey in 2010, while doctors worried about the impact on workflow prior to the intervention, those fears largely decreased after 1 year of sharing notes. Few doctors reported taking more time to prepare their notes and the majority reported that making notes available to patients was a good idea.[6] This survey also queried doctors about changes in note writing, but it focused on specific sensitive issues: obesity, substance abuse, cancer, and mental health. Physicians' views about changing documentation of Ob-Gyn specific issues has not been queried and is a good research question for future inquiry. We revised he discussion section to include some of the above content as requested.

**Reviewer #2:**
This is a QI initiative using OpenNotes with three aims: to assess ob/gyn patients interest in reading their notes, explore whether patients find errors in their notes and what types, and identify patient perceived sensitive language in notes. The authors do meet their aims showing 69% of patients read at least one note, about 25% of patients who provided comments found errors in notes, with a high percentage potentially posing patient safety problems, and very few patients identified sensitive language. Paper demonstrates ob/gyn patients will read notes with positive experiences. Another value is this process can uncover patients who do not totally understand what their provider said at the time of the visit. One drawback to process some patients mentioned was not understanding medical terminology. Authors do acknowledge reasons why their findings may not be generalizable to other patient populations. Conclusion can be stronger

1) Line 35-38 - please rephrase as this is not written as an objective. Objective stated clearly in lines 85-88
**Response:** We reworded the first paragraph of the abstract to focus explicitly on objectives outlined in the introduction, thank you for this suggestion.

2) Line 79-81 - the first part of this sentence is unclear, please rephrase

**Response:** This sentence has been rephrased to clarify the cited studies.

3) Line 115-122 - were patients consented and advised their comments would be part of a published paper? Or did patients think their information was only being used by the health system to improve the quality of the notes?

**Response:** We submitted a determination letter to the IRB; the IRB determined that the project was a quality improvement initiative (attached). The participation was entirely voluntary and patients could opt-out as desired. Patients were informed that their comments would be de-identified and shared with clinicians and other healthcare leaders to help with learning and quality improvements. We have expanded the section on QI determination in the methods.

4) Line 147 -how often were patient responses reviewed? What was the time frame for determining urgent issues?

**Response:** The patient responses were regularly reviewed, in most cases within 72 hours. We have added more details into the methods to clarify the process for identification and review of potential safety concerns.

5) Line 232-233 - what are examples of suggestions for improvement by patients?
**Response:** Although this report did not include comprehensive review of patient recommendations, some suggestions for improvement included access to medical definitions and universal access to notes across all their providers. Other comments reflected technical issues such as navigation of the portal. We have added in a sentence on lines 232-233.

6) Line 236-238 - what were the rates of patients opening at least one note in primary care and all-comer patients?

**Response:** Because of all the differences in EMRs and portals from institution to institution (not to mention the complexity of exactly what notes are released, what types of visits "count," whether an organization provides notifications to patients of new notes or not, and potential technical differences in exactly which clicks the portals track, it's not yet possible to make reliable comparisons. However, the observed open rate among Ob-Gyn patients signals substantial interest in reading notes, which was the primary point we wanted to make. We have removed the comparison to other organizations, as the method for calculating open rate may not have been standardized and we wanted to avoid mis-interpretation. In order to more fully respond to this question we ran additional queries examining the open rate stratified by whether patients were registered on the portal, and found consistent results to our Ob-Gyn data (similar open rates across over 50 departments/divisions using open notes) for patients on the portal. In addition, it is very similar to previously published rates of note-opening by primary care patients who participated in the initial open notes study.[6] We therefore modified the sentence in the text to read: "First, 69% of Ob-Gyn patients with an active portal account opened at least one note,

similar to open rates among primary care patients, [6] and demonstrating substantial interest in note reading."

**Reviewer #3:**
This is a report of a limited number of patients who completed a questionnaire about having read OpenNotes. The response rate was very low but most of the respondents liked the option of reading their outpatient notes and found them helpful. Patients identified errors in about a quarter of notes, the majority of which were considered important. Giving patients the opportunity to read their office notes is becoming increasingly common, thus the topic is interesting and important. Involving patients in assessing accuracy is a growing need with HER errors from copy/paste propagation of misinformation, "smart phrase" draw-ins of extraneous data, and signing of lengthy notes much of which the signer may not themselves actually have written (or proof-read).
Comments are as follows:

1) My biggest concern is the low response rate of 212/6594 = 3.2%. Adequate sampling and response rate are crucial in survey research, and convincing conclusions are difficult to draw from this small a proportion of respondents. It does appear that many patients are interested in reading their notes, but because so few completed the questionnaire, one cannot conclude that many of the total number of patients who used OpenNote had positive experiences. True, many of a tiny subset that responded reported positive experiences, but extending this to the entire population of note-readers is speculative.

**Response:**
As a quality improvement project, this project was meant to get real time feedback on patient's experiences reading their notes and patient-perceived errors in the notes and to act on these in a note-by-note basis (as opposed to a single point in time cross-sectional survey). It was not intended as a research study, and results were not intended to be generalizable. Instead, at a time when experts urge patient engagement in safety but few tangible methods exist, we hope that our QI process and our learning experience can help inform design, implementation, adaptation, and site-specific testing in other settings. One lesson is that to further test patient reporting, greater advertisement and encouragement for patients to submit reports is needed. We have added this to the limitations/discussion section. We were not aware of the QI submission category at the time of our initial submission, but the paper has also now been reformatted into a QI article type, per the editor's request, further clarifying the intended goals.

