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The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomised trial

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Progress towards the Millennium Development Goals (MDGs) has been uneven. Inequalities in child health are large and effective interventions rarely reach the most in need. Little is known about how to reduce these inequalities. We describe and explain the equity impact of a women's group intervention in India that strongly reduced the neonatal mortality rate (NMR) in a cluster-randomised trial. We conducted secondary analyses of the trial data, obtained through prospective surveillance of a population of 228 186. The intervention effects were estimated separately, through random effects logistic regression, for the most and less socio-economically marginalised groups. Among the most marginalised, the NMR was 59% lower in intervention than in control clusters in years 2 and 3 (70%, year 3); among the less marginalised, the NMR was 36% lower (35%, year 3). The intervention effect was stronger among the most than among the less marginalised (*P*-value for difference = 0.028, years 2-3; *P*-value for difference = 0.009, year 3). The stronger effect was concentrated in winter, particularly for early NMR. There was no effect on the use of health-care services in either group, and improvements in home care were comparable. Participatory community interventions can substantially reduce socio-economic inequalities in neonatal mortality and contribute to an equitable achievement of the unfinished MDG agenda.

Introduction

Progress towards the Millennium Development Goals (MDGs) has been uneven.[1–5] Inequalities in maternal and child health are especially large.[6,7] Few of the poorest women in developing countries receive professional care during delivery, whereas most wealthier women do.[8] The link between socio-economic disadvantage and health disadvantage has serious consequences: one third of global childhood deaths are attributable to inequalities in socio-economic mortality within countries.[9] Effective interventions are known,[10,11] but rarely reach those who need them most.[12–19] Even 'basic' interventions that are thought to favour the poor, such as oral rehydration therapy and immunisation, tend to predominantly reach those who are more economically comfortable.[12–14] Little is known about how to reduce socio-economic inequalities in mortality and how to support an equitable utilization of interventions.[20]

Reducing neonatal mortality is becoming increasingly important to achieve MDG4 ('reduce child mortality') as its relative contribution to under-5 mortality rises.[21] Although policy attention to newborn mortality has until recently been scant,[22] new initiatives for this have begun to emerge.[23] Community-based interventions, including home-based newborn care by community health workers and participatory women's groups, play an important role in strategies to improve neonatal survival, especially in South Asia, where about 50% of births happen at home without professional care.[24–30] Little is known about the equity impact of community-based health interventions.[31] Although there are some accounts of reductions in inequality in health-related behavior,[32,33] there are also indications that they may reinforce existing social hierarchies,[34–36] and there is no evidence about their effect on equity with respect to neonatal mortality.

A cluster-randomised controlled trial of a participatory women's group intervention in India, the 'Ekjut trial', provides a unique opportunity to assess the effect of community interventions on equity through the use of a 'gold standard' design. India is the site of a quarter of global neonatal deaths[37] and inequalities in mortality in the country are large.[38-40] The Ekjut trial showed a strong effect of women's groups on the neonatal mortality rate (NMR) in the population in whom the trial was conducted (a 45% decline in years 2 and 3 of the intervention).[28] Although the trial was conducted in deprived rural areas, these communities are, as in most low- and middle-income countries, not homogenous. Literacy, economic status, land ownership, and tribal status/caste are important dimensions of social stratification. Our study aimed to describe and explain the equity impact of the Ekjut intervention. In particular, we examined: (i) whether the strong effects of the intervention on NMR were also observed among lower socio-economic groups; and (ii) whether there were differences in the effect of the intervention on mortality in the most and less socio-economically marginalised groups. We also explored potential explanations for differences in the effect of the intervention.

Methods

Setting

The study areas were located in three contiguous districts in Orissa and Jharkhand, two of the poorest Indian states, with large tribal (adivasi) populations, of which the majority are classified as Scheduled Tribes under the Indian constitution. Within these districts, 36 poor clusters with a predominantly tribal population were identified and randomly assigned to intervention or control. The intervention arm of the trial received an intervention with participatory women's groups. The participatory groups met on a monthly basis, guided by a facilitator, throughout the 3-year study period. They used a participatory learning and action cycle, in which maternal and newborn health problems were identified and prioritized. Strategies to address these problems were developed, implemented, and evaluated, with the support of the entire community. The trial has been described elsewhere.[28]

Surveillance

All births and neonatal deaths in the study areas were recorded through prospective surveillance. Local key informants, covering about 200–250 households, identified all births, birth outcomes, and deaths to women of reproductive age on an ongoing basis. Every month, the informants reported the identified births and deaths to full-time salaried interviewers, who then verified all of the reported information. At about 6 weeks post-partum, the interviewer administered a questionnaire to the mother. The interview covered socio-economic and socio-demographic background characteristics; home-care practices; use of health-care services during pregnancy, delivery, and the neonatal period; and condition of the mother and baby, including the reported size at birth and gestational age of the baby. In the event of a stillbirth, neonatal death, or maternal death, a verbal autopsy was done with the mother or a close caregiver. The verbal autopsy consisted of a standard questionnaire that also included free text for elaboration on the sequence of events before death. Clinicians assigned cause of death on the basis of the information provided by the verbal autopsy. The surveillance system has been extensively tested in trials over the past 10 years, and has been described in detail elsewhere.[28,41] We included all live births (singletons and twins/triplets) among residents of the study area during the 9-month baseline and 3-year study periods. Mothers who had permanently emigrated from the study areas were excluded from the final study population. Loss to follow-up from migration or refusal of interview was low ($< 2\%$).[28]

