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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015285
Article Type:	Research
Date Submitted by the Author:	25-Nov-2016
Complete List of Authors:	Paudel, Deepak; Save the Children, Health, Nutrition, HIV AIDS; Ludwig Maximilians University, Center for International Health Shrestha, Ishwar; Tribhuvan University Institute of Medicine Siebeck, Matthias; Ludwig-Maximilians-Universitat Munchen Rehfues, Eva; University of Munich, Institute for Medical Informatics, Biometry and Epidemiology
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Evidence based practice, Public health
Keywords:	Community child health < PAEDIATRICS, PUBLIC HEALTH, HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts

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

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Word count, Tables, Figure:

Abstract:	225 (max 250)
Introduction:	390
Methods:	1223
Findings:	482
Discussion:	1134
Total words:	3229 (manuscript text only)
Tables:	5
Figures:	4
References:	31

Abstract

Objective: To evaluate the impact of the Community-Based Newborn Care Package (CBNCP) on six essential practices to improve neonatal health.

Methods: CBNCP pilot districts were matched to comparison districts using propensity scores. Impact on birth preparedness, antenatal care seeking, antenatal care quality, delivery by skilled birth attendant, immediate newborn care and postnatal care within 48 hours was assessed using Demographic and Health Survey (DHS) and Health Management Information System (HMIS) data through difference-in-differences and multivariate logistic regression analyses.

Findings: Changes over time in intervention and comparison areas were similar in difference-in-differences analysis of DHS and HMIS data. Logistic regression of DHS data also did not reveal any significant improvement in aggregate outcomes: birth preparedness, adjusted odds ratio (aOR)=0.8 (95% CI 0.4-1.7); antenatal care seeking, aOR=1.0 (0.6-1.5); antenatal care quality aOR=1.4 (0.9-2.1); delivery by skilled birth attendant, aOR=1.5 (1.0-2.3); immediate newborn care aOR=1.1 (0.7 – 1.9); postnatal care aOR=1.3 (0.9-1.9). Health providers' knowledge and skills in intervention districts were fair but showed much variation between different providers and districts.

Conclusions: This study did not identify significant improvements in newborn care practices and raises concerns regarding CBNCP implementation. It has contributed to the implementation of a revised CBNCP across Nepal, which should be carefully monitored for quality and impact. The study also highlights general challenges in evaluating the impacts of a complex health intervention under “real life” conditions.

Key words: neonatal health; community health worker; female community health volunteer; low- and middle-income country; complex intervention; natural experiment; propensity score

Strengths and limitations of this study

- ▶ We adopted a “natural experiment” approach to assess the impact of the Community-Based Newborn Care Package, a large-scale programme to reduce neonatal mortality in Nepal, by comparing changes in intervention areas with propensity score-matched comparison areas.

- ▶ We developed an a priori conceptual framework to describe causal pathways between programme components and multiple outcomes of this complex intervention. We used multiple routine data sources, each with their distinct strengths and limitations, and different statistical methods as a strategy to triangulate findings. An assessment of the impact of the programme on neonatal mortality was not feasible, as the number of births post-intervention was limited due to a short exposure time to the intervention (ranging from 5 to 12 months depending on district). Findings across all other outcomes, data sources and statistical analyses were largely coherent, suggesting no effect of the programme above background trends.

Introduction

While infant and child mortality in developing countries have declined rapidly in the past decades, newborn mortality has decreased much more slowly.[1] Nepal has demonstrated impressive reductions in child mortality of 76% since 1990 but over the same time period, neonatal mortality has decreased by only 50%.[2 3] With 23 deaths per 1000 live births in year 2014, neonatal mortality now constitutes 60% of under-five deaths.[4]

Over two thirds of newborn deaths could be prevented with relatively low-cost, low-tech interventions.[5] A systematic review based on five randomised controlled trials (RCTs) from South Asia concluded that visits during the antenatal and neonatal periods and home-based treatment for illness reduce the risk of neonatal deaths and improve neonatal care practices, with greater survival benefit when home visits are integrated with preventive and curative interventions.[6] Similarly, other South Asian studies employing different programme components and delivery approaches demonstrate improvements in uptake of antenatal care, institutional delivery and newborn care.[7-9] Consequently, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend home visits during the first week of life by appropriately trained and supervised community health workers to promote healthy behaviours and timely recognition of newborn illness, and to provide home treatment for infections and feeding problems.[10]

Based on global, regional and national evidence, the Ministry of Health (MOH) combined seven community- and home-based interventions in the community-based newborn care package (CBNCP) to tackle major causes of neonatal mortality.[11] This programme comprises :i) behaviour change communication for birth preparedness and newborn care; ii) institutional delivery or clean home delivery through skilled birth attendants; iii) postnatal care; iv) care for low birth weight newborns; v) management of newborn infections; vi) prevention of hypothermia; and vii) recognition of asphyxia, initial stimulation and resuscitation. The programme is delivered

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3 through facility- and community-based health workers as well as the Nepal-specific cadre of
4 female community health volunteers (FCHVs), and comprises training and supervision of the
5 health workforce and provision of essential commodities. The CBNCP was piloted in 10 out of
6 75 districts of Nepal in 2009 and 2010 with funding from MOH, the United States Agency for
7 International Development (USAID), UNICEF and Saving Newborn Lives (SNL).
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10 The objective of this study was to evaluate the impact of CBNCP on six essential practices to
11 improve neonatal health in pilot districts compared to propensity score-matched comparison
12 districts.
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15 **Methods**

16 *Study setting and population*

17 Nepal is characterised by three distinct geographies, i.e. *terai* or flatland, hill and mountain
18 areas. The CBNCP was piloted in four hill and six *terai* districts, constituting the 'intervention
19 area', to which we assigned a 'comparison area' (**Figure 1**). In both areas, one site was
20 purposively selected for an additional qualitative component of the study; methods and findings
21 of the latter are reported elsewhere.^[12 13]
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24 <Figure 1 about here>

25 The CBNCP targets all women of reproductive age, aiming to increase their interaction with the
26 health system during pregnancy, delivery and the postnatal period. Our study was undertaken
27 among women aged 15 to 49 years who had a live birth during 30 months pre-intervention
28 compared to those with a live birth taking place during 11 months post-intervention in view of
29 Demographic and Health Survey (DHS) data being available for this period.
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32 *Study design*

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3 This quasi-experimental study uses propensity score matching and multiple data sources to
4 assess the impact of the CBNCP (**Figure 2**). It includes: a) before-after analysis of essential
5 practices in the intervention vs. comparison area based on DHS data; b) before-after analysis of
6 those same practices in the intervention vs. comparison area based on Health Management
7 Information System (HMIS) data; and c) analysis of training coverage and knowledge and skills
8 of healthcare providers in the intervention area based on Newborn Health Information System
9 (NHIS) data.
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18 <Figure 2 about here>
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20 We developed a conceptual framework, which regards the CBNCP as a complex multi-
21 component intervention[14 15] and graphically presents the presumed causal pathway from
22 CBNCP implementation within the health system through changed practices of pregnant or
23 recently delivered women to impacts on neonatal health (**Figure 3**). This conceptual framework
24 was critical in our identification of relevant outcome variables.
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32 <Figure 3 about here>
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34 Implementation of the CBNCP pilot through training of facility- and community-based health
35 workers and FCHVs started in May 2009 and was completed in July 2010. Training dates were
36 obtained from the Ministry of Health (MOH) to define district-specific pre- and post-intervention
37 periods used in the analysis of DHS and HMIS data; any births taking place during training were
38 excluded from the analysis.
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46 *Propensity score matching* 47

48 Propensity score matching is widely used to estimate the effects of health and other policy
49 interventions, where RCTs are not feasible.[16] It uses statistical techniques to construct a
50 comparison group that is as similar as possible to the intervention group in an effort to reduce
51 selection bias.[17 18]
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3 Ten intervention districts were selected by the MOH in consultation with donors, considering
4 development need, donor presence, district interest and ability to implement and monitor the
5 programme (Personal communication, Parashuram Shrestha, Nepal Ministry of Health). To
6 reflect the propensity of a district to be selected for CBNCP implementation, we constructed a
7 propensity score based on (i) the four components of the district human development index
8 (HDI) value; ii) presence of donors involved in the CBNCP (i.e. USAID, UNICEF, SNL); iii)
9 percentage rural population; iv) the MOH district performance rank); and v) road density) (see
10 **Table 1** for details).

11
12 As CBNCP implementation was limited to hill and *terai* districts, mountain districts were
13 excluded. We used the *psmatch2* command in Stata Special Edition 12[19] to identify suitable
14 comparison districts based on the nearest-neighbour method without replacement. We checked
15 for balance in the distribution of propensity score components (using t-tests) and population and
16 health infrastructure characteristics (using Chi-square tests) between intervention (10 districts
17 pooled) and comparison areas (10 districts pooled).

18 *Data sources and variables*

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20 Multiple data sources were used to enable as complete an analysis of impact as possible and to
21 triangulate information between sources with different strengths and weaknesses. The DHS
22 provides nationally representative data on fertility, health-relevant behaviours and childhood
23 mortality based on a multi-stage cluster random sampling strategy.[20] The data for the Nepal
24 DHS for 2011 are in the public domain (www.dhsprogram.org). The HMIS, owned by the MOH
25 and primarily based on health facility records, provides information about health service
26 utilisation, morbidity and mortality, treatment outcomes and the availability of commodities. We
27 used data on regular service delivery for 2009-2011, publicly available at www.dohs.gov.np, as
28 well as the CBNCP-specific NHIS.[21]

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3 Neonatal mortality as the ultimate outcome of interest was not feasible to assess given available
4 data sources and sample sizes. Instead, with reference to our conceptual framework (**Figure 3**)
5 we examined changes in six essential practices to improve neonatal health by combining
6 relevant contributing practices in aggregate binary outcomes (coded as “better” or “worse”
7 practices).
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11 Relevant covariates were identified *a priori* as family characteristics (i.e. wealth quintile, rural vs.
12 urban location, caste/ethnicity); maternal characteristics (i.e. age at delivery, education and
13 access to media) and child characteristics (i.e. sex, parity). (see **Table 2** for details.)
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20 21 *Analysis*

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23 Difference-in-differences analysis estimates the change in outcome for the intervention area
24 over a given time period by subtracting any change in outcome for the comparison area over the
25 same time period. All outcomes were assessed at the aggregate level as percentage of
26 pregnant or recently delivered women adhering to ‘better’ practices.[22] For DHS data,
27 difference-in-differences analysis using Ordinary Least Square (OLS) regression was conducted
28 for births occurring pre- and post-intervention. Where a woman had given birth more than once
29 during the pre- or post-intervention period only the most recent birth was included in the
30 analysis to avoid non-independence of observations and to minimise recall bias. For HMIS data,
31 a similar approach was adopted, however, tests of significance were not possible as the data
32 were available only in aggregate at the district level. We also conducted logistic regression
33 analysis of DHS data to examine if any differences between intervention and comparison areas
34 persist after adjustment for all *a priori* identified covariates; here the outcome was assessed at
35 the individual level as either adhering or not adhering to ‘better’ practices. All analyses were
36 undertaken in Stata Special Edition 12.[19]
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54 55 *Ethical considerations*

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Ethical approval was obtained from the Nepal Health Research Council.

For peer review only

Findings

Baseline characteristics

Table 1 shows that intervention and comparison areas are balanced for propensity score components as well as relevant population and health infrastructure characteristics.

<Table 1 about here>

Using pre-intervention DHS data, 533 and 347 births took place in the intervention and comparison area respectively. **Table 2** compares outcome variables and covariates for the most recent births in the five years preceding the DHS survey. In both areas, a majority of children are from rural locations, disadvantaged families, and born to a mother with at least primary education. While respondents from intervention and comparison areas are largely comparable, there are statistically significant baseline differences in relation to family wealth status, maternal age at delivery and delivery by a skilled birth attendant even after matching.

<Table 2 about here>

Intervention coverage

In the ten pilot districts, a majority of health providers were trained, i.e. 1615 facility-based health workers, 902 community-based health workers and 7072 FCHVs. Overall, knowledge and skills as reported or demonstrated were fair with some variation by type of provider; availability of drugs and commodities was also good (**Table 3**). All of these, however, showed much variation between districts, pointing to concerns with respect to quality of training, supervision and logistics (data not shown).^[12]

<Table 3 about here>

Difference-in-differences analysis

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3 **Table 4** presents findings from the difference-in-differences analysis of DHS data. With the
4 exception of birth preparedness (no change) and postnatal care within 48 hours (increase in
5 intervention area, decrease in comparison area), improvements were observed but to a similar
6 extent in both areas with no statistically significant differences. For all six essential practices the
7 percentage of pregnant or recently delivered women adhering to better practices was lower in
8 the comparison area at both points in time.
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17 <Table 4 about here>
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20 Similarly, difference-in-differences analysis of HMIS data showed improvements in both
21 intervention and comparison areas for most of the practices assessed; HMIS does not collect
22 information on birth preparedness or immediate newborn care practices (data not shown).^[12]
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25 **Table 5** compares findings based on DHS and HMIS data, showing congruent trends for all
26 essential practices despite differences in the specification of some indicators. The contradictory
27 finding that iron supplementation decreased post-intervention in the HMIS (which collects data
28 from public service providers) but not in the DHS analysis (which reflects households seeking
29 care from both public and private providers) is explained by government health facilities having
30 run out-of-stock in October and November 2011.
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41 <Table 5 about here>
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44 *Logistic regression analysis*

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46 The unadjusted odds ratios suggest statistically significant improvements in antenatal care
47 quality (OR 1.8, 95% CI 1.1-2.9), delivery by a skilled birth attendant (OR 2.0, 95% CI 1.2-3.3)
48 and postnatal care within 48 hours (OR 2.7, 95% CI 1.1-2.6) but not in the other three essential
49 practices (**Figure 4**). However, when adjusted for *a priori* identified covariates none of the
50 changes in essential practices remained statistically significant.
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<Figure 4 about here>

Discussion

Key findings and their explanation

Nepal's CBNCP was developed based on existing studies, mostly from Nepal and South Asia, demonstrating effectiveness for a majority of the intervention components[23] but not for the package as a whole.[11] The analysis of DHS and HMIS data suggests that the CBNCP did not have a significant impact on essential practices to improve neonatal health above a generally increasing trend in these practices. Several factors are likely to interplay in explaining this lack of impact.

Packaging of multiple interventions: The CBNCP bundled a range of specific measures in a complex package and implemented this across a large geographical area with a loose implementation modality. In contrast, prior effectiveness studies usually examined a single and relatively simple component (e.g. chlorhexidine for cord care[24]) in a limited geographic area (e.g. MIRA[25]), implemented through a dedicated cadre of higher-level service providers (e.g. SEARCH[26]) or undertaken as a distinct research project (e.g. resuscitation[27]). It is therefore not surprising that the effectiveness of these interventions is diluted when merged in a package that is delivered by a lower-level service provider under "real life" conditions. Indeed, a similar reduction of effectiveness when moving from research studies to large-scale implementation has been observed elsewhere.[14 28]

Health care providers and their training: The CBNCP was implemented through training of the existing cadre of facility- (seven days) and community-based (five days) health workers in the government system as well as FCHVs (seven days) with very limited subsequent supervision and follow-up. While evidence from Nepal suggests that community health workers and FCHVs can identify and manage maternal and newborn health problems, this requires frequent training

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3 and mentoring.[29] This study suggests much variation in programme performance across
4 districts, generally indicating better results in areas where the CBNCP is implemented with more
5 intensity. In addition, the qualitative component showed that service providers perceived the
6 training as insufficient for them to be able to apply their skills confidently and to retain them over
7 prolonged periods of time. [12] Moreover, in a setting where medical shops are perceived to be
8 more convenient than government health facilities,[30] a programme that does not involve
9 private providers will show limited impact.
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19 *Other relevant health initiatives:* In the last decade, Nepal has witnessed a host of programmes
20 to improve maternal and child health, with many of these directly or indirectly impacting neonatal
21 health.[2] As adjustment for other relevant ongoing initiatives was not feasible in design or
22 analysis of this impact study, the observed trends in essential practices to improve neonatal
23 health and the lack of CBNCP impact in intervention relative to comparison areas are in part
24 likely to be due to the high level of background activity.
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32 33 *Strengths and limitations* 34

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36 *Study design:* The CBNCP is a complex intervention, where multiple components are intended
37 to improve a whole range of health provider and population behaviours throughout pregnancy,
38 delivery and the post-partum period. As its implementation was outside of the control of the
39 researchers, randomisation was not feasible and we had to adopt a “natural experiment”[31]
40 approach. While matching largely achieved balance between intervention and comparison
41 areas, some baseline differences persisted. Moreover, we did not match individual intervention
42 and comparison districts but intervention and comparison areas. A major strength in addition to
43 propensity score matching is this study’s utilisation of multiple data sources to assess impact.
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54 *Data:* The DHS is a cross-sectional survey with retrospective recording of all pregnancies and
55 births as well as relevant behaviours; it is thus subject to recall bias. DHS data are designed to
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3 be representative at the national level – for rare events, they are not necessarily representative
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5 at the district level and, consequently, assessment of impact on neonatal mortality was not
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7 feasible. The number of births covered is also limited, especially post-intervention, as exposure
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9 time to the intervention was short (ranging from 5 to 12 months) and there is thus limited power
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11 to reflect true changes between areas. It is possible that changes in the behaviour of pregnant
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13 and recently delivered women will only become manifest after longer periods of time, once
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15 health providers have internalised recommendations and implement them on a regular basis.
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17 The HMIS provides valuable information about intervention coverage, knowledge and skills of
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19 service providers and availability of key commodities and supplies in the health system.
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21 However, HMIS data are only available for the public sector and are thus not truly
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23 representative as many people rely on healthcare from informal and private providers.
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28 *Analysis:* Use of multiple data sources and multiple statistical methods has been an important
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30 strategy to validate findings or lack thereof. Difference-in-differences calculations are subject to
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32 limitations, as adjustment for confounders was not possible with the information available at
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34 district level. Filtering of births for analysis (i.e. before, during and after implementation) was
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36 customised by district, and the analysis excluded births taking place during training as a
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38 conservative strategy. We used an *a priori* conceptual framework to define the outcomes of the
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40 intervention.
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43 *Implications for research and practice*

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46 Overall, this study highlights that the design, piloting and implementation of a complex
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48 intervention such as the CBNCP must be carefully planned and evaluated. In fact, the
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50 assumption that combining a large number of intervention components, even where their
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52 individual effectiveness has been proven, will yield an effective intervention package that can be
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54 successfully implemented at scale does not hold. Importantly, evaluating under “real life”
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56 conditions is not necessarily straightforward, and may require the use of limited-quality routine
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3 data in combination with innovative study designs. Even though the CBNCP, as assessed
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5 through our study, was conceived as a pilot, rigorous assessment through the MOH and donors
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7 was lacking; despite increasing concerns about the quality of CBNCP implementation and a
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9 potential lack of impact, implementation continued and was rapidly extended beyond pilot
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11 districts.
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15 The findings presented here, supported by those of the qualitative component of the study,
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17 suggest that the programme may need a re-packaging and tightening of content as well as a
18
19 revision of its implementation modality. Components with high burden and greater effectiveness
20
21 (e.g. infections and care for low birthweight babies) should be strengthened, whereas
22
23 components with lower burden and less effectiveness (e.g. asphyxia) should be removed
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25 especially for FCHVs. With respect to implementation modality, more emphasis must be placed
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27 on focused, high-quality training of all involved healthcare providers and ongoing supervision
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29 and support.
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33 The CBNCP has been scaled up to 39 districts of Nepal. The findings presented here, which
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35 were previously shared with those in charge of the CBNCP, and a move towards more
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37 integrated approaches to improve child survival prompted a removal of selected components
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39 and integration of CBNCP interventions with the Integrated Management of Neonatal and
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41 Childhood Illness (IMNCI) programme. The IMCNI programme is currently being implemented in
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43 15 districts and monitored in terms of programme coverage, quality and impacts on behaviours,
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45 health and equity.
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Authors' contributions

DP, IBS and ER had the original idea for this paper. DP identified the data, carried out the analysis and prepared the first draft. IBS, ER and MS advised on selection and implementation of methods and interpretation of findings. IBS, ER and MS reviewed and revised the draft manuscript. All authors, except IBS because of his untimely demise during finalisation of this manuscript, read and approved the final manuscript.