We agree with the reviewer that voluntary participation in the reporting tool was low, (although not dis-similar from other published reports of patient reporting tools, as referenced in the methods and limitations. [1,7]) and therefore conclusions are difficult to draw, and have modified the language in the paper accordingly. We were encouraged by the results, because although the overall responses were low, they resonated with previous cross-sectional surveys with higher response rates. In other words, patients were expressing similar positive experiences with notes when surveyed at a single point in time (cross-sectional survey) and when they used the reporting tool at the 'point of care' on a note-by-note basis. However, the reviewer is correct that inferences should not be drawn from this particular experience and we have revised the discussion accordingly. We have modified any statements about positive experience to reflect the attitudes of patients who used the reporting tool (as opposed to patients in general) and have significantly expanded our limitations section to explicitly guard against generalization.

Most reporting systems do not focus on response rates but rather gathering information that can improve care and systems. We acknowledge that the population is biased, and that local adaptation and testing is needed in other organizations in the limitations section (results of the QI work are not intended to be generalizable). We hope our QI process can prove to be a learning experience for future research in wider-ranging populations. We want to make sure that the readers know that our findings are not generalizable, but are similar to previously published results on shared visit notes.[1,2,5,6]

2) I don't see any mention of IRB approval for this study. Even if it was begun as a quality improvement project, it should have some form of post hoc institutional review to be published as research. There is no mention of consenting patients who completed the questionnaire, or that they knew their answers would be part of a research project.

**Response:** We submitted a determination letter to the IRB; the IRB determined that the project was a quality improvement initiative (attached). The participation was entirely voluntary and patients could opt-out as desired. Patients were informed that their comments would be de-identified and shared with clinicians and other healthcare leaders to help with learning and quality improvements. Evaluation of QI work is encouraged at our institution, with a careful distinction that we are reporting on a QI project and not a study, and results are not meant to be generalizable. We were not aware of the QI submission category at the time of submission, but we have reformatted our paper as a QI submission at the suggestion of the editor, which we agree is an ideal fit. We also contacted the IRB to confirm that we did not need to submit a new proposal to publish our descriptive QI findings. The intent of reporting our QI process is to serve as a "springboard" to help others to think critically about patient engagement through visit notes and adapt and then test their own intervention in their own setting to assess the performance of shared visit notes in the context of local culture and QI practices. We have added in the text information about our IRB process at the end of the methods section and further emphasize lack of generalizability in the limitations section.

3) The statement in the 3rd Methods paragraph that those who read their notes "were invited to use a reporting tool" is vague. Did most patients actively decline to complete it, or did they not see it, or what? Were there differences between patients who completed it and those who did not?

**Response:** We have added more information about how the patients received the invitation in the methods. As the link to the tool was at the end of the note and not embedded in the email (this was not possible for our project), the patients would have to go into their notes and then read to the bottom of their notes to reach the tool. The patient reporting tool was not advertised in clinics or routinely discussed or encouraged by providers. Though we did not ask patients in this experience, in the previous primary care pilot about 50% of patients reported they did not use the tool because they did not know about it.[1]

4) Why was Family Planning not part of the project? The 1st paragraph of the Methods states that all clinicians and departments were expected to participate unless they explicitly presented a reason for not doing so. What was Family Planning's reason?

**Response:** When the Ob-gyn department implemented Open Notes, the Family Planning division opted out due to concerns for patient privacy and the sensitive nature of the care being given. The sentence has been revised to include this information to provide context for why Family Planning was excluded from the project.

5) It's not clear why MFM was grouped with generalists, whereas all the GYN subspecialties were put in a separate group. MFMs are subspecialists too, and often address different problems than do generalists.

**Response:** The Generalist and MFM grouping was selected to represent practices providing obstetric care in the department. Although we recognize that generalists also provide gynecologic care, this grouping enabled a view of predominantly obstetric care, (but does include some gynecology care, as discussed in our limitations). The gynecologic specialties grouping includes only gynecologic care. We have revised this sentence to provide an explanation of why we choose to group divisions together.

6) The title seems at odds with the results: based on the poor response rate, engagement with Safety and Quality actually was extremely low, but the authors' discussion implies that OpenNote did engage patients. The survey did identify a number of charting errors, but what impact OpenNote had on actual patient safety (i.e., outcomes) was not assessed.

**Response:** The intention of this project was to assess Ob-Gyn patient interest in reading notes and to invite patient reporting about patient-perceived errors in notes; both activities that engage patients in care. We know from larger cross-sectional surveys of primary care patients that reading notes helps engage patients with medication adherence, feeling in control of your care, visit recall and a number of other benefits.[2,5,9–11] We were not intending to assess safety outcomes (beyond QI review of patient-reported inaccuracies), but that is certainly a good next step for future research or QI work. Although the majority of patients with active portal accounts opened at least one note, we recognize that voluntary use of the patient reporting mechanism was low, as expected, and therefore adjusted the title to “An Opportunity to Engage Obstetric and Gynecology Patients through Shared Visit Notes.” Of the reports we received, the majority contributed to improved quality and safety. We have also added content to the limitations/future considerations section underscoring that greater attention to advertisement and encouragement of patient participation is needed.

7) Some of the Methods are unclear, e.g., various groups "collaborated for about a year to create and online tool to proactively report..."(could the authors be more specific?) "Responses...were incorporated into routine QI operations for real-time responses" (borders on jargon) " "Did you find tests or results that concerned you?" (concerned in what way? Were unaware of them? Concerned because they were serious? Because they didn't understand them?).

