



ORIGINAL ARTICLE

Community Kangaroo Mother Care: implementation and potential for neonatal survival and health in very low-income settings

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Objective: Immediate Kangaroo Mother Care (IMC), an intervention following childbirth whereby the newborn is placed skin-to-skin (STS) on mother's chest to promote thermal regulation, breastfeeding and maternal-newborn bonding, is being taught in very low-income countries to improve newborn health and survival. Existing data are reviewed to document the association between community-based IMC (CKMC) implementation and its potential benefits.

Study Design: New analyses of the sole randomized controlled study of CKMC in Bangladesh and others' experiences with immediate IMC are presented.

Result: Newborns held STS less than 7 h per day in the first 2 days of life do not experience substantially better health or survival than babies without being held STS.

Conclusion: Most women who were taught CKMC hold their newborns STS, but do so in a token manner unlikely to improve health or survival. Serious challenges exist to provide effective training and postpartum support to achieve adequate STS practices. These challenges must be overcome before scaling up.

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Keywords: Kangaroo Mother Care; skin-to-skin; newborn mortality

Introduction

In traditional Kangaroo Mother Care (KMC), clinically stabilized hospital-born newborns, usually weighing ≤ 2 kg at birth, are placed in continuous skin-to-skin (STS) contact with the mother's

breast. This promotes thermal regulation, on-demand breastfeeding and maternal–infant bonding. Some studies claim that KMC reduces newborn mortality (NMR) and infant mortality.^{1,2} However, scientific reviews³ of methodologically sound studies^{4–6} conclude that KMC reduces the incidence of morbidity in preterm and low birth weight infants. The evidence is insufficient to conclude regarding the effects of KMC on mortality.³ Traditional KMC may not prevent death because it is applied to clinically stabilized newborns. Most newborn deaths occur in the first few days of life, before many preterm babies are stabilized.

To determine whether KMC provided immediately after birth in settings with little access to neonatal care could reduce mortality, an international, multidisciplinary group successfully adapted traditional KMC for community-based application (community-based KMC (CKMC)) in rural Bangladesh.⁷ Bangladesh is a very low-income country with little access to specialized neonatal care. Over 90% of births occurred at home,⁸ and over one-third of births were considered low birth weight at the time of the study.⁹ In this setting, it was thought that CKMC might prevent hypothermia and pneumonia, improve exclusive breastfeeding and thus potentially prevent NMR. CKMC was designed to be taught to local professional trainers who would teach existing qualified community workers (CWs). The CWs would then teach CKMC to village women and their families. Like traditional KMC, CKMC teaches that STS should be provided continuously to ensure thermal regulation. Unlike KMC, CKMC is initiated immediately after birth, without being limited to clinically stabilized babies. CKMC is further described elsewhere.⁸

Our ($n = 35$) pilot study of the training protocol found that 77% of newborns were held STS in the first 2 days of life, of which 69% were held STS ≥ 7 h per day. In all, 41% of babies held STS were exclusively breastfed compared with 25% not held STS.⁷ The study team thought that this reflected adequate CKMC implementation. We then conducted a randomized controlled cluster trial (RCT) to determine the effects of CKMC on newborn

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and infant health and survival. The RCT found that 77% of babies in the CKMC group were held STS; however, only 24% were held STS ≥ 7 (average 4.5) hours per day in the first 2 days of life.¹⁰ Overall, NMR was nearly identical in the CKMC and control groups. Birth weight was modeled for babies whose weight was measured within 7 days of birth by adjusting for age at measurement. In babies whose birth weight was ≤ 2 kg, NMR was 22.5% in the control group and 9.5% ($P = 0.02$) in the CKMC group. However, the significantly lower NMR in small babies is inconclusive, as 43% of all babies and 68% of those dying in the newborn period were not weighed within 7 days nor was the relative overall change in NMR before and after the study period statistically different. To date, this is the only RCT of the effects of CKMC on health and survival.

Together with information from other KMC and early KMC (prompt postnatal implementation in hospitals) studies, the CKMC RCT generated broad international enthusiasm for promoting STS practices. The Millennium Development Goal 4 (MDG4) is to reduce mortality in children under age 5 by two-thirds between 1990 and 2015. As one of various fast track mechanisms to achieve MDG4, CKMC and early KMC are being promoted without hesitation and implemented without sufficient attention to training.^{11,12} This expansion of immediate KMC stems from a misunderstanding of evidence,¹³ selective review,² overly optimistic interpretation of information and insufficient caution.