Acknowledgements

We would like to acknowledge the USAID-funded MEASURE DHS for providing us with the Nepal DHS dataset and the MoH for sharing HMIS data. DP undertook this analysis as part of his research under the PhD programme at the Munich Center for International Health and was funded through a scholarship offered by the German Academic Exchange Service. At the time, DP was an employee of USAID and was offered flexible working hours and time off to undertake this study as part of this PhD dissertation. The opinions expressed in this paper are those of the authors and do not necessarily reflect the views of USAID or the other organizations the authors are affiliated with. We would also like to thank Jamie Bartram and Ulrich Mansmann for their helpful comments on a previous version of this manuscript.

Funding

This study was undertaken without dedicated research funding but made possible through a PhD scholarship offered to DP by the German Academic Exchange Service. The study utilized DHS data in the public domain and HMIS data made available to the authors upon request. All data were processed and analyzed by the authors with DP having full access to the data and all authors sharing the final responsibility for the decision to submit for publication. Neither those

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3 providing us with the data nor the German Academic Exchange Service had any involvement in
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5 data analysis, interpretation or writing of this manuscript.
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8 **Competing interest**

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11 At the time of study, DP was an employee of USAID and involved in monitoring the CBNCP
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13 programme.
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15 **Data sharing**

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18 No additional data available
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Table 1 Background characteristics in intervention and comparison areas, based on various data sources

	Intervention area	Comparison area	t	p-value
Propensity score components				
Human Development Index: life expectancy ¹	61.23	62.88	-0.76	0.457
Human Development Index: adult literacy (%) ¹	51.40	54.38	-0.73	0.475
Human Development Index: school enrolment (%) ¹	2.77	2.88	-0.33	0.742
Human Development Index: gross domestic product (PPP US\$) ¹	1293.6	1315.2	-0.15	0.883
Urban population (%) ²	16.79	17.85	-0.25	0.803
District performance score (average) ³ (as a proxy for a district's leadership ability and pro-activeness in implementing new initiatives)	74.25	73.77	0.28	0.781
Road density (km/square km) ² (as a measure of access and ability to monitor the programme)	0.251	0.258	-0.07	0.941
Donor presence (average number) ⁴	1.3	1.4	0.25	0.806
Population and health infrastructure characteristics⁵				
Population	4.9 million	4.4 million		
Expected pregnancies	142,000	128,000		
Number of hospitals	14	11		
Number of primary health care centres	39	39		
Number of health posts	87	89		
Number of sub-health posts	435	456		
Number of private health institutions	49	38		
Number of birthing centres	203	183		
Population per birthing centre	24,159	24,330		
Number of FCHVs	6,903	7,378		
Population per FCHV	710	603		

Data sources:

¹UNDP. Nepal Human Development Report, Kathmandu, Nepal, 2004²District Profile of Nepal 2007/08: A socio-economic development database of Nepal, Intensive Study and Research Center of Nepal, Kathmandu, 2009.³MOH. District Annual Performance Criteria, personal communication, Ghanashyam Pokharel, 2011⁴AIN. Health Mapping Report, Association of International NGOs in Nepal, Kathmandu, 2008⁵Health Management Information System database, made available on request by Management Division, 2010

Table 2 Baseline characteristics in intervention and comparison areas, for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data

		Intervention area (n=533)	Comparison area (n=347)	χ^2	p-value
Family characteristics					
Location	Rural	86.02	85.63	0.02	0.929
Wealth index	Poorer ¹	31.43	51.73	44.09	0.003
Caste and ethnicity	Disadvantaged ²	74.02	70.61	1.05	0.673
Maternal characteristics					
Education	No education ³	36.48	45.03	24.82	0.072
Age at delivery	Higher risk age group ⁴	31.92	23.04	6.92	0.022
Access to media	No ⁵	51.40	65.43	14.34	0.101
Child characteristics					
Sex	Female	45.71	49.03	1.98	0.187
Parity	Higher risk parity ⁶	56.47	51.05	2.12	0.211
Essential practices to improve neonatal health					
Birth preparedness	Better ⁷	6.22	4.85	0.63	0.568
Antenatal care seeking	Better ⁸	33.65	26.41	4.39	0.218
Antenatal care quality	Better ⁹	35.96	29.03	3.87	0.195
Delivery by skilled birth attendant	Yes ¹⁰	46.65	31.24	17.61	0.007
Immediate newborn care	Better ¹¹	74.36	64.25	8.63	0.091
Postnatal care within 48 hours	Yes ¹²	33.69	26.80	3.97	0.097

¹ Poorer: includes poorer and poorest quintiles i.e. lowest 40% in wealth ranking based on selected household assets.

² Disadvantaged caste and ethnicity: includes hill dalit, terai dalit, hill janajati, terai janajati, other terai caste, and Muslim.

³ No education: includes illiterates and those without any formal education but may have some literacy classes.

⁴ Higher risk group: those who delivered before 20 years or after 35 years

⁵ No access to media: those reporting not listening or watching any public health radio or television programme in the last month

⁶ Higher risk parity: First or more than third parity

⁷ Birth preparedness: aggregate variable including saving money, organising transportation, finding a blood donor, identifying a health worker to assist with the delivery and purchasing a safe delivery kit; coded as "better" if at least two items are fulfilled.

⁸ Antenatal care seeking: aggregate variable comprising number of antenatal visits (four or more), taking iron supplements(>90 tablets) and having been vaccinated against tetanus (at least two doses); coded as "better" if all items are fulfilled.

⁹ Antenatal care quality: aggregate variable comprising whether the woman had her blood pressure taken, a urine and/or blood sample collected, and was told about pregnancy complications and where to go in case of complications; coded as "better" if at least four items are fulfilled.

¹⁰ Delivery by skilled birth attendant: defined as delivery by a doctor, nurse or midwife at home or at a health institution.

¹¹ Immediate newborn care: aggregate variable comprising delayed bathing, drying, wrapping, placing the baby on the mother's breast or belly, applying chlorohexidine or nothing on the umbilical cord, and initiation of breastfeeding within one hour of birth; coded as "better" if at least three items are fulfilled.

¹² Postnatal care within 48 hours: defined as any newborn examination by a health worker or FCHV within 48 hours of birth.

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	Unit	Facility-based health worker	Community health worker	Female community health volunteer
Training coverage				
Number of individuals trained	Number	1615	902	7072
Knowledge				
Knowledge of immediate newborn care messages (i.e. thermal care, clean cord, skin-to-skin contact, immediate breastfeeding and delayed bathing)	% (sd)	70 (17.6)	62 (12.4)	57 (24.3)
Knowledge of correct dose of cotrimoxazole paediatric tablet	% (sd)	88 (11.5)	91 (5.6)	82 (16.5)
Skills				
Ability to demonstrate hand washing correctly	% (sd)	81 (9.8)	68 (17.1)	60 (14.3)
Ability to demonstrate resuscitation steps correctly using a doll	% (sd)	53 (19.6)	37 (17.0)	27 (17.7)
Availability of drugs and commodities				
Cotrimoxazole paediatric tablet	% (sd)	99 (1.6)	87 (12.6)	89 (10.2)
Gentamicin	% (sd)	95 (5.1)	78 (16.9)	--
Thermometer	% (sd)	--	--	85 (9.9)

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Table 4 Difference-in-differences analysis for six essential practices to improved neonatal health (aggregate outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data¹

		Intervention area			Comparison area			Diff. in differences	p-value
		Before (n=533)	After (n=168)	Diff.	Before (n=347)	After (n=104)	Diff.		
Birth preparedness	Better	6.22	8.43	2.21	4.84	6.00	1.16	1.05	0.810
Antenatal care seeking	Better	33.65	49.66	16.01	26.41	33.2	6.79	9.22	0.383
Antenatal care quality	Better	47.35	59.94	12.59	34.87	37.78	2.91	9.68	0.290
Delivery by skilled birth attendant	Yes	46.65	57.7	11.05	31.24	37.62	6.38	4.67	0.577
Immediate newborn care	Better	74.36	85.9	11.54	64.25	79.89	15.64	-4.1	0.605
Postnatal care within 48 hours	Yes	33.69	44.65	10.96	26.8	17.4	-9.4	20.36	0.036

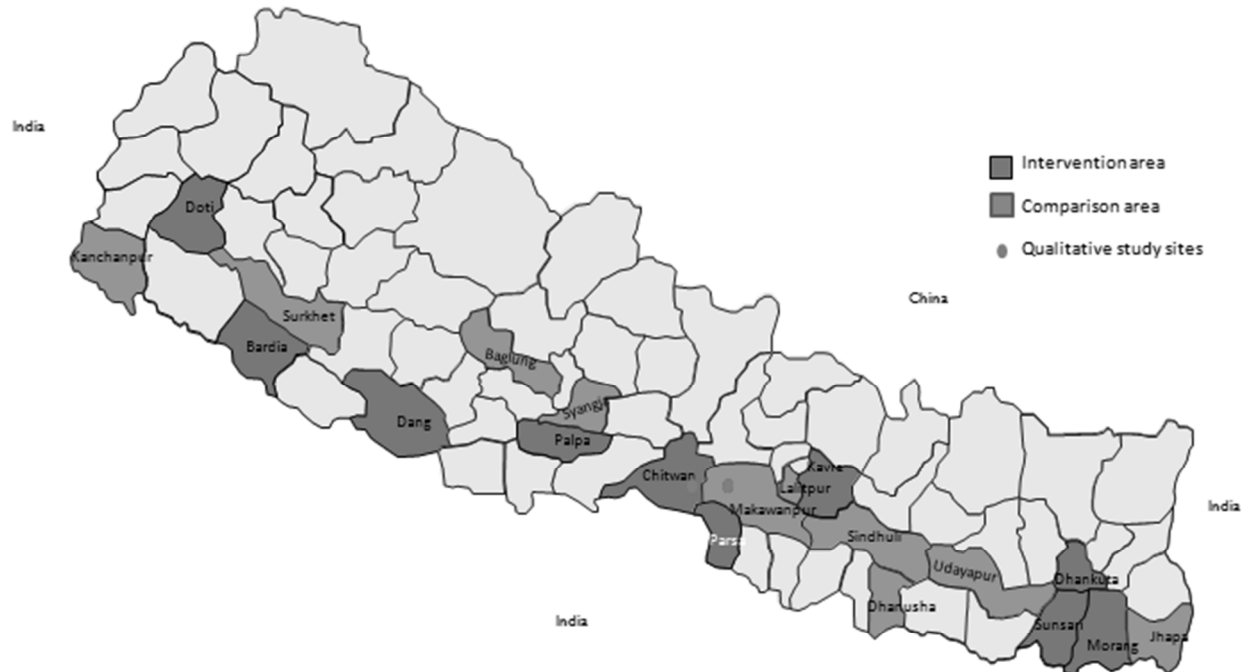
¹ See **Table 2** for details on variables.

Table 5 Comparison of difference-in-differences analysis for selected antenatal, delivery and postnatal indicators (in percent), between DHS and MIS data

Essential practices to improve neonatal health ¹	DHS					HMIS				
	Intervention		Comparison		Difference -in- differences	Intervention		Comparison		Difference -in- differences
	Before	After	Before	After		Before	After	Before	After	
Birth preparedness (aggregate)	6	8	5	6	1	-	-	-	-	-
Antenatal care seeking: Antenatal care contact (at least one)	63	70	53	64	-4	69	81	73	78	7
At least four ANC visits	52	64	41	56	-3	36	43	35	46	-4
Iron tablet taken	78	87	77	80	6	74	62	73	58	3
Antenatal care quality (aggregate)	42	45	41	41	3	-	-	-	-	-
Delivery by skilled birth attendant	47	58	31	38	4	27	38	25	36	0
Immediate newborn care	74	85	69	79	1	-	-	-	-	-
Postnatal care within 48 hours	34	45	27	17	21	44	54	41	45	6

¹ See Figure 3 for details on variables.

Figure 1 Map of Nepal showing intervention and comparison areas and qualitative study sites

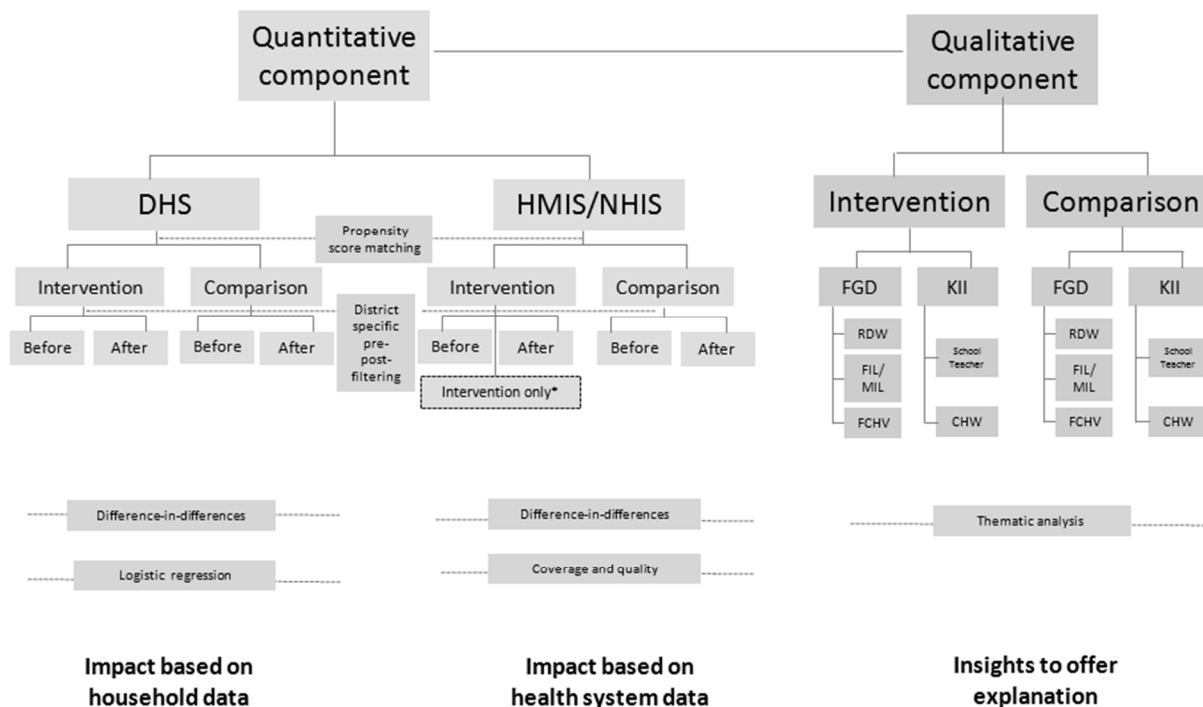


Intervention area: Four hill (i.e. Dhankuta, Kavre, Palpa and Doti) and six *terai* districts (i.e. Morang, Sunsari, Parsa, Chitwan, Dang and Bardiya).

Comparison area: Seven hill (i.e. Udayapur, Sindhuli, Makawanpur, Lalitpur, Syangja, Baglung, and Surkhet) and three *terai* districts (i.e. Jhapa, Dhanusha and Kanchanpur).

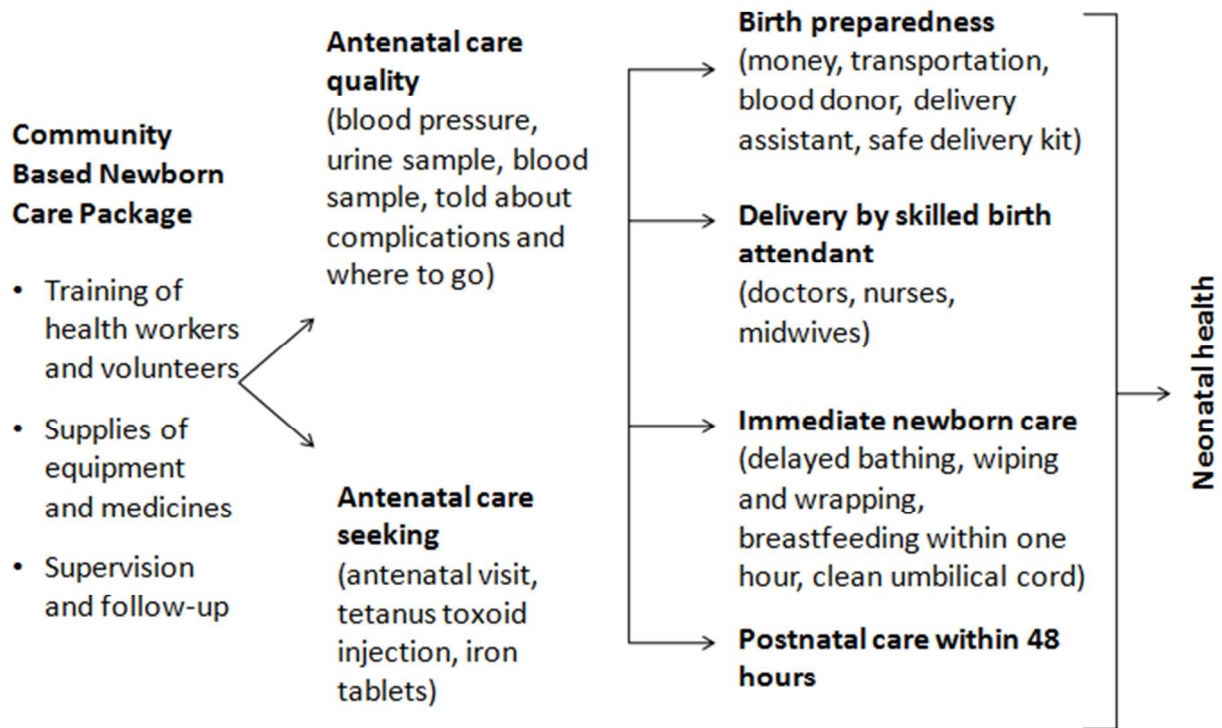
Qualitative study sites: Korak village in intervention district Chitwan and Palase village in comparison district Makawanpur.