**Response:** Thank you for this feedback, we have expanded the methods to provide more clarity on our process. Regarding concerning test results, our multi-disciplinary stakeholder group which included patients and families, safety experts, doctors and nurses, and representatives from social work, patient relations, Health Information Management and Information Systems wanted to be intentionally broad to capture as much information as we could about the patient experience. In other words, we wanted to build a patient-centered tool to know about labs that concerned patients, even if they were not considered “serious” by clinicians or if they didn’t understand them. We restricted our outreach about “concerning labs”to those that were not previously discussed by a provider. We used this approach to put a “net” under experiences that might be frightening to patients – finding a concerning result that no one discussed with them, but recognizing that there might be some results that were ‘concerning’ to them but had been discussed (ie not a QI issue). Indeed we found that 13% of reports indicated a concerning test result, but only 3% reported that this result was not previously discussed with a provider.

8) The authors state that they "avoided focusing on statistical comparisons" and do not describe any statistical methods, but Table 2 includes p-values (chi-square? Fishers?).

**Response:** Thank you for bringing this to our attention. The p-values should have been omitted (and were included in error). We intended to avoid statistical comparisons and instead provide descriptive data reflecting our experience; we have removed p-values from the tables.

9) Patient examples of "bothersome words" seem quite subjective, and some appear to be misinterpretations. It isn't clear how a clinician would know for a given patient what words or medical terminology she might find bothersome or objectionable. Also, although I understand that patients would like to understand notes written about them, medicine can be a highly technical field and has its own language. Medical notes are supposed to document what was said, done, thought, and planned so facilitate understanding of the interaction, thought process, and management. Complex medical diagnoses and treatments may not lend themselves to simple prose, and writing notes at the level of patients with widely varying degrees of medical literacy would be nearly impossible. Fortunately, the number of patients reporting bothersome words was fairly small.

**Response:** Thank you, we completely agree that notes serve many purposes, and many clinicians worry about this point when considering implementation of open notes. Although organizational implementation of open notes may be accompanied by preparation for clinicians and patients, including FAQs (see www.opennotes.org), many busy clinicians do not change the approach to documentation. Patient reactions to sensitive information was a major concern when the Obstetric and Gynecology department in our center implemented OpenNotes. We therefore focused a question specifically on this issue so we can begin to learn more about patients' experiences of reading Ob-Gyn notes. Broader inquiry is needed, but these early results are encouraging. Of course, open notes does not change a patient's right to their health information. By HIPAA, patients have a legal right to their medical record (notes) and providers should document knowing that patients could be reading their notes, whether open or not. We have expanded the discussion to include the above.

10) In the Discussion, the authors state "chart review was beyond the scope of this project," but 212 reviews would not be an insurmountable obstacle and review would have been valuable by allowing comparison of the what was written and the patient's interpretation of it. In fact, chart review WAS done when patients raised questions about errors.

**Response:** This project was part of a much larger QI initiative including other divisions of the medical center, and it would not be feasible to review each report. It was also implemented with the intent to be an ongoing part of QI (and is still running at our center) and we wanted to design a workflow that would be sustainable. Patient Relations did consult the patient's chart on an as needed basis, but this was not done in a systematic way for every report.

11) The authors do a good job acknowledging the limitations of the study. Documenting the number of errors and inaccuracies in the EHR is an important contribution in itself. Patients have a large potential role in keeping documentation accurate and honest, and in discouraging physicians from drawing in information and exams they did not actually review or do.

**Response:** Thank you.

**Reviewer #4:**
Thank you for the opportunity to review this interesting and well written manuscript. It explores an area not sufficiently studied in obstetrics and gynecology and would be read with interest by members of our specialty. The study looks at the uptake and patient reactions to the use of a feature in the authors electronic medical record system that allows patients to review their outpatient visit notes.

1) Line 110: Why was the Family Planning practice not included in the implementation of OpenNotes?

**Response:** When the Ob-gyn department implemented Open Notes, the Family Planning division opted out due to concerns for patient privacy and the sensitive nature of the care being given. We have added context to the exclusion of Family Planning within the manuscript.

2) Line 174: Among patients with open portal accounts--how many notes were generated and what number (percent) of notes were opened by a patient? It might be interesting to see how many patients opened one note and how many opened several notes (provided that there were several notes to review).

**Response:** There were 34,508 notes written for the 9550 patients with active portal accounts. There were 84,207 notes generated for all 25,603 discrete Ob-Gyn patients including those patients who had multiple visits. For this first explorative QI project we did not query differences between opening one note and multiple notes.

3) Line 191: What does this mean that there were concerning reports? Is it that the patients' were concerned about the test--or that the test was abnormal?

**Response:** The question asks for the patient's perspective of whether there was a concerning test or result documented in the visit note as well as if the provider addressed their concern. It does not necessarily mean the result was abnormal, but rather focuses on the patient's experience of results and their documentation. Our multi-disciplinary stakeholder group which included patients and families, safety experts, doctors and nurses, and representatives from social work, patient relations, Health Information Management and Information Systems wanted to be intentionally broad to capture as much information as we could about the patient experience in designing the patient reporting tool. In other words, we wanted to build a patient-centered tool to know about labs that concerned patients, even if they were not considered "serious" or "abnormal" by clinicians or if they were "concerning" because patients didn't understand them. We restricted our outreach about "concerning labs" to those that were not previously discussed by a provider. We used this approach to put a "net" under experiences that might be frightening to patients – finding a concerning result that no one discussed with them, but recognizing that there might be some results that were "concerning" to them but had been discussed (ie not a QI issue). Indeed we found that 13% of reports indicated a concerning test result, but only 3% reported that this result was not previously discussed with a provider. When

reviewing reports, Patient Relations did have access to a clinician with safety expertise to ask clinical questions, along with the ability to pull the patient's chart for clarifications.

