PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The impact of holding the baby following stillbirth on maternal mental health and wellbeing: findings from a national survey
AUTHORS	Redshaw, Maggie; Hennegan, Julie; Henderson, Jane

VERSION 1 - REVIEW

REVIEWER	Dr Shantini Paranjothy Cardiff University, U.K.
REVIEW RETURNED	28-Jan-2016

GENERAL COMMENTS	This manuscript reads well. The research questions that are addressed are important, given the inconsistent findings from various studies to date, this study aims to fill a gap in the evidence base - specifically addressing whether or not there are negative mental health effects associated with holding the baby following a stillbirth. The methods are appropriate and reported clearly in accordance with STROBE guidance. It was not clear what research permissions were needed and obtained or if the research had received any ethics approval. I have a few comments that could be addressed to provide clarification on the interpretation of the findings. 1. Respondents were asked to self-report whether or not a suite of physical and psychological symptoms were present or absent at three months and in the last few days. It would be helpful to have some discussion about the potential impact of having to recollect these type of symptoms over a period of time and to what extent recall bias may have influenced the validity of these findings. The measures used are not validated but the authors have acknowledged this limitation. 2. The survey response rate was 30% which is comparable to other postal surveys of this nature. The discussion section should include some consideration of what impact this response rate may have on the study findings. What is the likelihood that non-response may be associated with the outcomes of interest, and to what extent may this have influenced the observed associations?

REVIEWER	Carol Kingdon Senior Research Fellow School of Community Health and Midwifery University of Central Lancashire Preston England
REVIEW RETURNED	02-Feb-2016

GENERAL COMMENTS	Thank you for the opportunity to review this timely paper. As the authors point out there is a mixed body of evidence surrounding seeing and holding. They reference one recent systematic review in the area, but there are a few (please see below). This study does add new evidence to support concerns about the negative impact of holding the infant after stillbirth, but I would suggest the conclusion is toned down so as to not overstate the findings and highlight instead the importance of further research to disentangle the affects of seeing (which may be protective) and holding (which may be detrimental) to future mental health. It would also be helpful for guideline authors if the discussion were to highlight the commonalities between the quantitative and qualitative evidence (for example – the benefits of seeing and/or holding are affected by gestation and condition of the baby). This suggestion is minor, as is the amendment to the references to ensure the paper is up-to-date. The Lancet Stillbirth Series Update has also been published since this paper was submitted which the authors' may wish to make reference to. Other recent systematic review references: http://www.stillbirthfoundation.org.au/wp-content/uploads/2014/03/Stillbirth-systematic-review-report.pdf Kingdon C, O'Donnell E, Givens J, Turner M (2015) The Role of Healthcare Professionals in Encouraging Parents to See and Hold Their Stillborn Baby: A Meta-Synthesis of Qualitative Studies. PLoS ONE 10(7): e0130059. doi:10.1371/journal.pone.0130059 Kingdon, C, Givens, JL, O'Donnell, E, and Turner, M. Seeing and holding baby: systematic review of clinical management and parental outcomes after stillbirth. Birth. 2015; 42: 206–218

REVIEWER	Vicki Flenady, Fran Boyle and Dell Horey Vicki Flenady Mater Research Institute University of Queensland Brisbane, Australia Fran Boyle School of Public Health University of Queensland Australia Dell Horey La Trobe University Melbourne Australia
REVIEW RETURNED	08-Mar-2016

GENERAL COMMENTS	General comments: The paper presents a secondary analysis of survey data obtained from a postal population survey of women with a registered stillbirth in England in 2012. The authors compared mental health and wellbeing outcomes at three and nine months after the stillbirth between women who held and those who did not hold their baby. Provision of quality maternity care at the time of a stillbirth is