This paper presents new analyses of the Bangladesh RCT to quantify the amount of CKMC implementation necessary to influence newborn health and survival. We describe others' experiences with immediate KMC and discuss the association between training procedures and CKMC implementation. We also review the distribution of newborn deaths in the Bangladesh trial to understand the proportion of babies who might benefit from immediate KMC.

Methods

The CKMC RCT was conducted to test the effectiveness of CKMC to avert newborn and infant mortality. The study was conducted in 42 geographic units (unions consisting of 5 to 25 villages) in two districts of Bangladesh where infant mortality was particularly high and where the Bangladesh Rural Advancement Committee (BRAC) supervised community nutrition promoters in the National Nutrition Program.¹⁴ As CKMC is a behavioral intervention and as unions within each district were contiguous, a single village from each union was randomly selected, which was proportionate to the population size, to prevent control group exposure to CKMC messages.

A baseline survey of 39 888 age-eligible women (12 to 50 years old) living in nearly 25 000 households was conducted in the study villages between January and September 2004. Between October 2004 and March 2005 a household surveillance system was

initiated to prospectively identify pregnancies and births during the experimental trial. During the trial, Mitra and Associates, an independent research organization, identified consenting, eligible pregnant women through quarterly household surveillance for 15 consecutive months. Newborns were followed at ~ 30 to 45 days and infants were followed quarterly through their first birthday to assess CKMC behaviors, contact with the community-based workers and others, and health-care utilization, nutritional status, reported morbidity and vital status.¹⁰ Mothers were visited over a final 3-month period to determine the vital status of infants who had not completed their fourth quarterly assessment. CKMC implementation was assessed using numerous variables; however, only STS in the first 2 days of life was significantly associated with lower NMR. Although vital status was assessed for all babies through 28 days of life, newborn STS was not assessed for babies who were only followed up well after the newborn assessment to avoid recall bias. The study enrolled 4213 births, including 4165 live births and 160 stillbirths. The study is further described elsewhere.⁹

A BRAC physician from the CKMC pilot study selected and provided CKMC training to 12 BRAC field supervisors who were not experienced or professional trainers. The physician and the one supervisor most adept at CKMC training then trained 98 CWs and their 25 supervisors already employed in community NGO or government programs. The supervisors and CWs serving the 21 intervention group villages were trained in five groups of 6 to 22 people over a 2-month period. Once trained, the CWs, alone or jointly with the BRAC supervisors, taught CKMC to expectant mothers and their families in the intervention group villages. The CWs provided CKMC pamphlets to most pregnant intervention group women, and extra copies as requested for the woman's own use or for distribution to others.

Bivariate and multivariate analyses presented in this paper are conducted by hours of STS practiced and study group. Intention-to-treat analyses (for example, by study group only) have been previously published and do not quantify the association of amount of STS with outcome.¹² Only two control group mothers reported STS, and their reported STS was very little. In analyses including the control group, they are included in the control group. The χ^2 and Student's *t*-tests were used to evaluate the associations of STS groups and outcome for categorical and continuous variables, respectively. As death in the first 2 days of life, called very early NMR, influenced the provision of STS, most analyses presented in this paper exclude newborns dying in the first 2 days of life. Excluding very early newborn deaths ensures that all newborns in the analysis had a similar opportunity for being held STS. Multivariate regression analyses were conducted to identify whether parental characteristics influence the time babies were held STS. Analyses were conducted using SPSS version 17.0 software (IBM Corporation, Somers, NY, USA). The study was approved by the institutional

review board of the Population Council, Tufts University Medical Center (currently inactive), Columbia University Medical Center and the Bangladesh Medical Research Council. Others' experiences with CKMC and early KMC are discussed.

