Impact of family-centred postnatal training on maternal and neonatal health and care practices in district hospitals in two states in India: a pre-post study

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ABSTRACT

Background and objectives The Care Companion Program (CCP) is an in-hospital multitopic skill-based training programme provided to families to improve postdischarge maternal and neonatal health. The states of Punjab and Karnataka in India piloted the programme in 12 district hospitals in July 2017, and no study to date has evaluated its impact. Methods We compared telephonically self-reported maternal and neonatal care practices and health outcomes before and after the launch of the CCP programme in 11 facilities. Families in the preintervention group delivered between May to June 2017 (N=1474) while those in the intervention group delivered between August and October 2017 (N=3510). Programme effects were expressed as adjusted risk ratios obtained from logistic regression models. Results At 2-week postdelivery, the practice of dry cord care improved by 4% (RR=1.04, 95% CI 1.02 to 1.06) and skin-to-skin care by 78% (RR=1.78, 95% CI 1.37 to 2.27) in the postintervention group as compared with preintervention group. Furthermore, newborn complications reduced by 16% (RR=0.84, 95% CI 0.76 to 0.91), mother complications by 12% (RR=0.88, 95% CI 0.79 to 0.97) and newborn readmissions by 56% (RR=0.44, 95% CI 0.31 to 0.61). Outpatient visits increased by 27% (RR=1.27, 95% CI 1.10 to 1.46). However, the practice of exclusive breastfeeding, unrestricted maternal diet, hand-hygiene and being instructed on warning signs were not statistically different. Conclusion Postnatal care should incorporate predischarge training of families. Our findings demonstrate that it is possible to improve maternal and neonatal care practices and outcomes through a family-centered programme integrated into public health facilities in low and middle-income countries.

INTRODUCTION

Reducing neonatal morbidity and mortality remains a key goal of health systems in low and middle-income countries (LMICs) where 2.5 million neonatal deaths occur annually.1 India bears 27% of the global burden of neonatal deaths; 75,000 newborns die in India within the first month of life annually.2 Although institutional deliveries have nearly doubled in India over the past decade,3 inadequate follow-up has created several gaps in care. Families often miss coming back for scheduled follow-ups, with about 40% dropping out by the first follow-up visit in LMICs.4 Additionally, many patients fall through the safety net as health workers are not able to reach and provide care for the newborns at home.5 For many families, facility-based childbirth is the only window of opportunity to equip families with the knowledge and skills needed to care for their newborns.
Postnatal education, particularly predischarge education, has been identified as a ‘low-hanging fruit’ to improve newborn outcomes and reduce mortality by improving the adoption of newborn care practices. But key limitations have been identified in the implementation of such programmes. The majority of programmes focus on singular health topics, primarily breastfeeding or impart education to only one family member, most often the mother. These limitations need to be overcome to address unmet educational needs.

Hospitals in LMICs can play a key role in imparting postnatal education, but without established procedures, the delivery of critical health education in-hospital is limited or missed altogether. A survey in district hospitals in India found less than half the mothers reported receiving any amount of education postdelivery and before discharge. Moreover, low health literacy, sociocultural diversity, power dynamics and language barriers affect patient provider relationships, thereby adding to the difficulty in understanding the advice given by doctors and nurses. Often, families are not prepared for their roles as primary caregivers and essential newborn care practices that could save lives and avert suffering are not followed at home.

Program description

In July 2017, 12 district hospitals, 6 in each state, were selected by the governments of Punjab and Karnataka to launch the Care Companion Programme (CCP) as a pilot programme. These hospitals have monthly delivery volumes of 100–800 deliveries and are the primary government hospitals in their respective districts. The hospitals were selected based on need for the programme and willingness to implement the programme. Noora Health inspired CCP was implemented as a public-private partnership undertaking. The role of the private partner was to design the model including creating and deploying the teaching tools, training the hospital staff, working with administrators and other hospital staff to ensure integration of the training into their daily workflow. The formulation and approval of the curriculum, early testing of material and localisation and approvals from various stakeholders took place in the first half of 2017. The hospitals were to provide the infrastructure support, staff time and administrative support to help run the programme.

