

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Impact of the Community-Based Newborn Care Package in Nepal: a quasi-experimental evaluation
AUTHORS	Paudel, Deepak; Shrestha, Ishwar; Siebeck, Matthias; Rehfuss, Eva

VERSION 1 – REVIEW

REVIEWER	Jennifer Callaghan-Koru University of Maryland, Baltimore County, USA
REVIEW RETURNED	23-Mar-2017

GENERAL COMMENTS	<p>This paper addresses an important topic, the effectiveness of the community-based neonatal care package during initial scale up in Nepal. The evaluation primarily uses available DHS data to assess coverage of behaviors targeted by the CBNCP. A major limitation to this approach is that there was limited time between the implementation of training in the intervention districts and the measurements by the DHS survey (5 to 11 months as reported by the authors). Given the complex community-based nature of the program, and the fact that it targets behaviors across the maternal and neonatal continuum of care, the time period is extremely short to expect to see significant improvements. While this limitation does not necessarily invalidate the contribution of the study, revisions are needed in how the authors address the limitation. First, much more detail is needed on the timing of training and of data collection, and how much exposure time women in each district are likely to have had. Second, much caution is needed in the framing and interpretation of these results. It should be emphasized that this is a very early assessment, and that further evaluations are needed after the program has had more time to achieve an impact.</p> <p>Additional concerns and comments are presented below by relevant section of the manuscript.</p> <p>Introduction</p> <p>1. The literature cited is not the most up-to-date, and several key references are missing. For example, reference 1 and 5 should be replaced with more recent estimates. Early evaluations of the pilot of CBNCP in Bhardiya district by Sitrin et al and Nonyane et al are not included (see: Sitrin D, Guenther T, Waiswa P, Namutamba S, Namazzi G, Sharma S, et al. Improving newborn care practices</p>
-------------------------	--

through home visits: lessons from Malawi, Nepal, Bangladesh, and Uganda. *Global Health Action* 2015; 8:10.3402/gha.v3408.23963; Nonyane BAS, Kc A, Callaghan-Koru JA, Guenther T, Sitrin D, Syed U, et al. Equity improvements in maternal and newborn care indicators: results from the Bardiya district of Nepal. *Health Policy Plan* 2015)

Methods

2. Consider replacing or removing references to unpublished work (#12, 13)
3. The impact model for the intervention can be strengthened by revising it according to consensus work that has already been done on maternal and child health program evaluation, such as Bryce et al's "Common Evaluation Framework" for the scale up of MDG 4 and 5 (see: Bryce J, Victora CG, Boerma T, Peters DH, Black RE. Evaluating the scale-up for maternal and child survival: a common framework. *International Health* 2011; 3:139-146)
4. There is no description of how the HMIS data is collected. Since there are indicators of knowledge and quality being reported through the HMIS, it is essential to understand how they were measured
5. The labeling of practices as "better" and "worse" could be viewed as problematic. "Recommended" and "not recommended" would be preferable.
6. It is unclear why the authors only performed aggregate analysis and did not also consider regression analysis on individual observations with variables for exposure to the intervention as independent variables. This would allow for control of confounding factors, which as the authors note, is not possible with their current analysis approach.
7. The analysis' ability to build a plausibility case for a causal relationship between the intervention and the outcomes (or lack there of) would be greatly strengthened if they are able to provide additional measures of exposure to the intervention, such as antenatal contacts with community health workers and receipt of targeted counseling messages
8. Given the challenge with limited implementation time, it would be useful to conduct a sensitivity analysis comparing the results for districts with longer and shorter implementation time.

Results

9. Table 1 could be moved to a supplemental file
10. The definition of indicators in Table 2 presents some issues. Some of the actions included in the antenatal care seeking indicator are more appropriately measures of ANC quality (e.g. TT and iron). It would also be helpful to disaggregate the indicators, at least in a supplemental table, to see which components of the indicator are most contributing to limited coverage
11. Table 3 is labeled as reporting coverage, but these are not population level estimates, so may be more appropriately referred to as measures of intervention outputs and/or implementation strength. Also, see notes above about how these are measured.
12. I noted an arithmetic error in Table 5, ANC 1 indicator—should the difference-in-differences not be 2?