Figure 2 Study design comprising quantitative and qualitative components



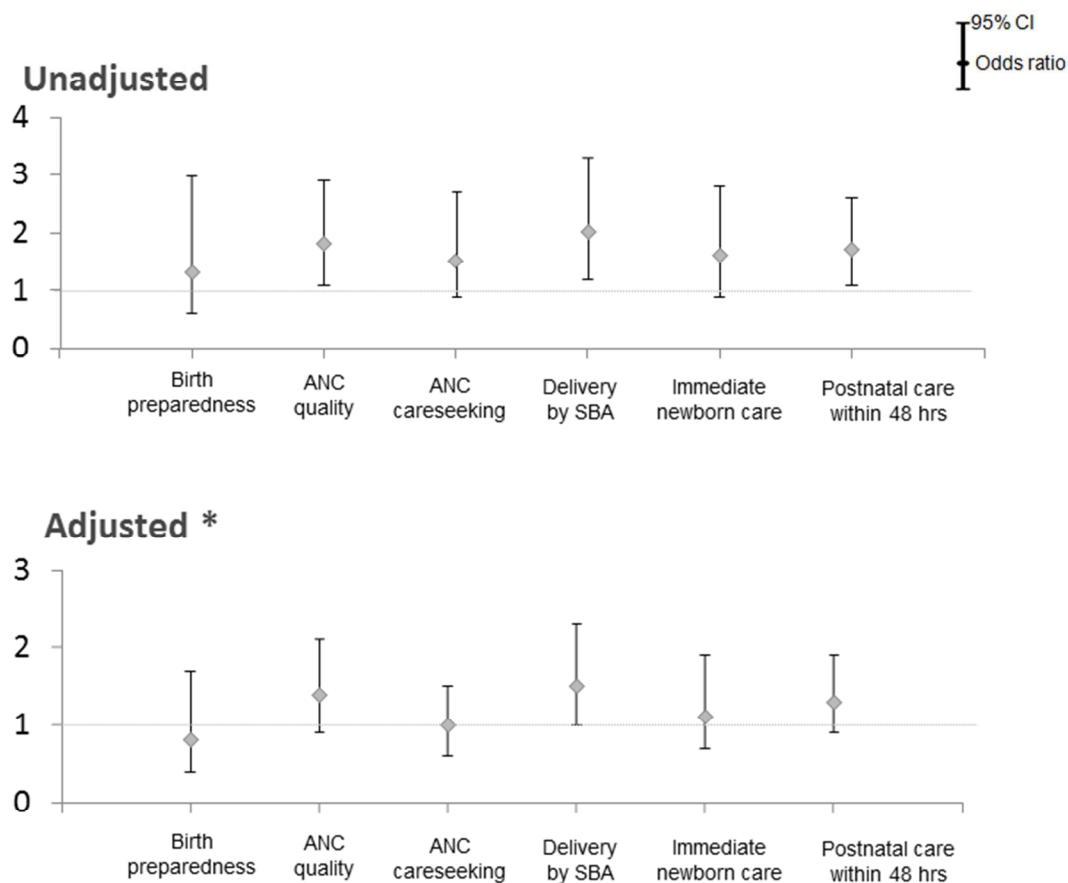
DHS: Demographic and Health Survey; HMIS: Health Management Information System; NHIS: Newborn Health Information System; FGD: Focus group discussion; KII: Key informant interview; RDW: Recently delivered woman; FIL: Father-in-law; MIL: Mother-in-law; FCHV: Female community health volunteer; CHW: Community health worker.

Figure 3 Conceptual framework for impact of CBNCP on neonatal health



- Birth preparedness includes saving money, organising transportation, finding a blood donor, identifying a health worker to assist with the delivery and purchasing a safe delivery kit.
- Antenatal care seeking comprises number of antenatal visits, taking iron supplements and having been vaccinated against tetanus.
- Antenatal care quality considers whether the woman had her blood pressure taken, a urine and/or blood sample collected, and was told about pregnancy complications and where to go in case of complications.
- Delivery by skilled birth attendant is defined as delivery by a doctor, nurse or midwife at home or at a health institution.
- Immediate newborn care comprises delayed bathing, drying, wrapping, placing the baby on the mother's breast or belly, applying chlorohexidine or nothing on the umbilical cord, and initiation of breastfeeding within one hour of birth.
- Postnatal care within 48 hours is defined as any newborn examination by a health worker or FCHV within 48 hours of birth.

Figure 4 Impact of CBNCP on six essential practices to improve neonatal health, based on logistic regression analysis of DHS data



* adjusted for wealth quintile, location, caste and ethnicity, maternal age at delivery, maternal education, access to media, child sex and parity

STROBE Statement—checklist of items that should be included in reports of observational studies

Checklist for Paudel D et al for BMJ Open Research Article

	Item No	Recommendation	Reported in the manuscript in line number below
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3-23
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	50-78
Objectives	3	State specific objectives, including any prespecified hypotheses	79-81
Methods			
Study design	4	Present key elements of study design early in the paper	95-133
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	84-94, 110-131
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	110-131
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	135-151
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of	135-151

		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	135-136, 149-151, 115-133
Study size	10	Explain how the study size was arrived at	120- 133
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	155-165
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	135-136, 149-151, 115-133

Continued on next page

Results			<i>Reported in the manuscript in line number below</i>
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	172-181
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	184-214
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	184-214
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	217-252
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	254-281
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	282-308
Generalisability	21	Discuss the generalisability (external validity) of the study results	254-281
Other information			

1
2 Funding 22 Give the source of funding and the role of the funders 330-337
3 for the present study and, if applicable, for the
4 original study on which the present article is based
5

6
7 *Give information separately for cases and controls in case-control studies and, if applicable, for exposed and
8 unexposed groups in cohort and cross-sectional studies.
9

10 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
11 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
12 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
13 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
14 available at www.strobe-statement.org.
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015285.R1
Article Type:	Research
Date Submitted by the Author:	21-Jul-2017
Complete List of Authors:	Paudel, Deepak; United States Agency for International Development; Ludwig Maximilians University, Center for International Health Shrestha, Ishwar; Tribhuvan University Institute of Medicine Siebeck, Matthias; Ludwig-Maximilians-Universitat Munchen Rehfuess, Eva; University of Munich, Institute for Medical Informatics Information Processing, Biometry and Epidemiology, Pettenkofer School of Public Health; Center for International Health, LMU Munich
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Evidence based practice, Public health
Keywords:	Neonatal health, Community health worker, Complex health intervention, Quasi-experimental, Propensity score, Nepal

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3 **Impact of the Community-Based Newborn Care Package in Nepal: a quasi-**
4 **experimental evaluation**
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35 **Word count, Tables, Figure:**

36 Abstract: 248 (max 250)

37 Introduction: 445

38 Methods: 1253

39 Findings: 480

40 Discussion: 1282

41 Total words: 3460 (max 4000, manuscript text only)

42 Tables: 5

43 Figures: 4

44 References: 38

45 Supplementary Information: 3 tables and 1 box
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Abstract

Objective: To evaluate the impact of the Community-Based Newborn Care Package (CBNCP) on six essential practices to improve neonatal health.

Methods: CBNCP pilot districts were matched to comparison districts using propensity scores. Impact on birth preparedness, antenatal care seeking, antenatal care quality, delivery by skilled birth attendant, immediate newborn care and postnatal care within 48 hours was assessed using Demographic and Health Survey (DHS) and Health Management Information System (HMIS) data through difference-in-differences and multivariate logistic regression analyses.

Findings: Changes over time in intervention and comparison areas were similar in difference-in-differences analysis of DHS and HMIS data. Logistic regression of DHS data also did not reveal any significant improvement in combined outcomes: birth preparedness, adjusted odds ratio (aOR)=0.8 (95% CI 0.4-1.7); antenatal care seeking, aOR=1.0 (0.6-1.5); antenatal care quality aOR=1.4 (0.9-2.1); delivery by skilled birth attendant, aOR=1.5 (1.0-2.3); immediate newborn care aOR=1.1 (0.7 – 1.9); postnatal care aOR=1.3 (0.9-1.9). Health providers' knowledge and skills in intervention districts were fair but showed much variation between different providers and districts.

Conclusions: This study, while representing an early assessment of impact, did not identify significant improvements in newborn care practices and raises concerns regarding CBNCP implementation. It has contributed to revisions of the package and it being merged with the Integrated Management of Neonatal and Childhood Illness programme. This is now being implemented in 15 districts and carefully monitored for quality and impact. The study also highlights general challenges in evaluating the impacts of a complex health intervention under "real life" conditions.

Key words: neonatal health; community health worker; complex health intervention; quasi-experimental; propensity score, Nepal

Strengths and limitations of this study

- ▶ Adopting a “natural experiment” approach, we used multiple data sources and multiple statistical methods as an important strategy to validate findings.
- ▶ The two datasets employed, the nationally representative cross-sectional DHS and the public sector healthcare reporting system HMIS, each have their own strengths and limitations but do not provide representative measures of coverage at population level.
- ▶ An *a priori* conceptual framework defined the outcomes of the intervention and guided the analysis; along with other careful measures, such as excluding births taking place during training, this was intended to minimise bias.
- ▶ Neonatal mortality as the ultimate outcome of interest could not be examined, as the datasets employed were insufficient for examining rare events at district level.

Introduction

While infant and child mortality in developing countries have declined rapidly in the past decades, newborn mortality has decreased much more slowly.¹ Nepal has demonstrated impressive reductions in child mortality of 76% since 1990 but over the same time period, neonatal mortality has decreased by only 50%.^{2,3} With 21 deaths per 1000 live births in year 2016, neonatal mortality now constitutes 54% of under-five deaths.⁴

Over two thirds of newborn deaths could be prevented with relatively low-cost, low-tech interventions.^{5,6} A systematic review based on five randomised controlled trials (RCTs) from South Asia concluded that visits during the antenatal and neonatal periods and home-based treatment for illness reduce the risk of neonatal deaths and improve neonatal care practices, with greater survival benefit when home visits are integrated with preventive and curative interventions.⁷ Similarly, other South Asian studies employing different programme components and delivery approaches demonstrate improvements in uptake of antenatal care, institutional delivery and newborn care.⁸⁻¹⁰ Consequently, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend home visits during the first week of life by appropriately trained and supervised community health workers to promote healthy behaviours and timely recognition of newborn illness, and to provide home treatment for infections and feeding problems.¹¹

Based on global, regional and national evidence, the Ministry of Health (MOH) combined seven community- and home-based interventions in the community-based newborn care package (CBNCP) to tackle major causes of neonatal mortality.¹² This programme comprises :i) behaviour change communication for birth preparedness and newborn care; ii) institutional delivery or clean home delivery through skilled birth attendants; iii) postnatal care; iv) care for low birth weight newborns; v) management of newborn infections; vi) prevention of hypothermia;

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3 and vii) recognition of asphyxia, initial stimulation and resuscitation. The programme is delivered
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5 through facility- and community-based health workers as well as the Nepal-specific cadre of
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7 female community health volunteers (FCHVs), and comprises training and supervision of the
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9 health workforce and provision of essential commodities. The package included seven days'
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11 training for facility-based health workers, five days' training for community-based health workers
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13 and seven days' training for FCHVs. Supervision and monitoring mostly utilises existing
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15 approaches, supplemented with pilot phase intensive supervision including, for example,
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17 monthly review meetings with FCHVs at the health facility level (see **Supplementary File, Box**
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19 **1 CBNCP programme components**)¹² The CBNCP was piloted in 10 out of 75 districts of
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21 Nepal in 2009 and 2010 with funding from MOH, the United States Agency for International
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23 Development (USAID), UNICEF and Saving Newborn Lives (SNL).
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28 The objective of this study was to evaluate the impact of CBNCP on six essential practices to
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30 improve neonatal health in pilot districts compared to propensity score-matched comparison
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32 districts.
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35 **Methods**

36 *Study setting and population*

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39 Nepal is characterised by three distinct geographies, i.e. *terai* or flatland, hill and mountain
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41 areas. The CBNCP was piloted in four hill and six *terai* districts, constituting the 'intervention
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43 area', to which we assigned a 'comparison area' (**Figure 1**). In both areas, one site was
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45 purposively selected for an additional qualitative component of the study; methods and findings
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47 of the latter are reported elsewhere.¹³
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53 <Figure 1 about here>

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55 The CBNCP targets all women of reproductive age, aiming to increase their interaction with the
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57 health system during pregnancy, delivery and the postnatal period. Our study was undertaken
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3 among women aged 15 to 49 years who had a live birth during 30 months pre-intervention
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5 compared to those with a live birth taking place during 7-14 months post-intervention in view of
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7 Demographic and Health Survey (DHS) data being available for this period.
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10 *Study design*

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13 This quasi-experimental study uses propensity score matching and multiple data sources to
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15 assess the impact of the CBNCP (**Figure 2**). It includes: a) before-after analysis of essential
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17 practices in the intervention vs. comparison area based on DHS data; b) before-after analysis of
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19 those same practices in the intervention vs. comparison area based on Health Management
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21 Information System (HMIS) data; and c) analysis of training coverage and knowledge and skills
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23 of healthcare providers based on Newborn Health Information System (NHIS) data, which was
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25 an integral part of the CBNCP pilot and available in the intervention area only.^{12 14}
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31 <Figure 2 about here>
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36 Drawing on the comprehensive evaluation framework for evaluating the scale-up for maternal
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38 and child survival by Bryce and colleagues,¹⁵ we developed a conceptual framework, which
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40 regards the CBNCP as a complex multi-component intervention^{16 17} and graphically presents the
41
42 presumed causal pathway from CBNCP implementation within the health system (process and
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44 outputs) through changed practices of pregnant or recently delivered women (outcomes) to
45
46 impacts on neonatal health (**Figure 3**). Importantly, while the CBNCP's main impetus is on
47
48 training of health workers, supplies of equipment and medicines as well as supervision and
49
50 follow-up, several of the outputs (e.g. taking a urine sample for proteinuria test) and outcomes
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52 (e.g. postnatal visits) could also be considered as components of the intervention. This
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54 conceptual framework was critical in our identification of relevant outcome variables.
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<Figure 3 about here>

Implementation of the CBNCP pilot through training of facility- and community-based health workers and FCHVs started in May 2009 and was completed in July 2010 in pilot districts (see **Table S1**). Training dates were obtained from the Ministry of Health (MOH) to define district-specific pre- and post-intervention periods used in the analysis of DHS and HMIS data; any births taking place during training were excluded from the analysis.

Propensity score matching

Propensity score matching is widely used to estimate the effects of health and other policy interventions, where RCTs are not feasible.^{18 19} It uses statistical techniques to construct a comparison group that is as similar as possible to the intervention group in an effort to reduce selection bias.^{20 21}

Ten intervention districts were selected by the MOH in consultation with donors, considering development need, donor presence, district interest and ability to implement and monitor the programme (personal communication, Parashuram Shrestha, Nepal Ministry of Health). To reflect the propensity of a district to be selected for CBNCP implementation, we constructed a propensity score based on (i) the four components of the district human development index (HDI) value; ii) presence of donors involved in the CBNCP (i.e. USAID, UNICEF, SNL); iii) percentage rural population; iv) the MOH district performance rank; and v) road density) (see **Table 1** for details).

As CBNCP implementation was limited to hill and *terai* districts, mountain districts were excluded. We used the *psmatch2* command in Stata Special Edition 12²² to identify suitable comparison districts based on the nearest-neighbour method without replacement. We checked for balance in the distribution of propensity score components (using t-tests) and population and

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3 health infrastructure characteristics (using Chi-square tests) between intervention (10 districts
4 pooled) and comparison areas (10 districts pooled).
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8 *Data sources and variables*

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11 Multiple data sources were used to enable as complete an analysis of impact as possible and to
12 triangulate information between sources with different strengths and weaknesses. The DHS
13 provides nationally representative data on fertility, health-relevant behaviours and childhood
14 mortality based on a multi-stage cluster random sampling strategy.²³ The data for the Nepal
15 DHS for 2011 are in the public domain (www.dhsprogram.org). The HMIS, owned by the MOH
16 and primarily based on health facility records, provides information about health service
17 utilisation, morbidity and mortality, treatment outcomes and the availability of commodities. We
18 used data on regular service delivery for 2009-2011, publicly available at www.dohs.gov.np. We
19 also obtained CBNCP-specific NHIS data from the CBNCP secretariat based at the Child Health
20 Division at the MOH.²⁴ These NHIS data were collected by the programme team as part of
21 CBNCP delivery and monitoring, and provided insights about the knowledge and skills of
22 programme-trained health workers and FCHVs.
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38 Neonatal mortality as the ultimate outcome of interest was not feasible to assess given available
39 data sources and sample sizes. Instead, with reference to our conceptual framework (**Figure 3**)
40 we examined changes in six essential practices to improve neonatal health by incorporating
41 relevant contributing practices in combined binary outcomes (coded as “better practices” or
42 “poorer practices”). Relevant covariates were identified *a priori* as family characteristics (i.e.
43 wealth quintile, rural vs. urban location, caste/ethnicity); maternal characteristics (i.e. age at
44 delivery, education and access to media) and child characteristics (i.e. sex, parity). (see **Table 2**
45 for details.)
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55 *Analysis*

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3 Difference-in-differences analysis estimates the change in outcome for the intervention area
4 over a given time period by subtracting any change in outcome for the comparison area over the
5 same time period. All outcomes were assessed as combined outcomes, i.e. as the percentage
6 of pregnant or recently delivered women adhering to 'better practices'.²⁵ Analyses for individual
7 outcomes are provided as background information in **Table S2**.
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15 For DHS data, difference-in-differences analysis using Ordinary Least Square (OLS) regression
16 was conducted for births occurring pre- and post-intervention. Where a woman had given birth
17 more than once during the pre- or post-intervention period only the most recent birth was
18 included in the analysis to avoid non-independence of observations and to minimise recall bias.
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20 For HMIS data, a similar approach was adopted, however, tests of significance were not
21 possible as the data were available only in aggregate at the district level. We also conducted
22 logistic regression analysis of DHS data to examine if any differences between intervention and
23 comparison areas persist after adjustment for all *a priori* identified covariates; here the outcome
24 was assessed at the individual level as either adhering or not adhering to 'better practices'. All
25 analyses were undertaken in Stata Special Edition 12.²²
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37 *Ethical considerations*

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40 Ethical approval was obtained from the Nepal Health Research Council.
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Findings

Baseline characteristics

Table 1 shows that intervention and comparison areas are balanced for propensity score components as well as relevant population and health infrastructure characteristics.