Primary outcome

We evaluated the equity impact of the intervention in terms of NMR (number of deaths during the first 28 days of life per 1000 live births; the primary outcome of the original trial) among lower and higher socio-economic groups. The trial paper reported the strongest impact on NMR as occurring in the last two study years, probably because of a lag-time in effect of 9–12 months.[42] Because we were interested in how these strong effects were distributed across socio-economic groups, and because the statistical power requirements of equity impact analyses are higher than for the testing of overall effects, we performed our main analyses on years 2 and 3 combined.

Socio-economic groups

The equity impact of the intervention was examined for those dimensions of social stratification that are important in the rural Indian context of the study: caste/tribal status (comparing Scheduled Tribes and Scheduled Castes, both of which are historically disadvantaged and recognised as such by the Indian constitution, with the rest of the study population), land ownership, literacy, and asset ownership. In conjunction with local collaborators, we constructed lower and higher socio-economic categories that were meaningful in the context of the study. Asset ownership was measured with an index constructed using principal component analysis (PCA) which was applied to all durable consumer items in the questionnaire (electricity generator, battery, tape, electric fan, television, refrigerator, motor, radio, bicycle). PCA was done on a data set including all years of the intervention. Further analysis showed that the poorest category owned nothing or only a bicycle. Because the study areas were socio-economically deprived, the distribution of socio-economic position was skewed, with 60–80% of live births occurring among women in the lowest categories (Table 1). Although it is important to examine whether the intervention benefited not only the 'elite' 20–40% of the study population, substantial effects of intervention are expected in lower socio-economic groups, given the strong overall effects of the intervention and that most of the population belongs to these groups. We therefore went one step further and examined whether the intervention benefited the most socio-economically marginalised persons in the population, consisting of those who were illiterate, and very poor, and had little or no land, and belonged to Schedule Tribes or Scheduled Castes, thereby explicitly considering the multi-dimensional aspect of social stratification in the context of the study. About 30% of the study population belong to the most socio-economically marginalised groups, with the remainder belonging to those less marginalised.

Analyses

First, we obtained cluster-adjusted estimates of the NMR for the total population and for each socio-economic category, year, and study arm (as presented in Table 2), using random-effects logistic regression (Equation 1). Separate models were made for each dimension of social stratification. For individual j in cluster i, the logarithm of the odds of neonatal death (NND) is:

$$\begin{aligned}\text{log odds NND} &= \alpha + \beta_1(\text{YearL\_i}) + \beta_2(\text{YearL\_c}) \\ &+ \beta_3(\text{YearH\_i}) + \beta_4(\text{YearH\_c}) + \beta_5(\text{Contint}) + \beta_6(\text{SEP}) \\ &+ \beta_7(\text{Contint}^*\text{SEP}) + \beta_8(\text{STRATA}) + \text{u}_\text{i} + \varepsilon_\text{j}\end{aligned} \tag{1}$$

where YearL_i, YearL_c, YearH_i, and YearH_c are the differences in NMR between consecutive intervention years (with year as categorical variable) and the baseline year for the low (L) and high (H) socio-economic groups in the intervention and control arms, respectively. Contint represents the difference in NMR between the intervention- and control-arms at baseline; SEP the effect of socio-economic position at baseline in the control arm; Contint*SEP the difference in effect of socio-economic position between the intervention and control arms; STRATA the adjustment for the stratified sampling design; and u the random-effect term, i.e. the difference for each cluster i vs. the baseline α.

We then estimated linear trends in NMR between baseline and year 3 for each socio-economic category and study arm by defining year as the interval variable in Equation 1. Next, we replicated the trial analysis by comparing the NMR in intervention and control areas for the total study population for years 2 and 3 combined, using a random-effects logistic regression model. We expanded this using Equation 2 to estimate the effects of intervention for lower and higher socio-economic groups separately (Table 3). For individual j in cluster i:

$$\begin{aligned}\text{log odds NND} &= \alpha + \beta_1(\text{INT\_L}) + \beta_2(\text{INT\_H}) \\ &+ \beta_3(\text{SEP}) + \beta_4(\text{STRATA}) + \text{u}_\text{i} + \varepsilon_\text{j}\end{aligned} \tag{2}$$

where INT_L and INT_H are the differences between the intervention and control arms among low- and high socio-economic groups respectively, and SEP is the effect of low socio-economic position in the control arm.