Discussion

13. The interpretation in the discussion should be more cautious with particular attention paid to the limited implementation time
14. The discussion reference variation in program performance across districts (page 13, line 3) but I could not find these results in the paper

	There is a reference to an article indicating preference for medical shops, but is this true for antenatal and delivery providers as well as treatme
--	--

REVIEWER	Matthew Ellis University of Bristol, UK
REVIEW RETURNED	27-Mar-2017

GENERAL COMMENTS	I enjoyed reviewing this important effectiveness report on a complex intervention designed to improve newborn health in Nepal - despite the disappointment of its conclusion. It is a timely reminder that the impact of complex interventions do not simply reflect the sum of their components as reported in efficacy trials. Programme realities on the ground are far more complex than this. Like the authors I suspect a longer 'run in' with programme reinforcement may be necessary before improvement becomes evident.
-------------------------	---

REVIEWER	Mary Adam, MD, MA, PhD Mary Adam, MD, MA, PhD Director, Kijabe Maternal Newborn Community Health Kijabe, Kenya
REVIEW RETURNED	20-May-2017

GENERAL COMMENTS	<p>The manuscript is addressing an important question, that of evaluating the effectiveness of a package of newborn care interventions implemented in Nepal. It is well written and the overall concept of the intervention is clear.</p> <p>The research is an evaluation of a package of interventions implemented at large scale and using Ministry of Health procedures, and as such it is an effectiveness trial. Effectiveness studies are of special interest in resource constrained areas because of the ability to examine a program in the real world setting under actual conditions. This study is of particular interest because the evaluation approach capitalizes on existing data sets available to the government of Nepal, bringing substantial strength of evaluation without additional cost. The authors have appropriately explained their recognition that each data source has distinct advantages and limitations. This is a necessary limitation in assessing effect of the intervention, and evaluation methods that use such a cost-conscious approach are both necessary and useful.</p> <p>The study methodology is quazi-experimental, and the use of propensity scores clearly documents the similarity between the control and intervention regions. The difference in difference methodology is also very appropriate to the study. The authors clearly note the limitation of relatively short time period (page 14 line 10) in the post intervention follow up "arm" that could limit power necessary to identify meaningful change.</p> <p>Implementation of the pilot CBNCP thru facility and community based health workers and the female volunteers is clear; however,</p>
-------------------------	---

the time line for how many days of “training” were given to each cadre and if that training happened in series or sequence in a given district is not stated. A description of the training and who the trainers were would give additional insight into how the training rolled out. Also a description of any routine supervision practices that are part of the routine standard of care and quality control may bring added perspective. Problems with supervision and follow up after training has been well documented in community health workers (Kok, 2014), and correct implementation of neonatal resuscitation practices can be influenced by availability of equipment like an Ambu Bag for inflating the lungs or other commodities. The availability of necessary equipment and commodities at the facility level is information that is not completely available as stated in page 14 line 21 . While the absence of a description of routine supervision and possible lack of supplies is noted. Again, the limitations of the routinely available data is noted. A brief explanation of what constitutes standard supervision practices, which theoretically would be applied in both intervention and control area might strengthen an already strong manuscript. The comment on limited supervision page 12 line 53 is vague.

Perhaps the most important questions raised by this manuscript are related to why this package of interventions when implemented in large scale did not work. These questions are addressed by the authors in the discussion but I would also point them to an article by Kumar et al¹(Kumar, 2010). It is not often that prior to a larger scale roll out that these key questions are formally thought about. If there is data about why certain elements were included in the package selected it would be beneficial to the reader, because it may help answer the big question about why there was not a larger effect size. Kumar et al point to the importance of the conceptual stage of choosing which interventions to include in the package. While the authors do comment about the specific effectiveness of an individual intervention in a specific and limited geographic region page 12 line 32, it is still worth asking, Were the interventions included know to be epidemiologically linked to problem outcomes in the larger region?

I might also question the use of the word effectiveness in page 12 line 30. I might consider labeling the chlorhexidine cord care an efficacy trial. It is well understood that these words, “effectiveness and efficacy” represent a continuum, but where you place an intervention on the effectiveness-efficacy scale matters.

Kumar et al also state, “the effectiveness of an intervention (or package of interventions) is constrained by the weakest link in the causal-intervention pathway..” The authors clearly address aspects of this question when they discuss limited supervision. The level of “dosage of training” the health care workers received may have been insufficient to promote meaningful change in their behaviors. Dosage effects are along the pathway of behavior change required in order see meaningful levels of change at the population level.

This paper is an example of excellent work, done using quazi-experimental design, cost efficient data sources, and it had the impressive impact of presenting policy makers with some actionable information.