<Table 1 about here>

Using pre-intervention DHS data, 533 and 347 births took place in the intervention and comparison area respectively. **Table 2** compares outcome variables and covariates for the most recent births in the five years preceding the DHS survey. In both areas, a majority of children are from rural locations, disadvantaged families, and born to a mother with at least primary education. While respondents from intervention and comparison areas are largely comparable, there are statistically significant baseline differences in relation to family wealth status, maternal age at delivery and delivery by a skilled birth attendant even after matching.

<Table 2 about here>

Intervention coverage

In the ten pilot districts, a majority of health providers were trained, i.e. 1615 facility-based health workers, 902 community-based health workers and 7072 FCHVs. Overall, knowledge and skills as reported or demonstrated were fair with some variation by type of provider; availability of drugs and commodities was also good (**Table 3**). All of these, however, showed much variation between districts, pointing to concerns with respect to quality of training, supervision and logistics (see **Table S3**).¹³

<Table 3 about here>

Difference-in-differences analysis

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3 **Table 4** presents findings from the difference-in-differences analysis of DHS data. With the
4 exception of birth preparedness (no change) and postnatal care within 48 hours (increase in
5 intervention area, decrease in comparison area), improvements were observed but to a similar
6 extent in both areas with no statistically significant differences. For all six essential practices the
7 percentage of pregnant or recently delivered women adhering to better practices was lower in
8 the comparison area at both points in time.
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20 Similarly, difference-in-differences analysis of HMIS data showed improvements in both
21 intervention and comparison areas for most of the practices assessed; ¹³ HMIS does not provide
22 information on birth preparedness or immediate newborn care practices. **Table 5** compares
23 findings based on DHS and HMIS data, showing congruent trends for all essential practices
24 despite differences in the specification of some indicators. The contradictory finding that iron
25 supplementation decreased post-intervention in the HMIS (which collects data from public
26 service providers) but not in the DHS analysis (which reflects households seeking care from
27 both public and private providers) is explained by government health facilities having run out-of-
28 stock in October and November 2011.
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41 <Table 5 about here>
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44 *Logistic regression analysis*

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46 The unadjusted odds ratios suggest statistically significant improvements in antenatal care
47 quality (OR 1.8, 95% CI 1.1-2.9), delivery by a skilled birth attendant (OR 2.0, 95% CI 1.2-3.3)
48 and postnatal care within 48 hours (OR 2.7, 95% CI 1.1-2.6) but not in the other three essential
49 practices (**Figure 4**). However, when adjusted for *a priori* identified covariates none of the
50 changes in essential practices remained statistically significant.
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<Figure 4 about here>

Discussion

Key findings and their explanation

Nepal's CBNCP was developed based on existing studies, mostly from Nepal and South Asia to ensure relevance to the country- or region-specific epidemiology, demonstrating effectiveness for a majority of the intervention components¹⁴. The choice of interventions for integration within the package was driven by both effectiveness and feasibility considerations. However, there was no evidence for the effectiveness of the package as a whole¹², and the additional feasibility challenges of implementation at scale were probably not given sufficient attention.

The analysis of DHS and HMIS data suggests that the CBNCP did not have a significant impact on essential practices to improve neonatal health above a generally increasing trend in these practices. These findings must be interpreted with caution, given the relatively short time period between training health workers and FCHVs, which ranged from 7 to 14 months depending on the district, and assessment of relevant outcomes among programme beneficiaries. In light of the complex nature of the programme, where multiple components are intended to improve a whole range of health provider and population behaviours throughout pregnancy, delivery and the post-partum period, the present evaluation represents a very early assessment of potential impact.

Several factors are likely to interplay in explaining this current lack of impact.

Packaging of multiple interventions: The CBNCP bundled a range of specific measures in a complex package and implemented this across a large geographical area with an implementation modality largely dependent on the existing health system. In Nepal, the health system suffers from a number of problems and there is strong reliance on FCHVs. In contrast, prior studies, concerned with efficacy or effectiveness under real-world conditions, usually

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3 examined a single and relatively simple component (e.g. chlorhexidine for cord care²⁶) in a
4 limited geographic area (e.g. MIRA²⁷), implemented through a dedicated cadre of higher-level
5 service providers (e.g. SEARCH²⁸) or undertaken as a distinct research project (e.g.
6 resuscitation²⁹). It is therefore not surprising that the effectiveness of these interventions is
7 diluted when merged in a package that is delivered by a lower-level service provider under “real
8 life” conditions. Indeed, a similar reduction of effectiveness when moving from research studies
9 to large-scale implementation has been observed elsewhere.^{16 30 31} When going to scale,
10 programme management, effective high coverage and a good match between community- and
11 facility-based service improvements is seen as critical.³²⁻³⁴

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14 *Health care providers and their training:* The CBNCP was implemented through training of the
15 existing cadre of facility- (seven days) and community-based (five days) health workers in the
16 government system as well as FCHVs (seven days) with limited subsequent supervision and
17 follow-up. Supervision is one of the most important elements of successful programmes, but
18 also one of the most challenging programme elements to implement and assess. As a general
19 indication, the Nepal Health Facility Survey³⁵ reported that nearly seven in ten health facility
20 based workers received any kind of supervision visits during the previous six months.
21 Comprehensive information on the extent and content of supervision in the context of the
22 CBNCP is lacking but anecdotal reports indicate concerns with respect to the frequency and
23 effectiveness of supervision visits. While evidence from Nepal suggests that community health
24 workers and FCHVs can identify and manage maternal and newborn health problems, this
25 requires frequent training and mentoring.³⁶ This study suggests much variation in programme
26 performance across districts (see **Table S3**), generally indicating better results in areas where
27 the CBNCP is implemented with more intensity. In addition, the qualitative component showed
28 that service providers perceived the training as insufficient for them to be able to apply their
29 skills confidently and to retain them over prolonged periods of time.¹³ Therefore, following the
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3 argument made by Kumar et al³⁷ that the effectiveness of an intervention is constrained by the
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5 weakest link in the causal-intervention pathway, the amount of training and subsequent
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7 supervision for this complex intervention package are likely to have been insufficient to promote
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9 meaningful behaviour change. Moreover, in a setting where medical shops are perceived to be
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11 more convenient than government health facilities,^{35 38} a programme that does not involve
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13 private providers is likely to show limited impact. In relation to antenatal services, private
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15 providers often provide specific components of those services (e.g. iron folic acid supplement)
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17 and on-call services.
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22 *Other relevant health initiatives:* In the last decade, Nepal has witnessed a host of programmes
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24 to improve maternal and child health, with many of these directly or indirectly impacting neonatal
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26 health.² As adjustment for other relevant ongoing initiatives was not feasible in design or
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28 analysis of this impact study, the observed trends in essential practices to improve neonatal
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30 health and the lack of CBNCP impact in intervention relative to comparison areas are in part
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32 likely to be due to the high level of background activity.
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35 36 *Implications for research and practice*

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39 Overall, this study highlights that the design, piloting and implementation of a complex
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41 intervention such as the CBNCP must be carefully planned and evaluated. In fact, the
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43 assumption that combining a large number of intervention components, even where their
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45 individual effectiveness has been proven, will yield an effective intervention package that can be
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47 successfully implemented at scale does not hold. Importantly, evaluating under “real life”
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49 conditions is not necessarily straightforward, and may require the use of limited-quality routine
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51 data in combination with innovative study designs. Even though the CBNCP, as assessed
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53 through our study, was conceived as a pilot, rigorous assessment through the MOH and donors
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55 was lacking; despite increasing concerns about the quality of CBNCP implementation and a
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3 potential lack of impact, implementation continued and was rapidly extended beyond pilot
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5 districts.
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9 The findings presented here, supported by those of the qualitative component of the study,¹³
10 suggest that the programme may need a re-packaging and tightening of content as well as a
11 revision of its implementation modality. Components with high burden and greater effectiveness
12 (e.g. infections and care for low birthweight babies) should be strengthened, whereas
13 components with lower burden and less effectiveness (e.g. asphyxia) should be removed
14 especially for FCHVs. With respect to implementation modality, more emphasis must be placed
15 on focused, high-quality training of all involved healthcare providers and ongoing supervision
16 and support.
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27 The CBNCP has been scaled up to 39 districts of Nepal. The findings presented here, which
28 were previously shared with CBNCP stakeholders, and a move towards more integrated
29 approaches to improve child survival prompted a removal of selected components and
30 integration of CBNCP interventions with the Integrated Management of Neonatal and Childhood
31 Illness (IMNCI) programme. The IMCNI programme is currently being implemented in 35
32 districts and monitored in terms of programme coverage, quality and impacts on behaviours,
33 health and equity.
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44 **Authors' contributions**

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47 DP, IBS and ER had the original idea for this paper. DP carried out data analysis and prepared
48 the first draft. IBS, ER, MS advised on methods and interpretation of findings. IBS, ER, MS
49 reviewed and revised the draft manuscript. All authors, except IBS because of his untimely
50 demise during finalisation of this manuscript, read and approved the final manuscript.
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Acknowledgements

We would like to acknowledge the USAID-funded MEASURE DHS for providing us with the Nepal DHS dataset and the MoH for sharing HMIS data. DP undertook this analysis as part of his research under the PhD programme at the Munich Center for International Health and was funded through a scholarship offered by the German Academic Exchange Service. At the time, DP was an employee of USAID and was offered flexible working hours and time off to undertake this study as part of this PhD dissertation. The opinions expressed in this paper are those of the authors and do not necessarily reflect the views of USAID or the other organizations the authors are affiliated with. We would also like to thank Jamie Bartram, Steve Hodgins and Ulrich Mansmann for their helpful comments on a previous version of this manuscript as well as Mary Adam, Jennifer Callaghan-Koru, Matthew Ellis and Zelee Hill for their thorough review and constructive feedback on the originally submitted manuscript.

Funding

This study was undertaken without dedicated research funding but made possible through a PhD scholarship offered to DP by the German Academic Exchange Service. The study utilized DHS data in the public domain and HMIS data made available to the authors upon request. All data were processed and analyzed by the authors with DP having full access to the data and all authors sharing the final responsibility for the decision to submit for publication. Neither those providing us with the data nor the German Academic Exchange Service had any involvement in data analysis, interpretation or writing of this manuscript.

Competing interest

At the time of study, DP was an employee of USAID and involved in monitoring the CBNCP programme.

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Data sharing

Additional data is available in Supplementary information.

For peer review only

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Table 1 Background characteristics in intervention and comparison areas, based on various data sources

	Intervention area	Comparison area	t	p-value
Propensity score components				
Human Development Index: life expectancy (years) ¹	61.23	62.88	-0.76	0.457
Human Development Index: adult literacy (%) ¹	51.40	54.38	-0.73	0.475
Human Development Index: school enrolment (%) ¹	2.77	2.88	-0.33	0.742
Human Development Index: gross domestic product (PPP US\$) ¹	1293.6	1315.2	-0.15	0.883
Urban population (%) ²	16.79	17.85	-0.25	0.803
District performance score (average) ³ (as a proxy for a district's leadership ability and pro-activeness in implementing new initiatives)	74.25	73.77	0.28	0.781
Road density (km/square km) ² (as a measure of access and ability to monitor the programme)	0.251	0.258	-0.07	0.941
Donor presence (average number) ⁴	1.3	1.4	0.25	0.806
Population and health infrastructure characteristics⁵				
Population	4.9 million	4.4 million		
Expected pregnancies (#)	142,000	128,000		
Number of hospitals	14	11		
Number of primary health care centres	39	39		
Number of health posts	87	89		
Number of sub-health posts	435	456		
Number of private health institutions	49	38		
Number of birthing centres	203	183		
Population per birthing centre	24,159	24,330		
Number of FCHVs	6,903	7,378		
Population per FCHV	710	603		

Data sources:

¹UNDP. Nepal Human Development Report, Kathmandu, Nepal, 2004²District Profile of Nepal 2007/08: A socio-economic development database of Nepal, Intensive Study and Research Center of Nepal, Kathmandu, 2009.³MOH. District Annual Performance Criteria, personal communication, Ghanashyam Pokharel, 2011⁴AIN. Health Mapping Report, Association of International NGOs in Nepal, Kathmandu, 2008⁵Health Management Information System database, made available on request by Management Division, 2010

Table 2 Baseline characteristics in intervention and comparison areas (in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data

		Intervention area (n=533)	Comparison area (n=347)	χ^2	p-value
Family characteristics					
Location	Rural	86.0	85.6	0.02	0.929
Wealth index	Poorer ¹	31.4	51.7	44.09	0.003
Caste and ethnicity	Disadvantaged ²	74.0	70.6	1.05	0.673
Maternal characteristics					
Education	No education ³	36.5	45.0	24.82	0.072
Age at delivery	Higher risk age group ⁴	31.9	23.0	6.92	0.022
Access to media	No ⁵	51.4	65.4	14.34	0.101
Child characteristics					
Sex	Female	45.7	49.0	1.98	0.187
Parity	Higher risk parity ⁶	56.5	51.1	2.12	0.211
Essential practices to improve neonatal health					
Birth preparedness	Better practices ⁷	6.2	4.9	0.63	0.568
Antenatal care seeking	Better practices ⁸	33.7	26.4	4.39	0.218
Antenatal care quality	Better practices ⁹	36.0	29.0	3.87	0.195
Delivery by skilled birth attendant	Yes ¹⁰	46.7	31.2	17.61	0.007
Immediate newborn care	Better practices ¹¹	74.4	64.3	8.63	0.091
Postnatal care within 48 hours	Yes ¹²	33.7	26.8	3.97	0.097

¹ Poorer: includes poorer and poorest quintiles i.e. lowest 40% in wealth ranking based on selected household assets.

² Disadvantaged caste and ethnicity: includes hill dalit, terai dalit, hill janajati, terai janajati, other terai caste, and Muslim.

³ No education: includes illiterates and those without any formal education but may have some literacy classes.

⁴ Higher risk group: those who delivered before 20 years or after 35 years

⁵ No access to media: those reporting not listening or watching any public health radio or television programme in the last month

⁶ Higher risk parity: First or more than third parity

⁷ Birth preparedness: combined variable including saving money, organising transportation, finding a blood donor, identifying a health worker to assist with the delivery and purchasing a safe delivery kit; coded as "better practices" if at least two items are fulfilled.

⁸ Antenatal care seeking: combined variable comprising number of antenatal visits (four or more), taking iron supplements(>90 tablets) and having been vaccinated against tetanus (at least two doses); coded as "better practices" if all items are fulfilled.

⁹ Antenatal care quality: combined variable comprising whether the woman had her blood pressure taken, a urine and/or blood sample collected, and was told about pregnancy complications and where to go in case of complications; coded as "better practices" if at least four items are fulfilled.

¹⁰ Delivery by skilled birth attendant: defined as delivery by a doctor, nurse or midwife at home or at a health institution.

¹¹ Immediate newborn care: combined variable comprising delayed bathing for 24 hours, drying, wrapping, placing the baby on the mother's breast or belly, applying chlorohexidine or nothing on the umbilical cord, and initiation of breastfeeding within one hour of birth; coded as "better practices" if at least three items are fulfilled.

¹² Postnatal care within 48 hours: defined as any newborn examination by a health worker or FCHV within 48 hours of birth.

Table 3 Intervention process indicators, based on NHIS data

	Unit	Facility-based health worker	Community health worker	Female community health volunteer
Training coverage				
Number of individuals trained	Number	1615	902	7072
Knowledge				
Knowledge of immediate newborn care messages (i.e. thermal care, clean cord, skin-to-skin contact, immediate breastfeeding and delayed bathing)	% (sd)	70 (17.6)	62 (12.4)	57 (24.3)
Knowledge of correct dose of cotrimoxazole paediatric tablet	% (sd)	88 (11.5)	91 (5.6)	82 (16.5)
Skills				
Ability to demonstrate hand washing correctly	% (sd)	81 (9.8)	68 (17.1)	60 (14.3)
Ability to demonstrate resuscitation steps correctly using a doll	% (sd)	53 (19.6)	37 (17.0)	27 (17.7)
Availability of drugs and commodities				
Cotrimoxazole paediatric tablet	% (sd)	99 (1.6)	87 (12.6)	89 (10.2)
Gentamicin	% (sd)	95 (5.1)	78 (16.9)	--
Thermometer	% (sd)	--	--	85 (9.9)

Table 4 Difference-in-differences analysis for six essential practices to improved neonatal health (combined outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data¹

		Intervention area			Comparison area			Diff. in differences	p-value
		Before (n=533)	After (n=168)	Diff.	Before (n=347)	After (n=104)	Diff.		
Birth preparedness	Better practices	6.2	8.4	2.2	4.8	6.0	1.2	1.0	0.810
Antenatal care seeking	Better practices	33.7	49.7	16.0	26.4	33.2	6.8	9.2	0.383
Antenatal care quality	Better practices	47.4	59.9	12.5	34.8	37.8	3.0	9.5	0.290
Delivery by skilled birth attendant	Yes	46.7	57.7	11.0	31.2	37.6	6.4	4.6	0.577
Immediate newborn care	Better practices	74.4	85.9	11.5	64.2	79.9	15.7	-4.2	0.605
Postnatal care within 48 hours	Yes	33.7	44.6	10.9	26.8	17.4	-9.4	20.3	0.036

¹ See **Table 2** for details on variables.

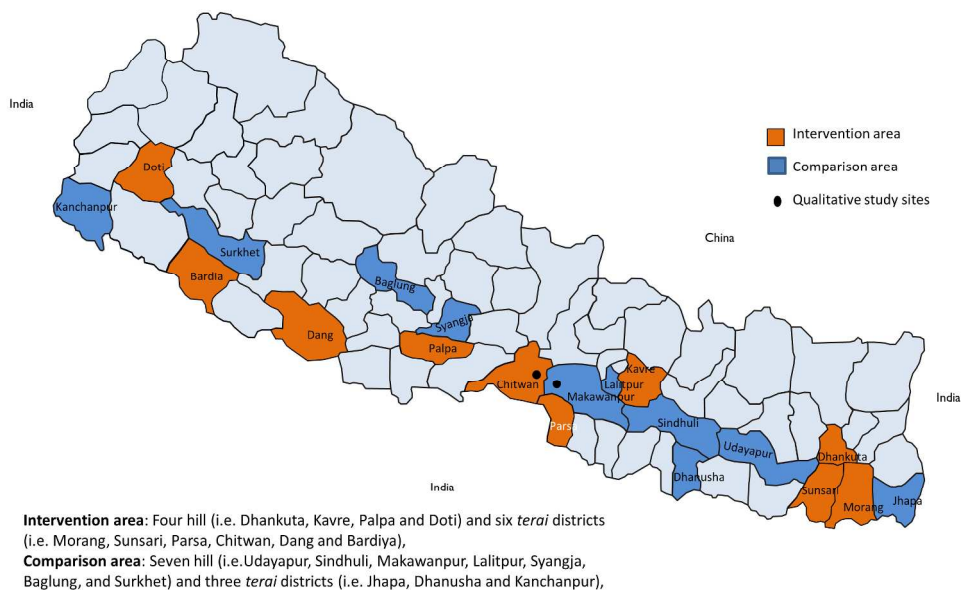
Table 5 Comparison of difference-in-differences analysis for selected antenatal, delivery and postnatal indicators (in percent), between DHS and MIS data

Essential practices to improve neonatal health ¹	DHS					HMIS				
	Intervention		Comparison		Difference -in- differences	Intervention		Comparison		Difference -in- differences
	Before	After	Before	After		Before	After	Before	After	
Birth preparedness (combined)	6	8	5	6	1	-	-	-	-	-
Antenatal care seeking: Antenatal care contact (at least one)	63	70	53	64	-4	69	81	73	78	7
At least four ANC visits	52	64	41	56	-3	36	43	35	46	-4
Iron tablet taken	78	87	77	80	6	74	62	73	58	3
Antenatal care quality (combined)	42	45	41	41	3	-	-	-	-	-
Delivery by skilled birth attendant	47	58	31	38	4	27	38	25	36	0
Immediate newborn care	74	85	69	79	1	-	-	-	-	-
Postnatal care within 48 hours	34	45	27	17	21	44	54	41	45	6

¹ See Figure 3 for details on variables.