Lastly, we tested the difference in the effect of intervention in lower vs. higher socio-economic groups, using a different parameterisation of Equation 2 (Equation 3; see also Table 3).

$$\begin{aligned}\text{log odds NND} &= \alpha + \beta_1(\text{INT\_H}) + \beta_2(\text{SEP}) \\ &+ \beta_3(\text{SEP} * \text{INT\_H}) + \beta_4(\text{STRATA}) + \text{u}_\text{i} + \varepsilon_\text{j}\end{aligned} \tag{3}$$

where SEP*INT_H is the difference in intervention effect between lower and higher socio-economic groups.

To explain our findings, we explored whether differences in effect between the most and less marginalised groups were concentrated in the early (days 1–7) or late (days 8–28) neonatal period. Furthermore, given the strong seasonality in NMR in our population, we examined whether differences in effect were seasonal. Additionally, using the equations given above, we explored whether the use of health care (particularly ante-natal, delivery, and post-natal care, and medical care-seeking in case of an infant illness), home-care practices (particularly practices related to prematurity, hypothermia, and infections), and attendance at the women's groups would explain our findings.

We examined whether baseline differences could explain our findings using Equation 1. Where baseline

Table 1 Distribution of live births (lbirth) and neonatal deaths (nnd) by socio-economic position and year, in intervention and control areas

Socio-economic position	Intervention												Control												Intervention and Control		
	baseline			Year 1			Year 2			Year 3			baseline			Year 1			Year 2			Year 3			Total		
	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd	lbirth	(%)	nnd
Total	2347	100%	145	3050	100%	167	3264	100%	121	3074	100%	109	2162	100%	116	2917	100%	153	2973	100%	177	2929	100%	188	22 716	100%	1176
Marginalisation[a]																											
Most marginalised	823	35%	58	1058	35%	66	1021	31%	31	889	29%	20	594	28%	39	916	31%	62	843	28%	46	795	27%	57	6939	31%	379
Less marginalised	1524	65%	87	1992	65%	101	2243	69%	90	2185	71%	89	1568	72%	77	2001	69%	91	2130	72%	131	2134	73%	131	15 777	69%	797
Literacy																											
Cannot read	1813	78%	125	2321	76%	129	2506	77%	93	2292	75%	82	1489	70%	85	2084	71%	118	2009	68%	125	2016	69%	134	16 530	73%	891
Can read (easily or with difficulty)	526	22%	19	729	24%	38	758	23%	28	782	25%	27	653	30%	29	833	29%	35	964	32%	52	913	31%	54	6158	27%	282
Asset ownership																											
Poorest	1692	72%	113	2183	72%	118	2331	71%	97	2136	69%	72	1299	60%	73	1742	60%	101	1721	58%	106	1651	56%	122	14 755	65%	802
Less poor	654	28%	32	867	28%	49	933	29%	24	938	31%	37	863	40%	43	1175	40%	52	1252	42%	71	1278	44%	66	7960	35%	374
Land ownership																											
Landless or < 2 bighas	1431	62%	88	1856	61%	110	1825	56%	57	1613	53%	52	1282	60%	81	1812	62%	105	1825	62%	106	1792	61%	120	13 436	60%	719
Owns 2 or more bighas	891	38%	53	1172	39%	56	1426	44%	63	1456	47%	57	857	40%	35	1088	38%	46	1121	38%	68	1129	39%	68	9140	40%	446
Caste/tribe																											
Scheduled Tribe or Scheduled Caste	1849	79%	118	2447	80%	141	2622	80%	101	2450	80%	84	1570	73%	90	2230	76%	123	2173	73%	140	2102	72%	133	17 443	77%	930
Other Backward Class or other	498	21%	27	603	20%	26	642	20%	20	624	20%	25	592	27%	26	687	24%	30	800	27%	37	827	28%	55	5273	23%	246

The number of missing values differs across the socio-economic variables. There were 108 pairs of twins and 1 pair of triplets in the intervention areas and 116 pairs of twins in the control areas.

[a]Most marginalised: illiterate and poorest and landless or < 2 bigha's and Scheduled Caste or Scheduled Tribe. Less marginalised: can read easily or with difficulty and/or less poor and/or owns ⩾ 2 bigha's land and/or Other Backward Class/other.