A fuller discussion of reasons that might have limited the ability of the study to detect change would strengthen the manuscript.

	<p>I recommend publication. The manuscript would be stronger if information is available to make minor revisions described.</p> <p>Editing comments: Page 27-I could not see the site of the qualitative study on the map in Chitwan very well.</p> <p>References</p> <ol style="list-style-type: none"> 1. KumarV, Kumar A, Darmstadt GL. Behavior change for newborn survival in resource-poor community settings: bridging the gap between evidence and impact. <i>Semin Perinatol.</i> 2010;34(6):446-461. 2. Kok MC, Kane S, TullochO, Ormel H, Theobald S, Dieleman M, Taegtemeyer M, Broerse JEW, de Koning K (2015) How does context influence performance of Community Health Workers in low and middle income countries? Evidence from the literature. Health Research Polic and Systems.
--	---

REVIEWER	Zelee Hill University College London, UK
REVIEW RETURNED	22-May-2017

GENERAL COMMENTS	<ol style="list-style-type: none"> 1. This is a clear and well written article that was a pleasure to read. 2. Major revision: More information is needed on the intervention. It is unclear if there are home visits, and if so when, and what exactly the different carders do. The conceptual framework suggests the intervention focuses on ANC. I found the conceptual framework simplistic, I suspect there are many more routes to behaviour change than improving ANC care seeking and quality within this intervention. It may also be that the PNC visits, that are measured as an outcome, are actually part of the intervention. This needs to be clarified. 3. Minor revision: In the discussion of impact at scale up/ previous studies mention more relevant studies in program setting. In addition to Azad they could cite: <p>Darmstadt, GL, Choi, Y, Arifeen, SE et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. <i>PLoS One.</i> 2010; 5: e9696</p> <p>Bhutta, ZA, Soofi, S, Cousens, S et al. Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. <i>Lancet.</i> 2011; 377: 403–412</p> <p>Bhandari, N, Mazumder, S, Taneja, S, Sommerfelt, H, Strand, TA, and Group, IES. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. <i>BMJ.</i> 2012; 344: e1634</p> <p>They could also reference the meta analysis in the NEWHINTs study</p>
-------------------------	---

	<p>from Ghana.</p> <p>4. Minor revision: Presenting data to two decimal places suggests the data are more accurate than they really are. One decimal place is sufficient. Also in the tables make sure it is clear the data are percentages.</p> <p>5. Minor revision: Title on coverage is misleading, as it really refers to training coverage and provider knowledge. Are there any HMIS data on contacts of women with the providers/coverage at the population level? Coverage has been a big issue in some of the programme level studies. If there are not data on this, it needs to be added to the limitation.</p> <p>6. Major revision: I have some concerns about the outcomes. First, they are not clearly defined, what is delayed bathing (6 hours, 24 hours something else?) etc. Second, the ANC variables are confusing. The ANC care seeking variable includes coverage, and issues that are more related to quality. Provision of TT and taking iron could be highly linked to ANC quality, yet are included as care seeking. For example, the authors report that there were stock outs of iron. This outcomes needs to be rethought. Third, I would like to see the newborn care practice indicators disaggregated. This would help understand the results in more detail. Currently the aggregated variable includes behaviours that are likely to be depended on provider behaviour, i.e. wrapping and drying and placing baby on chest, and behaviours that may be family led such as delayed bathing.</p>
--	--

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name

Jennifer Callaghan-Koru

Institution and Country

University of Maryland, Baltimore County, USA

Please state any competing interests or state 'None declared':

None declared

Please leave your comments for the authors below

Reviewer's comment:

This paper addresses an important topic, the effectiveness of the community-based neonatal care package during initial scale up in Nepal. The evaluation primarily uses available DHS data to assess coverage of behaviors targeted by the CBNCP. A major limitation to this approach is that there was limited time between the implementation of training in the intervention districts and the measurements by the DHS survey (5 to 11 months as reported by the authors). Given the complex community-based nature of the program, and the fact that it targets behaviors across the maternal and neonatal continuum of care, the time period is extremely short to expect to see significant improvements. While this limitation does not necessarily invalidate the contribution of the study, revisions are needed in

how the authors address the limitation. First, much more detail is needed on the timing of training and of data collection, and how much exposure time women in each district are likely to have had.

Authors' response:

We would like to thank Jennifer Callaghan-Koru for her careful analysis and detailed comments, and agree with her assessment of the main limitations of our approach. We have addressed all the specific suggestions made, as is detailed in the following sections.