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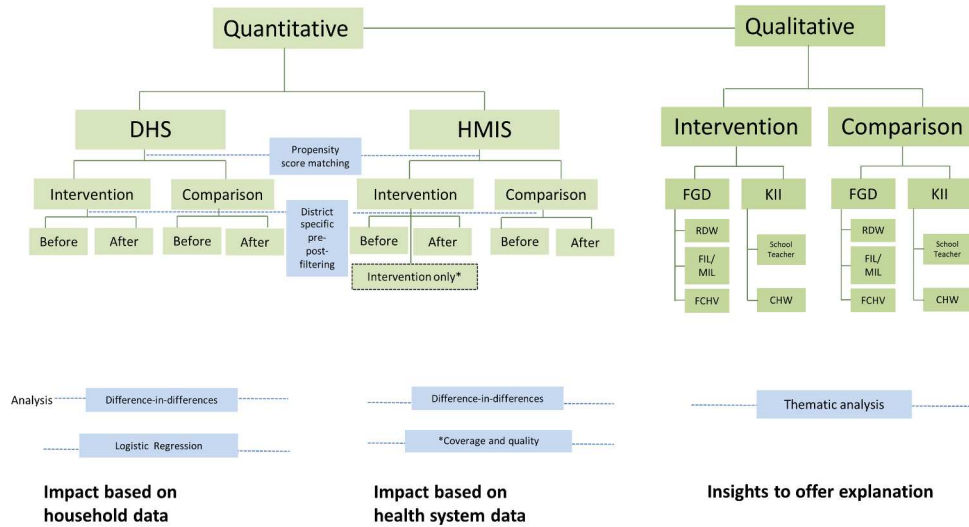
Figure 1 Map of Nepal showing intervention and comparison areas and qualitative study sites



Map of Nepal showing intervention and comparison areas and qualitative study sites

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Figure 2 Study design comprising quantitative and qualitative components



Abbreviation:

DHS: Demographic and Health Survey; **HMIS:** Health Management Information System; **FGD:** Focus Group Discussion; **KII:** Key Informant Interviews; **RDW:** Recently Delivered Women; **FIL:** Father-in-laws; **MIL:** Mother-in-laws; **FCHV:** Female Community Health Volunteer; **CHW:** Community Health Worker

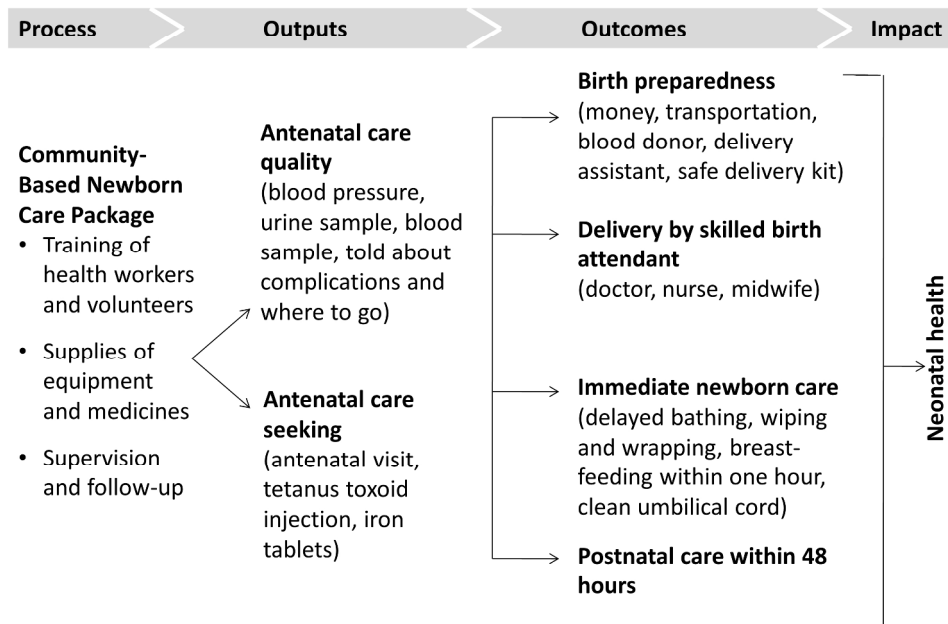
Study design comprising quantitative and qualitative components

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Figure 3 Conceptual framework

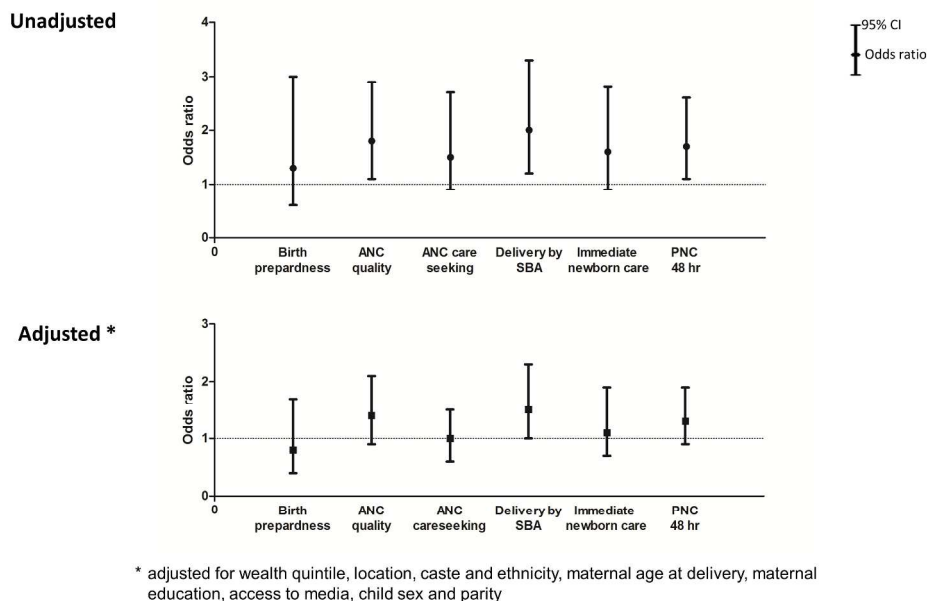


Conceptual framework

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Figure 4 Impact of CBNCP on six essential practices to improve neonatal health, based on logistic regression analysis of DHS data



Impact of CBNCP on six essential practices to improve neonatal health, based on logistic regression analysis of DHS data

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

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Supplementary Information

Table S1

CB NCP Training Outputs

District specific training start and end dates, DHS data collection dates, number of health workers trained and supporting agency

District	Training start date (month/year)	Training end date (month/year)	DHS data collection (month/year)	Exposure period (months)	# CHWs trained	# FCHVs trained	# facility-based HWs trained	Supporting agency
Bardiya	5/2009	12/2009	2-3/2011	14	56	842	132	SAVE
Chitwan	4/2010	7/2010	2-3/2011	7	74	340	136	UNICEF
Dang	11/2009	4/2010	4-6/2011	12	62	840	179	UNICEF
Dhankuta	4/2010	7/2010	3-4/2011	8	60	315	91	GON
Doti	6/2009	7/2010	5-6/2011	10	84	653	127	CARE
Kavre	11/2009	7/2010	6/2011	11	128	923	244	UNICEF
Morang	4/2010	7/2010	2-3/2011	7	114	594	184	GON
Palpa	4/2010	7/2010	4/2011	9	93	585	130	GON
Parsa	5/2009	7/2010	2-3/2011	7	132	999	231	PLAN
Sunsari	5/2009	2/2010	2-3, 5-6/2011	12	99	981	161	PLAN
TOTAL	--	--		7-14	902	7072	1615	

DHS: Demographic and Health Survey; CHW: community health worker; FCHV: female community health volunteer; HW: health worker; SAVE: Save the Children; GON: Government of Nepal; UNICEF: United Nations Children Fund; CARE: CARE International; PLAN: Plan International

Table S2
Difference-in-differences analysis for key practices to improved neonatal health (specific and aggregate outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data

		Intervention area			Comparison area			Diff. of differences	p-value
		Before (n=533)	After (n=168)	Diff.	Before (n=347)	After (n=104)	Diff.		
Saved money	Yes	37.6	39.7	2.1	28.0	37.3	9.3	-7.2	0.419
	No	62.4	60.3		72.0	62.7			
Arranged transport	Yes	3.8	6.7	2.9	3.7	7.6	3.9	-1.1	0.835
	No	96.2	93.3		96.3	92.4			
Found blood donor	Yes	0.7	1.4	0.7	0.0	0.0	0.0	0.7	na
	No	99.3	98.6		100.0	100.0			
Identified health worker	Yes	1.2	0.7	-0.5	0.2	0.0	-0.2	-0.3	0.622
	No	98.8	99.3		99.8	100.0			
Bought safe delivery kit	Yes	1.2	0.7	-0.5	2.4	0.2	-2.2	1.6	0.167
	No	98.8	99.3		97.6	99.8			
At least one ¹ preparation	Yes	42.4	44.6	2.2	31.5	39.1	7.6	-5.4	0.575
	No	57.6	55.4		68.5	60.9			
Birth preparedness² (combined)	Better	6.2	8.4	2.2	4.8	6.0	1.2	1.0	0.810
	Poorer	93.8	91.6		95.2	94.0			
Antenatal care by skilled provider	Yes	62.6	69.6	7.0	53.4	64.5	11.1	-4.1	0.607
	No	37.4	30.4		46.6	35.5			
Antenatal care visits, four or more	Yes	52.4	64.5	12.1	40.8	55.7	15.0	-2.8	0.813
	No	47.6	35.5		59.2	44.3			
Iron tablets taken	Yes	78.5	87.2	8.7	76.7	80.0	3.4	5.3	0.305
	No	21.5	12.8		23.3	20.0			
TT2 taken	Yes	74.5	75.7	1.2	68.6	63.8	-4.8	6.0	0.371
	No	25.5	24.3		31.4	36.2			
Blood pressure measured ³	Yes	75.8	85.4	9.6	71.5	81.0	9.6	0.0	0.998
	No	24.2	14.6		28.5	19.0			
Urine sample taken ³	Yes	54.1	65.0	10.9	42.5	46.7	4.2	6.8	0.351
	No	45.9	35.0		57.5	53.3			
Blood sample taken ³	Yes	42.0	48.7	6.7	36.5	42.0	5.5	1.2	0.897
	No	58.0	51.3		63.5	58.0			
Told about pregnancy complications ³	Yes	64.5	77.9	13.4	56.9	54.1	-2.8	16.2	0.15
	No	35.5	22.1		43.1	45.9			
Told about where to go in complications	Yes	65.5	78.2	12.7	55.1	53.8	-1.4	14.0	0.164
	No	34.5	21.8		44.9	46.2			
Antenatal care quality – at least one ⁴	Yes	36.0	43.8	7.8	29.0	30.9	1.9	5.9	0.524
	No	64.0	56.2		71.0	69.1			
ANC care seeking⁵ (combined)	Better	33.7	49.7	16.0	26.4	33.2	6.8	9.2	0.383
	Poorer	66.3	50.3		73.6	66.8			
ANC quality⁶ (combined)	Better	47.4	59.9	12.5	34.8	37.8	3.0	9.5	0.290
	Poorer	52.6	40.1		65.2	62.2			

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Table S2 (continue)									
Difference-in-differences analysis for key practices to improved neonatal health (specific and aggregate outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data									
Delivery at health institution	Yes	42.9	60.3	17.4	30.5	42.0	11.6	5.8	0.488
	No	57.1	39.7		69.5	58.0			
Delivery attended by SBA⁷	Yes	46.7	57.7	11.0	31.2	37.6	6.4	4.6	0.577
	No	53.3	42.3		68.8	62.4			
Bathed after 24 hours ⁸	Yes	58.1	74.9	16.9	46.7	57.6	10.9	6.0	0.492
	No	42.0	25.1		53.3	42.4			
Dried before placenta delivered ⁸	Yes	75.3	83.9	8.6	70.6	74.2	3.6	5.0	0.601
	No	24.7	16.1		29.4	25.8			
Wrapped in cloth ⁹	Yes	80.2	82.6	2.4	71.3	86.6	15.3	-12.9	0.072
	No	19.8	17.4		28.7	13.4			
Placed in belly or breast ⁸	Yes	49.6	66.3	16.7	41.6	57.4	15.7	1.0	0.888
	No	50.4	33.7		58.4	42.6			
Applied nothing or only CHX on the cord ⁸	Yes	71.2	87.5	16.3	65.9	72.9	7.1	9.2	0.277
	No	28.8	12.5		34.1	27.1			
Initiated breastfeeding within one hour ⁸	Yes	47.8	51.2	3.5	40.5	53.6	13.2	-9.7	0.228
	No	52.2	48.8		59.5	46.4			
Immediate newborn care⁹	Better	74.4	85.9	11.5	64.3	79.9	15.7	-4.2	0.605
	Poorer	25.6	14.1		35.8	20.1			
Postnatal care within 48 hours	Yes	33.7	44.6	10.9	26.8	17.4	-9.4	20.3	0.036
	No	66.3	55.4		73.2	82.6			

¹ At least one among: money, transport, blood donor, identified health worker, bought safe deliver kit

² Birth preparedness: is defined as "better practices" if at least any two preparations are arranged, and as "poorer practices" if less than two or no preparation among: money, transport, blood donor, identified health worker, bought safe deliver kit

³ These information were asked only for the women who received antenatal care, thus it was assumed that those who didn't receive care didn't receive these services as well

⁴ At least one among blood pressure, urine sample, blood pressure, told about pregnancy complication and told about where to go in complication

⁵ ANC care seeking is defined as "better practices" if all of the following were fulfilled and "poorer practices" if any of these were not fulfilled: ANC four or more visits, iron tablets (>90 tablets) taken, at least two doses of tetanus toxoid taken

⁶ ANC quality is defined as "better practices" if at least four of following five items were fulfilled and "poorer practices" if less than four items were fulfilled: blood pressure, urine sample, blood sample, told about pregnancy complication and told about where to go in complication

⁷ SBA (Skilled Birth Attendant): includes doctor, nurse and midwife

⁸ These information was asked only for home births and it was assumed that these practices were followed in case of institutional deliveries.

⁹ Immediate newborn care has been defined as "better" if at least three of the following were fulfilled and "poorer" if less than three were fulfilled among: delayed bathing, dried, wrapped, placed in belly or breast, applied nothing or only Chlorhexidine and initiated breastfeeding within one hour of birth

Box 1 CBNCP programme components

- i. **Program planning and orientation:** This includes orientation of stakeholders on training overview, changes in roles and responsibilities of providers and supervisors, reporting and service delivery, required support from different stakeholders at local, district and national level. A detailed program implementation and monitoring plan per district prepared after the orientation
- ii. **Training/human resource:** Five different training packages were prepared: Master Training of Trainers and Training of Trainers (7+2 days), Service Providers from Health Facilities (5 days), Outreach Service Providers (7 days), Female Community Health Volunteers (5 days) and Program managers (2 days)

Training content and service provision requirement covered following components:



behavior change communication for birth preparedness and newborn care



promotion of institutional or clean home delivery



postnatal care to promote essential newborn care



community-based diagnosis and management of possible infection



care of low birth weight newborns



prevention and management of hypothermia



recognition, initial stimulation and resuscitation for asphyxia

- iii. **Supervision, monitoring and evaluation:** Utilizing existing and regular supervision and monitoring approach topped up with additional pilot phase intensive supervision from center, region, district and health facility level. Use of IMCI tools and additional CB NCP pilot tools (six forms CB NCP 1-6). Monthly review meeting with FCHVs at HF level, trimester review meeting at *llaka* level with HF providers, semi-annual review meeting at district level with all HFs. Additional regional and national review meetings.
- iv. **Logistics and supply chain management:** Ensuring regular availability of key drugs and commodities (e.g. gentamycin injection, insulin syringe, De Lee suction tube, clean delivery kit, bag-and-mask, acute respiratory infection (ARI) timer, cotrimoxazole pediatric tablets) at district, health facility and volunteer level
- v. **Communication:** Community and social mobilization, behavioral change communication, mass media, advocacy.
- vi. **Pay for performance:** Performance based (based on number of cases treated by a group of volunteers) incentives for volunteers to compensate for their effort during very specific and demanding period (primarily counselling on birth preparedness, being present on the day of delivery, follow up visits on day 3, 7 and 28 days)

Source and further details:

Pradhan YV, Upreti SR, KC NP, et al. Fitting Community Based Newborn Care Package into the health systems of Nepal. J Nepal Health Res Counc 2011;9(2):119-28.

Table S3

Health providers' knowledge and skills

Percentage of health providers with correct knowledge of essential newborn care and dose of cotrimoxazole paediatric tablets to treat newborn babies with infections and ability to demonstrate hand washing and birth asphyxia steps as outlined in CBNCP training package based on NHIS data

District	Know all 5 essential newborn care messages ¹			Know correct dose of cotrimoxazole paediatric tablet ²			Demonstrate correct hand washing			Demonstrate management of birth asphyxia (using doll)		
	HW	CHW	FCHV	HWs	CHWs	FCHVs	HW	CHW	FCHV	HWs	CHWs	FCHVs
Bardiya	76	56	80	98	95	97	81	65	67	47	43	39
Chitwan	43	46	49	58	78	69	71	51	58	76	61	39
Dang	95	80	90	93	90	97	86	81	69	48	30	52
Dhankuta	87	57	37	89	96	86	67	42	58	61	39	47
Doti	na	na	na	82	95	84	76	57	38	43	24	9
Kavre	62	56	18	91	92	82	86	66	52	48	30	20
Morang	86	82	84	91	94	97	97	85	63	88	66	--
Palpa	70	59	61	90	87	59	73	70	55	42	23	19
Parsa	51	51	38	86	88	53	90	96	92	22	17	1
Sunsari	59	67	55	98	95	97	--	--	50	--	--	18
Mean (unweighted)	70	62	57	88	91	82	81	68	60	53	37	27

¹Five ENC messages: immediate drying; maintain skin-to-skin contact; apply nothing on cord; immediate breastfeeding; delayed bathing

²Correct dose of cotrimoxazole paediatric tablet: half a tablet twice daily for five days for newborns aged 0-28 days
CHW: community health worker; FCHV: female community health volunteer; HW: health worker.