Results

All of the 4165 livebirths in the Bangladesh RCT were followed through 28 days of life. Although some differences were statistically significant owing to the large sample size, the CKMC and control groups had similar sociodemographic and reproductive backgrounds.⁹ Over 40% of mothers were illiterate, (control 45%, CKMC 49%, NS). However, 27% CKMC and 34% control group mothers never attended school ($P \leq 0.001$). Women, on average, were 23.1 ± 5.9 years old (control and CKMC groups). In both groups, 7 out of 10 women were multiparous. Nearly 90% of women gave birth in their own or another's home (NS). Significantly, though only slightly, more women in the CKMC than in the control group had skilled assistance at delivery (37 versus 32%, $P = 0.002$). In all, 48% of control babies were male compared with 50% in the CKMC group ($P = 0.006$). Multiple gestations were 3.6% on average and similar in both groups. Average gestation was 285 ± 22 days in the control and 285 ± 21 days in the CKMC group.

Birth weight was not available for 983 of 1396 (70%) of babies born in facilities or in others' homes. Birth weight was also missing for 89 of the 113 (79%) newborns that died soon after birth, as it is culturally unacceptable to measure them after death in rural Bangladesh. Most NMR occurred in the first 2 days of life, 56% on the day of birth and an additional 5% on the following day. Weight was measured within 7 days of birth for 59.0% of CKMC and 54.2% of control group live-born infants ($P = 0.002$). In those measured within 7 days of birth, mean birth weight was 2701 ± 453 g in the control and 2690 ± 468 g in the CKMC groups ($P = 0.57$) and 8.4% of control and 10.4% of CKMC babies weighed ≤ 2 kg at birth ($P = 0.10$).

Most newborn deaths in the CKMC group occurred in babies who were held STS ≤ 1 h per day (NMR = 8.4%) or who had missing newborn STS assessment (NMR = 8.1%; Table 1). NMR was 2.8% in babies held STS between 2 and 6 h per day in the first 2 days of life. Only five newborn deaths (NMR = 0.9%) occurred in CKMC babies held STS ≥ 7 h per day in the first 2 days of life. The distribution of newborn deaths by STS in the first 2 days of life is the basis for the classification of STS in the first 2 days of life as: missing STS information, not held STS in the first 2 days of life, held STS ≤ 1 h a day, held >1 to <7 h a day and held ≥ 7 h a day.¹⁰

Sick babies, particularly those dying in the first days of life were less likely to be held STS than healthy babies. A total of 61% of newborn and 42% of infant deaths occurred in the first 2 days of life. Excluding newborns dying in their first 2 days of life, NMR was 4.6% in those missing newborn STS information, 2.8% in those not held STS, 2.0% in those held ≤ 1 h per day, 1.4%

Table 1 Distribution of newborn deaths in CKMC group by hours held skin-to-skin in first 2 days of life

Hours STS in the first 2 days of life	Newborn deaths (n = 97)	% of newborn deaths	Total (n = 2121)
Missing	11	11.3	136
0	54	55.7	580
1	8	8.2	158
2	4	4.1	144
3	4	4.1	153
4	2	2.1	138
5	5	5.2	125
6	4	4.1	112
7	0	0	103
8	1	1.0	97
9	1	1.0	78
10	0	0	62
11	0	0	48
12	0	0	45
13	0	0	28
14	0	0	18
15	0	0	10
16	1	1.0	22
17	0	0	18
18	0	0	16
19	0	0	13
20	0	0	5
21	1	1.0	4
22	1	1.0	6
23	0	0	1
24	0	0	1

Abbreviations: CKMC, community-based Kangaroo Mother Care; STS, skin-to-skin.

in those held >1 h and <7 h per day and 0.9% in those held ≥ 7 h per day.

CW contact in pregnancy was the single factor that most associated with time held STS.¹⁰ Only 47.6% of those never held STS reported CW contact in the last month of pregnancy compared with 77.1% held STS <1 h per day, 87.1% held STS ≥ 1 h to <7 h per day and 93.8% of those held STS ≥ 7 h per day. Except for when and how to initiate weaning practices, all of the CKMC behaviors (about STS, breastfeeding, sleeping with the baby, delay bathing the baby) are associated with daily hours of STS. Receiving the CKMC pamphlet was strongly associated with community nutrition promoters contact and daily hours of STS. STS was implemented equally in boys and girls. Fewer twins were held STS and twins held STS were mostly held <7 h per day in the first 2 days of life. Illiterate women held their babies STS for 0.7 h per day longer in the first 2 days of life than literate women ($P = -0.002$). The number of children under the age five living in the household had no association with STS.