	crucially important to mothers, fathers and families and this paper will be of interest to readers of BMJ. The purpose of the study and the methods employed to analyse the data are clear. Overall, the manuscript is written to a very high standard as one would expect from this experienced team of researchers. Major comments 1) The question and future research Holding the baby can't be treated as an isolated event and proposing a direct linear relationship between holding the baby and mental health outcome seems overly simplistic given the numerous factors that come into play in such a complex and highly emotional event. Many factors influence a mother's response to holding her baby including the context in which this option is offered and individual characteristics of the women. While this study has gone further than many previous studies in attempting to measure some of these factors, this limitation remains. Consideration of baseline characteristics of women (before the death) was not possible and may have shed some light on these findings. Mothers (as well as fathers and families) whose baby is stillborn face many difficult decisions while in a state of shock and grief, holding the baby is just one of these. We feel strongly that researchers need to move away from studies attempting to measure the impact of these single events and focus on the broader care package and the care environment if we are to progress the field and improve care and outcomes for these mothers. Well-designed prospective evaluations of programs of supportive respectful care to enable mothers and families to make the decisions for which they feel most comfortable must be prioritised. Aims of such studies should include identification of women at increased risk of adverse outcomes (abnormal response) and identification of appropriate preventive support. 2) Interpretation of the significance of the findings The authors conclude by cautioning that holding the baby is associated with adverse outcomes. This is based on the finding of increased anxiety at 3 and 9 months after the birth. However, the clinical importance of this finding is unknown. It remains unknown whether this effect may actually be associated with better longer term outcomes for these women and their families. Further, we feel the likelihood of residual confounding must be more clearly acknowledged. The secondary nature of the analysis, the small sample size (some cell sizes are very small for the group who did not hold the baby) and low response rates to the survey also diminish confidence with this finding. While the findings may corroborate other studies, these too share similar limitations. The authors do pay attention to their study's limitations and express caution about prescriptive practices, however we feel these are not reflected in the conclusions in the body of the manuscript or in the abstract. We feel further caution is needed in the wording of the conclusions as these may be easily misinterpreted to the detriment of quality care. Our concern is that, taken at face value, the conclusions as currently expressed may lead some health care professionals to dissuade women from seeing their baby, rather than engage in difficult conversations and genuinely shared decision-making. We need to learn more about the lived experiences of those women who experience high levels of anxiety and whether there are measures (other than not seeing their baby) that might have been put in place to assist them and prevent the occurrence of anxiety symptoms. A recent systematic review of studies by Hennegan et al (referenced in this study and including some of the same authors)

	found mixed findings but also found that mothers are largely satisfied with their decision to hold their baby. We noted that a relatively large proportion of the respondents reported that they were not offered opportunities to “parent” their baby, and suggest that it is possible that the survey itself raised anxiety among women who held their baby but were not given the opportunity of more active engagement (such as dressing or bathing). 3. Specific comments: Table 2: We are concerned about how these data are presented. We suggest the table is changed to present the proportion in each of the two groups – of course there are going to be a smaller proportion of women in group for those who did not hold when the two groups are so unequal in size. Recalculating some of these data for example showed the proportion who did not have a long-term physical problem in the “held” group was 382/394=97% and the “did not hold” group 72/74=97% yet Table 2 reports 84.1% vs 15.9%. We found this confusing. Page 2 , Line 11: Abstract, Methods: include response rate. Page 2 , Line 18: Include numbers in each group. Page 2 , Line 21: Include measures of mental health. Page 2, line 23: Remove this sentence “While some differences were no longer significant after adjustment, women who held their baby…..” and replace with to “After adjusting for potential confounders” at the beginning of the next sentence. Page 2, Line 29: Consider modifying the conclusions from: “This study supports concern about the negative impact of holding the infant after stillbirth. Results add important evidence to a mixed body of literature“ to “ While this study indicates that some mothers who hold their stillborn baby may be more likely to experience anxiety in the first year after the birth the limitations of the study do not permit firm conclusions to be made and the impact of this effect (if true) is unknown. Future research should focus on ensuring supportive care and informed decision-making rather than isolated components of care at this distressing and life changing time for mothers and families”. Page 6 Analysis. Include the level of statistical significance used (from bivariate analysis) used to select variables for inclusion in the multivariate analysis. Factors such as: “Type of delivery”; “Staff gave me the care I needed”; “Staff treated me as an individual”; and “Overall satisfaction with care “indicate trends which may be important to explore in the analysis. Could the authors comment on these trends? Page 16, Limitations of this study. Include that this study was a secondary analysis of a larger survey and include the purpose of the larger study Page 16, line 42” Change the wording from “however, the low response rate, and under-representation of some groups limits the generalisability of findings” to “however the low response rate limits the generalisability of findings”. It is not possible to be sure about the representativeness of the population of women included for all possible factors which may influence the findings. Page 18, line 18: Change “Seeing the baby, in contrast, demonstrated a protective effect on mental health.” To “ While numbers are too small to be confident of the findings, seeing the baby, in contrast, may be associated with less anxiety”. Page 18 line 19/20: “Results should be interpreted with caution given the observational nature of the study.” “Results should be interpreted with caution given the study design (secondary analysis of survey findings, with a low response rate) and the small numbers

	of women who did not hold their baby” General: suggest using “birth” throughout rather than “ delivery”