Data source: Assessment of the community-based newborn care package (August 2012)

STROBE Statement—checklist of items that should be included in reports of observational studies

Checklist for Paudel D et al for BMJ Open Research Article

	Item No	Recommendation	Reported in the manuscript in line number below
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1-2, line 1-60
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2, line 1-60
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, line 28-30
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6, line 10-30
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, line 40-50
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Page 5, line 55-60 Page 6, line 1-10
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 8, line 10-55
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of	Page 8, line 10-55

		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	<i>Page 9, line 15-35</i> <i>Page 3, line 10-35</i>
Study size	10	Explain how the study size was arrived at	<i>Page 7, line 48-60,</i> <i>Page 8 line 3-6</i>
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	<i>155-165</i>
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	<i>Page 9, line 1-35</i>

Continued on next page

Results			<i>Reported in the manuscript in line number below</i>
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	<i>Page , line 42 – Page 6, line 56 Page 29-30</i>
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	<i>Page 29-30</i>
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	<i>Page 10-11 Page 22-26, 30</i>
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	<i>Not applicable</i>
Discussion			
Key results	18	Summarise key results with reference to study objectives	<i>Page 12, line 10-45</i>
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	<i>Page 12, line 46-Page 14, line 35</i>
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	<i>Page 12, line 46-Page 14, line 35</i>
Generalisability	21	Discuss the generalisability (external validity) of the study results	<i>Page 14, line 40 - Page 15, line 40</i>
Other information			

1
2 Funding 22 Give the source of funding and the role of the funders *Page 16, line 35-50*
3 for the present study and, if applicable, for the
4 original study on which the present article is based
5

6
7 *Give information separately for cases and controls in case-control studies and, if applicable, for exposed and
8 unexposed groups in cohort and cross-sectional studies.
9

10 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
11 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
12 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
13 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
14 available at www.strobe-statement.org.
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015285.R2
Article Type:	Research
Date Submitted by the Author:	21-Aug-2017
Complete List of Authors:	Paudel, Deepak; United States Agency for International Development; Ludwig Maximilians University, Center for International Health Shrestha, Ishwar; Tribhuvan University Institute of Medicine Siebeck, Matthias; Ludwig-Maximilians-Universitat Munchen Rehfuess, Eva; University of Munich, Institute for Medical Informatics Information Processing, Biometry and Epidemiology, Pettenkofer School of Public Health; Center for International Health, LMU Munich
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Evidence based practice, Public health
Keywords:	Neonatal health, Community health worker, Complex health intervention, Quasi-experimental, Propensity score, Nepal

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3 **Impact of the Community-Based Newborn Care Package in Nepal: a quasi-**
4 **experimental evaluation**
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35 **Word count, Tables, Figure:**

36
37 Abstract: 248 (max 250)
38
39 Introduction: 445
40
41 Methods: 1253
42
43 Findings: 480
44
45 Discussion: 1282
46
47 Total words: 3460 (max 4000, manuscript text only)
48
49 Tables: 5
50
51 Figures: 4
52
53 References: 38
54
55 Supplementary Information: 3 tables and 1 box
56
57
58
59
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Abstract

Objective: To evaluate the impact of the Community-Based Newborn Care Package (CBNCP) on six essential practices to improve neonatal health.

Methods: CBNCP pilot districts were matched to comparison districts using propensity scores. Impact on birth preparedness, antenatal care seeking, antenatal care quality, delivery by skilled birth attendant, immediate newborn care and postnatal care within 48 hours was assessed using Demographic and Health Survey (DHS) and Health Management Information System (HMIS) data through difference-in-differences and multivariate logistic regression analyses.

Findings: Changes over time in intervention and comparison areas were similar in difference-in-differences analysis of DHS and HMIS data. Logistic regression of DHS data also did not reveal any significant improvement in combined outcomes: birth preparedness, adjusted odds ratio (aOR)=0.8 (95% CI 0.4-1.7); antenatal care seeking, aOR=1.0 (0.6-1.5); antenatal care quality aOR=1.4 (0.9-2.1); delivery by skilled birth attendant, aOR=1.5 (1.0-2.3); immediate newborn care aOR=1.1 (0.7 – 1.9); postnatal care aOR=1.3 (0.9-1.9). Health providers' knowledge and skills in intervention districts were fair but showed much variation between different providers and districts.

Conclusions: This study, while representing an early assessment of impact, did not identify significant improvements in newborn care practices and raises concerns regarding CBNCP implementation. It has contributed to revisions of the package and it being merged with the Integrated Management of Neonatal and Childhood Illness programme. This is now being implemented in 15 districts and carefully monitored for quality and impact. The study also highlights general challenges in evaluating the impacts of a complex health intervention under "real life" conditions.

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3 **Key words:** neonatal health; community health worker; complex health intervention; quasi-
4 experimental; propensity score, Nepal
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10 **Strengths and limitations of this study**
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13 ▶ Adopting a “natural experiment” approach, we used multiple data sources and multiple
14 statistical methods as an important strategy to validate findings.
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17 ▶ The two datasets employed, the nationally representative cross-sectional DHS and the
18 public sector healthcare reporting system HMIS, each have their own strengths and
19 limitations but do not provide representative measures of coverage at population level.
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22 ▶ An *a priori* conceptual framework defined the outcomes of the intervention and guided the
23 analysis; along with other careful measures, such as excluding births taking place during
24 training, this was intended to minimise bias.
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27 ▶ Neonatal mortality as the ultimate outcome of interest could not be examined, as the
28 datasets employed were insufficient for examining rare events at district level.
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Introduction

While infant and child mortality in developing countries have declined rapidly in the past decades, newborn mortality has decreased much more slowly.¹ Nepal has demonstrated impressive reductions in child mortality of 76% since 1990 but over the same time period, neonatal mortality has decreased by only 50%.^{2,3} With 21 deaths per 1000 live births in year 2016, neonatal mortality now constitutes 54% of under-five deaths.⁴

Over two thirds of newborn deaths could be prevented with relatively low-cost, low-tech interventions.^{5,6} A systematic review based on five randomised controlled trials (RCTs) from South Asia concluded that visits during the antenatal and neonatal periods and home-based treatment for illness reduce the risk of neonatal deaths and improve neonatal care practices, with greater survival benefit when home visits are integrated with preventive and curative interventions.⁷ Similarly, other South Asian studies employing different programme components and delivery approaches demonstrate improvements in uptake of antenatal care, institutional delivery and newborn care.⁸⁻¹⁰ Consequently, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend home visits during the first week of life by appropriately trained and supervised community health workers to promote healthy behaviours and timely recognition of newborn illness, and to provide home treatment for infections and feeding problems.¹¹

Based on global, regional and national evidence, the Ministry of Health (MOH) combined seven community- and home-based interventions in the community-based newborn care package (CBNCP) to tackle major causes of neonatal mortality.¹² This programme comprises :i) behaviour change communication for birth preparedness and newborn care; ii) institutional delivery or clean home delivery through skilled birth attendants; iii) postnatal care; iv) care for low birth weight newborns; v) management of newborn infections; vi) prevention of hypothermia;

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3 and vii) recognition of asphyxia, initial stimulation and resuscitation. The programme is delivered
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5 through facility- and community-based health workers as well as the Nepal-specific cadre of
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7 female community health volunteers (FCHVs), and comprises training and supervision of the
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9 health workforce and provision of essential commodities. The package included seven days'
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11 training for facility-based health workers, five days' training for community-based health workers
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13 and seven days' training for FCHVs. Supervision and monitoring mostly utilises existing
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15 approaches, supplemented with pilot phase intensive supervision including, for example,
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17 monthly review meetings with FCHVs at the health facility level (see **Supplementary File, Box**
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19 **1 CBNCP programme components**)¹² The CBNCP was piloted in 10 out of 75 districts of
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21 Nepal in 2009 and 2010 with funding from MOH, the United States Agency for International
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23 Development (USAID), UNICEF and Saving Newborn Lives (SNL).
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28 The objective of this study was to evaluate the impact of CBNCP on six essential practices to
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30 improve neonatal health in pilot districts compared to propensity score-matched comparison
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32 districts.
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35 **Methods**

36 *Study setting and population*

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39 Nepal is characterised by three distinct geographies, i.e. *terai* or flatland, hill and mountain
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41 areas. The CBNCP was piloted in four hill and six *terai* districts, constituting the 'intervention
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43 area', to which we assigned a 'comparison area' (**Figure 1**). In both areas, one site was
44
45 purposively selected for an additional qualitative component of the study; methods and findings
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47 of the latter are reported elsewhere.¹³
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53 <Figure 1 about here>

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55 The CBNCP targets all women of reproductive age, aiming to increase their interaction with the
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57 health system during pregnancy, delivery and the postnatal period. Our study was undertaken
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3 among women aged 15 to 49 years who had a live birth during 30 months pre-intervention
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5 compared to those with a live birth taking place during 7-14 months post-intervention in view of
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7 Demographic and Health Survey (DHS) data being available for this period.
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10 *Study design*

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13 This quasi-experimental study uses propensity score matching and multiple data sources to
14
15 assess the impact of the CBNCP (**Figure 2**). It includes: a) before-after analysis of essential
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17 practices in the intervention vs. comparison area based on DHS data; b) before-after analysis of
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19 those same practices in the intervention vs. comparison area based on Health Management
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21 Information System (HMIS) data; and c) analysis of training coverage and knowledge and skills
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23 of healthcare providers based on Newborn Health Information System (NHIS) data, which was
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25 an integral part of the CBNCP pilot and available in the intervention area only.^{12 14}
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36 Drawing on the comprehensive evaluation framework for evaluating the scale-up for maternal
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38 and child survival by Bryce and colleagues,¹⁵ we developed a conceptual framework, which
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40 regards the CBNCP as a complex multi-component intervention^{16 17} and graphically presents the
41
42 presumed causal pathway from CBNCP implementation within the health system (process and
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44 outputs) through changed practices of pregnant or recently delivered women (outcomes) to
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46 impacts on neonatal health (**Figure 3**). Importantly, while the CBNCP's main impetus is on
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48 training of health workers, supplies of equipment and medicines as well as supervision and
49
50 follow-up, several of the outputs (e.g. taking a urine sample for proteinuria test) and outcomes
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52 (e.g. postnatal visits) could also be considered as components of the intervention. This
53
54 conceptual framework was critical in our identification of relevant outcome variables.
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<Figure 3 about here>

Implementation of the CBNCP pilot through training of facility- and community-based health workers and FCHVs started in May 2009 and was completed in July 2010 in pilot districts (see **Table S1**). Training dates were obtained from the Ministry of Health (MOH) to define district-specific pre- and post-intervention periods used in the analysis of DHS and HMIS data; any births taking place during training were excluded from the analysis.

Propensity score matching

Propensity score matching is widely used to estimate the effects of health and other policy interventions, where RCTs are not feasible.^{18 19} It uses statistical techniques to construct a comparison group that is as similar as possible to the intervention group in an effort to reduce selection bias.^{20 21}

Ten intervention districts were selected by the MOH in consultation with donors, considering development need, donor presence, district interest and ability to implement and monitor the programme (personal communication, Parashuram Shrestha, Nepal Ministry of Health). To reflect the propensity of a district to be selected for CBNCP implementation, we constructed a propensity score based on (i) the four components of the district human development index (HDI) value; ii) presence of donors involved in the CBNCP (i.e. USAID, UNICEF, SNL); iii) percentage rural population; iv) the MOH district performance rank; and v) road density) (see **Table 1** for details).

As CBNCP implementation was limited to hill and *terai* districts, mountain districts were excluded. We used the *psmatch2* command in Stata Special Edition 12²² to identify suitable comparison districts based on the nearest-neighbour method without replacement. We checked for balance in the distribution of propensity score components (using t-tests) and population and

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3 health infrastructure characteristics (using Chi-square tests) between intervention (10 districts
4 pooled) and comparison areas (10 districts pooled).
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8 *Data sources and variables*

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11 Multiple data sources were used to enable as complete an analysis of impact as possible and to
12 triangulate information between sources with different strengths and weaknesses. The DHS
13 provides nationally representative data on fertility, health-relevant behaviours and childhood
14 mortality based on a multi-stage cluster random sampling strategy.²³ The data for the Nepal
15 DHS for 2011 are in the public domain (www.dhsprogram.org). The HMIS, owned by the MOH
16 and primarily based on health facility records, provides information about health service
17 utilisation, morbidity and mortality, treatment outcomes and the availability of commodities. We
18 used data on regular service delivery for 2009-2011, publicly available at www.dohs.gov.np. We
19 also obtained CBNCP-specific NHIS data from the CBNCP secretariat based at the Child Health
20 Division at the MOH.²⁴ These NHIS data were collected by the programme team as part of
21 CBNCP delivery and monitoring, and provided insights about the knowledge and skills of
22 programme-trained health workers and FCHVs.
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38 Neonatal mortality as the ultimate outcome of interest was not feasible to assess given available
39 data sources and sample sizes. Instead, with reference to our conceptual framework (**Figure 3**)
40 we examined changes in six essential practices to improve neonatal health by incorporating
41 relevant contributing practices in combined binary outcomes (coded as “better practices” or
42 “poorer practices”). Relevant covariates were identified *a priori* as family characteristics (i.e.
43 wealth quintile, rural vs. urban location, caste/ethnicity); maternal characteristics (i.e. age at
44 delivery, education and access to media) and child characteristics (i.e. sex, parity). (see **Table 2**
45 for details.)
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55 *Analysis*

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3 Difference-in-differences analysis estimates the change in outcome for the intervention area
4 over a given time period by subtracting any change in outcome for the comparison area over the
5 same time period. All outcomes were assessed as combined outcomes, i.e. as the percentage
6 of pregnant or recently delivered women adhering to 'better practices'.²⁵ Analyses for individual
7 outcomes are provided as background information in **Table S2**.
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11 For DHS data, difference-in-differences analysis using Ordinary Least Square (OLS) regression
12 was conducted for births occurring pre- and post-intervention. Where a woman had given birth
13 more than once during the pre- or post-intervention period only the most recent birth was
14 included in the analysis to avoid non-independence of observations and to minimise recall bias.
15 For HMIS data, a similar approach was adopted, however, tests of significance were not
16 possible as the data were available only in aggregate at the district level. We also conducted
17 logistic regression analysis of DHS data to examine if any differences between intervention and
18 comparison areas persist after adjustment for all *a priori* identified covariates; here the outcome
19 was assessed at the individual level as either adhering or not adhering to 'better practices'. All
20 analyses were undertaken in Stata Special Edition 12.²²
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37 *Ethical considerations*

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40 Ethical approval was obtained from the Nepal Health Research Council.
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Findings

Baseline characteristics

Table 1 shows that intervention and comparison areas are balanced for propensity score components as well as relevant population and health infrastructure characteristics.

Table 1 Background characteristics in intervention and comparison areas, based on various data sources				
	Intervention area	Comparison area		
Propensity score components			t	p-value
Human Development Index: life expectancy (years) ¹	61.23	62.88	-0.76	0.457
Human Development Index: adult literacy (%) ¹	51.40	54.38	-0.73	0.475
Human Development Index: school enrolment (%) ¹	2.77	2.88	-0.33	0.742
Human Development Index: gross domestic product (PPP US\$) ¹	1293.6	1315.2	-0.15	0.883
Urban population (%) ²	16.79	17.85	-0.25	0.803
District performance score (average) ³ (as a proxy for a district's leadership ability and pro-activeness in implementing new initiatives)	74.25	73.77	0.28	0.781
Road density (km/square km) ² (as a measure of access and ability to monitor the programme)	0.251	0.258	-0.07	0.941
Donor presence (average number) ⁴	1.3	1.4	0.25	0.806
Population and health infrastructure characteristics⁵				
Population	4.9 million	4.4 million		
Expected pregnancies (#)	142,000	128,000		
Number of hospitals	14	11		
Number of primary health care centres	39	39		
Number of health posts	87	89		
Number of sub-health posts	435	456		
Number of private health institutions	49	38		
Number of birthing centres	203	183		
Population per birthing centre	24,159	24,330		
Number of FCHVs	6,903	7,378		
Population per FCHV	710	603		

Data sources:

¹ UNDP. Nepal Human Development Report, Kathmandu, Nepal, 2004

² District Profile of Nepal 2007/08: A socio-economic development database of Nepal, Intensive Study and Research Center of Nepal, Kathmandu, 2009.

³ MOH. District Annual Performance Criteria, personal communication, Ghanashyam Pokharel, 2011

⁴ AIN. Health Mapping Report, Association of International NGOs in Nepal, Kathmandu, 2008

⁵ Health Management Information System database, made available on request by Management Division, 2010

Using pre-intervention DHS data, 533 and 347 births took place in the intervention and comparison area respectively. **Table 2** compares outcome variables and covariates for the most recent births in the five years preceding the DHS survey. In both areas, a majority of children are from rural locations, disadvantaged families, and born to a mother with at least primary education. While respondents from intervention and comparison areas are largely comparable, there are statistically significant baseline differences in relation to family wealth status, maternal age at delivery and delivery by a skilled birth attendant even after matching.

Table 2 Baseline characteristics in intervention and comparison areas (in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data					
		Intervention area (n=533)	Comparison area (n=347)	χ^2	p-value
Family characteristics					
Location	Rural	86.0	85.6	0.02	0.929
Wealth index	Poorer ¹	31.4	51.7	44.09	0.003
Caste and ethnicity	Disadvantaged ²	74.0	70.6	1.05	0.673
Maternal characteristics					
Education	No education ³	36.5	45.0	24.82	0.072
Age at delivery	Higher risk age group ⁴	31.9	23.0	6.92	0.022
Access to media	No ⁵	51.4	65.4	14.34	0.101
Child characteristics					
Sex	Female	45.7	49.0	1.98	0.187
Parity	Higher risk parity ⁶	56.5	51.1	2.12	0.211
Essential practices to improve neonatal health					
Birth preparedness	Better practices ⁷	6.2	4.9	0.63	0.568
Antenatal care seeking	Better practices ⁸	33.7	26.4	4.39	0.218
Antenatal care quality	Better practices ⁹	36.0	29.0	3.87	0.195
Delivery by skilled birth attendant	Yes ¹⁰	46.7	31.2	17.61	0.007
Immediate newborn care	Better practices ¹¹	74.4	64.3	8.63	0.091
Postnatal care within 48 hours	Yes ¹²	33.7	26.8	3.97	0.097

¹ Poorer: includes poorer and poorest quintiles i.e. lowest 40% in wealth ranking based on selected household assets.

² Disadvantaged caste and ethnicity: includes hill dalit, terai dalit, hill janajati, terai janajati, other terai caste, and Muslim.

³ No education: includes illiterates and those without any formal education but may have some literacy classes.