Table 2 Trends in neonatal mortality according to socio-economic position for intervention and control areas, adjusted for clustering

	Intervention						Control						***P*-value for difference in trend between intervention and control**[c]
	NMR (per 1000 live births)						NMR (per 1000 live births)						
	baseline	Y1	Y2	Y3	change (%)[a]	*P*-value[b]	baseline	Y1	Y2	Y3	change (%)[a]	*P*-value[b]	
Total	60	53	36	35	−48	0.000	52	51	58	63	26	0.046	0.000
Marginalisation													
Most marginalised	68	60	29	22	−71	0.000	63	65	53	70	4	0.844	0.000
Less marginalised	56	50	40	40	−33	0.007	48	45	60	60	37	0.022	0.000
Literacy													
Cannot read	67	54	36	35	−54	0.000	55	55	60	64	21	0.161	0.000
Can read (easily or with difficulty)	36	51	37	34	−18	0.454	44	42	54	59	46	0.091	0.098
Asset ownership													
Poorest	65	52	40	33	−52	0.000	55	56	60	72	35	0.038	0.000
Less poor	49	57	26	40	−37	0.054	49	44	56	51	14	0.499	0.054
Land ownership													
Landless or < 2 bighas	60	58	31	32	−56	0.000	62	56	57	66	9	0.559	0.000
Owns 2 or more bighas	59	47	43	38	−35	0.021	40	42	60	59	62	0.014	0.001
Caste/tribe													
Scheduled Tribe or Scheduled Caste	62	55	37	33	−51	0.000	56	54	63	62	17	0.223	0.000
Other Backward Class or other	55	44	32	40	−33	0.156	43	43	45	65	59	0.05	0.019

[a]Estimated % change in NMR between baseline and year 3 assuming a linear trend
[b]*P*-value for change in NMR
[c]*P*-value for difference in trend between intervention and control for each population group

Table 3 Effects of intervention for total population and for lower and higher socio-economic groups, adjusted for clustering

	NMR Intervention *Y 2+3*	*NMR Control* *Y 2+3*	*OR (95% CI)*[a]	*P*-value[b]
Total	36	61	0.57 (0.46; 0.69)	0.000
Marginalisation				0.028
Most marginalised	26	62	0.41 (0.28; 0.59)	
Less marginalised	40	61	0.64 (0.51; 0.80)	
Literacy				0.584
Cannot read	36	63	0.55 (0.44; 0.69)	
Can read (easily or with difficulty)	35	56	0.61 (0.43; 0.87)	
Asset ownership				0.569
Poorest	37	67	0.53 (0.43; 0.67)	
Less poor	33	54	0.60 (0.43; 0.83)	
Land ownership				0.079
Landless or < 2 bighas	31	62	0.49 (0.38; 0.63)	
Owns 2 or more bighas	41	59	0.67 (0.51; 0.89)	
Caste/tribe				0.638
Scheduled Tribe or Scheduled Caste	36	63	0.55 (0.44; 0.69)	
Other Backward Class or other	35	56	0.61 (0.42; 0.89)	

[a]Odds ratio for neonatal mortality in the intervention as compared with the control areas of the study.
[b]*P*-value for the test on difference in OR between the low and high socio-economic position categories. For the total population, the table gives the *P*-value for the the difference between the intervention and control areas of the study.

differences could explain the observed intervention effects, we have reported this in the text.

The quadrature approximation of the random-effects estimators was checked for all models. The Stata 10 software system (Stata, College Station, TX, USA) was used for all analyses. Ethics approval for the trial was received from an independent ethics committee (chaired by Dr A.K. Debdas) on the 14 June 2005 and from the Research Ethics Committee at the UCL Institute of Child Health.

Results

Description

In the intervention arm of the study, the NMR declined by more than 50% between baseline and year 3 among lower socio-economic groups, and by 71% among the most socio-economically marginalised groups (Table 2). Among higher socio-economic groups in the intervention arm, the NMR also declined, but less strongly. The difference in mortality trend between the most and less marginalised in the intervention areas was such that the mortality disadvantage of the most marginalised disappeared, and even reversed in year 3 (OR for the most/less marginalised in year 3: 0.54 (95% CI: 0.33, 0.90), results not shown). In the control areas, the NMR remained stable or increased among all social groups.

In a replication of the trial analysis, a large intervention effect was observed among lower socio-economic groups, and even among the most marginalised groups in the study (Table 3). Moreover, the effect was stronger among the most as compared with the less marginalised groups, with an estimated 59% effect in years 2 and 3 (70% in year 3) among the most marginalised as compared with an estimated 36% effect (35% in year 3) among the less marginalised (*P*-value for difference: 0.028 for years 2–3; 0.009 for year 3). The stronger effects among the most compared with the less marginalised are slightly inflated by baseline differences, but only to a small extent (Figure 1). Also for the other dimensions of stratification, effects were consistently stronger among lower strata, though the contrasts were less stark, and there was no power to detect these smaller differences.