REVIEWER	Charles E McCulloch University of California, San Francisco, USA
REVIEW RETURNED	28-Mar-2016

GENERAL COMMENTS	While the authors are forthright that there are drawbacks to the observational nature of their study design, they are clearly (and appropriately) interested in the causal effect of holding the newborn on later outcomes. If the association is not causal there is not much point in the research and causal language is used throughout (e.g., "impact" and "moderation"). So the value of the contribution to the literature depends crucially on how strongly the observational study design supports causal interpretations. Unfortunately the answer is not strongly. The basis of the study is a postal survey with a 30% response rate. While this is not unusual among postal surveys, it is very poor indeed as an observational study (70% missing data with noted differences between respondents and non-respondents). No attempts are made to handle missing data other than a complete case analysis. The authors mention that "The response rate, while typical of many surveys, may have biased the findings, however the number of those responding is relatively large." It is well known that if a response mechanism is biased, having a large sample does not help. The analysis strategy is likewise not convincing. What is the causal diagram that suggests that adjustment for a limited number of covariates (multiple pregnancy, ethnicity and fertility treatment) will control confounding? Are all the factors that are relevant even measured in this study? Were more sophisticated methods for confounding control considered? Of more minor concern: There are many outcomes (at two time points) and no adjustment for multiple testing is made. The PTSD symptoms variable seems not to be a validated scale and includes non-specific questions.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Dr Shantini Paranjothy
Institution and Country: Cardiff University, U.K.
Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below:
This manuscript reads well. The research questions that are addressed are important, given the inconsistent findings from various studies to date, this study aims to fill a gap in the evidence base - specifically addressing whether or not there are negative mental health effects associated with holding the baby following a stillbirth. The methods are appropriate and reported clearly in accordance with STROBE guidance. It was not clear what research permissions were needed and obtained or if the research had received any ethics approval.

Thank you for your positive comments, and for taking the time to review our manuscript. Ethical approval is listed at the end of the manuscript along with funding, acknowledgements etc. We believe

this to be the correct place given the journal requirements.

I have a few comments that could be addressed to provide clarification on the interpretation of the findings.
1. Respondents were asked to self-report whether or not a suite of physical and psychological symptoms were present or absent at three months and in the last few days. It would be helpful to have some discussion about the potential impact of having to recollect these type of symptoms over a period of time and to what extent recall bias may have influenced the validity of these findings. The measures used are not validated but the authors have acknowledged this limitation.

This is a good point and we have added reflection on this in the discussion. For the 9 month time-point this was the time of survey delivery so it should not be subject to this bias as the question asked about how women felt in the last few days. This does raise another important comment for the discussion, however, that recall may have been a factor for the 3 month time point and could also explain some of the difference in reports between the two time-points. Self-report and recall may also have underestimated the prevalence of difficulties in the sample.

2. The survey response rate was 30% which is comparable to other postal surveys of this nature. The discussion section should include some consideration of what impact this response rate may have on the study findings. What is the likelihood that non-response may be associated with the outcomes of interest, and to what extent may this have influenced the observed associations?

We have extended notes around the low response rate in the discussion. We've noted that women with poorer mental health may have been less likely to respond. We don't believe we can speculate about responding to the survey and having held the baby. We have also emphasised the low response rate further in the abstract and conclusions, to be clear about this limitation.