4) Line 205: Among reports identifying a possible inaccuracy, who noted that it was important? The reviewer or the patient?

**Response:** Patients who reported identifying an inaccuracy were asked to rate the significance of the inaccuracy, from their perspective. Patients rated the importance of the inaccuracy using a Likert scale ranging from 0-5 and all rated 4-5 were included as important. In our QI review, clinicians separately evaluated patient reports of safety concerns and assigned a rating of "major" or "minor" – depending on whether they had clinical relevance, as reported in the paper.

5) Line 243: Sometimes the discrepancies between what the patient believes should be in the note and what the provider wants to record--are different and not inaccuracies. For example, a patient who is viewed by the provider to be an unreliable historian or difficult. There is an implication here that these inaccuracies identified by patients were correct. Maybe in some, the provider's documentation is exactly what the provider felt should be in the record.

**Response:** Yes, we agree that there can certainly be discrepancies between the patient perspective and the clinical perspective and we were curious to explore these in our QI initiative. Clinician review of these responses identified that 75% were defined as "major: potential for impacting care now or in the future."In addition, some patients themselves reported inaccuracies that they rated as not very important.

6) Line 259: The authors seem to imply that giving patients access to their notes may be responding to a need that patients have and because they are not getting it from the providers they are turning to other sources. But what they seek online may be explanations of conditions and guidance as to the appropriate management. Things they may not find in the note. They may be double checking what their providers told them or seeking a deeper understanding of their condition or treatment (information that would not typically be in a note).

**Response:** Patients seek information independent of their providers for various reasons, including a desire for more information. Additionally, patients may not ask their provider their questions at or after a visit due to concerns about bothering their provider or taking too much time. Some patients who use open notes have commented that they find answers to their questions in the note. Many use notes to better remember what they heard or next steps after the visit. Patients who seek health information online often use multiple sources with sometimes conflicting information, which can generate stress or non-compliance.[12–14] Knowing a patient is reading the visit note can be an opportunity to convey accurate information that is relevant to that particular patient about a clinical condition and the plan of care and perhaps even over time, trusted resources for additional learning. Even without additional information, the note can serve as a springboard for seeking further information online, anchoring the patient more accurately than when relying on memory alone, particularly since some studies suggest that 40-80% of healthcare encounters are misremembered. In focus groups of open notes readers, patients commented that they went online to look up information they wanted to learn more about. This is important for two reasons: First, reading notes may further engage patients to learn more about their health or condition. Second, the online data world is broad and not always accurate. Clinicians may

prefer to ground patients in the clinician's own words/accounts of the patient's condition than have the patient rely solely on online information.

7) Line 281: The authors correctly note that while a large number of the notes were opened, patient participation in reporting on their reactions to being able to read the note was quite limited. This is the biggest limitation of this study. This whole part of the study is based on only 232 responses. Thus, limiting the strength of the conclusions significantly.

**Response:** We aniticipated a low participation rate with the patient reporting tool, as described in the methods and limitations. As a QI project, it was not a study, there was no advertisements or incentives. and the results were not intended to be generalized. We aimed to see whether Ob-Gyn patients would be interested in reading their notes (they were) and whether they could report note inaccuracies (a few did; and the majority of those were 'meaningful' from a QI perspective). Use of the reporting tool was similar to other published accounts of patient reporting tools. In one similar experience (a pilot in primary care), patient reporting rates exceeded clinician reporting rates in ambulatory care several-fold. [1] Most reporting systems do not focus on response rates but rather gathering information that can improve care and systems. Gaining further benefit from patient reporting would likely require broader advertisement and encouragement from clinicians to use the tool and further testing about feasibility in such settings. We fully acknowledge that respondents represent a biased population, but our intent with this project was to get initial feedback from Ob-Gyn patients on experiences with their shared notes, as there was limited data available, and we have modified our conclusions accordingly (guarding against generalization or drawing conclusions!). Our hope is that this project is a first step for future research with more expansive populations and that others can learn from our QI process and experience.

8) One other question that I have for the authors is whether they have any provider feedback on the OpenNote initiative. Did providers feel burdened by the initiative? Did they change how they wrote their notes and what the content was? Were they more frequently or less frequently contacted by patients after the initiative started? How did they respond to the inaccuracies that were pointed out to them? A companion survey of providers about the initiative would be very interesting.

**Response:** Provider assessment was not part of this QI project. However, provider attitudes have been previously examined as part of broad cross-sectional surveys and during our first pilot of the patient reporting tool in primary care. In surveys, the majority of clinicians believe sharing notes is a good idea and do not believe sharing their notes significantly affects their workflow. Most reported that it did not change their relationship with their patients, and some reported improvement. Some (roughly 20-30%) of providers reported that they changed how they wrote their note when writing about specific issues that were queried: obesity, cancer, mental health, and substance abuse. These reports are initial, and more research on clinician's perspective on opening their notes to patients is needed.[1,2,11] In terms of this QI initiative, provider feedback was not a focus and providers were only contacted when concerns for patient safety and quality arose. We took on a survey of provider experience after our first patient reporting tool pilot in primary care; in this very small pilot provider assessment, most clinicians thought the reporting tool should continue, none reported worsening workflow, two-thirds reported being contacted about a patient report and they rated the "meaningfulness" of the information as a mean of 5.4 (scale 0– 9).[1] As in the Ob-Gyn experience, most primary care patient reports were deemed to be a possible or actual safety concern on QI review. Overall, based on the results of the primary care pilot,

we expanded use of the patient reporting tool from primary care to Ob-Gyn (present report).