Explanation

The stronger effect of the intervention among the most marginalised groups in the study was, in the

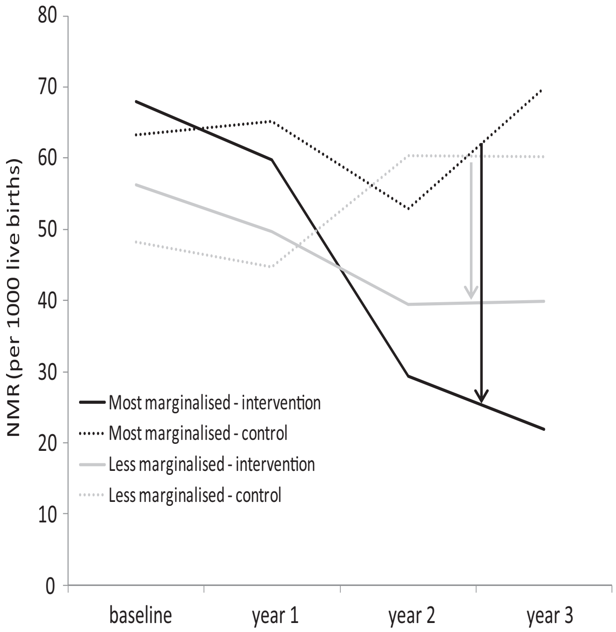


Figure 1 Neonatal mortality rate (adjusted for clustering) among the most marginalised and less marginalised groups in intervention and control areas per year. The arrows indicate the intervention effect among the most and the less marginalised groups in years 2 and 3 combined, taking into account that differences at baseline are small

first instance, concentrated in early NMR (Figure 2a). In year 3, this was complemented by an effect on the late NMR. The stronger effects on the total and early NMR were concentrated in winter (Figure 2b). Strong seasonal fluctuations, in particular winter peaks, largely in early NMR, were observed in the control areas of the study (results not shown). In the intervention areas, by contrast, these winter peaks largely disappeared over the course of the trial, especially among the most marginalised groups. The stronger effects of the intervention on late NMR in year 3 may have occurred in all seasons of the year, but confidence intervals were wide. Among the three major direct causes of neonatal death, prematurity and asphyxia may have contributed most to the stronger effect on early NMR in winter (Figure 2c) and infections to the stronger effect on late NMR in year 3.

The intervention may have influenced food intake during pregnancy, thermal care (except wrapping), and breastfeeding among the most and the less marginalised groups in the study areas, but confidence intervals were very wide and included 1 (Table 4). There was an effect on some hygienic practices for home deliveries, especially hand washing with soap by the birth attendant, and use of a plastic sheet, a new or boiled blade to cut the umbilical cord, and a boiled thread to tie the cord. These effects were comparable among the most and the less marginalised groups. Only the proportion of home deliveries for which all hygienic practices were used was higher ($P = 0.018$) among the most marginalised groups, although in absolute terms the differences in effect were small and could have been due to multiple testing.

There was no effect of the intervention on the utilization of health care among the most and less marginalised groups in the study. We cannot exclude the possibility of increased use of health care in cases of emergency situations, such as neonatal illness or prolonged labour, but the confidence intervals were wide.

Attendance at the women's groups strongly increased over time, but differences in attendance between the most and less marginalised groups remained small in absolute terms. Attendance increased from 11% and 15% of deliveries among the most and the less marginalised, respectively, in year 1, to 59% and 52% among the most and the less marginalised, respectively, in year 3 (results not shown).

Discussion

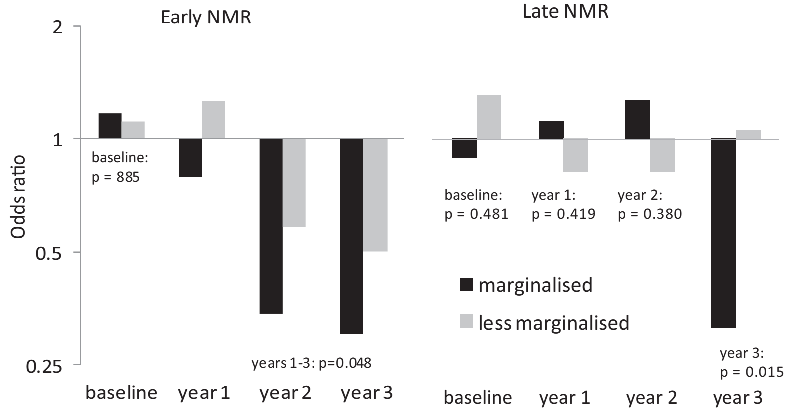
Our study shows that the women's group intervention strongly reduced the NMR among lower socio-economic groups in the areas of India in which the study was conducted. The effects were substantially stronger among the most socio-economically marginalised groups. This is remarkable, given that interventions often lead to increasing, rather than declining, socio-economic inequalities in mortality.[7,12,14,43,44] Our findings are important in view of the paucity of evidence for specifically effective means for reducing socio-economic inequalities in mortality. We show that a low-cost[45] participatory community intervention can contribute to an equitable achievement of MDG4.