Reviewer: 2
Reviewer Name: Carol Kingdon
Institution and Country: Senior Research Fellow, School of Community Health and Midwifery University of Central Lancashire
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below:
Thank you for the opportunity to review this timely paper. As the authors point out there is a mixed body of evidence surrounding seeing and holding. They reference one recent systematic review in the area, but there are a few (please see below). This study does add new evidence to support concerns about the negative impact of holding the infant after stillbirth, but I would suggest the conclusion is toned down so as to not overstate the findings and highlight instead the importance of further research to disentangle the affects of seeing (which may be protective) and holding (which may be detrimental) to future mental health. It would also be helpful for guideline authors if the discussion were to highlight the commonalities between the quantitative and qualitative evidence (for example – the benefits of seeing and/or holding are affected by gestation and condition of the baby). This suggestion is minor, as is the amendment to the references to ensure the paper is up-to-date. The Lancet Stillbirth Series Update has also been published since this paper was submitted which the authors' may wish to make reference to.

Other recent systematic review references:

http://www.stillbirthfoundation.org.au/wp-content/uploads/2014/03/Stillbirth-systematic-review-

report.pdf

Kingdon C, O'Donnell E, Givens J, Turner M (2015) The Role of Healthcare Professionals in Encouraging Parents to See and Hold Their Stillborn Baby: A Meta-Synthesis of Qualitative Studies. PLoS ONE 10(7): e0130059. doi:10.1371/journal.pone.0130059

Kingdon, C, Givens, JL, O'Donnell, E, and Turner, M. Seeing and holding baby: systematic review of clinical management and parental outcomes after stillbirth. Birth. 2015; 42: 206–218

Thank you for taking the time to review our paper and provide useful comments.
We have toned down both the abstract and discussion/conclusions of the paper. We have noted in discussion that sub-group comparisons were consistent with qualitative studies suggesting the condition of the baby influences the impact of holding the baby (pg. 16). The point is well taken that there are consistencies here in terms of condition of the baby, which will be very important for future research and for guideline developers.

We had been aware of the Lancet series that was published since we submitted the paper, although our background section is minimal and focuses on recent guidelines. We have incorporated additional references into the discussion section of the paper.

Reviewer: 3
Reviewer Name: Vicki Flenady, Fran Boyle and Dell Horey
Institution and Country: University of Queensland / La Trobe University Australia
Please state any competing interests or state 'None declared': All: None declared

Please leave your comments for the authors below:

General comments:
The paper presents a secondary analysis of survey data obtained from a postal population survey of women with a registered stillbirth in England in 2012. The authors compared mental health and wellbeing outcomes at three and nine months after the stillbirth between women who held and those who did not hold their baby. Provision of quality maternity care at the time of a stillbirth is crucially important to mothers, fathers and families and this paper will be of interest to readers of BMJ. The purpose of the study and the methods employed to analyse the data are clear. Overall, the manuscript is written to a very high standard as one would expect from this experienced team of researchers.

Thank you for taking the time to review our paper.

Major comments
1) The question and future research
Holding the baby can't be treated as an isolated event and proposing a direct linear relationship between holding the baby and mental health outcome seems overly simplistic given the numerous factors that come into play in such a complex and highly emotional event. Many factors influence a mother's response to holding her baby including the context in which this option is offered and individual characteristics of the women. While this study has gone further than many previous studies in attempting to measure some of these factors, this limitation remains. Consideration of baseline characteristics of women (before the death) was not possible and may have shed some light on these findings. Mothers (as well as fathers and families) whose baby is stillborn face many difficult decisions while in a state of shock and grief, holding the baby is just one of these. We feel strongly that researchers need to move away from studies attempting to measure the impact of these single events

and focus on the broader care package and the care environment if we are to progress the field and improve care and outcomes for these mothers. Well-designed prospective evaluations of programs of supportive respectful care to enable mothers and families to make the decisions for which they feel most comfortable must be prioritised. Aims of such studies should include identification of women at increased risk of adverse outcomes (abnormal response) and identification of appropriate preventive support.

We agree that the broader context of care is important. Indeed, this paper has been the most comprehensive to date in trying to note the broader set of factors (e.g., condition of the baby) that may impact the individual association studied here between contact and outcomes. Future studies should build on this.

We disagree that holding the baby should not be tested as an isolated event given it is a specific action which entails specific experiences such as tactile contact with the baby, which other aspects of care do not involve (for example; photos, having hand prints). We would have liked to have additional information on the type (e.g., skin-to-skin), duration and timing of holding the baby, which may have also provided some clarity around the effects. Unfortunately these items were not available in the data set.