The programme uses an evidence-based curriculum for postnatal counselling, covering multiple behaviours for improving neonatal and maternal health. Skills taught include key healthy behaviours like exclusive breastfeeding, dry cord care, skin to skin care, mother’s diet, early recognition of danger signs and complications for mother and baby and appropriate healthcare seeking by the families. Behaviour change specialists created tools and methods to teach this curriculum using a human-centred design process, including needs finding interviews with families and discussions with local and regional health experts. Visuals and materials were tailored to the cultural practices of local populations using field testing, key informant interviews and iterative design. The Department of Health in the respective states, as well as District Surgeons and Medical Officers of each hospital, provided final approvals for materials included in the training curriculum. These materials included videos played on a television monitor installed in the postnatal wards, flip-charts, dolls for role play and hand-outs. Examples of the training materials can be accessed at https://drive.google.com/drive/folders/1e6KL75IgLtxdXqkDDet2h2Ls9hcH1p

The initial training of trainers was conducted by a master trainer who trained nurses and counsellors from the 11 district hospitals in a workshop over two 8-hour days. Learning was assessed by a pre–post test. Nurses and counsellors were introduced to the tools, adult learning principles, health communication skills to engage their audiences and the specific health topics and skills that they needed to teach families. A hospital-specific rotational roster was created in order to maximise the number of deliveries covered, acknowledging that some families may discharge before being offered the class due to length of stay and resource constraints. Typically, 30–45 min sessions were held 1–2 sessions per week in the postnatal wards, including intensive care and caesarean delivery wards. In the hospitals, mothers and families were taught these skills by the nurses or counsellors in group sessions which facilitates behaviour adoption. On average 1–2 members of a family attended these sessions.

Classes were held at times outside of physician rounds and food services to ensure that nurses were available for teaching. Security guards often helped gather patients and families in the wards and made attempts to include maximum family members. The nurse or counsellor covered a predefined list of topics, using flip charts and demonstrations followed by a video. Interaction was encouraged throughout the class and a question and answer session took place at the end of the session. The nurses were also encouraged to bring in their expertise to adapt to the needs of the group and local context. Families were encouraged to practice some of the skills while still in the hospitals. Programme managers visited each hospital once a week to monitor the fidelity of the programme, gather learnings for future refinement and provide feedback to improve the sessions.

Training of the trainers occurred after the preintervention data collection phase in June 2017. The programme launched in July 2017 and by August 2017, all hospitals were running the CCP.

The primary SMART (Specific, Measurable, Applicable, Realistic, and Timely) aim of the CCP is to improve patients’ postdischarge outcomes, reduce complications and increase families’ adherence to recommended newborn and maternal care practices. Our objective in the study was to assess the effect of CCP on family’s reported adoption of newborn care practices and newborn outcomes in the neonatal period.
METHODS

Study design

We conducted a quasi-experimental study where a preintervention group received standard of care (SoC) and served as an historical control and the postintervention group receiving the CCP served as the intervention arm. All outcomes were self-reported by the mother or a primary caregiver who lived with the mother and were collected at 2-week postdelivery via telephone survey. We were interested in the overall effect of the programme at the systems level. Eleven sites in total were included in the study out of the 12 pilot sites; data collectors in one district hospital of Punjab could not be appointed in time before launch.

Sample

Field investigators created a list of deliveries each day referencing the hospital’s delivery registers. Using survey software, we selected a random sample of women who delivered a newborn in the hospital during the study timeframe. Field investigators checked for inclusion and exclusion criteria by talking to the families and using individual patients’ chart data and developed a final list. Families in the preintervention group were recruited between May and June 2017. For the postintervention group, recruitment occurred between August and October 2017. We calculated sample size to detect a 19% difference in postdischarge prevalence of exclusive breast feeding between the intervention and control groups. Assuming a design effect of 1.2 due to differences in hospital-level sampling and a 2:1 ratio of samples in intervention versus control groups, the required sample size to detect the difference with 80% power and 95% CI was 1710 in the control group and 3420 in the intervention group.

Inclusion and exclusion criteria

All women who delivered a live newborn in the selected district hospitals during the study recruitment were eligible and included in the study sampling frame. Families were excluded from participating if baby or mother died during hospital stay or if by the time of the survey call, mother was younger than 18 years, no one living near the mother had access to a telephone, no one living with the mother spoke one of the multiple languages the surveyors spoke, mother or baby were transferred to another hospital during their stay in the hospital, medico-legal cases and if the mother left the hospital before data collectors could collect telephone numbers.

Patient and public involvement

Study questionnaires were piloted with the target population prior to the start of study data collection and based on the pilot feedback. The instrument was fine tuned for the comfort and understanding of the patient population.