Detailed information on the timing of training and data collection is provided in Supplementary File Table S1. This is now being referred to under Methods, Study design.

Second, much caution is needed in the framing and interpretation of these results. It should be emphasized that this is a very early assessment, and that further evaluations are needed after the program has had more time to achieve an impact.

We agree with Jennifer Callaghan-Koru's comment and also realise that, while intended, this did not come out as strongly as it should have done in the manuscript. We have now added a paragraph under Discussion, Key findings and their explanation and in the Abstract.

Reviewer's comment:

Introduction

1. The literature cited is not the most up-to-date, and several key references are missing. For example, reference 1 and 5 should be replaced with more recent estimates. Early evaluations of the pilot of CBNCP in Bhardiya district by Sitrin et al and Nonyane et al are not included (see: Sitrin D, Guenther T, Waiswa P, Namutamba S, Namazzi G, Sharma S, et al. Improving newborn care practices through home visits: lessons from Malawi, Nepal, Bangladesh, and Uganda. *Global Health Action* 2015; 8:10.3402/gha.v3408.23963; Nonyane BAS, Kc A, Callaghan-Koru JA, Guenther T, Sitrin D, Syed U, et al. Equity improvements in maternal and newborn care indicators: results from the Bardiya district of Nepal. *Health Policy Plan* 2015)

Authors' response:

These suggestions are well taken – we have updated citations accordingly.

Reviewer's comment:

Methods

2. Consider replacing or removing references to unpublished work (#12, 13)

Authors' response:

We removed one unpublished reference (#13) but kept the other (#12) as it provides more detailed description and analysis, including the findings of the qualitative study.

Reviewer's comment:

3. The impact model for the intervention can be strengthened by revising it according to consensus work that has already been done on maternal and child health program evaluation, such as Bryce et al's "Common Evaluation Framework" for the scale up of MDG 4 and 5 (see: Bryce J, Victora CG, Boerma T, Peters DH, Black RE. Evaluating the scale-up for maternal and child survival: a common framework. *International Health* 2011; 3:139-146)

Authors' response:

The impact model by Bryce et al. (2011) provides a generic framework for the range of maternal and child healthcare interventions in the context of the MDGs, primarily applicable at national policy level. Our much more specific impact model for the CBNCP is entirely compatible with this broader framework. This has been highlighted by (i) adding the headings Process, Outputs and Outcomes to

Figure 3 and by (ii) explaining our emphasis on certain sub-sections of the broader framework in the context of its application at the programmatic level, e.g. capacity building as one aspect under Process.

4. There is no description of how the HMIS data is collected. Since there are indicators of knowledge and quality being reported through the HMIS, it is essential to understand how they were are measured

Authors' response:

Additional information on how HMIS and NHIS data are collected is now provided in the section on Data sources and variables.

Reviewer's comment:

5. The labeling of practices as "better" and "worse" could be viewed as problematic. "Recommended" and "not recommended" would be preferable.

Authors' response:

In response to this suggestion, we have explored different options for labelling these practices. Recommended vs. not recommended is not appropriate for these aggregate variables, i.e. those in the better group are adhering to a greater number (but not all) of the recommended practices, those in the worse group still follow some of the recommended practices. We have not changes the terminology to "better practices" and "poorer practices" in the text and tables.

Reviewer's comment:

6. It is unclear why the authors only performed aggregate analysis and did not also consider regression analysis on individual observations with variables for exposure to the intervention as independent variables. This would allow for control of confounding factors, which as the authors note, is not possible with their current analysis approach.

Authors' response:

We would like to thank Jennifer Callaghan-Koru for pointing us to an unclear description of our analysis strategy, and have tried to clarify this under Methods, Analysis. In particular, we are now referring to our outcome variables as "combined outcome variables" rather than "aggregate outcome variables" to avoid confusion.

Authors' response:

In brief, we undertook analyses at district level (difference-in-differences, no adjustment for confounders) and at individual level (logistic regression, adjustment for confounders, Figure 4). Due to the sheer number of specific outcomes, we focused on combined outcomes, e.g. birth preparedness as an outcome comprising the individual practices preparing money, blood, health worker, etc. An additional analysis for specific outcomes is now included in Table S2.

Reviewer's comment:

7. The analysis' ability to build a plausibility case for a causal relationship between the intervention and the outcomes (or lack there of) would be greatly strengthened if they are able to provide additional measures of exposure to the intervention, such as antenatal contacts with community health workers and receipt of targeted counseling messages

Authors' response:

Table 4 shows some of the suggested measures; more detailed information is, unfortunately, not available.