While broader care packages should be evaluated, these will always be comprised of many rather different individual components. It is unrealistic to expect researchers, and practitioners, not to question the impact of individual practices. Further, in the study of broader programs, trialists would be remiss in failing to try and identify 'active ingredients/core components' of their interventions and the contribution of individual factors.

While holding the baby is just one of many aspects of care and experiences after a stillbirth, the action is important to women. This is evident in the guidelines described in the background of this paper, in past papers on the topic, and in women's own accounts described in published qualitative work. Women and care providers need evidence to be available on the impact of various practices to enable shared decision making and informed decisions about care. Similarly, guideline authors are limited by the unavailability of studies testing effects and on this question have changed recommendations a number of times.

With regards to birth, women do make many decisions about many individual actions (e.g. management of the third stage of labour, who they want present at their birth, the use of water, the use of pain relief). In the context of a stillbirth they make decisions about what they may like to keep as mementos, having photos taken, or seeing and holding their baby, having an autopsy. Women are asked to make these decisions, so why would researchers not ask questions about the impact of these actions, both separately and in combination?

We have stressed the importance of care and the environment more generally in the discussion. As we have noted in the discussion, we agree that prospective studies would be best placed to answer this question and hope that future research addresses this.

2) Interpretation of the significance of the findings
The authors conclude by cautioning that holding the baby is associated with adverse outcomes. This is based on the finding of increased anxiety at 3 and 9 months after the birth. However, the clinical importance of this finding is unknown. It remains unknown whether this effect may actually be associated with better longer term outcomes for these women and their families. Further, we feel the likelihood of residual confounding must be more clearly acknowledged. The secondary nature of the analysis, the small sample size (some cell sizes are very small for the group who did not hold the

baby) and low response rates to the survey also diminish confidence with this finding. While the findings may corroborate other studies, these too share similar limitations. The authors do pay attention to their study's limitations and express caution about prescriptive practices, however we feel these are not reflected in the conclusions in the body of the manuscript or in the abstract. We feel further caution is needed in the wording of the conclusions as these may be easily misinterpreted to the detriment of quality care. Our concern is that, taken at face value, the conclusions as currently expressed may lead some health care professionals to dissuade women from seeing their baby, rather than engage in difficult conversations and genuinely shared decision-making. We need to learn more about the lived experiences of those women who experience high levels of anxiety and whether there are measures (other than not seeing their baby) that might have been put in place to assist them and prevent the occurrence of anxiety symptoms. A recent systematic review of studies by Hennegan et al (referenced in this study and including some of the same authors) found mixed findings but also found that mothers are largely satisfied with their decision to hold their baby. We noted that a relatively large proportion of the respondents reported that they were not offered opportunities to "parent" their baby, and suggest that it is possible that the survey itself raised anxiety among women who held their baby but were not given the opportunity of more active engagement (such as dressing or bathing).

We have added to the discussion section of the paper, placing more emphasis on the risks of confounding. As the reviewers note, this paper has been the most comprehensive to date on this question in confounder adjustment, but the concern related to pre-stillbirth factors and other confounders remains important (baseline differences in anxiety particularly so). We have taken more care to note these, and the limitations of the available data in the abstract and conclusions. We would also note that it would be very difficult for prospective studies to measure pre-pregnancy characteristics and still achieve an adequate sample size of women who go on to have a stillbirth.

As reviewers note we have always been mindful that the findings simply contribute to our body of knowledge in this area, but are not prescriptive. See updated abstract and conclusions.

We agree that some proportion of the responders were not offered opportunities to "parent" their baby. However, rates of many activities including having photos, naming, spending time with the baby and having hand or footprints were high. 48% were not offered the opportunity to bath their baby. This may have been the women with earlier stillbirths where this was not possible.

3. Specific comments:
Table 2: We are concerned about how these data are presented. We suggest the table is changed to present the proportion in each of the two groups – of course there are going to be a smaller proportion of women in group for those who did not hold when the two groups are so unequal in size. Recalculating some of these data for example showed the proportion who did not have a long-term physical problem in the "held" group was 382/394=97% and the "did not hold" group 72/74=97% yet Table 2 reports 84.1% vs 15.9%. We found this confusing.