**STATISTICAL EDITOR:**
1) lines 173-177: Need to expand this analysis to address potential selection bias. That is, only 37% had active patient portals, among that subset, 69% used the portal opening at least once, while some patients had multiple visits, with >84 k visits among 6594 patients. In turn, how did the 212 respondents in this series who were volunteers relate to those figures? Were they representative of the entire group?

**Response:** Thank you for pointing this out. We made a point to limit statistical comparisons in this QI initiative and intended to omit p values or "corrective" analyses to avoid over-interpretation of the findings, which were meant to be descriptive of our experience and not generalizable. We noted that the p-values were accidentally included in the table, and have now been omitted. We know that the patients using the reporting tool represent a biased sample, in part because they are likely more "activated" than all patients by virtue of being registered on the portal and responding to the invitation for feedback, and in-part because the overall patient population at our organization is largely Caucasian and highly educated. We have further characterized the bias by examining the demographic characteristics of all Ob-Gyn patients (in 2017). Compared to these patients, those patients who used the tool were older on average (53 vs. 46), more likely to report white race (81% vs 68%), less likely to report Hispanic ethnicity (2.4% vs. 6%), more likely to have a college education (81% vs. 63%), and more likely to report English as a preferred language (98% vs. 92%). There are very similar differences when comparing the patients who filled out the reporting tool to the general patient population at our health center. Patients who used the reporting tool were more likely white, educated, and English-speaking. However, the demographic characteristics of these patients are very similar to previously published demographics of patients responding to cross-sectional surveys about open notes with higher response rates.[3] We have added this information to the results and limitations, as well as the need for future work to expand our knowledge about the experiences of more vulnerable populations.

2) Table 1: How did these demographic profiles relate to the overall patient profile?
**Response:** Please see the above response which addresses the demographics of the overall Ob-Gyn and organizational patient population.

3) Table 2: Two issues with this analysis. First, there were 20 more responses than individuals, so the counts of patient perceptions are not independent events. Should either have corrected for that, or provided analysis using only a randomly chosen response from any individual with > 1 response. Under the heading "Did you find inaccuracies?" the comparison of "Yes" (18.1 % vs 30.2%) is significantly different , the comparison of "I am not sure" response rates was NS and if those were aggregated, then difference has p value = .06. Also, how does this Table relate to lines 166-167 where the Authors stated that "We avoided statistical comparisons and use descriptive tools given the low expected response rate ..."
**Response:** Thank you for addressing this issue. There were two major reasons why we decided to include multiple responses from the same patients (as noted by the editor in the 232 responses and 212 patients). Although the same patient may have filled out more than one reporting tool form, each survey originated from a distinct clinical interaction or visit. Because the goal was to invite patient reporting on possible note inaccuracies, each new note provided a new opportunity to find possible patient-perceived errors. However, selecting one random response from each patient with > 1 response

is very reasonable., We repeated our analysis using that methodology and the results are very similar. Please note that p-values were included in the tables erroneously. We did not intend to compare compare Ob and Gyn patients statistically, but rather to describe their experiences. We described the places where their responses are qualitatively different, (as pointed out by the editor above regarding frequency of reporting inaccuracies) in the text, but without a statistical comparison.

4) Table 3: Some of these reported inaccuracies could be checked, e.g., when the Mirena was inserted, or how Grave's disease was treated whether an HPV vaccine was given. Were those checked vs a medical or surgical record?

**Response:** This project was part of a much larger QI initiative including other divisions of the medical center, and it would not be feasible to review each report. It was also implemented with the intent to be an ongoing part of QI (and is still running at our center) and we wanted to design a workflow that would be sustainable. Patient Relations did consult the patient's chart on an as needed basis, but this was not done in a systematic way for every report.

**EDITOR COMMENTS:**

- As this is a QI project, please reformat it to be a "clinical practice and quality " submission. Please see the Instructions for Authors for the formatting specifications for that article type.

**Response:** Thank you for this clarification, manuscript has been reformatted to fit the "clinical practice and quality" submission.

- we don't use abbreviations in the precis
**Response:** This has been fixed.

- Make sure you read the Instructions for Authors regarding the Clinical Practice and Quality article type. There is specific guidance there for abstract, word counts, etc
**Response:** Thank you for pointing this out, the manuscript has been reformatted.

- It seems from your paper that this project was throughout your organization, not just Ob GYN, but that you carved out the Ob GYN data. That needs to be made clear in your methods.
**Response:** OpenNotes had already been implemented across our institution at the time of this project. The reporting tool was piloted in 2 teams in primary care from 2014 to 2015. After positive results from this limited pilot experience, the Ob-Gyn department implemented the reporting tool beginning in April 2016. As anticipated with our QI initiative, the primary care teams continued to participate and those clinics as well as the Ob-Gyn department continue to use the tool at the time of this writing (now 5 years from the initial launch in primary care). We wanted to examine the Ob-Gyn experience, as some clinicians were particularly concerned about what this population of patients might report after reading their notes. Hence we examined the first consecutive set of responses from these patients using the tool, roughly after 16 months of implementing the patient reporting tool in this department. We have clarified the methods to make sure that our QI background and process are clear.

- Is this denominator for your whole medical center, or just ob gyn?
**Response:** This denominator is for Ob-Gyn.