Reviewer's comment:

8. Given the challenge with limited implementation time, it would be useful to conduct a sensitivity analysis comparing the results for districts with longer and shorter implementation time.

Authors' response:

We agree that it would be very useful to conduct a sensitivity analysis. Unfortunately, given the nature of the DHS survey, this would not be feasible or appropriate. The DHS is not designed to provide district level estimates for all variables and we would run into sample size problems. No changes made.

Reviewer's comment:

Results

9. Table 1 could be moved to a supplemental file.

Authors' response:

Table 1 forms the basis for the propensity score matching and thus for ensuring comparability of the intervention and control areas. We would therefore prefer to keep this table in the main manuscript. If the Editors feel strongly that it should be moved to a Supplementary File, we will do so.

Reviewer's comment:

10. The definition of indicators in Table 2 presents some issues. Some of the actions included in the antenatal care seeking indicator are more appropriately measures of ANC quality (e.g. TT and iron). It would also be helpful to disaggregate the indicators, at least in a supplemental table, to see which components of the indicator are most contributing to limited coverage

Authors' response:

Table 2 describes how the combined outcomes are created; we have now provided an analysis of the individual outcomes in Table S2 as additional background information.

With respect to placing individual outcomes within combined outcomes, we agree that there may be different ways of doing so and that there is some overlap between ANC quality and care seeking. With reference to our framework (Figure 3), we conceived "quality of antenatal care" as a provider-driven variable and "care seeking" as a community-driven variable. In Nepal, women frequently obtain iron and folic acid supplements as well as tetanus toxoid injections from sources other than the healthcare provider (e.g. women may go only once for ANC but obtain their re-supply of iron and folic acid from FCHVs; they obtain their tetanus toxoid injections from private medical shops). Contact with FCHVs is not considered an ANC visit, neither is the contact with private medical shops. These decisions were made a priori and we therefore feel that we should stay truthful to our conceptual framework and current analysis.

Reviewer's comment:

11. Table 3 is labeled as reporting coverage, but these are not population level estimates, so may be more appropriately referred to as measures of intervention outputs and/or implementation strength. Also, see notes above about how these are measured.

Authors' response:

We have re-labelled these as "intervention process indicators" in line with our conceptual framework.

Reviewer's comment:

12. I noted an arithmetic error in Table 5, ANC 1 indicator—should the difference-in-differences not be 2?

Authors' response:

We have checked all calculations and have not been able to find any error in Table 5.

Reviewer's comment:

Discussion

13. The interpretation in the discussion should be more cautious with particular attention paid to the limited implementation time

Authors' response:

We fully agree; please see our response to the earlier comment above and the changes made under Discussion, Key findings and their explanation and in the Abstract.

Reviewer's comment:

14. The discussion reference variation in program performance across districts (page 13, line 3) but I could not find these results in the paper

Authors' response:

We have now included information on district variation for key knowledge and skills indicators in Supplementary File Table S3.

Reviewer's comment:

There is a reference to an article indicating preference for medical shops, but is this true for antenatal and delivery providers as well as treatment

Authors' response:

We agree that seeking care from medical shops for antenatal and delivery services is not as common as care seeking for other treatments, but private providers offer some components of these services. Thus, we added the following text in the manuscript. "In relation to antenatal services, private providers often provide specific components of those services (e.g. tetanus toxoid vaccines) and on-call services."

Reviewer: 2

Reviewer Name

Matthew Ellis

Institution and Country

University of Bristol, UK

Please state any competing interests or state 'None declared':

None declared

Please leave your comments for the authors below

Reviewer's comment:

I enjoyed reviewing this important effectiveness report on a complex intervention designed to improve newborn health in Nepal - despite the disappointment of its conclusion. It is a timely reminder that the impact of complex interventions do not simply reflect the sum of their components as reported in efficacy trials. Programme realities on the ground are far more complex than this. Like the authors I suspect a longer 'run in' with programme reinforcement may be necessary before improvement becomes evident.

Author's response:

Thank you for your comment and the encouraging feedback.