Once published, participants will be informed of the results through a dedicated section in the website (www.noorahealth.org), each hospital involved will be sent the results and the Government stakeholders at the state level will be informed.

Measurements

Population-based surveys like the Demographic and Health Survey and National Family Health Survey collect limited data about newborn care practices and neonatal and postpartum maternal health, only measuring breastfeeding practice and the occurrence of excessive vaginal bleeding or fever in the postpartum period. The study team developed and tested a phone survey to additionally measure other newborn care practices shown to reduce newborn illness and death: skin to skin care, exclusive breast feeding, infection prevention including handwashing and clean umbilical cord care and care seeking for newborn illness. In addition, we chose to measure receipt of postdelivery instructions and challenges like hospitalisation and readmissions.

A phone survey was developed in English and translated into Kannada, Hindi and Punjabi by certified translators. Where there was overlap in measurement, questions about exclusive breast feeding (EBF) and postpartum complications were adapted from the National Family Health Survey (NFHS) and District Health Survey (DHS) surveys. The translated surveys were evaluated for face and content validity by survey managers fluent in the language and familiar with the study aims. Subsequently, the survey pilot was tested with 20 families for understandability and changes were made to question ordering, phrasing and option choices. Finally, the survey with modifications after testing was back translated by the study team that was bilingual and assessed for adherence to the original question concepts. Given all measures were self-reported, several techniques were employed in the design of the survey to minimise desirability bias and recall bias: open-ended questions, small recall periods and specific question ordering. An example of the use of neutral interviewing style and open-ended questioning to mitigate desirability bias was asking ‘How did you clean the umbilical cord?’ without immediately prompting specific items to elicit information about whether the mother reported ever cleaning the umbilical cord.

The survey was electronically programmed into SurveyCTO, a tool for digital data collection. Required responses, response validity checks and skip patterns, were used to ensure completeness of data; thus, only missing data occurred when a survey respondent abandoned the survey. In addition, survey phone calls were recorded with permission of families and one survey per interviewer was audited daily by survey managers for survey response accuracy and quality. Interviewers were women, from the same or nearby district, spoke the local language and were either trained as social workers or nurses. Families were asked to provide two phone numbers and preferred time of calling. Phone calls were made at 2 weeks postdelivery for 5–7 consecutive days before classifying families as not contactable. The primary outcome measures are described in table 1. Confounders measured were age of

the mother, sex of the baby, whether the baby was premature or not, education of the mother, birth weight less than 2500 g, parity, delivery type and whether the baby was sent to Special Newborn Care Unit (SNCU).

Data analysis
Frequencies and percentages were used to describe maternal and child sociodemographic characteristics and confounding variables such as birth weight, gender of baby, whether the delivery was premature, whether it was first pregnancy, type of delivery, baby’s gender, birth weight (<2500 g) and preterm status were similar between the two groups. Furthermore, mother’s educational attainment was significantly different (p=0.01) in both phases. However, when combining the education categories, the counts education. All models were executed for the full sample. Model information efficiency was compared using Akaike’s information criterion. Effect estimates are reported in terms of risk ratios (RRs) which were calculated from ORs and significance was reported at 95% CI. Absolute risk differences are also reported in table 3.

RESULTS
We collected 1507 survey responses from the control families receiving SoC before the launch of the CCP and 3634 responses from the intervention families in the CCP group. Out of the two selected states, there were more respondents from Karnataka in the SoC group (57.4%) as well as the CCP group (68.9%).

Participant demographics are detailed in table 2. Overall, the mother’s age distribution, first pregnancy, type of delivery, baby’s gender, birth weight (<2500 g) and preterm status were similar between the two groups. Furthermore, mother’s educational attainment was significantly different (p=0.01) in both phases. However, when combining the education categories, the counts

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**Table 1** Self-reported outcomes assessed at 2 weeks post-delivery