- The first paragraph of your introduction does not really seem to relate to patients reading clinical notes, but rather to their seeking additional information about their health care outside of the clinical visit. Please either make a stronger link between the content of the first paragraph OR replace it with some background information form other areas of medicine about patients reading their notes and then introduce the gap about reproductive health and what your are studying.
**Response:** Thank you for this suggestion, we have reworked the introduction to provide more background on open notes and modified the first paragraph to better set the stage regarding Ob-gyn specific interests and experiences with online health information, continuing on to what role open notes might play.

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell the words out throughout the manuscript. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper.
**Response:** Apologies for the unexplained abbreviations, we have gone through the text to make sure all our abbreviations are acceptable or explained.

- Their website describes this as an international initiative. In the introduction, it would be important to explicate Open Notes a bit more. Perhaps including the URL, their mission statement or some part of it. . OpenNotes is an international movement advocating fundamental change in the way visit notes are managed. We're committed to spreading the availability of open visit notes and studying the effects. We believe that providing ready access to notes can empower patients, families, and caregivers to feel more in control of their healthcare decisions, and improve the quality and safety of care.

**Response:** Thank you for this suggestion. We realized reading the manuscript that more of an explanation of OpenNotes would be helpful to readers not familiar with the initiative. The introduction has been revised with background information about OpenNotes and its mission as well as reference to the url.

- is the department "chief" the person in charge of a service line or is it the same as a department chair?
**Response:** The designated department official may have varied from one department to another; we therefore changed the text to "department leadership."

- Do your generalists provide any GYN care or only OB?
**Response:** Yes, generalists provider both obstetrics and gynecology care, but the majority of the generalist clinic visits are obstetric. We recognize that coupling the generalist clinic with MFM was "imperfect" (included in limitations) but it was the most practical way to be inclusive of all obstetric visits.

- one reviewer wants to know why FP is not included. I'm agnostic about whether you decide to include that information, although it may be interesting in case others are considering joining the open notes movement.
**Response:** When the Ob-gyn department implemented Open Notes, the Family Planning division opted out due to concerns for patient privacy and the sensitive nature of the care being given, and we have added in this information to the manuscript to provide context for the readers.

- This is after the publication of the use of the reporting tool you reference below. Why did you select this time frame, rather than extending it?

**Response:** The original pilot was only in primary care and the reference describes the experience from Aug 2014-Aug 2015. Due to interest in Ob-Gyn patient's experience reading their notes, potentially with sensitive information in them and lack of data on Ob-Gyn and shared visit notes, the reporting tool was then adapted for use in the Ob-Gyn department, starting April of 2016. We report here on roughly the first consecutive 16 months of experience in Ob-Gyn.

- was this reporting tool something that preexisted your QI project or was it new for this?
**Response:** The reporting tool previously existed in primary care, where it was first launched in 2014. Based on our positive experiences with the patient reporting tool in primary care, its use was expanded to Ob-gyn (and also to a pediatric hospital). We reviewed patient and provider responses to the reporting tool experience to iteratively improve it, and also engaged Ob-Gyn providers as stakeholders to develop a slightly revised patient reporting tool, which was launched in 2016 for the Ob-Gyn department.

- not sure what this means? How did the clinicians participate or do you mean, that all of the notes of the all of the clinicians were included?
**Response:** We mean that all notes from clinicians were included, with the exception of hidden notes which generally occur for less than one percent of notes in our organization (and we also found to be extremely rare in our Ob-Gyn QI experience, as reported herein). We rephrased this sentence to clarify the point.

- how would a patient then know that the reporting tool exists?
**Response:** The patient reporting tool was implemented in a "real world" environment. It was not advertised or discussed routinely by providers. Patients routinely receive a secure message notifying them that a note is available. In the message, we told them that a feedback feature was available. However, patients could only get to the reporting tool by logging on to the patient portal and reading to the bottom of their note, where there was a link to fill out the reporting tool. We have revised the manuscript to clarify the QI process in the methods section.

- OK, so here is this information about the development of the tool. Again, was this for the whole medical center or just Ob GYN?
**Response:** The development of the tool was the same process as the initial tool developed for primary care and later implemented by Ob-Gyn.

- how is it presented to the patient in the portal? When was it first available to patients and was it advertised or promoted at that time?
**Response:** Patients could only access the reporting tool through a link at the bottom of their note. It was first available in Ob-Gyn in April 2016. There was no advertisement or promotion. We have added more information on the details of the reporting tool in the methods section.

- The Journal style doesn't not use the virgule (/) except in numeric expressions. Please edit here and in all instances.
**Response:** Thank you, we have reviewed and removed all instances of the virgule excluding when used in numeric expression.

- Is the process only for Ob GYn or was it throughout the medical center?
**Response:** This process was for Ob-Gyn, it was the same as the process used in the pilot in primary care.

- ob gyns?
**Response:** One Ob-Gyn and one Internal Medicine physician with expertise in patient safety and patient engagement reviewed the responses; we have clarified this in the text as well.

- This is where you need to be clearer. Please state your primary and secondary outcomes. On lines 85-88 you listed 3 aims: the first is apparently open rates and thereafter, its results from the reporting tool. You don't provide any methods about open rates (read rates) and how you got that data.

**Response:** We calculated open rates using portal tracking data: the proportion of patients who clicked on at least one note on the portal during the QI review period, of all patients who had visit notes available and an active portal account during the same time. We expanded upon the methods for the administrative data and have stated our primary and secondary outcomes as requested.