Reviewer: 3

Reviewer Name

Mary Adam, MD, MA, PhD

Institution and Country

Mary Adam, MD, MA, PhD

Director, Kijabe Maternal Newborn Community Health Kijabe, Kenya

Please state any competing interests or state 'None declared':

None declared

Please leave your comments for the authors below See attached file

BMJ Open Review 2017

Paudal, D. et al

Impact of the Community-Based Newborn Care Package in Nepal: a quasi-experimental evaluation

Reviewer's comment:

Dear Editor, Thank you for allowing me to review the manuscript titled, "Impact of the Community Based Newborn Care Package in Nepal: a quasi-experimental evaluation". The manuscript is addressing an important question, that of evaluating the effectiveness of a package of newborn care interventions implemented in Nepal. It is well written and the overall concept of the intervention is clear.

The research is an evaluation of a package of interventions implemented at large scale and using Ministry of Health procedures, and as such it is an effectiveness trial. Effectiveness studies are of special interest in resource constrained areas because of the ability to examine a program in the real world setting under actual conditions. This study is of particular interest because the evaluation approach capitalizes on existing data sets available to the government of Nepal, bringing substantial strength of evaluation without additional cost. The authors have appropriately explained their recognition that each data source has distinct advantages and limitations. This is a necessary limitation in assessing effect of the intervention, and evaluation methods that use such a cost-conscious approach are both necessary and useful.

The study methodology is quasi-experimental, and the use of propensity scores clearly documents the similarity between the control and intervention regions. The difference in difference methodology is also very appropriate to the study. The authors clearly note the limitation of relatively short time period (page 14 line 10) in the post intervention follow up "arm" that could limit power necessary to identify meaningful change.

Implementation of the pilot CBNCP thru facility and community based health workers and the female volunteers is clear; however, the time line for how many days of "training" were given to each cadre and if that training happened in series or sequence in a given district is not stated. A description of the training and who the trainers were would give additional insight into how the training rolled out. Also a description of any routine supervision practices that are part of the routine standard of care and quality control may bring added perspective.

Author's response

Thank you for your observations.

We have added the following information in the Introduction, accompanied by a reference: "The package included seven days training for facility-based workers, five days training for community-based health workers and seven days training for FCHVs". We also added a sentence on the supervision practices that form part of the CBNCP package. Additional info is provided in Table S1.

Reviewer's comment:

Problems with supervision and follow up after training has been well documented in community health workers (Kok, 2014), and correct implementation of neonatal resuscitation practices can be influenced by availability of equipment like an Ambu Bag for inflating the lungs or other commodities. The availability of necessary equipment and commodities at the facility level is information that is not completely available as stated in page 14 line 21 . While the absence of a description of routine supervision and possible lack of supplies is noted. Again, the limitations of the routinely available data is noted. A brief explanation of what constitutes standard supervision practices, which theoretically would be applied in both intervention and control area might strengthen an already strong manuscript. The comment on limited supervision page 12 line 53 is vague.

Author's response

We agree that supervision is a critical element of successful programmes, and have now reported more details under Discussion, Key findings and their explanation.

Reviewer's comment:

Perhaps the most important questions raised by this manuscript are related to why this package of interventions when implemented in large scale did not work. These questions are addressed by the authors in the discussion but I would also point them to an article by Kumar et al1 (Kumar, 2010). It is not often that prior to a larger scale roll out that these key questions are formally thought about. If there is data about why certain elements were included in the package selected it would be beneficial to the reader, because it may help answer the big question about why there was not a larger effect size. Kumar et al point to the importance of the conceptual stage of choosing which interventions to include in the package. While the authors do comment about the specific effectiveness of an individual intervention in a specific and limited geographic region page 12 line 32, it is still worth asking, Were the interventions included known to be epidemiologically linked to problem outcomes in the larger region?

Author's response

We appreciated Mary Adam's suggestion to review the very insightful article by Kumar et al. (2010). This has been referenced in the appropriate location, and we have made substantial revisions to the Discussion as a result.

Reviewer's comment:

I might also question the use of the word effectiveness in page 12 line 30. I might consider labeling the chlorhexidine cord care an efficacy trial. It is well understood that these words, "effectiveness and efficacy" represent a continuum, but where you place an intervention on the effectiveness-efficacy scale matters.

Author's response

This is an important comment and studies indeed included both efficacy and effectiveness studies. We have clarified this in the manuscript as "... previous studies, concerned with efficacy or effectiveness under real-world conditions, ..."

Reviewer's comment:

Kumar et al also state, "the effectiveness of an intervention (or package of interventions) is constrained by the weakest link in the causal-intervention pathway.." The authors clearly address aspects of this question when they discuss limited supervision. The level of "dosage of training" the health care workers received may have been insufficient to promote meaningful change in their behaviors. Dosage effects are along the pathway of behavior change required in order see meaningful levels of change at the population level.