Evaluation of data and methods

Measurement bias is unlikely to explain our findings. Neonatal mortality rate was the primary outcome measure of the original trial, and stringent measures were taken to ensure completeness and reliability of the data relating to this measure.[41] Birth and newborn death data in the trial were collected through prospective surveillance,[41] which constitutes an important advance over often-used retrospective surveys, which rely on mothers' recall.[46–47]

At baseline, the differences in NMR in the intervention and control arms of the study were largely comparable among the most and less marginalised groups. Although the stronger effect of intervention among the most as compared with the less marginalised groups is probably slightly inflated by baseline differences, this is so only to a small extent.

Programmes supported by the government of India, such as the Integrated Child Development Service, were present in the study area. Some such programs *a.* Intervention effects (comparing intervention and control areas) on early and late neonatal mortality rate among the most and less marginalised groups in the study.



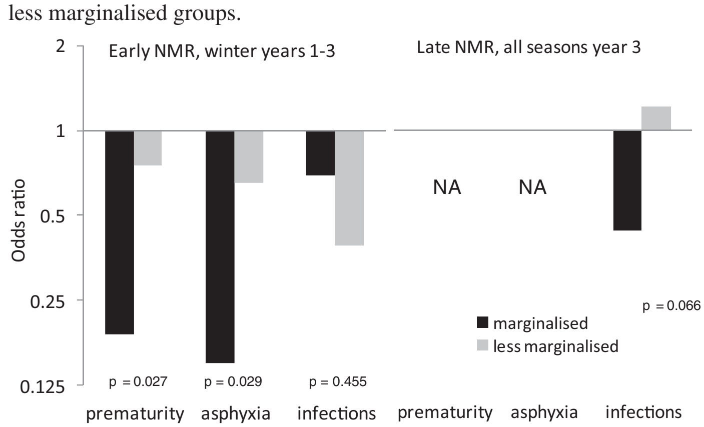
P-values are given for the difference in intervention effect between the most and less marginalised groups. (Number of early neonatal deaths: 799; number of late neonatal deaths: 377).

b. The intervention effect on total neonatal mortality rate and early and late neonatal mortality rate by season

	NMR Y1-3 OR (95% CI)	P-value for difference (*)	*Early NMR Y1-3 OR (95% CI)*	P-value for difference (*)	*Late NMR Y3 OR (95%CI)*	P-value for difference (*)
Monsoon						
Most marginalised	0.89 (0.57; 1.39)		0.73 (0.43; 1.23)		0.83 (0.19; 3.65)	
Less marginalised	0.99 (0.72; 1.36)	0.674	1.00 (0.71; 1.40)	0.319	1.50 (0.62; 3.63)	0.479
Winter						
Most marginalised	0.40 (0.25; 0.63)		0.24 (0.13; 0.45)		0.27 (0.05; 1.40)	
Less marginalised	0.75 (0.55; 1.03)	0.013	0.65 (0.45; 0.94)	0.005	1.00 (0.44; 2.32)	0.151
Summer						
Most marginalised	0.63 (0.40; 0.98)		0.67 (0.38; 1.16)		0.10 (0.01; 0.77)	
Less marginalised	0.57 (0.42; 0.78)	0.732	0.53 (0.37; 0.75)	0.487	0.73 (0.28; 1.94)	0.083

**P*-value for difference between the most and less marginalised. Monsoon: July–October, winter: November-February, summer: March-June.

c. The intervention effects (comparing intervention and control areas) on cause specific mortality, among the most and less marginalised groups.



P-values are given for the difference in intervention effect between most and less marginalised. NA: Too few cases were available to conduct analyses for asphyxia (0 deaths) and prematurity (7 deaths) in the late neonatal period.

Figure 2 Effects of intervention on the early and late neonatal mortality rate among the most and less marginalised groups in the study by year, season, and cause of death

Table 4 Health behaviours: cluster-adjusted percentages and odds ratios in a comparison of intervention and control areas of the study, for years 2 and 3 combined