⁴ Higher risk group: those who delivered before 20 years or after 35 years

⁵ No access to media: those reporting not listening or watching any public health radio or television programme in the last month

⁶ Higher risk parity: First or more than third parity

⁷ Birth preparedness: combined variable including saving money, organising transportation, finding a blood donor, identifying a health worker to assist with the delivery and purchasing a safe delivery kit; coded as "better practices" if at least two items are fulfilled.

- ⁸ Antenatal care seeking: combined variable comprising number of antenatal visits (four or more), taking iron supplements (>90 tablets) and having been vaccinated against tetanus (at least two doses); coded as “better practices” if all items are fulfilled.
- ⁹ Antenatal care quality: combined variable comprising whether the woman had her blood pressure taken, a urine and/or blood sample collected, and was told about pregnancy complications and where to go in case of complications; coded as “better practices” if at least four items are fulfilled.
- ¹⁰ Delivery by skilled birth attendant: defined as delivery by a doctor, nurse or midwife at home or at a health institution.
- ¹¹ Immediate newborn care: combined variable comprising delayed bathing for 24 hours, drying, wrapping, placing the baby on the mother’s breast or belly, applying chlorohexidine or nothing on the umbilical cord, and initiation of breastfeeding within one hour of birth; coded as “better practices” if at least three items are fulfilled.
- ¹² Postnatal care within 48 hours: defined as any newborn examination by a health worker or FCHV within 48 hours of birth.

Intervention coverage

In the ten pilot districts, a majority of health providers were trained, i.e. 1615 facility-based health workers, 902 community-based health workers and 7072 FCHVs. Overall, knowledge and skills as reported or demonstrated were fair with some variation by type of provider; availability of drugs and commodities was also good (**Table 3**). All of these, however, showed much variation between districts, pointing to concerns with respect to quality of training, supervision and logistics (see **Table S3**).¹³

Table 3 Intervention process indicators, based on NHIS data				
	Unit	Facility-based health worker	Community health worker	Female community health volunteer
Training coverage				
Number of individuals trained	Number	1615	902	7072
Knowledge				
Knowledge of immediate newborn care messages (i.e. thermal care, clean cord, skin-to-skin contact, immediate breastfeeding and delayed bathing)	% (sd)	70 (17.6)	62 (12.4)	57 (24.3)
Knowledge of correct dose of cotrimoxazole paediatric tablet	% (sd)	88 (11.5)	91 (5.6)	82 (16.5)
Skills				
Ability to demonstrate hand washing correctly	% (sd)	81 (9.8)	68 (17.1)	60 (14.3)
Ability to demonstrate resuscitation steps correctly using a doll	% (sd)	53 (19.6)	37 (17.0)	27 (17.7)
Availability of drugs and commodities				
Cotrimoxazole paediatric tablet	% (sd)	99 (1.6)	87 (12.6)	89 (10.2)
Gentamicin	% (sd)	95 (5.1)	78 (16.9)	--
Thermometer	% (sd)	--	--	85 (9.9)

Difference-in-differences analysis

Table 4 presents findings from the difference-in-differences analysis of DHS data. With the exception of birth preparedness (no change) and postnatal care within 48 hours (increase in intervention area, decrease in comparison area), improvements were observed but to a similar extent in both areas with no statistically significant differences. For all six essential practices the percentage of pregnant or recently delivered women adhering to better practices was lower in the comparison area at both points in time.

		Intervention area			Comparison area			Diff. in differences	p-value
		Before (n=533)	After (n=168)	Diff.	Before (n=347)	After (n=104)	Diff.		
Birth preparedness	Better practices	6.2	8.4	2.2	4.8	6.0	1.2	1.0	0.810
Antenatal care seeking	Better practices	33.7	49.7	16.0	26.4	33.2	6.8	9.2	0.383
Antenatal care quality	Better practices	47.4	59.9	12.5	34.8	37.8	3.0	9.5	0.290
Delivery by skilled birth attendant	Yes	46.7	57.7	11.0	31.2	37.6	6.4	4.6	0.577
Immediate newborn care	Better practices	74.4	85.9	11.5	64.2	79.9	15.7	-4.2	0.605
Postnatal care within 48 hours	Yes	33.7	44.6	10.9	26.8	17.4	-9.4	20.3	0.036

¹ See **Table 2** for details on variables.

Similarly, difference-in-differences analysis of HMIS data showed improvements in both intervention and comparison areas for most of the practices assessed;¹³ HMIS does not provide information on birth preparedness or immediate newborn care practices. **Table 5** compares findings based on DHS and HMIS data, showing congruent trends for all essential practices despite differences in the specification of some indicators. The contradictory finding that iron supplementation decreased post-intervention in the HMIS (which collects data from public service providers) but not in the DHS analysis (which reflects households seeking care from

both public and private providers) is explained by government health facilities having run out-of-stock in October and November 2011.

Table 5 Comparison of difference-in-differences analysis for selected antenatal, delivery and postnatal indicators (in percent), between DHS and MIS data

Essential practices to improve neonatal health ¹	DHS					HMIS				
	Intervention		Comparison		Difference-in-differences	Intervention		Comparison		Difference-in-differences
	Before	After	Before	After		Before	After	Before	After	
Birth preparedness (combined)	6	8	5	6	1	-	-	-	-	-
Antenatal care seeking: Antenatal care contact (at least one)	63	70	53	64	-4	69	81	73	78	7
At least four ANC visits	52	64	41	56	-3	36	43	35	46	-4
Iron tablet taken	78	87	77	80	6	74	62	73	58	3
Antenatal care quality (combined)	42	45	41	41	3	-	-	-	-	-
Delivery by skilled birth attendant	47	58	31	38	4	27	38	25	36	0
Immediate newborn care	74	85	69	79	1	-	-	-	-	-
Postnatal care within 48 hours	34	45	27	17	21	44	54	41	45	6

¹ See Figure 3 for details on variables.

Logistic regression analysis

The unadjusted odds ratios suggest statistically significant improvements in antenatal care quality (OR 1.8, 95% CI 1.1-2.9), delivery by a skilled birth attendant (OR 2.0, 95% CI 1.2-3.3) and postnatal care within 48 hours (OR 2.7, 95% CI 1.1-2.6) but not in the other three essential practices (Figure 4). However, when adjusted for *a priori* identified covariates none of the changes in essential practices remained statistically significant.

<Figure 4 about here>

Discussion

Key findings and their explanation

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3 Nepal's CBNCP was developed based on existing studies, mostly from Nepal and South Asia to
4 ensure relevance to the country- or region-specific epidemiology, demonstrating effectiveness
5 for a majority of the intervention components¹⁴. The choice of interventions for integration within
6 the package was driven by both effectiveness and feasibility considerations. However, there
7 was no evidence for the effectiveness of the package as a whole¹², and the additional feasibility
8 challenges of implementation at scale were probably not given sufficient attention.
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12 The analysis of DHS and HMIS data suggests that the CBNCP did not have a significant impact
13 on essential practices to improve neonatal health above a generally increasing trend in these
14 practices. These findings must be interpreted with caution, given the relatively short time period
15 between training health workers and FCHVs, which ranged from 7 to 14 months depending on
16 the district, and assessment of relevant outcomes among programme beneficiaries. In light of
17 the complex nature of the programme, where multiple components are intended to improve a
18 whole range of health provider and population behaviours throughout pregnancy, delivery and
19 the post-partum period, the present evaluation represents a very early assessment of potential
20 impact.
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37 Several factors are likely to interplay in explaining this current lack of impact.
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40 *Packaging of multiple interventions:* The CBNCP bundled a range of specific measures in a
41 complex package and implemented this across a large geographical area with an
42 implementation modality largely dependent on the existing health system. In Nepal, the health
43 system suffers from a number of problems and there is strong reliance on FCHVs. In contrast,
44 prior studies, concerned with efficacy or effectiveness under real-world conditions, usually
45 examined a single and relatively simple component (e.g. chlorhexidine for cord care²⁶) in a
46 limited geographic area (e.g. MIRA²⁷), implemented through a dedicated cadre of higher-level
47 service providers (e.g. SEARCH²⁸) or undertaken as a distinct research project (e.g.
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3 resuscitation²⁹). It is therefore not surprising that the effectiveness of these interventions is
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5 diluted when merged in a package that is delivered by a lower-level service provider under “real
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7 life” conditions. Indeed, a similar reduction of effectiveness when moving from research studies
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9 to large-scale implementation has been observed elsewhere.^{16 30 31} When going to scale,
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11 programme management, effective high coverage and a good match between community- and
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13 facility-based service improvements is seen as critical.³²⁻³⁴

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17 *Health care providers and their training:* The CBNCP was implemented through training of the
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19 existing cadre of facility- (seven days) and community-based (five days) health workers in the
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21 government system as well as FCHVs (seven days) with limited subsequent supervision and
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23 follow-up. Supervision is one of the most important elements of successful programmes, but
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25 also one of the most challenging programme elements to implement and assess. As a general
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27 indication, the Nepal Health Facility Survey³⁵ reported that nearly seven in ten health facility
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29 based workers received any kind of supervision visits during the previous six months.
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31 Comprehensive information on the extent and content of supervision in the context of the
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33 CBNCP is lacking but anecdotal reports indicate concerns with respect to the frequency and
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35 effectiveness of supervision visits. While evidence from Nepal suggests that community health
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37 workers and FCHVs can identify and manage maternal and newborn health problems, this
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39 requires frequent training and mentoring.³⁶ This study suggests much variation in programme
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41 performance across districts (see **Table S3**), generally indicating better results in areas where
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43 the CBNCP is implemented with more intensity. In addition, the qualitative component showed
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45 that service providers perceived the training as insufficient for them to be able to apply their
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47 skills confidently and to retain them over prolonged periods of time.¹³ Therefore, following the
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49 argument made by Kumar et al³⁷ that the effectiveness of an intervention is constrained by the
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51 weakest link in the causal-intervention pathway, the amount of training and subsequent
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53 supervision for this complex intervention package are likely to have been insufficient to promote
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3 meaningful behaviour change. Moreover, in a setting where medical shops are perceived to be
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5 more convenient than government health facilities,^{35 38} a programme that does not involve
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7 private providers is likely to show limited impact. In relation to antenatal services, private
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9 providers often provide specific components of those services (e.g. iron folic acid supplement)
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11 and on-call services.
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16 *Other relevant health initiatives:* In the last decade, Nepal has witnessed a host of programmes
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18 to improve maternal and child health, with many of these directly or indirectly impacting neonatal
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20 health.² As adjustment for other relevant ongoing initiatives was not feasible in design or
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22 analysis of this impact study, the observed trends in essential practices to improve neonatal
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24 health and the lack of CBNCP impact in intervention relative to comparison areas are in part
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26 likely to be due to the high level of background activity.
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29 30 *Strengths and limitations*

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33 *Study design:* The CBNCP is a complex intervention, where multiple components are intended
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35 to improve a whole range of health provider and population behaviours throughout pregnancy,
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37 delivery and the post-partum period. As its implementation was outside of the control of the
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39 researchers, randomisation was not feasible and we had to adopt a “natural experiment”
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41 approach. While matching largely achieved balance between intervention and comparison
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43 areas, some baseline differences persisted. Moreover, we did not match individual intervention
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45 and comparison districts but intervention and comparison areas. A major strength in addition to
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47 propensity score matching is this study’s utilisation of multiple data sources to assess impact.
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51 *Data:* The DHS is a cross-sectional survey with retrospective recording of all pregnancies and
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53 births as well as relevant behaviours; it is thus subject to recall bias. DHS data are designed to
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55 be representative at the national level – for rare events, they are not necessarily representative
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57 at the district level and, consequently, assessment of impact on neonatal mortality was not
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3 feasible. The number of births covered is also limited, especially post-intervention, as exposure
4 time to the intervention was short (ranging from 7 to 14 months) to reflect true changes between
5 areas. It is possible that changes in the behaviour of pregnant and recently delivered women will
6 only become manifest after longer periods of time, once health providers have internalised
7 recommendations and implement them on a regular basis. The HMIS provides valuable
8 information about healthcare utilisation, knowledge and skills of service providers and
9 availability of key commodities and supplies in the health system. However, HMIS data are only
10 available for the public sector and thus do not provide representative measures of coverage at
11 population level, as many people rely on healthcare from informal and private providers.
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24 *Analysis:* Use of multiple data sources and multiple statistical methods was an important
25 strategy to validate findings or lack thereof. Difference-in-differences calculations are subject to
26 limitations, as adjustment for confounders was not possible with the information available at
27 district level. Filtering of births for analysis (i.e. before, during and after implementation) was
28 customised by district, and the analysis excluded births taking place during training as a
29 conservative strategy. We used an *a priori* conceptual framework to define the outcomes of the
30 intervention and to guide the analysis.
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41 *Implications for research and practice*

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44 Overall, this study highlights that the design, piloting and implementation of a complex
45 intervention such as the CBNCP must be carefully planned and evaluated. In fact, the
46 assumption that combining a large number of intervention components, even where their
47 individual effectiveness has been proven, will yield an effective intervention package that can be
48 successfully implemented at scale does not hold. Importantly, evaluating under “real life”
49 conditions is not necessarily straightforward, and may require the use of limited-quality routine
50 data in combination with innovative study designs. Even though the CBNCP, as assessed
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3 through our study, was conceived as a pilot, rigorous assessment through the MOH and donors
4 was lacking; despite increasing concerns about the quality of CBNCP implementation and a
5 potential lack of impact, implementation continued and was rapidly extended beyond pilot
6 districts.
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13 The findings presented here, supported by those of the qualitative component of the study,¹³
14 suggest that the programme may need a re-packaging and tightening of content as well as a
15 revision of its implementation modality. Components with high burden and greater effectiveness
16 (e.g. infections and care for low birthweight babies) should be strengthened, whereas
17 components with lower burden and less effectiveness (e.g. asphyxia) should be removed
18 especially for FCHVs. With respect to implementation modality, more emphasis must be placed
19 on focused, high-quality training of all involved healthcare providers and ongoing supervision
20 and support.
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31 The CBNCP has been scaled up to 39 districts of Nepal. The findings presented here, which
32 were previously shared with CBNCP stakeholders, and a move towards more integrated
33 approaches to improve child survival prompted a removal of selected components and
34 integration of CBNCP interventions with the Integrated Management of Neonatal and Childhood
35 Illness (IMNCI) programme. The IMCNI programme is currently being implemented in 35
36 districts and monitored in terms of programme coverage, quality and impacts on behaviours,
37 health and equity.
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49 **Authors' contributions**

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52 DP, IBS and ER had the original idea for this paper. DP carried out data analysis and prepared
53 the first draft. IBS, ER, MS advised on methods and interpretation of findings. IBS, ER, MS
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3 reviewed and revised the draft manuscript. All authors, except IBS because of his untimely
4
5 demise during finalisation of this manuscript, read and approved the final manuscript.
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9 10 **Acknowledgements**

11 We would like to acknowledge the USAID-funded MEASURE DHS for providing us with the
12
13 Nepal DHS dataset and the MoH for sharing HMIS data. DP undertook this analysis as part of
14
15 his research under the PhD programme at the Munich Center for International Health and was
16
17 funded through a scholarship offered by the German Academic Exchange Service. At the time,
18
19 DP was an employee of USAID and was offered flexible working hours and time off to undertake
20
21 this study as part of this PhD dissertation. The opinions expressed in this paper are those of the
22
23 authors and do not necessarily reflect the views of USAID or the other organizations the authors
24
25 are affiliated with. We would also like to thank Jamie Bartram, Steve Hodgins and Ulrich
26
27 Mansmann for their helpful comments on a previous version of this manuscript as well as Mary
28
29 Adam, Jennifer Callaghan-Koru, Matthew Ellis and Zelee Hill for their thorough review and
30
31 constructive feedback on the originally submitted manuscript.
32
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40 **Funding**

41
42 This study was undertaken without dedicated research funding but made possible through a
43
44 PhD scholarship offered to DP by the German Academic Exchange Service. The study utilized
45
46 DHS data in the public domain and HMIS data made available to the authors upon request. All
47
48 data were processed and analyzed by the authors with DP having full access to the data and all
49
50 authors sharing the final responsibility for the decision to submit for publication. Neither those
51
52 providing us with the data nor the German Academic Exchange Service had any involvement in
53
54 data analysis, interpretation or writing of this manuscript.
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Competing interest

At the time of study, DP was an employee of USAID and involved in monitoring the CBNCP programme.

Data sharing

Additional data is available in Supplementary information.