Author's response

We agree with Mary Adam's suggestion. We therefore highlight the case of program implementation quality and intensity in the discussion section and provided additional information in Supplementary Table 3.

We also added the following sentence:

"Therefore, following the argument made by Kumar et al, 2010 that the effectiveness of an intervention is constrained by the weakest link in the causal-intervention pathway, the amount of training and subsequent supervision for this complex intervention package are likely to have been insufficient to promote meaningful behaviour change."

Reviewer's comment:

This paper is an example of excellent work, done using quazi-experimental design, cost efficient data sources, and it had the impressive impact of presenting policy makers with some actionable information. A fuller discussion of reasons that might have limited the ability of the study to detect change would strengthen the manuscript. I recommend publication.

Author's response

Thank you very much.

Reviewer's comment:

Page 27-I could not see the site of the qualitative study on the map in Chitwan very well.

Author's response

We changed the colour to make the site more legible.

Reviewer's comment:

References 1. Kumar V, Kumar A, Darmstadt GL. Behavior change for newborn survival in resource poor community settings: bridging the gap between evidence and impact. *Semin Perinatol*. 2010;34(6):446-461.

2. Kok MC, Kane S, Tulloch O, Ormel H, Theobald S, Dieleman M, Taegtemeyer M, Broerse JEW, de Koning K (2015) How does context influence performance of Community Health Workers in low and middle income countries? Evidence from the literature. *Health Research Polic and Systems*.

Author's response

We have now referred to these references in the relevant places.

Reviewer: 4

Reviewer Name
Zelee Hill

Institution and Country
University College London, UK

Please state any competing interests or state 'None declared':
None

Please leave your comments for the authors below

Reviewer's comment:

1. This is a clear and well written article that was a pleasure to read.

Author's response:

Thank you for your kind feedback.

Reviewer's comment:

2. Major revision: More information is needed on the intervention. It is unclear if there are home visits, and if so when, and what exactly the different carders do. The conceptual framework suggests the intervention focuses on ANC. I found the conceptual framework simplistic, I suspect there are many more routes to behaviour change than improving ANC care seeking and quality within this intervention. It may also be that the PNC visits, that are measured as an outcome, are actually part of the intervention. This needs to be clarified.

Author's response:

Additional information about the intervention has been included in the manuscript (Background) and in Supplementary Information, programme components.

In accordance with this comment and comments from Reviewer 1, we have updated our conceptual framework. We also added the following qualification in the manuscript (Methods): Importantly, while the CBNCP's main impetus is on training of health workers, supplies of equipment and medicines as well as supervision and follow-up, several of the outputs (e.g. taking a urine sample under "quality of antenatal care") and outcomes (e.g. postnatal visits) could also be considered a component of the intervention.

Similarly, promotion of PNC visits is part of the intervention, but actual uptake depends on the perceived importance of those visits, quality of services during those visits and an individual's ability to visit the provider. Thus, we considered the number of PNC visits as an outcome, just like for ANC visits.

To clarify this, we inserted following text in the Methods section.

"Importantly, while the CBNCP's main impetus is on training of health workers, supplies of equipment and medicines as well as supervision and follow-up, several of the outputs (e.g. taking a urine sample) and outcomes (e.g. postnatal visits) could also be considered as components of the intervention."

Reviewer's comment:

3. Minor revision: In the discussion of impact at scale up/ previous studies mention more relevant studies in program setting. In addition to Azad they could cite:

Darmstadt, GL, Choi, Y, Arifeen, SE et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS One*. 2010; 5: e9696

Bhutta, ZA, Soofi, S, Cousens, S et al. Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. *Lancet*. 2011; 377: 403–412

Bhandari, N, Mazumder, S, Taneja, S, Sommerfelt, H, Strand, TA, and Group, IES: cluster randomised controlled trial. *BMJ*. 2012; 344: e1634

They could also reference the meta analysis in the NEWHINTs study from Ghana.

Author's response:

Thank you for pointing us to these important studies, which we have cited in the appropriate places.

Reviewer's comment:

4. Minor revision: Presenting data to two decimal places suggests the data are more accurate than they really are. One decimal place is sufficient. Also in the tables make sure it is clear the data are percentages.

Author's response:

We agree with this suggestion. Decimal places have been changed to one decimal place in the tables (except for the outcomes of statistical tests). We also clarified if the value referred to a number or percentage.