Table 2 Newborn factors influenced by the daily hours of STS in the first 2 days of life, excluding babies dying in the first 2 days of life and those missing early STS data

Newborn (~ 28 days) assessment	All weighed and not weighed						
	CKMC group						
	Control group. % (n)	Total CKMC. % (n)	Never, % (n)	>0. ≤ 1 h. % (n)	>1. < 7 h. % (n)	≥ 7 h. % (n)	P (within CKMC)
Exclusively breastfed	3.20 (1875)	6.10 (1931)	3.10 (541)	4.60 (153)	7.10 (662)	17.60 (576)	≤ 0.001
Saw breastfed	64.60 (1835)	72.2 ^a (1894)	60.70 (524)	68.20 (151)	76.80 (650)	78.60 (n = 569)	≤ 0.001
Caressed baby	75.50 (1835)	81.9 ^a (1894)	78.20 (524)	86.80 (151)	81.70 (650)	84.40% (569)	0.024
Bathed on DOB	73.20 (1872)	29.50 (1930)	53.00 (540)	37.30 (153)	26.30 (662)	9.00 (575)	≤ 0.001
Well baby care	1.10 (1873)	1.30 (1924)	2.40 (538)	3.30 (153)	0.30 (660)	0.90 (574)	≤ 0.001
Sick baby care	7.70 (1865)	8.20 (1925)	10.00 (541)	11.10 (153)	7.40 (658)	6.60 (574)	0.088
Morbidity (past 2 weeks)	(1848)	(1916)	(527)	(151)	(652)	(572)	
Fever	48.30	46.50	52.30	48.70	44.10	44.20	0.016
Cough	54.10 (1844)	49.40	57.80	60.50	46.10	45.70	≤ 0.001
Rapid breathing	19.50	19.00	23.50	23.00	16.30	17.80	0.005
Did not want to breast feed	12.50	11.80	15.3	12.50	9.60	11.40	0.029
Became agitated	17.00 (1844)	15.10	20.30	16.40	11.90	14.00	≤ 0.001
Mortality	(1875)	(1931)	(541)	(153)	(662)	(575)	
NMR	1.80	1.80	2.80	2.00	1.40	0.90	0.018
Weighed < 2 kg in first 7 days of life							
Newborn (~ 28 days) assessment	CKMC group						
	Control group. % (n)	Total CKMC. % (n)	Never, % (n)	>0. ≤ 1 h. % (n)	>1. < 7 h. % (n)	≥ 7 h. % (n)	P (within CKMC)
	Exclusively breastfed	1.10 (88)	5.00 (121)	0 (19)	12.50 (8)	5.60 (54)	5.00 (40)
Saw breastfed	64.50 (88)	76.10 (121)	70.60 (17)	50.00 (8)	84.60 (52)	72.50 (40)	0.13
Caressed baby	72.40 (88)	83.80 (121)	82.40 (17)	50.00 (8)	86.5 (n = 52)	87.50 (40)	0.06
Bathed on DOB	76.10 (88)	23.10 (121)	57.90 (19)	37.50 (8)	22.20 (54)	5.00 (40)	≤ 0.001
Well baby care	0 (88)	0 (121)	0 (19)	0 (8)	0 (54)	0 (40)	NA
Sick baby care	4.50 (88)	5.30 (121)	0 (19)	5.60 (8)	5.00 (54)	5.00 (40)	0.93
Morbidity (past 2 weeks)	(88)	(117)	(18)	(7)	(52)	(40)	
Fever	48.80	58.10	61.10	71.40	46.20	70.00	0.11
Cough	53.80	50.40	44.40	57.10	48.10	55.00	0.84

Table 2 Continued

Newborn (~28 days) assessment	All weighed and not weighed						P (within CKMC)
	Control group, % (n)	Total CKMC, % (n)	Never, % (n)	>0, ≤1 h, % (n)	>1, <7 h, % (n)	≥7 h, % (n)	
Rapid breathing	20.00	24.80	22.20	0	23.10	32.50	0.29
Did not want to breast feed	13.80	17.90	16.70	14.30	11.50	27.50	0.26
Became agitated	13.80	20.50	16.70	42.90	17.30	22.50	0.44
Mortality	(88)	(123)	(19)	(8)	(54)	(40)	
NMR	13.60	3.3 ^b	5.30	12.50	3.70	0	0.42

Abbreviations: CKMC, community-based Kangaroo Mother Care; DOB, day of birth; NA, not applicable; NMR, newborn mortality; STS, skin-to-skin.