For peer review only

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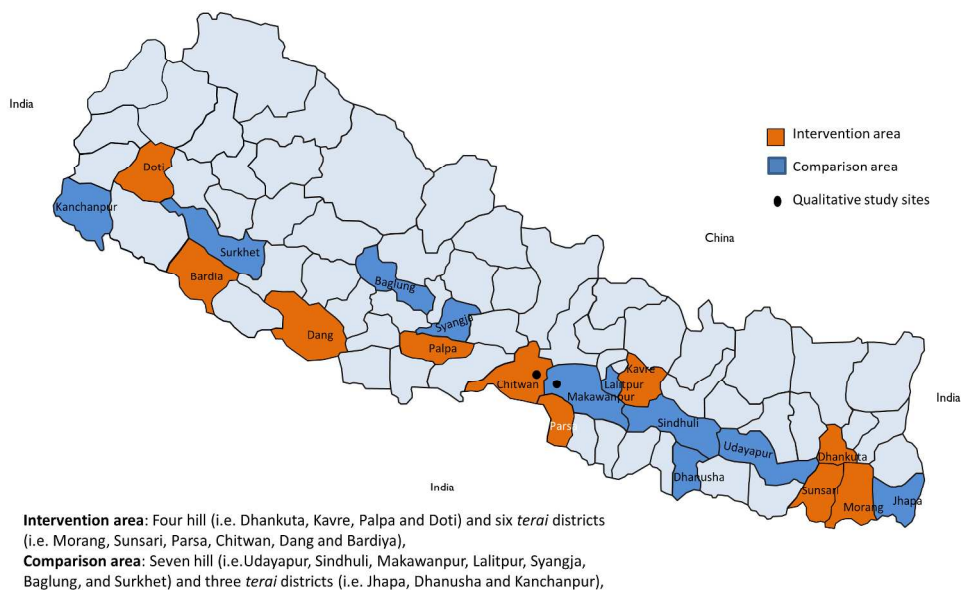
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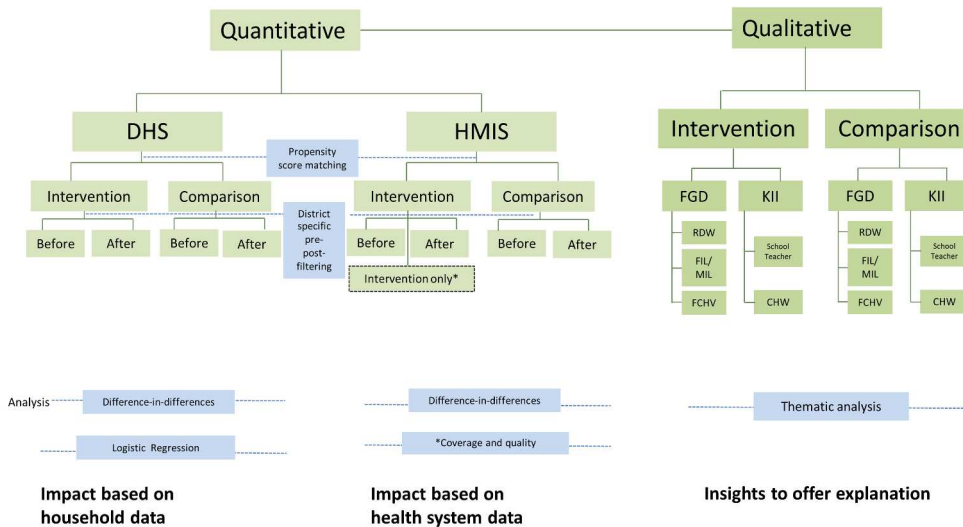
Figure 1 Map of Nepal showing intervention and comparison areas and qualitative study sites



Map of Nepal showing intervention and comparison areas and qualitative study sites

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Figure 2 Study design comprising quantitative and qualitative components



Abbreviation:

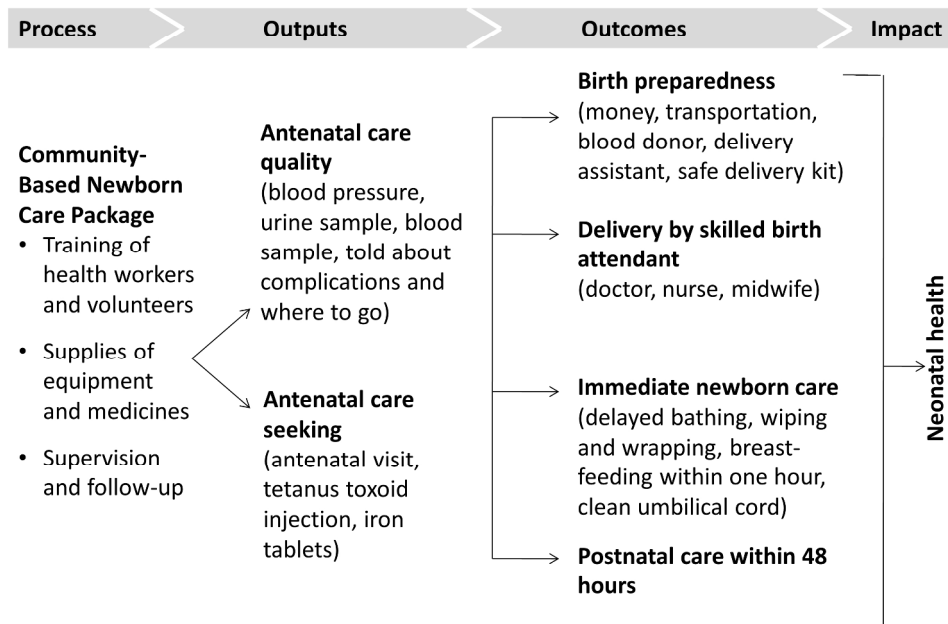
DHS: Demographic and Health Survey; **HMIS:** Health Management Information System; **FGD:** Focus Group Discussion; **KII:** Key Informant Interviews; **RDW:** Recently Delivered Women; **FIL:** Father-in-laws; **MIL:** Mother-in-laws; **FCHV:** Female Community Health Volunteer; **CHW:** Community Health Worker

Study design comprising quantitative and qualitative components

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Figure 3 Conceptual framework



Conceptual framework

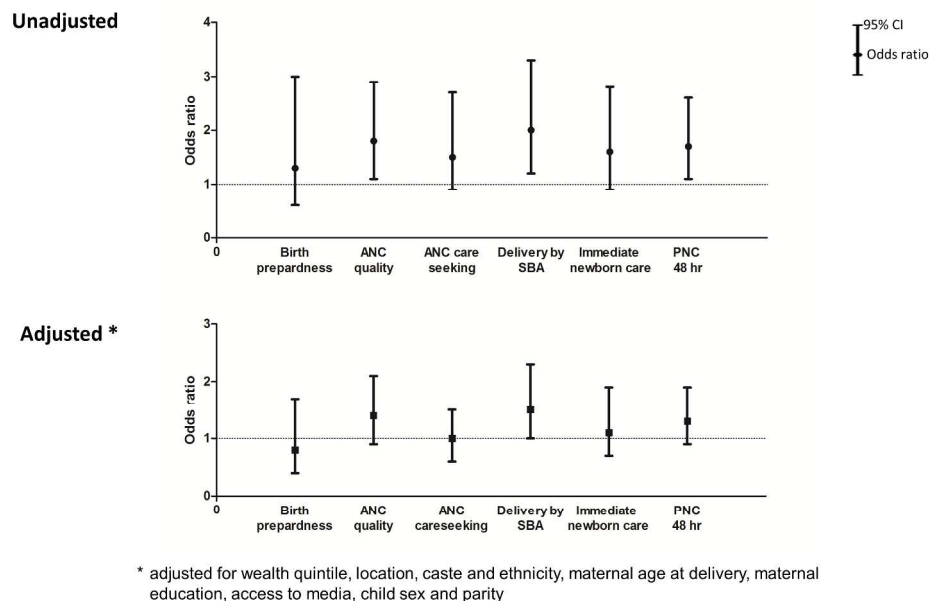
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Figure 4 Impact of CBNCP on six essential practices to improve neonatal health, based on logistic regression analysis of DHS data



Impact of CBNCP on six essential practices to improve neonatal health, based on logistic regression analysis of DHS data

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

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Supplementary Information

Table S1

CB NCP Training Outputs

District specific training start and end dates, DHS data collection dates, number of health workers trained and supporting agency

District	Training start date (month/year)	Training end date (month/year)	DHS data collection (month/year)	Exposure period (months)	# CHWs trained	# FCHVs trained	# facility-based HWs trained	Supporting agency
Bardiya	5/2009	12/2009	2-3/2011	14	56	842	132	SAVE
Chitwan	4/2010	7/2010	2-3/2011	7	74	340	136	UNICEF
Dang	11/2009	4/2010	4-6/2011	12	62	840	179	UNICEF
Dhankuta	4/2010	7/2010	3-4/2011	8	60	315	91	GON
Doti	6/2009	7/2010	5-6/2011	10	84	653	127	CARE
Kavre	11/2009	7/2010	6/2011	11	128	923	244	UNICEF
Morang	4/2010	7/2010	2-3/2011	7	114	594	184	GON
Palpa	4/2010	7/2010	4/2011	9	93	585	130	GON
Parsa	5/2009	7/2010	2-3/2011	7	132	999	231	PLAN
Sunsari	5/2009	2/2010	2-3, 5-6/2011	12	99	981	161	PLAN
TOTAL	--	--		7-14	902	7072	1615	

DHS: Demographic and Health Survey; CHW: community health worker; FCHV: female community health volunteer; HW: health worker; SAVE: Save the Children; GON: Government of Nepal; UNICEF: United Nations Children Fund; CARE: CARE International; PLAN: Plan International

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Table S2
Difference-in-differences analysis for key practices to improved neonatal health (specific and aggregate outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data

		Intervention area			Comparison area			Diff. of differences	p-value
		Before (n=533)	After (n=168)	Diff.	Before (n=347)	After (n=104)	Diff.		
Saved money	Yes	37.6	39.7	2.1	28.0	37.3	9.3	-7.2	0.419
	No	62.4	60.3		72.0	62.7			
Arranged transport	Yes	3.8	6.7	2.9	3.7	7.6	3.9	-1.1	0.835
	No	96.2	93.3		96.3	92.4			
Found blood donor	Yes	0.7	1.4	0.7	0.0	0.0	0.0	0.7	na
	No	99.3	98.6		100.0	100.0			
Identified health worker	Yes	1.2	0.7	-0.5	0.2	0.0	-0.2	-0.3	0.622
	No	98.8	99.3		99.8	100.0			
Bought safe delivery kit	Yes	1.2	0.7	-0.5	2.4	0.2	-2.2	1.6	0.167
	No	98.8	99.3		97.6	99.8			
At least one ¹ preparation	Yes	42.4	44.6	2.2	31.5	39.1	7.6	-5.4	0.575
	No	57.6	55.4		68.5	60.9			
Birth preparedness² (combined)	Better	6.2	8.4	2.2	4.8	6.0	1.2	1.0	0.810
	Poorer	93.8	91.6		95.2	94.0			
Antenatal care by skilled provider	Yes	62.6	69.6	7.0	53.4	64.5	11.1	-4.1	0.607
	No	37.4	30.4		46.6	35.5			
Antenatal care visits, four or more	Yes	52.4	64.5	12.1	40.8	55.7	15.0	-2.8	0.813
	No	47.6	35.5		59.2	44.3			
Iron tablets taken	Yes	78.5	87.2	8.7	76.7	80.0	3.4	5.3	0.305
	No	21.5	12.8		23.3	20.0			
TT2 taken	Yes	74.5	75.7	1.2	68.6	63.8	-4.8	6.0	0.371
	No	25.5	24.3		31.4	36.2			
Blood pressure measured ³	Yes	75.8	85.4	9.6	71.5	81.0	9.6	0.0	0.998
	No	24.2	14.6		28.5	19.0			
Urine sample taken ³	Yes	54.1	65.0	10.9	42.5	46.7	4.2	6.8	0.351
	No	45.9	35.0		57.5	53.3			
Blood sample taken ³	Yes	42.0	48.7	6.7	36.5	42.0	5.5	1.2	0.897
	No	58.0	51.3		63.5	58.0			
Told about pregnancy complications ³	Yes	64.5	77.9	13.4	56.9	54.1	-2.8	16.2	0.15
	No	35.5	22.1		43.1	45.9			
Told about where to go in complications	Yes	65.5	78.2	12.7	55.1	53.8	-1.4	14.0	0.164
	No	34.5	21.8		44.9	46.2			
Antenatal care quality – at least one ⁴	Yes	36.0	43.8	7.8	29.0	30.9	1.9	5.9	0.524
	No	64.0	56.2		71.0	69.1			
ANC care seeking⁵ (combined)	Better	33.7	49.7	16.0	26.4	33.2	6.8	9.2	0.383
	Poorer	66.3	50.3		73.6	66.8			
ANC quality⁶ (combined)	Better	47.4	59.9	12.5	34.8	37.8	3.0	9.5	0.290
	Poorer	52.6	40.1		65.2	62.2			

Table S2 (continue)

Difference-in-differences analysis for key practices to improved neonatal health (specific and aggregate outcomes in percent), for most recent births to women aged 15-49 years in the five years preceding the survey based on DHS data

Delivery at health institution	Yes	42.9	60.3	17.4	30.5	42.0	11.6	5.8	0.488
	No	57.1	39.7		69.5	58.0			
Delivery attended by SBA⁷	Yes	46.7	57.7	11.0	31.2	37.6	6.4	4.6	0.577
	No	53.3	42.3		68.8	62.4			
Bathed after 24 hours ⁸	Yes	58.1	74.9	16.9	46.7	57.6	10.9	6.0	0.492
	No	42.0	25.1		53.3	42.4			
Dried before placenta delivered ⁸	Yes	75.3	83.9	8.6	70.6	74.2	3.6	5.0	0.601
	No	24.7	16.1		29.4	25.8			
Wrapped in cloth ⁹	Yes	80.2	82.6	2.4	71.3	86.6	15.3	-12.9	0.072
	No	19.8	17.4		28.7	13.4			
Placed in belly or breast ⁸	Yes	49.6	66.3	16.7	41.6	57.4	15.7	1.0	0.888
	No	50.4	33.7		58.4	42.6			
Applied nothing or only CHX on the cord ⁸	Yes	71.2	87.5	16.3	65.9	72.9	7.1	9.2	0.277
	No	28.8	12.5		34.1	27.1			
Initiated breastfeeding within one hour ⁸	Yes	47.8	51.2	3.5	40.5	53.6	13.2	-9.7	0.228
	No	52.2	48.8		59.5	46.4			
Immediate newborn care⁹	Better	74.4	85.9	11.5	64.3	79.9	15.7	-4.2	0.605
	Poorer	25.6	14.1		35.8	20.1			
Postnatal care within 48 hours	Yes	33.7	44.6	10.9	26.8	17.4	-9.4	20.3	0.036
	No	66.3	55.4		73.2	82.6			

¹ At least one among: money, transport, blood donor, identified health worker, bought safe deliver kit

² Birth preparedness: is defined as "better practices" if at least any two preparations are arranged, and as "poorer practices" if less than two or no preparation among: money, transport, blood donor, identified health worker, bought safe deliver kit

³ These information were asked only for the women who received antenatal care, thus it was assumed that those who didn't receive care didn't receive these services as well

⁴ At least one among blood pressure, urine sample, blood pressure, told about pregnancy complication and told about where to go in complication

⁵ ANC care seeking is defined as "better practices" if all of the following were fulfilled and "poorer practices" if any of these were not fulfilled: ANC four or more visits, iron tablets (>90 tablets) taken, at least two doses of tetanus toxoid taken

⁶ ANC quality is defined as "better practices" if at least four of following five items were fulfilled and "poorer practices" if less than four items were fulfilled: blood pressure, urine sample, blood sample, told about pregnancy complication and told about where to go in complication

⁷ SBA (Skilled Birth Attendant): includes doctor, nurse and midwife

⁸ These information was asked only for home births and it was assumed that these practices were followed in case of institutional deliveries.

⁹ Immediate newborn care has been defined as "better" if at least three of the following were fulfilled and "poorer" if less than three were fulfilled among: delayed bathing, dried, wrapped, placed in belly or breast, applied nothing or only Chlorhexidine and initiated breastfeeding within one hour of birth

Box 1 CBNCP programme components

- i. **Program planning and orientation:** This includes orientation of stakeholders on training overview, changes in roles and responsibilities of providers and supervisors, reporting and service delivery, required support from different stakeholders at local, district and national level. A detailed program implementation and monitoring plan per district prepared after the orientation
- ii. **Training/human resource:** Five different training packages were prepared: Master Training of Trainers and Training of Trainers (7+2 days), Service Providers from Health Facilities (5 days), Outreach Service Providers (7 days), Female Community Health Volunteers (5 days) and Program managers (2 days)

Training content and service provision requirement covered following components:



behavior change communication for birth preparedness and newborn care



promotion of institutional or clean home delivery



postnatal care to promote essential newborn care



community-based diagnosis and management of possible infection



care of low birth weight newborns



prevention and management of hypothermia



recognition, initial stimulation and resuscitation for asphyxia

- iii. **Supervision, monitoring and evaluation:** Utilizing existing and regular supervision and monitoring approach topped up with additional pilot phase intensive supervision from center, region, district and health facility level. Use of IMCI tools and additional CB NCP pilot tools (six forms CB NCP 1-6). Monthly review meeting with FCHVs at HF level, trimester review meeting at *llaka* level with HF providers, semi-annual review meeting at district level with all HFs. Additional regional and national review meetings.
- iv. **Logistics and supply chain management:** Ensuring regular availability of key drugs and commodities (e.g. gentamycin injection, insulin syringe, De Lee suction tube, clean delivery kit, bag-and-mask, acute respiratory infection (ARI) timer, cotrimoxazole pediatric tablets) at district, health facility and volunteer level
- v. **Communication:** Community and social mobilization, behavioral change communication, mass media, advocacy.
- vi. **Pay for performance:** Performance based (based on number of cases treated by a group of volunteers) incentives for volunteers to compensate for their effort during very specific and demanding period (primarily counselling on birth preparedness, being present on the day of delivery, follow up visits on day 3, 7 and 28 days)

Source and further details:

Pradhan YV, Upreti SR, KC NP, et al. Fitting Community Based Newborn Care Package into the health systems of Nepal. *J Nepal Health Res Counc* 2011;9(2):119-28.

Table S3

Health providers' knowledge and skills

Percentage of health providers with correct knowledge of essential newborn care and dose of cotrimoxazole paediatric tablets to treat newborn babies with infections and ability to demonstrate hand washing and birth asphyxia steps as outlined in CBNCP training package based on NHIS data

District	Know all 5 essential newborn care messages ¹			Know correct dose of cotrimoxazole paediatric tablet ²			Demonstrate correct hand washing			Demonstrate management of birth asphyxia (using doll)		
	HW	CHW	FCHV	HWs	CHWs	FCHVs	HW	CHW	FCHV	HWs	CHWs	FCHVs
Bardiya	76	56	80	98	95	97	81	65	67	47	43	39
Chitwan	43	46	49	58	78	69	71	51	58	76	61	39
Dang	95	80	90	93	90	97	86	81	69	48	30	52
Dhankuta	87	57	37	89	96	86	67	42	58	61	39	47
Doti	na	na	na	82	95	84	76	57	38	43	24	9
Kavre	62	56	18	91	92	82	86	66	52	48	30	20
Morang	86	82	84	91	94	97	97	85	63	88	66	--
Palpa	70	59	61	90	87	59	73	70	55	42	23	19
Parsa	51	51	38	86	88	53	90	96	92	22	17	1
Sunsari	59	67	55	98	95	97	--	--	50	--	--	18
Mean (unweighted)	70	62	57	88	91	82	81	68	60	53	37	27

¹Five ENC messages: immediate drying; maintain skin-to-skin contact; apply nothing on cord; immediate breastfeeding; delayed bathing

²Correct dose of cotrimoxazole paediatric tablet: half a tablet twice daily for five days for newborns aged 0-28 days
CHW: community health worker; FCHV: female community health volunteer; HW: health worker.

Data source: Assessment of the community-based newborn care package (August 2012)

STROBE Statement—checklist of items that should be included in reports of observational studies

Checklist for Paudel D et al for BMJ Open Research Article

	Item No	Recommendation	Reported in the manuscript in line number below
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1-2, line 1-60
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2, line 1-60
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, line 28-30
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6, line 10-30
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, line 40-50
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	Page 5, line 55-60 Page 6, line 1-10
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 8, line 10-55
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of	Page 8, line 10-55

assessment methods if there is more than one group

Bias	9	Describe any efforts to address potential sources of bias	<i>Page 9, line 15-35</i> <i>Page 3, line 10-35</i>
Study size	10	Explain how the study size was arrived at	<i>Page 7, line 48-60,</i> <i>Page 8 line 3-6</i>
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	<i>155-165</i>
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	<i>Page 9, line 1-35</i>

Continued on next page

Results	<i>Reported in the manuscript in line number below</i>	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		

1
2 Funding 22 Give the source of funding and the role of the funders *Page 16, line 35-50*
3 for the present study and, if applicable, for the
4 original study on which the present article is based
5

6
7 *Give information separately for cases and controls in case-control studies and, if applicable, for exposed and
8 unexposed groups in cohort and cross-sectional studies.
9

10 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
11 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
12 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
13 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
14 available at www.strobe-statement.org.
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