- This seems like a large number of discrete Ob GYN patients in 16 months, although certainly possible. Could you provide the use for the entire medical center during ths same time period (# of discrete patients, % with active accounts, # opening at least one note, # hidden...etc)
**Response:**
It's very difficult to identify discrete patients across our organization (or any institution). But we did look at number of visits, which was approximately 480,000 over 2017. Corrected for the 16 months of the QI review period, ObGyn leadership believes 13% is a credible estimate of volume related to the overall institution. The % of hidden notes in our organization is <1%. There were several requests for additional information and additional analyses from the reviewers and editors. We were able to pursue most but not all the requests as some extend well beyond the scope of this Ob-Gyn QI paper.

- as noted by the statistical editor, and even though this is a descriptive study, you need to do something about repeat reports by the same person. The same person may always report problems with tests, etc.
**Response:** There were two major reasons why we decided to include multiple responses from the same patients (as noted by the editor in the 232 responses and 212 patients). Although the same patient may have filled out more than one reporting tool form, each feedback form originated from a distinct clinical encounter. Because the goal was to invite patient reporting on possible note inaccuracies, each new note provided a new opportunity to find possible patient-perceived errors. However, selecting one random response from each patient with > 1 response (as suggested by the statistical editor) is very reasonable. We repeated our analysis using that methodology and the results are very similar.

- since you are noting a difference in these findings between groups, please provide OR and CI's. That will need to be included in your methods as well--how you made those statistical comparisons.
**Response:** The p-values have been removed from the tables, as they were included in error since we did not intend to focus on statistical comparisons in the QI work. We have made a point to avoid statistical comparisons and have added the rationale for that in the methods.

- As patients sometimes misremember things, was there any effort to look in the EMR to verify what was true?
**Response:** As accurately surmised above, this project was part of a much larger QI initiative including other divisions of the medical center, and it would not be feasible to review each report. It was also implemented with the intent to be an ongoing part of QI (and is still running at our center) and we wanted to design a workflow that would be sustainable. Patient Relations did consult the patient's chart on an as needed basis, but this was not done in a systematic way for every report. We agree that patients may misremember events or that providers may disagree with patient reported inaccuracies. In

our first primary care pilot experience we tracked the  percent of patient reports that generated a change to the record or in practice (the majority of completed cases). Providers declined to make a change in only a small fraction (4/51, 8%) of patient safety concerns confirmed by patient relations.

- This is called a primacy claim (your paper is the first or biggest) and must either be deleted or supported by providing the search terms used, dates, and data bases searched (Medline, Ovid, Pubmed, Google Scholar, etc) in order to substantiate your claim.
**Response:** The sentence has been deleted from the manuscript.

- this is one place to highlight whether your open rate is higher than that of other programs at BIDMC
**Response:** Thank you for bringing this up, we have added more information on the open rates of the institution as a whole and in comparison to other rates reporting by other organizations.

- Think you should include this light of insights that despite a 69% read rate, very few (3%) used the reporting tool. This will need to be included in the discussion of the limits of your study (with respect to any sort of conclusions or generalizations you can make about the results of the reporting tool) but its also a finding of your study. the third comment here is not really supported by your data: Among the few who read their notes and used the reporting tool, patients reported positive..... Same true for the 4th point.
**Response:** Yes, thank you, we have added more discussion of our read rate, the reporting tool uptake, and the lack of generalizability to our limitations section. We have qualified any statements regarding results to “patients who used the reporting tool” (rather than “patients”). Notably, the reporting tool use rate was very similar to our experience in primary care (2.6%), although it’s interesting to note that in primary care, the reporting rate exceeded the reporting rate of the established online clinician ambulatory event reporting system several fold. In practice, most reporting systems don’t measure response rates, but rather try to use the data that is available to examine patterns of events and implement quality improvements that may prevent future harms.  We have also removed “conclusions” and revised our discussion to avoid generalizations as suggested.

- see note above...most do not report anything.
**Response:** We have clarified this to make sure our scope and intent are understood to readers. We have also added more to our limitations on our low response rate to the reporting tool.

- what about sexual activity?
**Response:** The comment was about the patient’s dissatisfaction with the provider’s description of their sexual activity.

- not sure what an "activated patient" is. Does that refer to activation of their portal registration or do you mean motivated?
**Response:** Sorry for the confusion, we mean motivated, and clarified this in the text.

- here is your explanation of sexual activity. You may want to say something in text that a patient was bothered by a description of her sexual activity.
**Response:** Yes, we agree, thank you for the suggestion. We have added in more information on the examples from the table in the text.

- This is particularly important I think and should probably be mentioned. Billing language is necessary but I can sure see how a patient would misinterpret it. If opennotes becomes more universal CMS may need to allow some flexibility in the way billing phrases are used.
**Response:** This is a very good point, thank you. We added more discussion surrounding how patients perceive billing language and how that may affect the future of notes.

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## Randi Zung

**From:** Harcourt,Kendall (BIDMC - General Medicine) [redacted]
**Sent:** Thursday, March 28, 2019 3:54 PM
**To:** Randi Zung
**Subject:** RE: Your Revised Manuscript 19-99R1
**Attachments:** OBGYN RT 3.28.19 Revised.docx

Hi Randy,

Apologies for the confusion regarding Appendix one. I have added a citation in text, and the updated manuscript is attached.

Additionally, I have sent another reminder email to Dr. Golen, and will let you know when she completes it.

Let me know if there is anything else that is needed.