^aCKMC versus control $P \leq 0.001$.

^bCKMC versus control $P \leq 0.01$.

Table 2 presents the association of STS with other behaviors promoted in CKMC and with health and survival. The data exclude babies who died in their first 2 days of life and babies with missing STS information (from both intervention and control groups) to ensure all babies in the analysis had similar opportunity for being held STS.

Twice as many CKMC as control babies were exclusively breastfed at the newborn assessment (Table 2). Babies held STS ≥ 7 h per day in the first 2 days of life had an exclusive breastfeeding rate substantially higher (17.6%) than the control group (3.5%). The rates of exclusive breastfeeding by study group and by STS group were nearly identical in the total sample compared with babies born in their mother's own home (data not shown).

Babies held STS longer in the first 2 days of life were more likely to be breastfed and caressed during the interview. In all, 73% of control mothers bathed their babies on the day they were born. Most CKMC mothers delayed bathing the baby beyond the day of birth. Only 10% of mothers who held their babies STS ≥ 7 h per day in the first 2 days of life bathed their newborns on their day of birth.

There was little utilization of preventive or therapeutic health care in the CKMC and control groups. In babies weighing ≤ 2 kg at birth, none had well baby visits. Use of health care significantly declined with longer duration of STS.

Newborn fever, cough, breathing problems, agitation and not wanting to breastfeed generally declined with hours held STS in the entire CKMC sample, but generally increased with hours held STS in babies weighing ≤ 2 kg at birth. There is a significant dose-response relation between hours of STS in the first 2 days of life and NMR, particularly in those held STS ≥ 7 h per day. There is no difference in overall NMR between the CKMC and control groups in the entire sample. The difference in NMR (control = 13.6%, CKMC = 3.3%) is highly significant in babies with birth weight ≤ 2 kg. Of the 32 newborn deaths in CKMC babies surviving the

first 2 days of life, 14 were classified by verbal autopsy as due to septicemia, 9 to pneumonia, 4 to birth asphyxia, 2 to prematurity, 1 to jaundice and 2 to congenital cyanotic heart disease. Birth asphyxia, pneumonia and diarrhea were the most common causes of death in babies with birth weight ≤ 2 kg.

Discussion

CKMC continues to be a promising but unproven way to prevent NMR. The new analyses presented by STS implementation indicate that impact on survival is concentrated in those held STS ≥ 7 h a day in the first 2 days of life. NMR in CKMC babies missing STS data or not held STS was about twice the rural NMR (4.1%) during the study period (Table 1).¹⁵ Even after excluding babies dying in their first 2 days of life, NMR was much higher in those held ≤ 1 h per day, with fewer but still a considerable number of deaths in those held >1 to <7 h a day. NMR was one quarter of the national rural norm in those held STS ≥ 7 h per day.

Only 24% of trial CKMC mothers held their babies STS ≥ 7 h per day compared with 69% in the pilot study. There are many reasons why mothers in the RCT held their babies for shorter periods. We believe STS implementation in the RCT was diminished by engaging individuals who were not experienced trainers and were not trained by KMC experts. Most postpartum Bangladeshi women are permitted a few days rest, so this should not have constrained STS. The CKMC trial and pilot studies also covered a similar number of intervention villages ($n = 21$ and 19, respectively). The trial was considerably longer than the pilot study yet time held STS increased only slightly over the RCT study period. The CWs had contact with the vast majority of women who were living in and delivered in their own homes. In Bangladesh, it is common for women, particularly primiparous women, to go to their relatives' home to deliver. Women who go to their relatives' homes to deliver usually go in their last few months of pregnancy. Women who did

not deliver in their own homes had significantly less contact with the CWs. The CWs convinced most women with whom they had contact to hold their newborns STS, but were generally unable to convince most women to hold their babies STS continuously. Although more adept CWs may not require training from experienced professional trainers, such expertise may make all the difference in the ability of the average CW to convince mothers to hold their babies STS continuously.