<table>
<thead>
<tr>
<th>Healthy behaviours</th>
<th>[Yes] If family reported only feeding breastmilk in the previous 24 hours</th>
<th>[No] If family reported feeding anything else</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper umbilical cord care (nothing on cord) since birth</td>
<td>[Yes] If family applied nothing or only ointment/powder provided by doctor</td>
<td>[No] For all other situations</td>
</tr>
<tr>
<td>Home practice of skin-to-skin care for any duration as described by baby without clothes (with/without diaper) being placed prone on the mother's bare chest</td>
<td>[Yes] If family reported being aware of skin-to-skin care and any member practicing it with the baby at home</td>
<td>[No] If the family was not aware or had not practiced it at home</td>
</tr>
<tr>
<td>Handwashing as measured by use of soap</td>
<td>[Yes] If family reported (unprompted) using soap when washing their hands</td>
<td>[No] Does not use soap</td>
</tr>
<tr>
<td>Unrestricted maternal diet (no restriction of specific foods, no restriction on total quantity of food or water)</td>
<td>[Yes] If the mother had not restricted either food or water after delivery</td>
<td>[No] If the mother had decreased either food or water</td>
</tr>
<tr>
<td>Complications</td>
<td>[Yes] If mother reported any of the following: ▶ Fever Pus or redness from the caesarean section site or vaginal episiotomy area ▶ Swelling or pain in the breast</td>
<td>[No] For all other situations</td>
</tr>
<tr>
<td>Baby complication</td>
<td>[Yes] If baby experienced any of the following: ▶ Fever, cough ▶ Umbilical problem (pus or redness) ▶ Sustained inactivity or inconsolable crying or refusal to feed</td>
<td>[No] For all other situations</td>
</tr>
<tr>
<td>Healthcare seeking</td>
<td>Baby ever readmitted to hospital post-discharge</td>
<td>[Yes] [No]</td>
</tr>
<tr>
<td>Baby ever taken to a clinic or hospital for outpatient visit</td>
<td>[Yes] [No]</td>
<td></td>
</tr>
</tbody>
</table>
were not statistically different with approximately 1273 (86.3%) of participants in the preintervention group with no schooling and 3125 (89%) participants in the postintervention group with some schooling. In each intervention group, almost 50% had attained schooling up to the 6th–10th grade category.

In table 3, we present the unadjusted and adjusted RRs for outcomes in the CCP group compared with the SoC group. Figure 1 visualises the adjusted RRs for the postintervention group CCP group as compared with the preintervention SoC group across all outcomes.

**Health system engagement instructions**

Participants in the CCP group were 10% more likely to have received baby care instructions (RR=1.10, 95% CI 1.01 to 1.19). Participants in the CCP group were more likely to report receiving instructions on baby warning signs, but this difference was not statistically significant.

**Healthy behaviours**

Furthermore, we examined healthy behaviours and found skin-to-skin/kangaroo care and dry cord care practices to be significantly improved in the CCP group. Participants in the CCP group were 78% (RR=1.78, 95% CI 1.37 to 2.27) more likely to adopt kangaroo care practices and 4% (RR=1.04, 95% CI 1.02 to 1.06) more likely to practice dry cord care. Exclusive breast feeding and mothers’ following an unrestricted diet were increased in the CCP group, but this was not statistically significant. There was a statistically non-significant decrease in reported hand hygiene in the CCP group.

**Healthcare seeking**

Health-seeking behaviours were significantly improved in the CCP group compared with the SoC group. Outpatient visits were 27% (RR=1.27, 95% CI 1.10 to 1.46) more likely in the CCP group. Readmissions in the newborn, adjusted for confounders, were 56% (RR=0.44, 95% CI 0.31 to 0.61) lower in the CCP group.

**Complications**

The overall risk of mother or newborn complications reduced significantly in the CCP group as compared with the SoC group. Risks of newborn complications were reduced by 16% (RR=0.84, 95% CI 0.76 to 0.91) and mother complications by 12% (RR=0.88, 95% CI 0.79 to 0.97).

**DISCUSSION**

**Summary**

This study explored the feasibility and effectiveness of a hospital-run, family-focused training programme that provides education on multiple evidence-based newborn care practices. Our findings indicate that participation in the in-hospital programme was associated with an increase in the uptake of multiple key newborn care practices and health-seeking behaviours.
The CCP incorporates postnatal care principles to facilitate the transfer of healthy practices during the critical window of newborn care. Our study showed positive behaviour uptake in the right direction for all behaviours except handwashing. However, only behavioural changes associated with skin-to-skin care and dry cord care were statistically significant.

### Interpretation

The prevalence of dry cord care in several studies from community settings in India varied from 49% to 72%. Our study showed a much higher prevalence at 88%, even before the intervention; this may be because it consisted of only hospital-delivered populations. Our skin-to-skin care was very low in the SoC group at about 5% as compared with other studies in rural India reporting 15%. The reason for this difference from other studies was that we measured this practice only after discharge and did not include in-hospital behaviours. We also saw a high uptake of skin-to-skin care as compared with other behaviours. One reason could be that in most hospitals, skin to skin care is promoted only for premature and low-birth weight babies, whereas our training included this for all babies. Breastfeeding levels were high at baseline and did not show change with CCP. This may be due to a ceiling effect as most women were already breast feeding. However, we did not observe this ceiling effect with dry cord care.