Reviewer's comment:

5. Minor revision: Title on coverage is misleading, as it really refers to training coverage and provider knowledge. Are there any HMIS data on contacts of women with the providers/coverage at the population level? Coverage has been a big issue in some of the programme level studies. If there are not data on this, it needs to be added to the limitation.

Author's response:

The title of Table 3 was changed to "Intervention process indicators, based on NHIS data".

Unfortunately, true coverage data at population level is not available for most of the indicators in question (e.g. pregnant women reached by FCHVs and Health Workers with CBNCP messages). Table 5 provides some indication of program reach and outcomes of those reach. Accordingly, we added this aspect under Discussion, Strengths and limitations.

Reviewer's comment:

6. Major revision: I have some concerns about the outcomes. First, they are not clearly defined, what is delayed bathing (6 hours, 24 hours something else?) etc. Second, the ANC variables are confusing. The ANC care seeking variable includes coverage, and issues that are more related to quality. Provision of TT and taking iron could be highly linked to ANC quality, yet are included as care seeking. For example, the authors report that there were stock outs of iron. This outcomes needs to be rethought. Third, I would like to see the newborn care practice indicators disaggregated. This would help understand the results in more detail. Currently the aggregated variable includes behaviours that are likely to be depended on provider behaviour, i.e. wrapping and drying and placing baby on chest, and behaviours that may be family led such as delayed bathing.

Author's response:

Thank you, Zelee Hill, for drawing our attention to this lack of clarity.

With respect to the first point, we have added the timeframe for delayed bathing (24 hours) in the footnote of Table 2. With respect to the second point, we have clarified why TT injection and iron supplements are grouped with care seeking (see response to Reviewer 1, comment 10). With respect to the third point, we have added a table with more detailed analyses for individual outcomes (Table S2).

Deepak, Eva, Matthias

VERSION 2 – REVIEW

REVIEWER	Matthew Ellis University of Bristol UK
REVIEW RETURNED	10-Aug-2017

GENERAL COMMENTS	This paper has been extensively amended by the authors in line with reviewer suggestions and in my view is now ready for publication
-------------------------	--

REVIEWER	Mary B. Adam, MD, MA, PhD AIC Kijabe Hospital Kijabe, Kenya
REVIEW RETURNED	04-Aug-2017

GENERAL COMMENTS	<p>The manuscript is addressing an important question, that of evaluating the effectiveness of a package of newborn care interventions implemented in Nepal. It is well written and the overall concept of the intervention is clear.</p> <p>This revision incorporates areas of weakness I identified in my review.</p> <p>I recommend publication.</p>
-------------------------	--

REVIEWER	Zelee Hill University College London, UK
REVIEW RETURNED	31-Jul-2017

GENERAL COMMENTS	The authors have responded to all my comments adequately
-------------------------	--

VERSION 2 – AUTHOR RESPONSE

Reviewer: 4

Reviewer Name: Zelee Hill

Institution and Country: University College London, UK

Please state any competing interests: None declared

Please leave your comments for the authors below

The authors have responded to all my comments adequately

Authors' response:

Thank you

Reviewer: 3

Reviewer Name: Mary B. Adam, MD, MA, PhD

Institution and Country: AIC Kijabe Hospital, Kijabe, Kenya, Strathmore University, Nairobi, Kenya

Please state any competing interests: None

Please leave your comments for the authors below

BMJ Open Review 2017

Paudal, D. et al Revision dated July 18, 2017

Impact of the Community-Based Newborn Care Package in
Nepal: a quasi-experimental evaluation

Dear Editor,

Thank you for allowing me to review the manuscript titled, "Impact of the Community-Based Newborn Care Package in Nepal: a quasi-experimental evaluation".

The manuscript is addressing an important question, that of evaluating the effectiveness of a package of newborn care interventions implemented in Nepal. It is well written and the overall concept of the intervention is clear.

This revision incorporates areas of weakness I identified in my review.

I recommend publication.

With Regards,

Mary B. Adam, MD, MA, PhD

Director, Kijabe Maternal Newborn Community Health Program, Kijabe, Kenya

Authors' response:

Thank you

Reviewer: 2

Reviewer Name: Matthew Ellis

Institution and Country: University of Bristol, UK

Please state any competing interests: None Declared

Please leave your comments for the authors below

This paper has been extensively amended by the authors in line with reviewer suggestions and in my view is now ready for publication

Authors' response:

Thank you