	Years 2-3													
	Intervention marginalised		Intervention less marginalised		Control marginalised		Control less marginalised		OR (95%CI) marginalised		OR (95%CI) less marginalised		*P*-value difference
	number	%	number	%	number	%	number	%					
Denominators													
Mothers with live births	1897		4384		1612		4219						
Mothers with live births - home deliveries only	1706		3616		1448		3113						
Live born infants	1910		4428		1638		4264						
Live born infants - home deliveries only	3455		6701		2817		6073						
Determinants of prematurity													
Did not eat less during pregnancy (*)	1087	62	2844	59	739	49	2111	48	1.68	(0.72; 3.91)	1.55	(0.67; 3.58)	0.428
Birth interval (*)	1125	75	2281	77	945	74	2127	76	1.08	(0.86; 1.34)	1.03	(0.86; 1.23)	0.703
Thermal care and breastfeeding													
Infant wiped within 30 mins (‖)	941	69	2563	70	928	61	2014	67	1.42	(0.39; 5.21)	1.13	(0.31; 4.11)	0.077
Infant wrapped within 30 mins (‖)	569	28	1566	34	686	35	1391	40	0.78	(0.23; 2.67)	0.72	(0.21; 2.46)	0.508
Infant not bathed within 24 hrs (‖)	474	27	1215	32	247	20	794	27	1.40	(0.59; 3.34)	1.29	(0.55; 3.02)	0.487
Infant put to breast within 4 hrs (‡‡)	1290	70	2903	74	928	66	2671	70	1.19	(0.45; 3.16)	1.20	(0.46; 3.16)	0.799
Hygiene													
Birth attendant washed hands with soap (†)	619	37	1710	48	190	13	717	20	4.30	(1.95; 9.44)	3.60	(1.67; 7.78)	0.166
Plastic sheet used (†)	347	19	774	20	106	6	251	6	3.59	(2.05; 6.31)	3.80	(2.24; 6.47)	0.712
Cord cut with new or boiled blade (‖)	1444	88	3271	93	1120	82	2696	88	1.77	(0.98; 3.19)	1.79	(1.01; 3.19)	0.916
Cord tied with boiled thread (‖)	573	29	1540	39	132	7	373	11	6.12	(2.65; 14.10)	5.27	(2.34; 11;88)	0.293
Cord undressed or dressed with antiseptic (‖)	1594	97	3299	96	1339	97	2896	97	1.11	(0.36; 3.50)	0.93	(0.30; 2.87)	0.318
Hygiene combined index (‖)	154	5	380	6	5	0	35	1	26.87	(7.85; 92.02)	8.23	(3.37; 20.09)	0.018
Health care													
3+ Antenatal care (*)	447	21	1595	36	475	27	1964	50	0.67	(0.30; 1.48)	0.58	(0.27; 1.27)	0.179
Institutional delivery (*)	191	7	768	17	164	8	1106	24	0.80	(0.41; 1.55)	0.64	(0.35; 1.20)	0.114
Post-natal checkup for baby at medical facility (‡‡)	70	2	495	5	59	3	378	7	0.65	(0.27; 1.55)	0.76	(0.34; 1.72)	0.415
Visit to medical facility for sick child (††)	56	12	183	19	43	9	279	22	1.25	(0.59; 2.63)	0.85	(0.45; 1.61)	0.136

P-value difference gives the *P*-value for the difference in odds ratios between the most and less marginalised.
Hygiene combined index: 1 if scored yes on all hygiene practices; the remainder are categorised as 0.
Denominators used for each of the variables: (*) mothers with live births; (†) mothers with live births - home deliveries only; (‡‡) live born infants; (‖) live born infants - home deliveries only; (††) infants who had suffered an infant illness in the first 28 days of life – infants that were alive at 28 days only.

even target the poor, such as the subsidised food grains for people with Below Poverty Line cards. These programmes were, however, similarly common in both arms of the trial. More generally, because the study used a randomised design, potential confounders are expected to be evenly distributed between the study arms.

Mechanisms

Two complementary mechanisms may explain the stronger intervention effect among the most marginalised groups in the study. First, the uptake of the intervention (women's group attendance, behavioural improvements) was similar among the most and less marginalised groups, whereas interventions normally reach higher socio-economic groups to a greater extent. The openness of the women's groups in the study to non-members, the accessible language used, the picture cards employed to utilize visual literacy, the use of games and stories that relate to the experiences of the most marginalised groups, the locations (hamlets instead of the main village), the dates and timings (decided by the group members) of the meetings, and the Scheduled Tribe background of many of the facilitators probably made the intervention effectively reach groups that are normally left out of health interventions.[48]

Second, when their utilization is similar, then effective and appropriate interventions arguably have stronger effects on mortality among high-risk groups.[49] The fairly simple home-care practices discussed in the women's group meetings in the Ekjut trial probably addressed important causes of death among groups with high rates of neonatal mortality. Neonatal death often results from a combination of and interaction between morbidities. Therefore, the spin-off effects of addressing one risk factor on other risk factors are arguably greater among the more vulnerable.[50] This has been reported for immunisation, refuting the replacement mortality hypothesis.[51–53] Similarly, addressing infection brings greater survival benefits to babies of low birth weight.[50] Likewise, the observed improvements in hygienic practices in the trial may have had stronger effects on mortality among the most marginalised groups.

If similar behavioural improvements have stronger mortality effects among vulnerable groups, this is arguably even more true for babies born in these groups in the risky winter season, especially those who are born too small or prematurely or both.[50] A major success of the intervention described here was its strong effect on the NMR in winter among the most marginalised groups. Winter in India is associated with a much higher prevalence of newborn hypothermia than is the case in summer.[54] Hypothermia, prematurity, asphyxia and infection, are interacting causes of neonatal death. Premature or small babies are at a higher risk of hypothermia,[54–55] infections,[56–57] and asphyxia[58] than are babies of normal weight. The observed improvements in hygienic practices, and perhaps thermal care, may have had particularly strong effects on mortality among the most marginalised groups during winter.