Thanks,

**Kendall Harcourt** | Clinical Research Assistant
Beth Israel Lahey Health
Beth Israel Deaconess Medical Center
[redacted]

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**From:** Randi Zung <RZung@greenjournal.org>
**Sent:** Thursday, March 28, 2019 3:16 PM
**To:** Harcourt,Kendall (BIDMC - General Medicine) [redacted]
**Subject:** [External] RE: Your Revised Manuscript 19-99R1

Hi:

Regarding the query for Appendix 1, we need you to insert a call out in the manuscript text. Where should it be cited?

Please let me know when Toni Golen has completed the form.

The latest version of your manuscript is attached. Please send me your updated version when you are ready.

Thanks,
Randi

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**From:** Harcourt,Kendall (BIDMC - General Medicine) <kharcour@bidmc.harvard.edu>
**Sent:** Thursday, March 28, 2019 1:46 PM
**To:** Randi Zung <RZung@greenjournal.org>
**Subject:** RE: Your Revised Manuscript 19-99R1

Hello,

Our responses to the reviewers on our manuscript are below. The revised manuscript is attached, as well as appendix one.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.
Thank you for the additional review of our manuscript, we have gone through to make sure all of the edits are correct and tracked our changes.

2. Toni Golen will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.
Thank you for the reminder, we have asked her again to complete the copyright transfer agreement.

3. Line 17-21: Please be specific about how they contributed. The journal does not permit general thanks.
Specific acknowledgements have been added.

4. Abstract-Methods: Add the type of study you conducted to this section.
We clarified that this was a quality improvement project in the methods section of the abstract.

5. Line 50: Should this read, "Past health problems," as it does on page 14?
Yes, thank you for catching this. We have revised the sentence to say "health problems" instead of "problem list." We also corrected the term on p14.

6. Line 72: Please state the references here.
We added the reference at the end of the sentence. Sorry for the confusion.

7. Line 81: From the Open Notes website: *OpenNotes* is the international movement dedicated to making health care more open and transparent by encouraging doctors, nurses, therapists…
We clarified the sentence on line 81 to say international instead of national movement.

8. Methods Section: Similar to Query 4. Add the type of study you conducted to this section.
We revised the beginning of the methods section to state that this was a quality improvement initiative.

9. Line 123: Please make it clear in this section that the feedback process was not just an Ob Gyn initiative. It still reads like it was "we modified"….for example.
We clarified the methods section to explain the chronological sequence of establishing the reporting tool in primary care and then later implementing it in ob-gyn to specify that this was not just an ob-gyn initative and to move the reader through the timeline more sequentially..

10. Line 136: You initiated in 2013. Was this process for developing the feedback tool between 2013 and 2016 when you started using OpenNotes? Since ob gyn wasn't using the OpenNotes then, was ob gyn involved?
See #9. Feedback tool development was between 2013-2014, when it was implemented in primary care. We involved Ob-gyn input prior to implementation in ob-gyn, and the tool was modified in 2016. We revised the methods slightly to state this point.

11. Line 188; What was the 0 anchor?
"Not at all important" – We added this to the methods.

12. Line 198: It's pretty clear that one of your authors is from the overall institution. Here you say, "based on "our" positive experiences in primary care". However, you are writing from the Ob GYN department perspective. Could you look through the paper to see other places this may happen and edit? For here, a reasonable edit might be "Nonetheless, we proceeded with this exploratory QI initiative based on the BIDMC primary care experience". It sometimes just gets a bit confusing as the perspective from the larger institution to just Ob GYN changes.
Thank you for pointing this out. We have gone through the manuscript to make sure we are writing from one perspective and revised the sentence on line 98 as suggested. We are in agreement with modifying any sentences we inadvertently missed in our review of "voice" perspective.

13. Line 202: Do you intend to say, "ob-gyn" or "obstetrics and gynecology" here?

Obstetrics and gynecology is fine.

14. Line 219: Is this edit correct?
Yes, this is correct, thank you for the clarification.

15. Line 273: If there were 62 errors reported and you had 62 participants who did so, then they each reported only 1. Correct? You could delete then "Who identified at least one documentation inaccuracy".
We removed this sentence for clarity. 62 reports included a potential mistake(s). However, some reports included more than one inaccuracy.

16. Line 311: Is this edit ok?
Yes, thank you.

17. Appendix (Page 30): Please add an in-text citation for Appendix 1. It should read, "Appendix 1 online at http://links.lww.com/xxx."26
We added this to the Appendix.

Thanks,

**Kendall Harcourt** | Clinical Research Assistant
Beth Israel Lahey Health
Beth Israel Deaconess Medical Center
[redacted]

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**From:** Randi Zung <RZung@greenjournal.org>
**Sent:** Tuesday, March 26, 2019 2:38 PM
**To:** Harcourt,Kendall (BIDMC - General Medicine) [redacted]
**Subject:** [External] Your Revised Manuscript 19-99R1

Dear Dr. Harcourt:

Your revised manuscript is being reviewed by the Editors. Before a final decision can be made, we need you to address the following queries. Please make the requested changes to the latest version of your manuscript that is attached to this email. **Please track your changes and leave the ones made by the Editorial Office.** Please also note your responses to the author queries in your email message back to me.

1. General: The Manuscript Editor and Dr. Chescheir have made edits to the manuscript using track changes. Please review them to make sure they are correct.

2. Toni Golen will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.

3. Line 17-21: Please be specific about how they contributed. The journal does not permit general thanks.

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16. Line 311: Is this edit ok?

17. Appendix (Page 30): Please add an in-text citation for Appendix 1. It should read, "Appendix 1 online at http://links.lww.com/xxx."26

To facilitate the review process, we would appreciate receiving a response within 48 hours.

Best,
Randi Zung

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**Randi Zung (Ms.)**
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