Exclusive or predominant breastfeeding and breastfeeding within an hour of birth, associated with infant survival in very low resource countries,^{16,17} was only substantially increased in those held ≥ 7 hours per day in the first 2 days of life. There was little association of STS with utilization of health care or reported symptoms of newborn morbidity. Improving health-care utilization is challenging in such settings.¹⁸ Morbidity based on lay reports in areas with minimal literacy is unreliable. Thus, the study may have been unable to detect differences in illness. However, the dose response between hours held STS in the first 2 days of life and NMR is strong and statistically significant, and it persists even after excluding those dying in the first 2 days of life.

Similar to the observations in Bangladesh, STS was slightly but significantly associated with survival in the Shivgarh, India, essential newborn care trial that included CKMC as an intervention.¹⁹ And, similarly STS implementation was limited. In the Shivgarh intervention group, about 75% of newborns were held STS for <1 h one to three times a day.²⁰ Program evaluations from Nepal where CKMC training was didactic, with shorter training periods and larger training groups than the Bangladesh RCT, show that 2–7% of babies are held STS round-the-clock, with 62 to 73% of babies held ≥ 3 h of STS per day.²¹ In rural Ghana where training included practice, other barriers were encountered.²² Experienced clinical investigators engaged in improving newborn care in rural India found community-based STS promotion infeasible (Personal communication, Abhay Bang).

Although some profess KMC, CKMC and early KMC improve survival; methodologically sound evidence does not exist to justify this claim. Numerous small and otherwise methodologically challenged studies of STS and early STS suggest that under certain conditions, early STS is safe and is as or more effective than standard incubator care in maintaining temperature, prevention and treatment of hypothermia and respiratory conditions, and improving breastfeeding practices.^{23–26} However, studies that compare outcomes before, during and after STS have encountered a negative effect on oxygen saturation during STS that is not transient in cold environments.²⁷ A 43% (not statistically significant) lower infant mortality has been observed with traditional KMC in Columbia.²⁸ Lower 24 h mortality²⁹ and mortality before discharge³⁰ were associated with early KMC in two small African studies; however, important differences in study group characteristics were not controlled in analysis. A larger Indian study of early KMC had differential loss to follow-up.³¹

A greater than temporally expected historical improvement in survival of babies weighing 1000 to 1999 g at birth was associated with early KMC in Zimbabwe and South Africa;^{32,33} however, large temporal swings in mortality of babies weighing 1000 to 1999 g have been observed elsewhere without any such intervention.³⁴

The application of KMC in communities and hospitals promotes constant STS to achieve the thermal regulation that would otherwise be achieved by fairly constant containment in an incubator. The average duration of STS in the Bangladesh and Shivgarh RCTs and in CKMC programs is less and inconstant to impart life-saving thermal regulation. Although minimal STS is associated with somewhat lower NMR, we suggest that the criterion of STS ≥ 7 h per day, which was most associated with lower NMR, equivalent to 1/5 of NMR in rural Bangladesh at the time of the study, is an important marker of adequate training, dose and impact.

Given the extremely limited evidence, additional methodologically sound studies are needed to confirm whether and to what extent CKMC and early KMC can prevent NMR in resource-poor settings. A large portion of NMR, before and after the first 2 days of life, is unassociated with prematurity caused by conditions that KMC and CKMC will not affect.

Promotion of CKMC and early KMC, particularly to illiterate, vulnerable populations, with the promise of improved survival is unfounded. Use of preventive care has a critical role in KMC's ability to reduce infant morbidity.⁵ KMC and CKMC quickly become popular.^{9,10,35,36} Programs that minimize training instill token levels of STS that could be difficult to improve, and may actually limit the potential benefits of CKMC while simultaneously encouraging false confidence. In impoverished settings, false confidence may dissuade families from seeking formal health-care services that have been demonstrated to save lives.³⁷ Improvement in training and methodologically sound assessment of CKMC training is needed before scaling up. Families should also be advised that even if CKMC could save some babies' lives, it cannot alone resolve all neonatal conditions. Recommendation and use of specialized care with adequate institutional support is critical for some babies.

Conclusion

CKMC remains a promising but unproven intervention that requires further sound evaluation. To avert neonatal mortality in very low-income settings, CKMC must overcome serious challenges including training and support that achieve STS ≥ 7 h per day in the first 2 days of life. Improving the availability, quality and use of clinical services is also essential to improve newborn survival.

Role of the funding source

The funding sources had no role in the study design, data collection, analysis, interpretation or report composition.

Conflict of interest

The authors declare no conflict of interest.

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