Of note, our study found greater changes in complications and readmissions than changes in newborn and maternal care practices. The apparent difference in effect may be because different care practices have varying influence on complication risk. Probably illness recognition and timely care seeking, improved as reported by increased outpatient visits in the CCP group. This may have had an effect on reducing complications and readmissions. On the other hand, it is also possible that our

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**Table 3** Risk ratios for the post-intervention CCP group as compared with the pre-intervention SoC group

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>SoC N (%)</th>
<th>CCP N (%)</th>
<th>ARD</th>
<th>Risk ratio</th>
<th>Unadjusted</th>
<th>Adjusted†</th>
<th>95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health systems engagement instructions</td>
<td></td>
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</tr>
<tr>
<td>Baby care</td>
<td>482 (32.70)</td>
<td>1268 (36.13)</td>
<td>3.43</td>
<td>1.10</td>
<td>1.10 (1.01 to 1.19)‡</td>
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<tr>
<td>Warning signs</td>
<td>428 (29.04)</td>
<td>1171 (33.36)</td>
<td>4.32</td>
<td>1.15</td>
<td>1.08 (0.97 to 1.18)</td>
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<tr>
<td>Healthy behaviours</td>
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<tr>
<td>Exclusive breast feeding</td>
<td>1232 (83.58)</td>
<td>3076 (87.64)</td>
<td>4.06</td>
<td>1.05</td>
<td>1.02 (0.99 to 1.04)</td>
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<tr>
<td>Skin to skin care</td>
<td>71 (4.82)</td>
<td>324 (9.23)</td>
<td>4.41</td>
<td>1.92</td>
<td>1.78 (1.37 to 2.27)‡</td>
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<tr>
<td>Dry cord care</td>
<td>1292 (87.65)</td>
<td>3201 (91.20)</td>
<td>3.55</td>
<td>1.04</td>
<td>1.04 (1.02 to 1.06)‡</td>
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<tr>
<td>Mother’s diet</td>
<td>449 (30.46)</td>
<td>1083 (30.85)</td>
<td>0.39</td>
<td>1.01</td>
<td>1.03 (0.94 to 1.13)</td>
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<tr>
<td>Hand hygiene</td>
<td>1150 (78.02)</td>
<td>2666 (75.95)</td>
<td>2.07</td>
<td>0.97</td>
<td>0.98 (0.94 to 1.01)</td>
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<tr>
<td>Healthcare seeking</td>
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<tr>
<td>Readmission</td>
<td>70 (4.75)</td>
<td>78 (2.22)</td>
<td>2.53</td>
<td>0.47</td>
<td>0.44 (0.31 to 0.61)‡</td>
<td></td>
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<tr>
<td>Outpatient visits</td>
<td>218 (14.81)</td>
<td>658 (18.76)</td>
<td>3.95</td>
<td>1.27</td>
<td>1.27 (1.10 to 1.46)‡</td>
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<tr>
<td>Complications</td>
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<tr>
<td>Newborn</td>
<td>553 (37.52)</td>
<td>1065 (30.34)</td>
<td>7.18</td>
<td>0.81</td>
<td>0.84 (0.76 to 0.91)‡</td>
<td></td>
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<tr>
<td>Mother</td>
<td>464 (31.48)</td>
<td>935 (26.64)</td>
<td>4.84</td>
<td>0.85</td>
<td>0.88 (0.79 to 0.97)‡</td>
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</table>


*95% CI, Confidence Interval of Adjusted Risk Ratio.

†Adjusted for age and educational status of mother, gender of baby, prematurity, low birth weight (<2500 grams), gravida and type of delivery.

‡Significant with CI not including null value.

CCP, Care Companion Programme; SoC, standard of care.
The primary strengths of our study are its large sample size, measurement of multiple health behaviours and representation of public health settings spanning 11 hospitals in two states. Prior studies evaluating hospital-based postnatal programmes consisted of single sites with small sample sizes or only assessed impact of education on single behaviours like breast feeding. Additionally, this study took place in district hospitals which account for a large proportion of deliveries occurring in government run facilities.