This table presents the demographic characteristics of the women, and indicates the proportion of women who held or did not hold their baby. The percentages are set up to best answer the question "who held their baby?". For example, of 16-19 year olds 75% held their baby, while 25% did not, while 89.5% of 20-29 year olds held their baby and 10.5% did not.
We have reworded the preceding text accompanying the table to make this clearer.
We believe it is important to display the numbers this way to best indicate who held their baby. This is useful for readers to understanding the proportion of those holding their baby according to demographics. Given the demographic factors precede the stillbirth, this also makes sense. In addition, this table highlights the much smaller proportion who did not hold their baby in every group. As noted by these, and other reviewers it is important that readers understand the much smaller

proportion of women who did not hold their baby.
We see how this could have been confusing in the text before, however, and have reworded to better prepare readers for the way these data are presented.

Page 2 , Line 11: Abstract, Methods: include response rate.
Page 2 , Line 18: Include numbers in each group.
Page 2 , Line 21: Include measures of mental health.
Page 2, line 23: Remove this sentence “While some differences were no longer significant after adjustment, women who held their baby…..” and replace with to “After adjusting for potential confounders” at the beginning of the next sentence.

Page 2, Line 29: Consider modifying the conclusions from: “This study supports concern about the negative impact of holding the infant after stillbirth. Results add important evidence to a mixed body of literature“ to “ While this study indicates that some mothers who hold their stillborn baby may be more likely to experience anxiety in the first year after the birth the limitations of the study do not permit firm conclusions to be made and the impact of this effect (if true) is unknown. Future research should focus on ensuring supportive care and informed decision-making rather than isolated components of care at this distressing and life changing time for mothers and families”.

We have revised the abstract of the paper in accordance with the associate editor’s review, and the comments here.

Page 6 Analysis. Include the level of statistical significance used (from bivariate analysis) used to select variables for inclusion in the multivariate analysis. Factors such as: “Type of delivery”; “Staff gave me the care I needed”; “Staff treated me as an individual”; and “Overall satisfaction with care “indicate trends which may be important to explore in the analysis. Could the authors comment on these trends?

We have added the level of significance ($p<.05$) to the analysis section. We have added to the discussion regarding these care points, although significance levels were very low here and only 5% difference in the raw comparisons may not be indicative of a trend.

Page 16, Limitations of this study. Include that this study was a secondary analysis of a larger survey and include the purpose of the larger study Page 16, line 42” Change the wording from “however, the low response rate, and under-representation of some groups limits the generalisability of findings” to “however the low response rate limits the generalisability of findings”. It is not possible to be sure about the representativeness of the population of women included for all possible factors which may influence the findings.
Page 18, line 18: Change “Seeing the baby, in contrast, demonstrated a protective effect on mental health.” To “ While numbers are too small to be confident of the findings, seeing the baby, in contrast, may be associated with less anxiety”.
Page 18 line 19/20: “Results should be interpreted with caution given the observational nature of the study.” “Results should be interpreted with caution given the study design (secondary analysis of survey findings, with a low response rate) and the small numbers of women who did not hold their baby”
General: suggest using “birth” throughout rather than “ delivery”

We have revised the discussion section of the paper and incorporated these suggested wording changes. Thank you.

VERSION 2 – REVIEW

REVIEWER	Shantini Paranjothy Cardiff University, Wales, UK
REVIEW RETURNED	12-May-2016

GENERAL COMMENTS	The authors have responded adequately to the points raised in the review process.

REVIEWER	Carol Kingdon University of Central Lancashire, United Kingdom
REVIEW RETURNED	26-May-2016

GENERAL COMMENTS	I am satisfied that the papers claims have been sufficiently toned down. Thank you for adding to the discussion that sub-group comparisons are consistent with qualitative studies suggesting the condition of the baby influences the impact of holding the baby, and incorporating up-to-date additional references into the discussion.

REVIEWER	Vicki Flenady, Dell Horey, Fran Boyle Vicki Flenady and Fran Boyle University of Queensland Australia Dell Horey La Trobe University Australia
REVIEW RETURNED	13-Jun-2016

GENERAL COMMENTS	The authors have adequately addressed the concerns we raised. Thank you