Similarly, newborn deaths often result from a combination of omissions and commissions, rather than from one isolated behaviour. In other words, multiple component causes together constitute a sufficient cause of death.[59] Many different combinations of behaviours can constitute a sufficient cause of death. Small behavioural improvements, in the right combinations, in a small group of vulnerable babies, may not be easily discernible in population data. Even in rural India, where neonatal mortality is an important problem, most newborns do survive. Perhaps, through the women's groups in the Ekjut trial, the most marginalised populations have become more pro-active and more alert, reacting more quickly to problems such as cold weather or a small baby (Box 1). Thus, small changes in a range of behaviors, or component causes, in a vulnerable group may lead to large decreases in newborn mortality, even without population-wide behavioural improvements.

Although a reduction in mortality from asphyxia, especially in winter, is not implausible, given the focus of the intervention on the perinatal period, with discourse about the cleaning of newborn infants' airways, the uncertainty surrounding a single cause-of-death is large. Clinical presentations of prematurity, hypothermia, infection, and asphyxia can overlap and be difficult to distinguish with verbal autopsy data.[60] Neonates with sepsis, for example, may present with respiratory distress,[60] and asphyxiated infants can present with hypothermia.[54]

Caution is also needed when interpreting behavioural data. The behaviours in the present trial were measured at 6 weeks post-partum and depended on maternal recall; in particular, differential misclassification may occur between the mothers of surviving newborns and of newborns that die. Unmeasured behaviours, such as the quality of wrapping of an infant, which is important to prevent hypothermia, may also have played a role in the effect of the trial.

Box 1

Minka, a young mother, stated that ''My child was delivered at home. She had a low birth weight, as she was born before her due month. The group members, who assisted me during my delivery, told me that the baby had a low birth weight and had to be kept warm, with her body covered. I was to exclusively breastfeed my baby and was advised not to bathe her till she had gained weight. I exclusively breastfed her and protected her from cold by keeping her covered. I maintained cleanliness. Now she is healthy.''

Additionally, unmeasured behavioural restrictions, e.g. relating to a ritual understanding of pollution among the members of Other Backward Classes and other castes in the trial, may have tempered the decline in mortality among the less marginalised groups.

Implications

This study shows that socio-economic inequalities in neonatal mortality can be reduced through community-based participatory intervention. We argue that effective interventions, given equal coverage, can have stronger effects on newborns at high risk for mortality, especially if they are triply vulnerable: socio-economically (the most marginalised), seasonally (born in winter), and physically (born premature/small and/or at risk of developing asphyxia because of a lack of skilled birth attendance). The challenge in reducing inequalities in newborn mortality therefore lies in ensuring an equitable uptake of effective interventions.[14,61] Villages are not monolithic. The challenge is to make institutions and initiatives, like self-help groups and community health-worker schemes, inclusive. Ekjut's strategy seems to work well, with the use of regional targeting (selecting underserved areas in poor districts in poor states), combined with a universal strategy at the community level[48] (ensuring that no person is omitted and that social cohesion is not disrupted by overt-targeting or by inclusion or exclusion criteria), while ensuring that the messages and activities of the intervention are understandable for and refer to those who need them most. Arguably, equity is a design issue, with universal coverage combined with 'soft' targeting[20] (targeting by fitting the intervention design to the target group rather than by applying strict inclusion and exclusion criteria) contributing to equitable outcomes. Obviously, the intervention needs to be effective in the first place, and of sufficient duration and intensity to ensure an effect on mortality, explaining the divergence between an equitable intervention uptake and the lack of an equitable effect on mortality in some studies.[32]

Our study shows that reducing the NMR and inequalities in NMRs is feasible in high-mortality contexts, even without improvements in routine health care. The trial achieved substantial reductions in mortality, and even in rates of early neonatal mortality, with rates of institutional delivery that remained extremely low, especially among the most marginalised groups in the study. We cannot exclude the possibility that the utilization of health care in emergency situations, such as newborn illness, contributed to this. However, use of such care remained much lower among the most as compared with the less marginalised groups, and therefore is not the full explanation for the results of the study. Clearly, improving access to and quality of health care is vital. However, our findings show that there is no need to wait for this in high-mortality contexts.

Little is known about how to reach lower socio-economic groups and reduce socio-economic inequalities in health. The Commission on Social Determinants of Health recommends that the equity impacts of interventions be monitored to help fill the deficiency in evidence on how this might be accomplished.[62] Our study suggests that universal coverage of effective interventions combined with their 'soft targeting' of high-risk groups can have very substantial and equitable effects on mortality.

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KEY MESSAGES

- The effects of the women's group intervention on NMR were substantially stronger among the most socio-economically marginalised than among less marginalised groups in the Ekjut trial.
- Socio-economic inequalities in neonatal mortality can be substantially reduced through a low-cost participatory community intervention.
- Universal coverage combined with 'soft targeting' of high-risk groups with effective interventions can have very substantial and equitable effects on mortality.

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