Despite these strengths, there are important limitations to this study. The observed outcomes are self-reported and subject to desirability bias. It is also possible that other programmatic changes could have influenced observed outcomes during the study period. In particular, the LaQshya programme, which aimed at improving labour room and operation theatre quality, was launched soon after the postintervention period in December 2017, and one hospital successfully gained quality improvement accreditation. These factors may contribute to an overoptimistic estimate of the effects.

Additionally, it is uncertain and possibly context dependent whether any trained healthcare staff can train families, what is the ‘correct’ format and intensity of training and how much customisation versus standardisation of training content is appropriate. The current model is suited for facilities with dedicated manpower like nursing or counselling staff, groups of patients present simultaneously with similar conditions and buy-in from stakeholders about the importance of patient and family engagement. Until, CCP has been implemented in 152 district hospitals and 10 medical colleges—facilities with the number of beds ranging from 75 to 500—and 41 subdistrict hospitals which have 31 to 100 beds. Replicability of this CCP model to smaller facilities and health centres may be limited. To adapt to these care settings and scale-up CCP effectively, programme modifications like shorter training sessions, mobile-based postdischarge patient and family engagement are being tested and evaluated.

In terms of sustainability, CCP is implemented through a joint partnership between the state and the development partner, but the latter does monitoring and support for the programme. The transition of these responsibilities to the implementing states is also being explored.

**Strengths and limitations**

The family-centred care model is useful in discharge planning by equipping families with essential newborn health skills and improving newborn outcomes. The CCP sessions are held with groups of families and the programme emphasises the ability of family members to learn together and practice multiple high-impact health skills. The CCP taps into the collectivist mindset, increasing willingness to learn during life events. Hospital staff also are able to address any concerns and answer questions during training sessions, which allows for increased engagement and group discussion of difficult care practices.

Within overburdened care settings, educational interventions face implementation challenges due to limited availability of healthcare workers. The streamlined CCP design with rotation of staff conducting sessions coupled with group classes alleviates the burden of individual and repetitive counselling. In hospital, postnatal education using existing resources can be cost-effective compared with community outreach. The in-hospital setting is often the only form of newborn education families receive and prevents missed opportunities to deliver comprehensive information on newborn care. The multitopic curriculum can be delivered using multiple modalities to target caregiver activation during hospital stays and can improve neonatal outcomes.

**Figure 1** Adjusted risk ratios for the post intervention group CCP group as compared with the pre-intervention SoC group. CCP Care Companion Program; SoC standard of care.
CONCLUSIONS
This study demonstrated that an in-hospital postnatal education programme can effectively cover multiple newborn care practices and improve outcomes through a family-centred approach. This is a key finding that can inform further efforts to design and evaluate improved postnatal education programmes in healthcare settings, particularly, in LIMCs. Positive behaviour change varied with different behaviours. There is an opportunity for the ongoing programme evaluation to allow replication to promote caregiver uptake of newborn care practices following hospital discharge.

The CCP model lends itself for use in LMIC hospital settings, especially where there are supportive family structures for chronic health conditions or where the family is the most consistent factor in the patient’s life and well-being. The simple yet engaging training infrastructure can be integrated into formalised hospital processes as a way to relieve overburdened healthcare systems from downstream complications. The programme equips family members with skills that will benefit the patient and enable caregivers to view their roles as an essential component of care delivery.

REFERENCES

Competing interests Yes, there are competing interests for one or more authors and I have provided a Competing Interests statement.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by ACE Independent Ethics CommitteeITEM-01/SOP-03-v03. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data that support the findings of this study are available from the corresponding author, upon reasonable request.

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Acknowledgements We would like to thank colleagues from Ariadne Labs, Megan Marx Delaney, Lauren Bobanski, and Katherine Semrau, and Noorea colleagues Shirley Yan and Arjun Rangarajan for their review and technical editing. Additionally, we would like to thank Pradeep Kumar K, trainers from NHM and data collectors for coordinating data collection and permissions. Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) publication guidelines guided the manuscript submission.

Contributors SK, NR, SD and RP were involved in planning of the study and supervised the work. SK, AFS and SM drafted the manuscript. Pant performed the analysis, and wrote up the results. BK, RN gave inputs on the partnership and scalability aspects in the manuscript. AK added details on the training section. TS and BP wrote the methods section. AK, TS and BP helped with revisions of the manuscript. SA conceptualised the intervention and did critical review of the manuscript and is the guarantor. SK is the All authors discussed the results, commented on the manuscript and approved the final draft.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors. Publication of this article is made Open Access with funding from the Nationwide Quality of Care Network.